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WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

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2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: September 13; at 9:00 a.m.
WHERE: Office of the Federal Register,
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Presidential Documents

Title 3—

The President

Executive Order 12648 of August 11, 1988

Relating to the Implementation of the Convention on the Civil Aspects of International Child Abduction

The United States of America deposited its instrument of ratification of the Hague Convention on the Civil Aspects of International Child Abduction ("Convention") on April 29, 1988. The Convention entered into force for the United States on July 1, 1988. Article 6 of the Convention imposes upon Contracting States an obligation to designate a "Central Authority" for the purpose of discharging certain specified functions.

In order that the Government of the United States of America may give full and complete effect to the Convention, and pursuant to section 7 of the International Child Abduction Remedies Act, Public Law No. 100–300 (1988), it is expedient and necessary that I designate a Central Authority within the Executive branch of said Government:

NOW, THEREFORE, by virtue of the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of Title 3 of the United States Code and section 7 of the International Child Abduction Remedies Act, it is ordered as follows:

Section 1. *Designation of Central Authority.* The Department of State is hereby designated as the Central Authority of the United States for purposes of the Hague Convention on the Civil Aspects of International Child Abduction. The Secretary of State is hereby authorized and empowered, in accordance with such regulations as he may prescribe, to perform all lawful acts that may be necessary and proper in order to execute the functions of the Central Authority in a timely and efficient manner.

Ronald Reagan

THE WHITE HOUSE,
August 11, 1988.

[FR Doc. 88-18555
Filed 8-12-88; 10:57 am]
Billing code 3195-01-M

Presidential Documents

Executive Order 12649 of August 11, 1988

Offsets in Military-Related Exports

By virtue of the authority vested in me as President by the Constitution and laws of the United States of America, including the Defense Production Act of 1950, as amended (50 U.S.C. App. 2061 *et seq.*), and in order to provide for the performance of certain reporting functions with respect to the effect of offsets in international trade, it is hereby ordered that Executive Order No. 10480 of August 18, 1953, as amended, is further amended by deleting the text of Section 602(d)(2) of the Order and inserting in lieu thereof the following:

"(d)(2) In order to ensure that information gathered pursuant to this authority shall be subject to appropriate confidentiality protections, the Bureau of Economic Analysis of the United States Department of Commerce, which previously has been designated a 'central collecting agency' in gathering this information under 44 U.S.C. 3509, is authorized pursuant to Section 705 of the Defense Production Act, as amended, to collect the information required for compilation of the data base to be used in preparation of the reports to Congress required by Section 309 of the Defense Production Act."

Ronald Reagan

THE WHITE HOUSE,
August 11, 1988.

[FR Doc. 88-18556
Filed 8-12-88; 10:58 am]
Billing code 3195-01-M

Presidential Documents

Memorandum of August 11, 1988

Memorandum for the Director of the Office of Management and Budget

By the authority vested in me as President of the United States by the Constitution and Section 301 of Title 3 of the United States Code, I hereby delegate to the Director of the Office of Management and Budget the function of submitting notifications to the Congress required by Section 251(d)(3)(C) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended by the Balanced Budget and Emergency Deficit Control Reaffirmation Act of 1987 (2 U.S.C. 901 *et seq.*).

This memorandum shall be published in the **Federal Register.**

Ronald Reagan

THE WHITE HOUSE,
Washington, August 11, 1988.

[FR Doc. 88-18557
Filed 8-12-88; 10:59 am]
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

Farmers Home Administration

7 CFR Parts 1948, 1951, 1955

Intermediary Relending Program

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) is creating a regulation for an Intermediary Relending Program (IRP). This action is needed to implement the provisions of section 407 of the Health and Human Services Act of 1986 which amended section 1323 of the Food Security Act of 1985. The intended effect of this action is to provide regulations for making loans to nonprofit, public, Indian and cooperative entities who will in turn provide financial assistance to rural businesses and community development projects for employment opportunities as well as provide a diversification of the economy in rural areas and for servicing the IRP loans made by FmHA and the Rural Development Loan Fund (RDLF) loans that were transferred from the U.S. Department of Health and Human Services to the U.S. Department of Agriculture.

The Farmers Home Administration (FmHA) is also amending various other existing regulations to add references to these new regulations for making IRP loans and servicing the IRP and RDLF loans.

EFFECTIVE DATE: August 15, 1988.

FOR FURTHER INFORMATION CONTACT: Dwight A. Carmon, Director, Business and Industry Division, Farmers Home Administration, USDA, Room 6321, 14th and Independence Avenue SW., Washington, DC 20250, Telephone (202) 475–4100.

SUPPLEMENTARY INFORMATION:

Classification

This final action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291 and has been determined to be non-major since the annual effect on the economy is less than $100 million and there will be no significant increase in costs or prices for consumers, individual industries, organizations, governmental agencies or geographic regions. There will be no 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.

Intergovernmental Review

The programs covered by this action will be listed in the Catalog of Federal Domestic Assistance under numbers 10.437, Rural Development Loan Fund, and 10.438, Intermediary Relending Program, and are subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (7 CFR 3105, Subpart V; 48 FR 29112, June 24, 1983; 49 FR 2267, May 31, 1984; 50 FR 14088, April 10, 1985)

Environmental Impact Statement

The proposed action has been reviewed in accordance with FmHA Instruction 1940–G, "Environmental Program." FmHA has determined that this final rule does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

Discussion of Major Provisions of the Rule

Part 1948, Subpart C

Section 1948.101 Introduction.

This section describes the purpose of the program which provides loans from the Farmers Home Administration (FmHA) to nonprofit organizations, public agencies, Indian and cooperative entities (intermediaries) which will in turn reloan the loan funds to local businesses (ultimate recipients) for business facilities and community development projects in rural areas. It also identifies the Director, Business and Industry Division, as the focal point and the contact person for processing activities.

Section 1948.103 Eligibility requirements.

This section prescribes the eligibility criteria for intermediaries under the provisions of this program. It also requires that at least 51 percent of the outstanding interest in any intermediary or ultimate recipient be owned by citizens of the United States and requires that credit is not otherwise available at reasonable rates and terms.

Section 1948.109 Loan purposes.

FmHA loan funds must be used for the establishment or expansion of a business or community development facility. This section also provides guidelines on specific eligible uses of FmHA-related loan funds.

The intermediary is to certify that the FmHA-related funds under its control are to be used only for eligible purposes as defined by the guidelines in this section.

Section 1948.110 Ineligible assistance purposes.

Specific ineligible assistance purposes are defined in this section including intermediaries' administrative costs, agricultural production, recreation, tourist homes, hotels, motels, charitable and educational institutions. FmHA loan funds will not be used to finance more than 75 percent of the total project cost of any ultimate recipient.

Section 1948.111 Terms of loans.

This section provides for the structure of loan repayment terms between FmHA and the intermediary. It limits the maximum repayment term to 30 years.

Section 1948.112 Interest rates.

This section identifies the interest rates that can be charged by FmHA to the intermediary and between the intermediary and ultimate recipients.

Section 1948.113 Security.

This section describes the type of security required for the loan and indicates that the security for the loan must be adequate. FmHA may require additional security during the term of a loan to an intermediary.

Section 1948.114 Conflict of interest.

This section restricts intermediaries from participation in the program if there is a conflict of interest between the intermediary and the ultimate recipient.

Section 1948.116 Fees and charges.

This section provides guidelines for fees to be charged by FmHA and intermediary in regard to their financial assistance under the administration and execution of this program.

Section 1948.117 Other regulatory requirements.

The section provides regulatory requirements dealing with the following:

(a) Intergovernmental consultation which allows for State and local offices to review proposals to be funded with FmHA funds.

(b) Environmental reviews which are subject to FmHA Instruction 1940–G.

(c) Equal opportunity and nondiscrimination in accordance with Title V of Pub. L. 93–495 and refers to FmHA Instruction 1901, Subpart E, as the applicable regulation for this program.

Section 1948.118 Loan agreements.

The loan agreement executed by the intermediary and FmHA contains provisions for the loan. This include: amount, rates, terms, and repayment of the loan, late charges, disbursement procedures, defaults, FmHA reporting requirements. Forms and lending policy of the intermediary are also discussed.

Sections 1948.122–1948.124 Applications, filing, processing and evaluation.

Specific information and FmHA forms to be used in the application are identified in this section of the regulations.

Loan applications will be filed with the FmHA National Office, Director, Business and Industry Division, Washington, DC. Intermediaries must file a complete application in one package. Applications will be considered in the order received. However, priority consideration may be given intermediaries who provide more assistance to low-income persons and farm families or involve more funds from other sources.

The FmHA Administrator or designee will evaluate the application and make a determination whether the proposed loan complies with all applicable statutes and regulations. If FmHA is able to provide the loan, it will provide the intermediary a letter of conditions listing all requirements for such loan. If FmHA determines it is unable to provide the loan, the proposed intermediary will be informed in writing.

Section 1948.128 Request to make loans to ultimate recipients.

No commitment of FmHA derived loan funds to an ultimate recipient may be made by the intermediary until an affirmative decision is rendered by FmHA that the intermediary may make a loan to an ultimate recipient. Information to be included in a request for FmHA approval is discussed.

Section 1948.130 Non-Federal funds.

When FmHA-derived loan funds (Federal funds) have been utilized by the intermediary to the ultimate recipient and new ultimate recipients are subsequently financed from the revolving loan fund (non-Federal funds) of the intermediary, these regulations will not be imposed upon the ultimate recipient.

Section 1948.143 Appeals.

This section provides guidelines on the appeal rights of intermediaries due to an adverse decision by FmHA.

Section 1948.148 Exception authority.

The Administrator may in individual cases and under certain circumstances grant exceptions to requirements of this subpart.

Section 1948.149 Exhibits.

This section provides for three exhibits to the regulations. These include names and numbers for forms in a loan docket, a suggested Loan Agreement, and a suggested Promissory Note. The exhibits were inadvertently published with the proposed rule but are not being published with the final rule. They are available from the FmHA National Office.

Part 1951, Subpart F

The Intermediary Relending Program (IRP) is added to the list of programs that are excepted from FmHA's graduation review requirements.

Part 1951, Subpart R

Section 1951.851 Introduction.

This section describes the purpose of the regulation, which is to service the IRP loans and those Rural Development Loan Fund (RDLF) loans that were previously approved and serviced by the Secretary of the U.S. Department of Health and Human Services under 45 CFR Part 1076. It also identifies the Director, Business and Industry Division, as the focal point and the contact for loan servicing activities within the U.S. Department of Agriculture.

Section 1951.854 Ineligible assistance purposes.

This section provides a listing and discussion of ineligible purposes for which FmHA loan funds may not be used by the intermediary. These include:

(a) Charitable and educational institutions, churches, organizations affiliated with or sponsored by churches, and fraternal organizations.

(b) For relending in a city with a population of twenty-five thousand or more as determined by the latest decennial census.

(c) For any line of credit.

This section also provides ineligible purposes for which loan funds may not be used by ultimate recipients:

(a) Agricultural production.

(b) For financing community antenna television services or facilities.

(c) For any legitimate business activity when more than 10 percent of the annual gross revenue is derived from legalized gambling activity.

(d) For any illegal activity.

(e) For any hotels, motels, tourist homes, or convention centers.

(f) For any tourist, recreation, or amusement centers.

Section 1951.859 Terms of loans.

This section provides that no loans shall be extended for a period exceeding 30 years and the terms of loan repayment will be those stipulated in the loan agreement and/or promissory note.

Section 1951.860 Interest on loans, allowable costs.

This section identifies the interest rates that can be charged by FmHA to the intermediary and between the intermediary and ultimate recipients.

Section 1951.866 Security.

This section sets forth FmHA security and appraisal requirements for intermediary loans to ultimate recipients.

Section 1951.867 Conflict of interest.

This section restricts intermediaries from participation in the program when FmHA determines there is a conflict of interest between the intermediary and the ultimate recipient.

Section 1951.872 Other regulatory requirements.

The section provides regulatory requirements dealing with the following:

(a) Intergovernmental consultation which allows for State and local offices

to review proposals to be funded with FmHA funds.

(b) Environmental reviews which are subject to FmHA Instruction 1940–G.

(c) Equal opportunity and nondiscrimination in accordance with Title V of Pub. L. 93–495 and refers to FmHA Instruction 1901, Subpart E, as the applicable regulation for this program.

Section 1951.877 Loan agreements.

The loan agreement executed by the intermediary and FmHA contains loan provisions and servicing activities for the loan. These include: amount, rates, terms, and repayment of the loan, late charges, disbursement procedures, defaults, FmHA reporting requirements. Forms and lending policy of the intermediary are also discussed.

Section 1951.884 Non-Federal funds.

This section provides that FmHA will exempt the intermediary from the requirements of the regulation on Federal funds for future loans to ultimate recipients when the intermediary has provided assistance to the ultimate recipients in an amount equal to the financial assistance the borrower has received from FmHA.

Section 1951.896 Appeals.

This section provides guidelines on the appeal rights of intermediaries and ultimate recipients due to an adverse appealable decision by FmHA.

Section 1951.897 Exception authority.

The Administrator may in individual cases and under certain circumstances grant exceptions to requirements of this subpart.

Part 1955, Subpart A

The application of FmHA's regulation on liquidation of loans to the Rural Development Loan Fund, Nonprofit National Corporations, and Intermediary Relending programs is clarified.

Part 1955, Subpart B

The application of FmHA's regulation on management of inventory property to the Rural Development Loan Fund, Nonprofit National Corporations, and Intermediary Relending programs is clarified.

Part 1955, Subpart C

The application of FmHA's regulation on disposal of inventory property to the Rural Development Loan Fund, Nonprofit National Corporations, and Intermediary Relending programs is clarified

Comments

This action was published as a proposed rule for public comment on May 16, 1988, in Volume 53, No. 94, of the **Federal Register**, beginning on page 17201. Ten letters of comments were received. Most of the letters commented on several issues.

One commenter felt that recreation facilities, motels and tourism facilities should be eligible for assistance. FmHA believes these facilities tend to be high risk, seasonal, and capital intensive relative to the number of jobs created. They remain ineligible.

One commenter suggested funds be allocated on a State or regional basis. Due to the small amount of funds available and the short time remaining in the fiscal year, FmHA still believes it is best to operate the program on a National basis from our National Office. The proposed rule will not be changed.

Four commenters asked that the eligibility requirements for intermediaries be clarified or changed. The concern was to ensure that National and regional intermediaries and electric co-ops are eligible for assistance. Section 1948.103(a) has been revised to provide that private nonprofit corporations may be eligible without regard to the area they serve.

Five commenters objected to the requirement that the intermediary have equity available for lending equal to 10 percent of the FmHA loan. FmHA agrees that some nonprofit organizations that should be considered for funding may not able to meet this requirement and the requirement has been removed.

One commenter also objected to the requirements of § 1948.103(b)(3)(iv) regarding capitalization of the intermediary. FmHA believes that capitalization is an important measure of an organization's financial strength and ability to remain in operation and repay a loan. Therefore, it is retained as one factor that will be considered in evaluating an applicant's ability to successfully assist rural businesses.

Two commenters objected to the requirement that an intermediary have recent successful experience in making and servicing loans. No change has been made on this issue. However, the rule states that intermediaries will "normally" have such experience, so FmHA may make exceptions when it is justified.

Three commenters requested that the description of eligible loan purposes be broadened. One suggeted the term "infrastructure" be used and another expressed concern about transportation facilities. Sections 1948.109 and 1951.853 have been revised to include community development projects as eligible and to remove the requirement that transportation services be incidental to business development.

Four commenters objected to the prohibition on loans to churches, charitable institutions, and educational institutions. FmHA believes loans to such organizations tend to be financially weak and difficult to service. This prohibition is consistent with other FmHA programs and is retained. However, this does not prevent loans to all tax-exempt nonprofit organizations.

Three commenters objected to the requirement that FmHA funds not be used for more than 75 percent of the cost of an ultimate recipient's project. Three commenters objected to the $150,000 limit on FmHA funds loaned to any one ultimate recipient. FmHA believes these requirements are needed to ensure that limited funds are shared among more recipients and that loans are leveraged with funds from other sources. The requirement is retained. However, § 1948.100(a)(9) dealing with this subject has been revised for clarity.

Seven commenters objected to FmHA review of each loan from an intermediary to an ultimate recipient. Four commenters where specifically concerned about intergovernmental review procedures and three commenters were specifically concerned about the environmental review process. FmHA shares the concerns about the potential impact of these reviews on processing time. However, we believe part of the concern is based on misunderstanding of the intent of the rule. FmHA does not intend to review the entire project file or to do a financial analysis for each loan to an ultimate recipient. Basic environmental review requirements are set out in the National Environmental Policy Act and in 7 CFR 1940, Subpart G. Intergovernmental consultation requirements are set out in Executive Order 12372, 7 CFR 3015, Subpart V, and FmHA Instruction 1940–J (available in any FmHA office). FmHA is required to make those two reviews. In order to complete the environmental review, FmHA will have to know the exact loan purpose so it will be a simple matter to confirm that the proposed loan is for an eligible purpose. When the intermediary intends to assign its interest in the security offered by the ultimate recipient, as part of the security for the intermediary's loan from FmHA, then FmHA will review the security. That is the extent of the review intended by FmHA. No change from the proposed rule has been made.

Six commenters questioned the procedure for disbursement of funds and

requested that intermediaries be able to draw FmHA loan funds prior to the time they are needed by an ultimate recipient. The disbursement procedure requested by the commenters in contrary to general policy for the operation of Government loan programs and would increase the cost to the Government for operating the program. It also tends to encourage intermediaries to hold the funds for investment purposes rather than relending them to ultimate recipients as intended by the program. For these reasons the disbursement procedure outlines in the proposed rule is being retained.

Four commenters objected to §§ 1948.118(b)(8) and 1951.866(b), which require intermediaries to agree to provide additional security if requested by FmHA during the term of a loan. FmHA believes this requirement is necessary to protect the Government's interest. Many intermediaries will not be able to pledge specific security for the term of the loan, but will be continuously adjusting and substituting security. These paragraphs have been revised for clarity.

Two commenters questioned the need for all intermediaries to be approved by the Governor of each State where they intend to operate. FmHA agrees that this requirement may be an unnecessary burden. The requirement has been removed.

Two commenters wanted the $3 million limit on the amount of loan to one intermediary removed. Due to the limited amount of funds expected for the program, FmHA believes a limit is needed to ensure that several applicants will be able to share in the funds. The requirement, therefore, is retained.

Two commenters requested clarification or removal of the prohibition on using funds for a line of credit. A line of credit is not amortized. The amount of debt may vary from week to week and after any period of time, the principal balance may be as large as it was in the beginning. Sound administration of a line of credit requires close monitoring of borrower operations, inventory and accounts receivable. Using IRP/RDLF funds for a line of credit would complicate loan servicing for both FmHA and the intermediary and the prohibition is retained. IRP/RDLF funds may be used for term working capital loans. No change is made to the proposed rule.

Two commenters objected to the requirement that intermediaries agree to not change their articles of incorporation, charter, or bylaws without FmHA concurrence. FmHA believes this safeguard is essential, as changes in organizational structure could effect an intermediary's eligiblity or legal capacity to function and meet its agreements. The requirement is retained.

Three commenters objected to requirements regarding life insurance on principals and key employees. FmHA believes this requirement for life insurance on key people is essential for a sound program and is a normal commercial lending practice. The requirement is retained.

Two commenters objected to the prohibition on an ultimate recipient receiving funds from more than one intermediary. No change in this requirement has been made. FmHA believes an ultimate recipient should normally deal with only one intermediary for purposes of sound credit and to share the available funds with more recipients. However, the restriction was written so that it may be done with prior FmHA concurrence.

One commenter objected to the prohibition in § 1951.854(a)(10) on investment of loan funds. One commenter also objected to the restriction in § 1951.871(b) on uses of interest earned. Review of these two paragraphs revealed an apparent conflict. Both paragraphs have been rewritten. RDLF loan funds may not be invested for more than 30 days without prior FmHA concurrence. Any RDLF loan funds that have not been used for loans to ultimate recipients within 6 months will be returned to FmHA. This is needed to help ensure that the funds are used for the objectives of the program.

Loan funds that are held temporarily and funds obtained from lending RDLF funds and recollecting them, that are not needed immediately for relending to ultimate recipients, should be placed in an insured interest-bearing deposit. The restriction on the use of the interest earned on such accounts is retained to comply with § 1951.853 and ensure that the loan results in a revolving loan program.

One commenter said FmHA should not require full collateral coverage. The rule states that loans to intermediaries will be adequately secured but leaves considerable flexibility for FmHA to determine what is adequate on a case-by-case basis. Any reduction in this requirement would leave the Government's interest insufficiently protected. Section 1948.118(b)(2) has been revised to clarity security options.

One commenter felt public agencies should not be eligible intermediaries. The authorizing legislation provides for loans to public and private nonprofit organizations or agencies. No change has been made.

One commenter suggested that ability to target benefits to low-income persons should be an eligibility requirement for intermediaries. The rule states that priority will be given to applications from intermediaries that will provide assistance to ultimate recipients that provide the greatest benefit to low-income persons, farm families, and displaced farm families. However, FmHA does not believe this should be a requirement of all intermediaries. No change has been made.

One commenter objected to the requirement that FmHA determine that each ultimate recipient is unable to obtain adequate financing elsewhere. FmHA agrees that this implies a more thorough review of the ultimate recipient by FmHA than intended. Section 1948.103(c)(2) has been revised so that the intermediary may make the determination. The same commenter suggested that the requirement that the intermediary be unable to obtain other credit be removed. This is a statutory requirement and no change has been made.

One commenter requested that recipients of 1983 Rural Development Loan Funds (RDLF) should be excluded from the $3 million cap on loans to intermediaries. FmHA does not see any justification for treating previous RDLF borrowers differently from other potential applicants and wishes to ensure that the limited funds will be shared by several organizations. No change has been made.

One commenter suggested alternative language in § 1948.109(b)(1)(ii) regarding assistance to low-income persons and displaced farm families. FmHA believes the language used accomplishes the intended purpose and no change has been made.

One commenter suggested that intermediaries be allowed to guarantee bank loans. FmHA believes that including loan guarantees would further complicate the program and make servicing more difficult. No change has been made.

One commenter suggested language that apparently would allow intermediaries to make loans to ultimate recipients located in nonrural areas if they would employ or benefit rural people. FmHA believes that requiring ultimate recipients to be located in rural areas will help to ensure maximum benefits to rural residents. No change has been made.

One commenter suggested that RDLF/IRP deposited funds be utilized to guarantee a bank line of credit. FmHA believes that only direct loans would be made with the use of Federal funds from

the program and that lines of credit would complicate loan servicing for both FmHA and the intermediary. Therefore, the prohibition is retained. IRP/RDLF funds may be used for term working capital loans.

One commenter suggested a 5-year deferral of principal payments in order to allow for buildup of reserves. FmHA believes that a deferment of principal payment up to 3 years should provide adequate time for the intermediary to establish a financially viable revolving loan program and that a 5-year deferment is excessive. This requirement is retained.

One commenter suggested that language regarding commitments of financial support from public agencies and private organizations be eliminated. FmHA believes that an important measure of an organization's financial strength and abilities is that it be able to secure other needed funds in implementing a sound loan program. Therefore, it is retained as one factor that will be considered in evaluating an applicant.

One commenter suggested that FmHA target funds to "other low income targeted populations such as AFDC recipients and dislocated workers." FmHA in its instruction targets "low-income persons" which would in most instances include AFDC recipients and dislocated workers. Thus, no change from the proposed rule has been made.

One commenter suggested that the requirement for cash flow projections in applications be rewritten to require more frequent projections of cash flow monthly for 1 year and quarterly for 2 more years. FmHA agrees this would be desirable for analysis. However, such a reporting requirement may be too much of a burden on applicants to make it a minimum requirement. The requirement for 3 years of annual cash flow projections is retained.

One commenter requested that there should be an application deadline to file an IRP loan application. FmHA believes a deadline on the receipt of IRP applications is not necessary. This is to ensure that the application process is open to all qualified applicants and reviewed in the order that the applications were received. The request is denied.

One commenter commented on FmHA procedures in § 1948.123(d) regarding timeframes for processing applications and suggested that FmHA amend this section to apply to projects above $150,000 or 10 percent of the principal loan balance. This section contains instructions on the time limit in processing the IRP application by FmHA and does not apply to the FmHA concurrence required on loans made by the intermediary to an ultimate recipient. The requirement is related.

FmHA has made several minor revisions from the proposed rule to clarify the regulation and adjust internal operating procedures. The definition of a debtor is not needed and has been removed. Sections 1948.101(b), 1948.109(a), 1948.110(a)(1), 1951.853(a), and 1951.854(a)(1) have been revised to clarify that FmHA loan funds must be used by intermediaries to relend to ultimate recipients and may not be used by the intermediaries for their own administrative expenses or for providing guarantees or other technical and financial assistance. This is a revision in language for clarity, and not a change in the intent of the rule. Sections 1948.125 (c), (e), (f), and (g) have been revised regarding the procedures for obligating a loan. This is a change in internal FmHA procedures and has no effect on the public. Sections 1948.113(d) and 1951.866(c) regarding appraisals, §§ 1948.117(a) and 1951.872(a) regarding intergovernmental consultation, §1948.122(b)(9) regarding work plans, § 1948.123(d) regarding processing time, §§ 1948.124(c)(2) and 1948.126(b)(4) regarding adverse changes in intermediaries, and 1951.866(a) regarding security, have all been revised for clarity. Sections 1951.867, 1951.883, 1951.884, 1951.890, 1951.866(c), 1951.871(b), and 1951.877(b) have been revised to make the language in 1951–R conform to the language used in 1948–C on the same subjects. No change in the meaning of the rule is intended. Section 1951.872(b)(2) has been removed. This paragraph contained environmental requirements which are applicable to new loans to intermediaries but not to loans from intermediaries to ultimate recipients. It was included in the proposed rule in error. Revisions have been made in Subparts A, B, and C of Part 1955 to include references to the Nonprofit National Corporations program. These revisions deal with internal agency procedures and do not impact on the public.

List of Subjects

7 CFR Part 1948

Credit, Business and industry, Economic development.

7 CFR Part 1951

Loan programs—Agriculture, Rural areas.

7 CFR Part 1955

Foreclosure, Government acquired property, Government property management, Sale of Government acquired property, Surplus Government property.

Accordingly, Title 7, Chapter XVIII, of the Code of Federal Regulations is amended as follows:

PART 1948—RURAL DEVELOPEMNT

1. The authority citation for Part 1948 is added to read as follows:

Authority: 7 U.S.C. 1932 note; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

2. Part 1948 is amended by adding Subpart C to read as follows:

Subpart C—Intermediary Relending Program (IRP)

Sec.

1948.101 Introduction.
1948.102 Definitions and abbreviations.
1948.103 Eligibility requirements.
1948.104–1948.108 [Reserved]
1948.109 Loan purposes.
1948.110 Ineligible loan purposes.
1948.111 Terms of loans to intermediaries.
1948.112 Interest rates.
1948.113 Security.
1948.114 Conflict of interest.
1948.115 Post award requirements.
1948.116 Fees and charges.
1948.117 Other regulatory requirements.
1948.118 Loan agreements between FmHA and the intermediary.
1948.119–1948.121 [Reserved]
1948.122 Application.
1948.123 Filing and processing applications for loans.
1948.124 FmHA evaluation of application.
1948.125 Loan approval and obligating funds.
1948.126 Loan closing.
1948.127 [Reserved]
1948.128 Request to make loans to ultimate recipients.
1948.129 [Reserved]
1948.130 Non-Federal funds.
1948.131–1948.137 [Reserved]
1948.138 Office of Inspector General and Office of General Counsel referrals.
1948.139–1948.142 [Reserved]
1948.143 Appeals.
1948.144–1948.147 [Reserved]
1948.148 Exception authority.
1948.149 Exhibits.
1948.150 OMB Control Number.

Subpart C—Intermediary Relending Program (IRP)

§ 1948.101 Introduction.

(a) This subpart contains regulations for loans made by the Farmers Home Administration (FmHA) to eligible intermediaries and applies to borrowers and other parties involved in making such loans. The provisions of this subpart supersede conflicting provisions of any other subpart. The servicing and liquidation of such loans will be in accordance with Subpart R of Part 1951 of this Chapter.

(b) The purpose of the program is to finance business facilities and community development projects in rural areas. This purpose is achieved through loans made by FmHA to intermediaries that establish programs for the purpose of providing loans to ultimate recipients for business facilities and community development in a rural area. It is anticipated that businesses assisted through this program will, to the maximum extent practicable, use farm labor and products as well as provide services to the farm community.

(c) The loan program is administered by the FmHA National Office. The Director, Business and Industry Division, is the point of contact for processing activities unless otherwise delegated by the Administrator.

§ 1948.102 Definitions and abbreviations.

(a) *General definitions.* The following definitions are applicable to the terms used in this subpart.

(1) *Applicant.* The intermediary applying to FmHA for loan funds for relending to ultimate recipients for business facilities and community development in a rural area.

(2) *Intermediary* (Borrower). The entity receiving FmHA loan funds for relending to ultimate recipients pursuant to FmHA requirements found in § 1948.103.

(3) *Letter of Conditions.* FmHA's letter of proposed terms and conditions to the intermediary which when accepted by the intermediary provides the binding conditions under which FmHA will make a loan to the intermediary.

(4) *Loan Agreement.* The signed agreement between FmHA and the intermediary setting forth the terms and conditions of the loan.

(5) *Low-income.* The level of income of a person or family which is at or below the Poverty Guidelines as defined in Section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)).

(6) *Market value.* The most probable price which property should bring, as of a specific date in a competitive and open market, assuming the buyer and seller are prudent and knowledgeable, and the price is not affected by undue stimulus such as forced sale or loan interest subsidy.

(7) *Principals of intermediary.* Include members, officers, directors, entities, and other entities directly involved in the operation and management of an intermediary organization.

(8) *Ultimate recipient.* The entity or individual receiving financial assistance from the intermediary.

(9) *Rural area.* Includes all territory of a State that is not within the outer boundary of any city having a population of twenty-five thousand or more.

(10) *State.* Any of the fifty States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(11) *Technical assistance or service.* Technical assistance or service is any function unreimbursed by FmHA performed by the intermediary for the benefit of the ultimate recipient.

(12) *Working capital.* The excess of current assets over current liabilities. It identifies the liquid portion of total enterprise capital which constitutes a margin or buffer for meeting obligations within the ordinary operating cycle of the business.

(13) *Intermediary Relending Program (IRP).* A program operated by an intermediary whereby the intermediary uses loan funds received from FmHA, along with any other available funds, to make loans to ultimate recipients. Relending programs will normally establish revolving funds so that income from loans made to ultimate recipients, in excess of necessary operating expenses and debt payments, will be used to make additional loans to ultimate recipients.

(b) *Abbreviations.* The following abbreviations are applicable to this subpart:

(1) *B&I*—Business and Industry
(2) *FmHA*—Farmers Home Administration
(3) *IRP*—Intermediary Relending Program
(4) *OGC*—Office of the General Counsel
(5) *OIG*—Office of Inspector General
(6) *RDLF*—Rural Development Loan Fund
(7) *USDA*—United States Department of Agriculture

§ 1948.103 Eligibility requirements.

(a) The intermediaries which may receive FmHA loan funds for relending to ultimate recipients are:

(1) Private nonprofit corporations.

(2) Public agencies—Any State or local government, or any branch or agency of such government having the authority to act on behalf of that government, borrow funds, and engage in activities eligible for funding under this subpart.

(3) Indian groups—Indian tribes on a Federal or State reservation or other federally recognized tribal groups.

(4) Cooperatives—Incorporated or unincorporated associations, at least 51 percent of whose members are rural residents, whose members have one vote each, and which conduct, for the mutual benefit of their members, such operations as producing, purchasing, marketing, processing or other activities aimed at improving the income of their members as producers or their purchasing power as consumers.

(b) The intermediary must:

(1) Be fully bonded against losses occurring from theft, fraud, nonperformance, etc.

(2) Have the legal authority necessary for carrying out the proposed loan purposes and for obtaining, giving security for, and repaying the proposed loan.

(3) Have a proven record of successfully assisting rural business and industry. Such record will normally consist of:

(i) Recent experience in loanmaking and servicing for loans that are similar in nature to this program;

(ii) A delinquency rate acceptable to FmHA on the loans in the intermediary's portfolio;

(iii) A background and expertise of the intermediary's staff that will be making and servicing the portfolio acceptable to FmHA; and

(iv) Capitalization of the intermediary (for making such loans) acceptable to FmHA.

(c) No loans will be extended to an intermediary unless:

(1) There is adequate assurance of repayment of the loan based on the fiscal and managerial capabilities of the applicant.

(2) The loan is not otherwise available on reasonable (i.e., usual and customary) rates and terms from private sources or other Federal, State or local programs. The intermediary and each ultimate recipient must certify and document that the ultimate recipient is unable to finance the proposed project from their own resources or through commercial credit or other Federal, State or local programs at reasonable rates and terms.

(3) The amount of the loan, together with other funds available, is adequate to assure completion of the project or achieve the purposes for which the loan is made.

(4) The total amount of FmHA loan funds requested by the intermediary plus the outstanding balance of existing FmHA loan(s) will not exceed $3,000,000 per intermediary.

(d) At least 51 percent of the outstanding interest in any intermediary and ultimate recipient must have membership or be owned by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence.

§ 1948.104–1948.108 [Reserved]

§ 1948.109 Loan purposes.

(a) *Intermediaries.* FmHA loan funds will be used by the intermediary to provide loans to ultimate recipients in accordance with paragraph (b) of this section. Prior to receiving FmHA's concurrence to make a loan to an ultimate recipient, the intermediary must certify to FmHA that any assistance to the ultimate recipient, involving FmHA-related funds, complies with the criteria in this section and § 1948.110 of this subpart.

(b) *Ultimate recipients.* (1) Financial assistance from the intermediary to the ultimate recipient must be for community development projects, the establishment of new businesses and/or the expansion of existing businesses, creation of employment opportunities and/or saving existing jobs. Additionally, the ultimate recipients must:

(i) Meet the objective and purpose of the program as described in § 1948.101(b) of this subpart,

(ii) To the maximum extent possible use labor of low-income persons, farm families, and displaced farm families needing additional income to supplement their farming operations, and

(iii) To the maximum extent possible be innovative in providing services and/or products for the public.

(2) Financial assistance involving FmHA loan funds from the intermediary to the ultimate recipient may include but not be limited to:

(i) Business acquisitions, construction, conversion, enlargement, repair, modernization, or developent cost.

(ii) Purchasing and development of land, easements, rights-of-way, building, facilities, leases, or materials.

(iii) Purchasing of equipment, leasehold improvements, machinery or supplies.

(iv) Pollution control and abatement.

(v) Transportation services.

(vi) Startup operating costs and working capital.

(vii) Interest (including interest on interim financing) during the period before the facility becomes income producing, but not to exceed 3 years.

(viii) Feasibility studies.

(ix) Reasonable fees and charges only as specifically listed in this subparagraph. Authorized fees include loan packaging fees, environmental data collection fees, and other professional fees rendered by professionals generally licensed by individual State or accreditation associations, such as Engineers, Architects, Lawyers, Accountants, and Appraisers. The amount of fee will be what is reasonable and customary in the community or region where the project is located. Any such fees are to be fully documented and justified as outlined in § 1948.116(b) of this subpart.

(x) Aquaculture including conservation, development, and utilization of water for aquaculture. Aquaculture means the culture or husbandary of aquatic animals or plants by private industry for commerical purposes including the culture and growing of fish by private industry for the purpose of granting or augmenting publicly-owned or regulated stocks of fish.

§ 1948.110 Ineligible loan purposes.

(a) *Intermediaries.* FmHA loans may *not* be used by the intermediary:

(1) For payment of the intermediary's own administrative costs or expenses.

(2) To purchase goods or services or render assistance in excess of what is needed to accomplish the purpose of the ultimate recipient's project.

(3) For distribution or payment to the owner, partners, shareholders, or beneficiaries of the ultimate recipient or members of their families when such persons will retain any portion of their equity in the ultimate recipient.

(4) For charitable and educational institutions, churches, organizations affiliated with or sponsored by churches, and fraternal organizations.

(5) For assistance to government employees, military personnel, or principals or employees of the intermediary who are directors, officers or have major ownership (20 percent or more) in the ultimate recipient.

(6) For relending in a city with a population of twenty-five thousand or more as determined by the latest decennial census.

(7) For a loan to an ultimate recipient which has applied or received a loan from another intermediary unless FmHA provides prior written approval for such loan.

(8) For any line of credit.

(9) To finance more than 75 percent of the total cost of a project by the ultimate recipient. The total amount of FmHA loan funds requested by the ultimate recipient plus the total outstanding balance of any existing FmHA financial assistance consisting of loans and guarantees will not exceed $150,000. Other loans, grants, and/or intermediary or ultimate recipient contributions or funds from other sources must be used to make up the difference between the total cost and the assistance provided by FmHA.

(b) *Ultimate recipients.* Ultimate recipients may *not* use assistance received from intermediaries involving FmHA funds:

(1) For agricultural production, which means the cultivation, production (growing), harvesting, either directly or through integrated operations, of agricultural products (crops, animals, birds and marine life, either for fiber or food for human consumption, and disposal or marketing thereof, the raising, housing, feeding, breeding, hatching, control and/or management of farm and domestic animals). Exceptions to this definition are:

(i) Aquaculture as identified under eligible purposes.

(ii) Commercial nurseries primarily engaged in the production of ornamental plants and trees and other nursery products such as bulbs, florists' greens, flowers, shrubbery, flower and vegetable seeds, sod, the growing of vegetables from seed to the transplant stage.

(iii) Forestry, which includes establishments primarily engaged in the operation of timber tracts, tree farms, forest nurseries, and related activities such as reforestation.

(iv) Financial assistance for livestock and poultry processing as identified under eligible purposes.

(v) The growing of mushrooms or hydroponics.

(2) For the transfer of ownership unless the loan will keep the business from closing, or prevent the loss of employment opportunities in the area, or provide expanded job opportunities.

(3) For community antenna television services or facilities.

(4) For any legitimate business activity when more than 10 percent of the annual gross revenue is derived from legalized gambling activity.

(5) For any illegal activity.

(6) For any otherwise eligible project that is in violation of either a Federal, State or local environmental protection law or regulation or an enforceable land use restriction unless the financial assistance required will result in curing or removing the violation.

(7) For any hotels, recreation, or amusement centers.

(8) For any tourist, recreation, or amusement centers.

§ 1948.111 Terms of loans to intermediaries.

(a) No loans to intermediaries shall be extended for a period exceeding 30 years. Principal payments on these loans will be made at least annually. The initial principal payment may be deferred (during the period before the facility becomes income producing) by FmHA, but not more than 3 years.

(b) The terms of loan repayment to intermediaries will be those stipulated in the loan agreement and/or promissory note, as agreed to and executed by FmHA and intermediaries.

§ 1948.112 Interest rates.

(a) Loans made by FmHA pursuant to this subpart shall bear interest at a fixed rate of one percent (1%) per annum over the term of the loan.

(b) Interest rates charged by intermediaries to ultimate recipients shall be negotiated by those parties. Intermediaries are encouraged to make loans at the lowest possible rate, taking into account the cost of the loan funds to the intermediary and the cost of administering the loan portfolio.

(c) Interest income, service fees, and other authorized financing charges received by intermediaries operating relending programs may be used to pay for: The costs of administering the IRP, the provision of technical assistance to borrowers, the absorption of bad debts associated with IRP loans, and repayment of debt. Proposed budgets to cover the administrative costs of intermediaries must be submitted annually to FmHA. All proceeds in excess of those needed to cover authorized expenses, as described above, must revolve back into the IRP and be available for relending to eligible ultimate recipients.

§ 1948.113 Security.

(a) *Loans to intermediaries.* Unless otherwise approved by FmHA, security for the FmHA loan will be separate and apart from security for other loans for which the intermediary is either maker or payee. All loans to intermediaries will be adequately secured. Security for such loans may include but is not limited to:

(1) any realty, personalty, or intangibles capable of being mortgaged, pledged, or otherwise encumbered by the intermediary in favor of FmHA; and

(2) any realty, personalty, or intangibles capable of being mortgaged, pledged, or otherwise encumbered by an ultimate recipient in favor of FmHA.

(b) *Loans from intermediaries to ultimate recipients.* Security requirements for loans from intermediaries to ultimate recipients will be negotiated between the intermediaries and ultimate recipients. FmHA concurrence is required only when security for the loan from the intermediary to the ultimate recipient will also serve as security for the FmHA loan.

(c) *Additional security.* The FmHA may require additional security at any time during the term of a loan to an intermediary if, after review and monitoring, an assessment indicates the need for such security to protect the Government's interest.

(d) *Appraisals for security for all loans to intermediaries and for loans to ultimate recipients serving as security for loans to intermediaries.* Real property serving as security will be appraised by a qualified appraiser. For all other types of property, a valuation shall be made using any recognized, standard technique for the type of property involved (including standard reference manuals), and this valuation shall be described in the loan file.

§ 1948.114 Conflict of interest.

The intermediary will, for each proposed loan to an ultimate recipient, inform FmHA in writing and furnish such additional evidence as FmHA requests as to whether and the extent to which the intermediary or its principal officers (including immediate family) hold any legal or financial interest or influence in the ultimate recipient, or the ultimate recipient or any of its principal officers (including immediate family) holds any legal or financial interest or influence in the intermediary. FmHA shall determine whether such ownership, influence or financial interest is sufficient to create a potential conflict of interest. In the event FmHA determines there is a conflict of interest, the intermediary's assistance to the ultimate recipient will not be approved until such conflict is eliminated.

§ 1948.115 Post award requirements.

(a) Intermediaries receiving loans under this program shall be governed by these regulations, the Loan Agreement, the approved work plan, security interests, and any other conditions which the FmHA may impose in awarding a loan. Prior to making a loan commitment to an ultimate recipient, the intermediary must receive FmHA's concurrence in the proposed use of loan funds outlined in § 1948.128 of this Subpart.

(b) Unless otherwise specifically agreed to in writing by the FmHA, any loan funds held by an intermediary and any funds obtained from loaning FmHA-derived funds and recollecting them, that are not immediately needed by the intermediary for an ultimate recipient, should be deposited in an interest bearing account in a bank or other financial institution which will be covered by a form of federal deposit insurance. Any interest or income earned as a results of such deposits shall be used by the intermediary only for purposes authorized by FmHA.

§1948.116 Fees and charges.

(a) *Late payment charges.* Unpaid principal or interest on the loan to the intermediary will be handled as specified in the Loan Agreements attached as Exhibit II to these regulations. Late payment charges on a loan to an ultimate recipient may be made when a loan payment has not been received within the customary timeframe allowed as agreed upon by the ultimate recipient and intermediary. The term "payment received" means that the payment in cash or check, money order, or similar medium has been received by the intermediary at its designated place of payment.

(b) *Documentation of fees.* All fees and charges must be specifically documented and justified on Form FmHA 1948–1, "Application for Loan (Intermediary Relending Program)," or on an addendum to the application at the time the loan request is submitted to FmHA for processing. Allowable fees will be those reasonably and customarily charged intermediaries in similar circumstances in the ordinary course of business and are subject to FmHA review and concurrence.

(c) *Eligible packagers and payment of fees.* Packaging fees include services rendered by others in connection with preparation of the application and seeing the transaction through to final decision. These services may or may not be performed by an investment banker. If an investment banker provides needed assistance in addition to the packaging of the loan, additional charges may be added to the packaging fee. The maximum allowable packaging fees are 2 percent of the total principal amount. Packaging fees, investment banker fees, and any other fees and charges not specifically provided for in this section are permitted subject to FmHA review and written approval.

§1948.117 Other regulatory requirements.

(a) *Intergovernmental consultation.* The Intermediary Relending Program is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. The approval of a loan to an intermediary will be the subject to intergovernmental consultation. For each ultimate recipient to be assisted with a loan under this subpart and for which the State in which the ultimate recipient is to be located has elected to review the program under their intergovernmental review process, the State Point of Contact must be notified. Notification, in the form of a project description, can be initiated by the intermediary or the ultimate

recipient. Any comments from the State must be included with the intermediary's request to use the FmHA loan funds for the ultimate recipient. Prior to FmHA's decision on the request, compliance with the requirements of intergovernmental consultation must be demonstrated for each ultimate recipient. These requirements should be carried out in accordance with FmHA Instruction 1940–J, "Intergovernmental Review of Farmers Home Administration Programs and Activities," available in any FmHA office.

(b) *Environmental requirements.* (1) Unless specifically modified by this section, the requirements of Subpart G of Part 1940 of this Chapter apply to this subpart. FmHA will give particular emphasis to ensuring compliance with the environmental policies contained in §§ 1940.303 and 1940.304 in Subpart G of Part 1940 of this Chapter. Intermediaries and ultimate recipients of loans must consider the potential environmental impacts of their projects at the earliest planning stages and develop plans to minimize the potential to adversely impact the environment.

(2) As part of the intermediary's application for a loan, the intermediary must provide a completed Form FmHA 1940–20, "Request for Environmental Information," for each Class I or Class II project specifically identified in its plan submitted with its loan application. FmHA will review the application, supporting materials, and any required Forms FmHA 1940–20, and initiate a Class II environmental assessment for the application. This assessment will focus on the potential cumulative impacts of the projects as well as any environmental concerns or problems that are associated with individual projects and that can be identified at this time from the information submitted. Because neither the completion of the environmental assessment nor the approval of the application is an FmHA commitment to the use of loan funds for a specific project, no public notification requirements for a Class II assessment will apply to the application. The affected public has not been sufficiently identified at this stage of the FmHA review. Should an application be approved, each project to be assessed will undergo the applicable environmental review and public notification requirements in Subpart G of Part 1940 of this Chapter prior to FmHA's consent to use loan funds for an ultimate recipient. FmHA will prepare an Environmental Impact Statement for any application for a loan determined to have a significant effect on the quality of the human environment. Both the intermediary and the ultimate recipient will cooperate and furnish such information and assistance as FmHA needs to make any of its environmental determinations.

(3) As part of the intermediary's request to FmHA for concurrence to make a loan to an ultimate recipient, the intermediary will include for the ultimate recipient a properly completed Form FmHA 1940–20, if it is classified as a Class I or Class II action. FmHA will complete the environmental review required by Subpart G of Part 1940 of this Chapter. The results of this review will be used by FmHA in making its decision on the request.

(c) *Equal opportunity and nondiscrimination requirements.* (1) In accordance with Title V of Pub. L. 93–495, the Equal Credit Opportunity Act, neither the intermediary nor FmHA will discriminate against any applicant on the basis of race, color, religion, national origin, age, physical or mental handicap (provided that the applicant has the capacity to enter into a binding contract), sex or marital status with respect to any aspect of a credit transaction anytime FmHA loan funds are involved.

(2) The regulations contained in Part 1901, Subpart E of this Chapter apply to loans made under this program.

(3) The Administrator will assure that equal opportunity and nondiscrimination requirements are met in accordance with Title VI of the Civil Rights Act of 1964, "Nondiscrimination in Federally Assisted Programs," 42 U.S.C. 2000d–2000d–4. If there is indication of noncompliance with these requirements, such facts will be reported in writing to the Administrator, ATTN: Equal Opportunity Officer.

§ 1948.118 Loan agreements between FmHA and the intermediary.

A loan agreement must be executed by the intermediary and FmHA at loan closing for each loan. The loan agreement will be prepared by FmHA and reviewed by OGC prior to the loan closing. Part 1948, Subpart C, Exhibit II (available from the FmHA National Office or any FmHA State Office), may be used as a guide. The loan agreement, as a minimum, must contain the following provisions:

(a) The loan agreement will set out:

(1) The amount of the loan.

(2) The interest rate.

(3) The term and repayment schedule.

(4) The provisions for late charges. The intermediary shall pay a late charge of 4 percent of the payment due of principal and/or interest if payment for either of these is not received within 15 calendar days following the due date. The late charge shall be considered unpaid if not received within 30 calendar days of the missed due date for which it was imposed. Any unpaid late charge shall be added to principal and be due as an extra payment at the end of the term. Acceptance of a late charge by FmHA does not constitute a waiver of default.

(5) Disbursement procedure. Disbursement of loan funds by FmHA to the intermediary shall take place after the loan agreement and promissory note are executed, and any other conditions precedent to disbursement of funds are fully satisfied. The intermediary may draw down only such funds as are necessary to cover a 30-day period in implementing its approved work program. Advances will be requested by the intermediary in writing. The intermediary 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." The date of such drawdown shall constitute the date the funds are advanced under the loan agreement for purposes of computing interest payments.

(6) Provisions regarding default. On the occurrence of any event of default, FmHA may declare all or any portion of the debt and interest to be immediately due and payable and may proceed to enforce its rights under the loan agreement or any other instruments securing or relating to the loan and in accordance with the applicable law and regulations. Any of the following may be regarded as an "event of default" in the sole discretion of the FmHA:

(i) Failure of the intermediary to carry out or comply with the specific activities in its loan application as approved by FmHA, or loan terms and conditions, or any terms or conditions of the loan agreement, or any applicable Federal or State laws, or with such USDA or FmHA regulations as may become generally applicable at any time.

(ii) Failure of the intermediary to pay within 15 calendar days of its due date any installment of principal or interest on its promissory note to FmHA.

(iii) The occurrence of:

(A) The intermediary's becoming insolvent, or ceasing, being unable, or admitting in writing its inability to pay its debts as they mature, or making a general assignment for the benefit of, or entering into any composition or arrangement with creditors;

(B) Proceedings for the appointment of a receiver, trustee or liquidator of the intermediary, or of a substantial part of

its assets, being authorized or instituted by or against it.

(iv) Submission or making of any report, statement, warranty, or representation by the intermediary or agent on its behalf to USDA or FmHA in connection with the financial assistance awarded hereunder which is false, incomplete or incorrect in any material respect.

(v) Failure of the intermediary to remedy any material adverse change in its financial or other condition (such as the representational character of its board of directors or policymaking body) arising since the date of FmHA's award of assistance hereunder, which condition was an inducement to FmHA's original award.

(7) *Insurance requirements.* (i) Hazard insurance with a standard mortgage clause naming the intermediary as beneficiary will be required by the intermediary on every ultimate recipient's project in an amount that is at least the lesser of the depreciated replacement value of the property being insured or the amount of the loan. Hazard insurance includes fire, windstorm, lightning, hail, business interruption, explosion, riot, civil commotion, aircraft, vehicle, marine, smoke, builder's risk, public liability, property damage, flood or mudslide, or any other hazard insurance that may be required to protect the security. The intermediary's interest in the insurance will be assigned to the FmHA.

(ii) Ordinarily, life insurance, which may be decreasing term insurance, is required for the principals and key employees of the ultimate recipient and will be assigned or pledged to the intermediary and subsequently to FmHA. A schedule of life insurance available for the benefit of the loan will be included as part of the application.

(iii) Workmen's compensation insurance on ultimate recipients is required in accordance with State law.

(iv) The intermediary is responsible for determining if an ultimate recipient is located in a special flood or mudslide hazard area anytime FmHA loan funds are involved. If the ultimate recipient is in a flood or mudslide area, then flood or mudslide insurance must be provided in accordance with Subpart B of Part 1806 of this Chapter (FmHA Instruction 426.2).

(b) The intermediary will agree:

(1) Not to make any changes in the intermediary's articles of incorporation, charter, or by-laws without the concurrence of FmHA.

(2) Not to make a loan commitment to an ultimate recipient without first receiving FmHA's written concurrence in the proposed use of loan funds.

(3) To maintain a separate ledger and segregated account for IRP funds.

(4) To FmHA reporting requirements on the intermediary by providing:

(i) An annual audit; dates of audit report period need not necessarily coincide with other reports on the IRP. Audits shall be due 90 days following the audit period. Audits must cover all of the intermediary's activities. Audits will be performed by an independent certified public accountant or by an independent public accountant licensed and certified on or before December 31, 1970, by a regulatory authority of a State or other political subdivision of the United States. An acceptable audit will be performed in accordance with generally accepted auditing standards and include such tests of the accounting records as the auditor considers necessary in order to express an opinion on the financial condition of the intermediary. FmHA does not require an unqualified audit opinion as a result of the audit. Compilations or reviews do not satisfy the audit requirement.

(ii) Quarterly reports for periods ending March 31, June 30, September 30, and December 31 (due 30 days after the end of the period). FmHA at its option may change this requirement to semiannual reports. These reports shall contain information only on the IRP loan funds, or if other funds are included, the IRP loan program portion shall be segregated from the others; and in the case where the intermediary has more than one IRP loan, from FmHA, a separate report shall be made for each of these IRP loans. The reports will include:

(A) Form FmHA 1951-4, "Report of IRP/RDLF Lending Activity" (available in the FmHA National Office). This report will include information on the intermediary's lending activity, income and expenses, and financial condition and a summary of names and characteristics of the ultimate recipients the intermediary has financed.

(B) Project Progress Review Narrative

(iii) An annual report on the extent on which increased employment, income and ownership opportunities are provided to low-income persons, farm families, and displaced farm families for each loan made by such intermediary.

(iv) Proposed budget for the following year.

(v) Other reports as FmHA may require from time to time.

(5) Before the first relending of FmHA funds to the ultimate recipient, to obtain written FmHA approval of:

(i) All forms to be used for relending purposes, including application forms, loan agreements, promissory notes, and security instruments.

(ii) Intermediary's policy with regard to the amount and form of security to be required.

(6) To obtain approval of FmHA before making any major changes in forms or policy.

(7) To secure the indebtedness by pledging its portfolio of investments derived from the proceeds of the loan award, and/or pledging its real and personal property, and other rights and interests as FmHA may require.

(8) To provide additional security and execute any additional lien instruments as FmHA may require at any time during the term of the loan if, after review and monitoring, an assessment indicates the need for such security to protect the Government's interest.

§§ 1948.119–1948.121 [Reserved]

§ 1948.122 Application.

An application will consist of:

(a) Form FmHA 1948–1, "Application For Loan (Intermediary Relending Program)."

(b) A written work plan and other evidence FmHA requires to demonstrate the feasibility of the intermediary's program to meet the objectives of this program. The plan must, at a minimum:

(1) Document the intermediary's ability to administer an Intermediary Relending Program in accordance with the provisions of this subpart. In order to adequately demonstrate the ability to administer the program, the intermediary must provide a complete listing of all personnel responsible for administering this program along with a statement of their qualifications and experience. The personnel may be either members or employees of the intermediary's organization or contract personnel hired for this purpose. If the personnel are to be contracted for, the contract between the intermediary and the entity providing such service will be submitted for FmHA's review and the terms of the contract and its duration must be sufficient to adequately service the FmHA loan through to its ultimate conclusion. If FmHA determines the personnel lack the necessary expertise to administer the program, the loan request will not be approved.

(2) Document the intermediary's ability to commit financial resources under the control of the intermediary to the establishment of an Intermediary Relending Program. This should include a statement of the source(s) of non-FmHA funds for administration of the intermediary's operations and financial assistance for projects.

(3) Include a proposal for adequately securing the FmHA loan. The proposal

should specifically address those items of security outlined in § 1948.113 of this subpart.

(4) Include a detailed statement of the proposed use of FmHA loan funds. This should include an outline of what will constitute project eligibility for financial assistance the intermediary will make available to ultimate recipients.

(5) Demonstrate a need for loan funds. As a minimum, the intermediary should identify a sufficient number of proposed and known ultimate recipients it has on hand to justify FmHA funding of its loan request.

(6) Include a list of proposed fees and other charges it will assess the ultimate recipients it funds.

(7) Demonstrate to FmHA's satisfaction that the intermediary has secured commitments of significant financial support from public agencies and private organizations.

(8) Provide evidence to FmHA's satisfaction that the intermediary has a proven record of obtaining private and/or philanthropic funds for the operation of similar programs to the one contained in this subsection.

(9) Include the intermediary's plan (specific loan purposes) for relending the loan funds. The plan must be of sufficient detail to provide FmHA with a complete understanding of what the intermediary will accomplish by lending the funds to the ultimate recipient and the complete mechanics of how the funds will get from the intermediary to the ultimate recipient. The eligibility criteria, the application process, method of disposition of the funds to the ultimate recipient, monitoring of the ultimate recipient's accomplishments, and reporting requirements by the ultimate recipient's management are some of the items that must be addressed by the intermediary's relending plan.

(c) Form FmHA 1940–20, "Request for Environmental Information," for all projects identified in the intermediary's plan that are Class I or Class II actions under Subpart G of Part 1940 of this Chapter.

(d) Comments from the State single point of contact, if the State has elected to review the program under Executive Order 12372, "Intergovernmental Review of Federal Programs."

(e) Cost estimates and forecasts of contingency funds to cover inflation or project changes.

(f) A pro forma balance sheet at startup and for at least 3 additional projected years; financial statements for the last 3 years, or from inception of the operations of the intermediary if less than 3 years; and projected cash flow and earnings statements for at least 3 years supported by a list of assumptions showing the basis for the projections.

(g) A written agreement will be signed by the intermediary to assure that there is no misunderstanding concerning FmHA audit requirements.

(h) Form FmHA 400–1, "Equal Opportunity Agreement."

(i) Form FmHA 400–4, "Assurance Agreement."

(j) Complete organizational documents, including evidence of authority to conduct the proposed activities.

(k) Evidence that the loan is not available at reasonable rates and terms from private sources or other Federal, State, or local programs.

(l) Latest audit report, if available.

§ 1948.123 Filing and processing applications for loans.

(a) *Intermediaries' contact.* Intermediaries desiring FmHA assistance in this subpart may file applications with the FmHA National Office, Director, Business and Industry (B&I) Division, Washington, DC 20250. The Director, Business and Industry Division, may be contacted to discuss assembly, preparation, and processing of applications.

(b) *Filing applications.* Intermediaries must file the complete application, in one package. Applications received by FmHA will be considered in the order received.

(c) *Loan priorities.* Priority consideration will be given to intermediaries whose written plan, as required by § 1948.122, demonstrates that the intermediary:

(1) Will provide financial assistance to ultimate recipients that provide the greatest benefit to low-income persons, farm families, and displaced farm families.

(2) Will involve the most financial assistance from other sources in providing assistance to the ultimate recipients as provided by this program.

(d) *Timeframe for processing applications for loans.* All loan applications must be approved or disapproved, and the intermediary notified in writing, not later than 60 calendar days after receipt of a completed application.

(1) If an application is not complete, the intermediary will be notified, in writing, not later than 20 calendar days after receipt of the application by FmHA, of the reason(s) the application is incomplete.

(2) When an application is disapproved, the written notification to the intermediary will state the reason(s) for disapproval.

(3) When an application is disapproved and subsequent action, as the result of an appeal, reverses or revises the initial decision, FmHA will notify the intermediary of such action within 15 calendar days after the reversal/revision decision is made.

§ 1948.124 FmHA evaluation of application.

(a) FmHA will prepare Form FmHA 2033–34, "Management System Card—Business and Industry," in accordance with FmHA Instruction 2033–F.

(b) Applications will be organized in a loan file in accordance with FmHA Instruction 2033–A. The intermediary's Internal Revenue Service (IRS) tax number preceded by State and County code numbers will constitute the case number to be used on all FmHA forms.

(c) The FmHA Administrator or designee will evaluate the application and make a determination whether: the intermediary is eligible; the proposed loan is for an eligible purpose; there is reasonable assurance of repayment ability, sufficient collateral, and sufficient equity; there is a need for an environmental impact statement or environmental mitigation; there are any unresolved intergovernmental consultation issues; and the proposed loan complies with all applicable statutes and regulations. If FmHA determines it is unable to provide the loan, the intermediary will be informed in writing. Such notification will include the reasons for denial of the loan. If FmHA is able to provide the loan, it will provide the intermediary a letter of conditions listing all requirements for such loan.

(1) Requirements listed in letters of conditions will ordinarily include: maximum amount of loan which may be considered, terms of loan, description of the use of loan funds, verification requirements, disbursement of funds, security requirements, and audit reports required.

(2) The 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, project scope, or any other significant changes in the project of intermediary 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 $_____.

The intermediary must certify at loan closing that since FmHA's issuance of the letter of conditions there has been no material adverse change(s) in its financial condition nor any other material adverse change in the intermediary.

The loan will be considered approved on the date 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.

If the conditions set forth in this letter are not met within _____ days from the date hereof, the processing of the application is automatically terminated.

(3) The Administrator or designee is the only person authorized to execute the letter of conditions.

(d) Immediately after reviewing the conditions and requirements in the letter of conditions, the intermediary should complete, sign and return the Form FmHA 422–46 to the FmHA Administrator. If certain conditions cannot be met, the borrower may propose alternate conditions to FmHA. The Administrator or designee must concur with any changes made to the initially issued or proposed letter of conditions.

(e) If at any time prior to loan approval it is decided that favorable action will not be taken on an application, FmHA 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 in accordance with Subpart B of Part 1900 of this Chapter.

§ 1948.125 Loan approval and obligating funds.

The loan will be considered approved on the date the signed copy of Form FmHA 1940–1 is mailed to the intermediary. The Administrator or designee may request an obligation of funds when available and according to the following:

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

(b) 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.

(c) The Administrator or designee will request an obligation of loan funds by signing Form FmHA 1940–1, contacting the Finance Office Appropriation Accounting Section by telephone, and then mailing a copy of the Form FmHA 1940–1 to the Finance Office.

(d) The obligation date and date the intermediary is notified of loan approval is six working days from the date funds are reserved unless an exception is granted by the National Office.

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

(f) The Administrator or designee will record the date of intermediary notification on the original of Form FmHA 1940–1 and include it as a permanent part of the official FmHA file.

(g) If a transfer of obligation of funds is necessary, complete Form FmHA 450–10, "Advice of Borrower's Change of Address, Name, Case Number, or Loan Number," and mail a copy to the Finance Office. An obligation of funds established for an intermediary may be transferred to a different (substituted) intermediary provided:

(1) The substituted intermediary is eligible to receive the assistance approved for the original intermediary;

(2) The substituted intermediary bears a close and genuine relationship to the original intermediary; and

(3) The need for and scope of the project and the purpose(s) for which FmHA funds will be used remain substantially unchanged.

§ 1948.126 Loan closing.

(a) After the letter of conditions has been issued and proposed closing documents have been prepared, FmHA will forward the loan docket to the Regional OGC in the region in which the borrower is located for review. For the purpose of this paragraph, the District of Columbia is considered to be in Maryland. After an administrative review, FmHA will include with the docket a letter with recommendations and indicating any special items, documents, or problems that need to be addressed specifically which may have a significant impact upon the loan or may be contrary to the regulation. The docket will be assembled for OGC review and indexed and tabbed. The OGC will review the docket and furnish advice to FmHA on noted deficiencies. Upon receipt of the OGC's advice, FmHA will correct or cause to be corrected any noted deficiencies. Loans will be closed by FmHA with the assistance of the OGC Regional Attorney who will issue closing instructions detailing the requirements and any actions necessary to proceed with the loan closing.

(b) In all cases, the Administrator or designee will conduct a review before the loan is closed to assure that all requirements of the application, letter of conditions, and Loan Agreement have been met including required certifications, and will provide such verification in the loan file, including arrangements for annual audit reports. The intermediary's certifications will include the following:

(1) No major changes have been made in the intermediary's work plan except those approved in the interim by FmHA.

(2) All requirements of the letter of conditions have been met.

(3) Equity requirements have been met. A reconciliation of the intermediary's assets and net worth from the latest financial statement to the date of loan closing will be provided with this certification.

(4) There has been no material adverse change in the intermediary's financial condition nor any material adverse change in the intermediary since the issuance of the letter of conditions. If there have been adverse changes, they must be explained by the intermediary. They may be waived, at the sole discretion of FmHA. Financial data must not be more than 60 days old at loan closing.

(c) FmHA personnel shall not sign any documents other than those specifically provided for in this subpart.

(d) The National Office will review any requests for changes to the letter of conditions. The National Office will approve only minor changes which do not materially affect the project, its capacity, employment, original projections or credit factors. Changes in legal entities or where tax considerations are the reason for change will not be approved.

(e) At loan closing the intermediary will provide sufficient evidence to enable FmHA to ascertain that no claim or liens of laborers, materialmen, contractors, subcontractors, suppliers of machinery and equipment, or other parties are against the security of the intermediary, and that no suits are pending or threatened that would adversely affect the security of the intermediary when the security instruments are filed.

§ 1948.127 [Reserved]

§ 1948.128 Requests to make loans to ultimate recipients.

(a) When an intermediary proposes to use funds obtained from FmHA to make a loan to an ultimate recipient, and prior

to final approval of such loan, the intermediary will submit to FmHA a copy of the ultimate recipient's application and provide certification that the ultimate recipient is eligible; the proposed loan is for an eligible purpose; and the proposed loan complies with all applicable statutes and regulations. No commitment of loan funds to the ultimate recipient may be made by the intermediary until an affirmative decision on proceeding with funding to the ultimate recipient is rendered by FmHA.

(b) As part of the intermediary's request to FmHA for concurrence to make a loan to an ultimate recipient, the intermediary will include for the project a properly completed Form FmHA 1940–20 executed by the ultimate recipient. FmHA will review the Form FmHA 1940–20, and complete the environmental review in accordance with § 1948.117 of this Subpart. The results of this review will be used by FmHA in making its decision on the request.

(c) The intermediary will provide, for FmHA review, all comments obtained in accordance with paragraph (a) of § 1948.117 of this Subpart, "Intergovernmental review."

(d) If FmHA determines it is unable to concur with the loan request, the intermediary will be informed in writing the reasons for denial.

§ 1948.129 [Reserved]

§ 1948.130 Non-Federal funds.

Once all the FmHA-derived loan funds have been utilized by the intermediary for assistance to ultimate recipients according to the provisions of these regulations and loan agreement, new ultimate recipients financed thereafter from the intermediary's revolving loan fund shall not be considered as being derived from Federal funds and the requirements of these regulations will not be imposed on those new ultimate recipients. Ultimate recipients assisted by the intermediary with FmHA-derived loan funds shall be required to comply with the provisions of these regulations and/or loan agreement.

§§ 1948.131–1948.137 [Reserved]

§ 1948.138 Office of Inspector General and Office of General Counsel referrals.

When facts or circumstances indicate that criminal violations, civil fraud, misrepresentations, or regulatory violations may have been committed by an applicant or an intermediary, FmHA will refer the case to the appropriate Regional Inspector General for Investigations, OIG, USDA, in accordance with FmHA Instruction 2012–B (available in any FmHA office) for criminal investigation. Any questions as to whether a matter should be referred will be resolved through consultation with OIG for Investigations and the FmHA designee and confirmed in writing. In order to assure protection of the financial and other interests of the Government, a duplicate of the notification will be sent to OGC. OGC will be consulted on legal questions. After OIG has accepted any matter for investigation, FmHA staff must coordinate with OIG in advance regarding routine servicing actions on existing loans.

§§ 1948.139–1948.142 [Reserved]

§ 1948.143 Appeals.

Any appealable adverse decision made by FmHA which affects the borrower may be appealed upon written request of the aggrieved party in accordance with Subpart B of Part 1900 of this Chapter.

§§ 1948.144–1948.147 [Reserved]

§ 1948.148 Exception authority.

The Administrator may in individual cases grant an exception to any requirement or provision of this Subpart which is not inconsistent with an applicable law or opinion of the Comptroller General, provided the Administrator determines that application of the requirement or provision would adversely affect the Government's interest. The basis for this exception will be fully documented. The documentation will: demonstrate the adverse impact; identify the particular requirement involved; and show how the adverse impact will be eliminated.

§ 1948.149 Exhibits.

The following documents may be used in connection with this program; they are incorporated into this Subpart and made a part hereof. They are not published in the **Federal Register** but may be obtained in any FmHA State Office or in the National Office.

(a) Exhibit I, "Note (Intermediary Relending Program)."

(b) Exhibit II, "Loan Agreement (Intermediary Relending Program)."

(c) Exhibit III, "Loan Docket."

§ 1948.150 OMB Control Number.

The collection of information requirements in this regulation have been approved by the Office of Management and Budget and assigned OMB Control Number 0575–0130. In accordance with 5 CFR 1320, summarized below is the annualized public reporting burden for this regulation.

Sect. of Regulations	Title	Form No. (if any)	Estimated No. of respondents	Reports filed annually	Total annual responses (d) × (e)	Est. No. of man-hrs. per response	Est. total man-hours (f) × (g)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
Reporting Requirements—No Forms							
1948.103(b)(1)	Evidence of 10% equity	Written	35	1	35	1.0	35.0
1948.103(b)(2)	Endorsement of the Governor	Written	35	1	35	1.0	35.0
1948.103(b)(5)	Evidence of ability to administer revolving loan program.	Written	35	1	35	1.0	35.0
1948.103(c)(2)	Certification of lack of financing	Written	35	1	35	1.0	35.0
1948.109(a)	Certificate of Compliance	Written	10	On occasion	50	2.0	100.0
1948.114	Conflict of interest	Written	10	On occasion	50	1.0	50.0
1948.117(a)	State comments	Written	10	On occasion	50	1.5	75.0
1948.122(b)	Intermediary's work plan to demonstrate feasibilty of its operation.	Written plan	35	1	35	120	4200.0
1948.124(c)	Letter of Conditions	Written	15	1	15	1.5	22.5
1948.126	Loan Closing Certification	Written	10	1	10	3.5	35.0
1948.128	Certification to make loans to ultimate recipients	Written	10	On occasion	50	2.0	100.0
1948.143	Request for Appeal	Letter	5	1	5	2.0	10.0

Sect. of Regulations	Title	Form No. (if any)	Estimated No. of respondents	Reports filed annually	Total annual responses (d) × (e)	Est. No. of man-hrs. per response	Est. total man-hours (f) × (g)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
Form Approved with this Docket							
1948.122	Application for Loan (Intermediary Relending Program).	1948-1	35	1	35	50.0	1750.0
Reporting Requirements Approved Under Other Numbers							
1948.117(b)(2)	Request for Environmental Information	1940-20 (0575-0094).					
1948.1118(b)(4)(ii)(A)	Report of IRP/RDLF Lending Activity	1951-4 (approval requested with 7 CFR 1951-R).					
1948.124(d)	Letter of Intent to Meet Conditions	442-46 (0575-0015).					
Recordkeeping Requirements							
Exh. I	Promissory Note		10			1.0	10.0
1948.118 Exh. II	Loan Agreement		10			1.5	15.0
	Total Reporting				440		6,482
	Total Recordkeeping						25
	Docket Total				440		6,507

PART 1951—SERVICING AND COLLECTIONS

3. The authority citation for Part 1951 is revised to read as follows:

Authority: 7 U.S.C. 1989; 7 U.S.C. 1932 note; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart F—Analyzing Credit Needs and Graduation of Borrowers

4. Section 1951.251 is revised to read as follows:

§ 1951.251 Purpose.

This subpart prescribes the policies to be followed when analyzing a borrower's needs for continued Farmers Home Administration (FmHA) supervision, further credit and graduation. All borrowers' loan account(s) will be reviewed for graduation in accordance with this subpart, except Guaranteed, Watershed, Resource Conservation and Development, Rural Development Loan Fund and Intermediary Relending Program loans.

5. Part 1951 is amended by adding Subpart R to read as follows:

Subpart R—Rural Development Loan Servicing

Sec.

1951.851 Introduction.
1951.852 Definitions and abbreviations.
1951.853 Loan purposes for undisbursed RDLF loan funds from HHS.
1951.854 Ineligible assistance purposes.
1951.855–1951.858 [Reserved]
1951.859 Terms of loans.
1951.860 Interest on loans.
1951.861—1951.865 [Reserved]
1951.866 Security.
1951.867 Conflict of interest.
1951.868—1951.870 [Reserved]
1951.871 Post award requirements.
1951.872 Other regulatory requirements.
1951.873—1951.876 [Reserved]
1951.877 Loan agreements.
1951.878–1951.880 [Reserved]
1951.881 Loan servicing.
1951.882 Field visits.
1951.883 Reporting requirements.
1951.884 Non-Federal funds.
1951.885 Loan classifications.
1951.886–1951.888]Reserved]
1951.889 Transfer and assumption.
1951.890 Office of Inspector General and Office of General Counsel referrals.
1951.891 Liquidation; default.
1951.892–1951.893 [Reserved]
1951.894 Debt settlement.
1951.895 [Reserved]
1951.896 Appeals.
1951.897 Exception authority.
1951.898–1951.899 [Reserved]
1951.900 OMB Control Number.

Subpart R—Rural Development Loan Servicing

§ 1951.851 Introduction.

(a) This Subpart contains regulations for servicing or liquidating loans made by the Farmers Home Administration (FmHA) under the Intermediary Relending Program (IRP) to eligible IRP intermediaries and applies to ultimate recipients and other involved parties. The provisions of this Subpart supersede conflicting provisions of any other Subpart.

(b) This Subpart also contains regulations for servicing the existing Rural Development Loan Fund (RDLF) loans previously approved and administered by the U.S. Department of Health and Human Services (HHS) under 45 CFR Part 1076. This action is needed to implement the provisions of Section 1323 of the Food Security Act of 1985, Pub. L. 99–198, which provides for the transfer of the loan servicing authority for those loans from the HHS to the U.S. Department of Agriculture (USDA).

(c) The portion of this regulation pertaining to loanmaking applies to RDLF intermediaries cited in § 1951.851(b) which have RDLF funds from HHS and have not fully utilized relending of those funds to ultimate recipients at the date of these regulations. The loanmaking of all other

IRP loans serviced by this regulation is in accordance with Part 1948, Subpart C of this Chapter.

(d) These regulations do not negate contractual arrangements that were previously made by the HHS, Office of Community Services (OCS), or the intermediaries operating relending programs that have already been entered into with ultimate recipients under previous regulations.

(e) The loan program is administered by the FmHA National Office. The Director, Business and Industry Division, is the point of contact for servicing activities unless otherwise delegated by the Administrator.

§ 1951.852 Definitions and abbreviations.

(a) *General definitions.* The following definitions are applicable to the terms used in this Subpart.

(1) *Intermediary* (Borrower). The entity receiving FmHA loan funds for relending to ultimate recipients. FmHA becomes an intermediary in the event it takes over loan servicing and/or liquidation.

(2) *Loan Agreement.* The signed agreement between FmHA and the intermediary setting forth the terms and conditions of the loan.

(3) *Low-income.* The level of income of a person or family which is at or below the Poverty Guidelines as defined in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)).

(4) *Market value.* The most probable price which property should bring, as of a specific date in a competitive and open market, assuming the buyer and seller are prudent and knowledgeable, and the price is not affected by undue stimulus such as forced sale or loan interest subsidy.

(5) *Principals of intermediary.* Includes members, officers, directors, and other entities directly involved in the operation and management of an intermediary organization.

(6) *Ultimate recipient.* The entity receiving financial assistance from the intermediary. This may be interchangeable with the term "subrecipient" in some documents previously issued by HHS.

(7) *Rural area.* Includes all territory of a State that is not within the outer boundary of any city having a population of twenty-five thousand or more.

(8) *State.* Any of the fifty States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(9) *Technical assistance or service.* Technical assistance or service is any function unreimbursed by FmHA performed by the intermediary for the benefit of the ultimate recipient.

(10) *Working capital.* The excess of current assets over current liabilities. It identifies the liquid portion of total enterprise capital which constitutes a margin or buffer for meeting obligations within the ordinary operating cycle of the business.

(b) *Abbreviations.* The following abbreviations are applicable:

(1) *B&I*—Business and Industry
(2) *CSA*—Community Services Administration
(3) *EIS*—Environmental Impact Statement
(4) *FmHA*—Farmers Home Administration
(5) *HHS*—U.S. Department of Health and Human Services
(6) *IRP*—Intermediary Relending Program
(7) *OCS*—Office of Community Services
(8) *OIG*—Office of Inspector General
(9) *OGC*—Office of the General Counsel
(10) *RDLF*—Rural Development Loan Fund
(11) *USDA*—United States Department of Agriculture

§ 1951.853 Loan purposes for undisbursed RDLF loan funds from HHS.

(a) *RDLF Intermediaries.* Rural Development Loan funds will be used by the RDLF intermediary to provide loans to ultimate recipients in accordance with paragraph (b) of this section. Interest income, service fees, and other authorized financing charges received by RDLF intermediaries operating relending programs may be used to pay for: The costs of administering the RDLF relending program, the provision of technical assistance to borrowers, the absorption of bad debts associated with RDLF loans, and repayment of debt. All proceeds in excess of those needed to cover authorized expenses, as described above, must be returned to FmHA.

(b) *Ultimate recipients.*

(1) Financial assistance from the intermediary to the ultimate recipient must be for business facilities and community development projects in rural areas.

(2) Financial assistance involving Rural Development Loan funds from the intermediary to the ultimate recipient may include but not be limited to:

(i) Business acquisitions, construction, conversion, enlargement, repair, modernization, or development cost.

(ii) Purchasing and development of land, easements, rights-of-way, building, facilities, leases, or materials.

(iii) Purchasing of equipment, leasehold improvements, machinery or supplies.

(iv) Pollution control and abatement.

(v) Transportation services.

(vi) Startup operating costs and working capital.

(vii) Interest (including interest on interim financing) during the period before the facility becomes income producing, but not to exceed 3 years.

(viii) Feasibility studies.

(ix) Reasonable fees and charges only as specifically listed in this subparagraph. Authorized fees include loan packaging fees, environmental data collection fees, and other professional fees rendered by professionals generally licensed by individual State or accreditation associations, such as Engineers, Architects, Lawyers, Accountants, and Appraisers. The amount of fee will be what is reasonable and customary in the community or region where the project is located. Any such fees are to be fully documented and justified as outlined in § 1948.116(b) of Part 1948, Subpart C.

(x) Aquaculture including conservation, development, and utilization of water for aquaculture. Aquaculture means the culture or husbandry of aquatic animals or plants by private industry for commercial purposes including the culture and growing of fish by private industry for the purpose of granting or augmenting publicly-owned or regulated stock of fish.

§ 1951.854 Ineligible assistance purposes.

(a) *RDLF Intermediaries.* RDLF loans may *not* be used by the intermediary:

(1) For payment of the intermediary's own administrative costs or expenses.

(2) To purchase goods or services or render assistance in excess of what is needed to accomplish the purpose of the ultimate recipient project.

(3) For distribution or payment to the owner, partners, shareholders, or beneficiaries of the ultimate recipient or members of their families when such persons will retain any portion of their equity in the ultimate recipient.

(4) For charitable and educational institutions, churches, organizations affiliated with or sponsored by churches, and fraternal organizations.

(5) For assistance to government employees, military personnel, or principals or employees of the intermediary who are directors, officers or have major ownership (20 percent or more) in the ultimate recipient.

(6) For relending in a city with a population of twenty-five thousand or

more as determined by the latest decennial census.

(7) For a loan to an ultimate recipient which has applied or received a loan from another intermediary unless FmHA provides prior written approval for such loan.

(8) For any line of credit.

(9) To finance more than 75 percent of the total cost of a project by the ultimate recipient. The total amount of RDLF loan funds requested by the ultimate recipient plus the outstanding balance of any existing RDLF loan(s) will not exceed $150,000. Other loans, grants, and/or intermediary or ultimate recipient contributions or funds from other sources must be used to make up the difference between the total cost and the assistance provided with RDLF funds.

(10) For any investments in securities or certificates of deposit of over 30-day duration without the concurrence of FmHA. If the RDLF funds have been unused to make loans to ultimate recipients for 6 months or more, those funds will be returned to FmHA unless FmHA provides an exception to the RDLF intermediary. Any exception would be based on evidence satisfactory to FmHA that every effort is being made by the intermediary to utilize the RDLF funding in conformance with program objectives.

(b) *Ultimate recipients.* Ultimate recipients may *not* use assistance received from RDLF intermediaries involving RDLF funds:

(1) For agricultural production, which means the cultivation, production (growing), harvesting, either directly or through integrated operations, of agricultural products (crops, animals, birds and marine life, either for fiber or food for human consumption, and disposal or marketing thereof, the raising, housing, feeding, breeding, hatching, control and/or management of farm and domestic animals). Exceptions to this definition are:

(i) Aquaculture as identified under eligible purposes.

(ii) Commercial nurseries primarily engaged in the production of ornamental plants and trees and other nursery products such as bulbs, florists' greens, flowers, shrubbery, flower and vegetable seeds, sod, the growing of vegetables from seed to the transplant stage.

(iii) Forestry, which includes establishments primarily engaged in the operation of timber tracts, tree farms, forest nurseries, and related activities such as reforestation.

(iv) Financial assistance for livestock and poultry processing as identified under eligible purposes.

(v) The growing of mushrooms or hydroponics.

(2) For the transfer of ownership unless the loan will keep the business from closing, or prevent the loss of employment opportunities in the area, or provide expanded job opportunities.

(3) For community antenna television services or facilities.

(4) For any legitimate business activity when more than 10 percent of the annual gross revenue is derived from legalized gambling activity.

(5) For any illegal activity.

(6) For any otherwide eligible project that is in violation of either a Federal, State or local environmental protection law or regulation or an enforceable land use restriction unless the financial assistance required will result in curing or removing the violation.

(7) For any hotels, motels, tourist homes, or convention centers.

(8) For any tourist, recreation, or amusement centers.

§§ 1951.855–1951.858 [Reserved]

§ 1951.859 Term of loans.

(a) No loans shall be extended for a period exceeding 30 years. Principal payments on loans will be made at least annually. The initial principal payment may be deferred not more than 3 years.

(b) The terms of loan repayment will be those stipulated in the loan agreement and/or promissory note.

§ 1951.860 Interest on loans.

(a) RDLF intermediaries: When the RDLF loan portfolio was transferred from HHS to USDA as required under Pub. L. 99–198, section 1323 of the Food Security Act of 1985, there were provisions that affected the interest rates on those loans.

(1) Those loans made in 1980 and 1981 carried an original note rate of 1 percent interest when they were first issued. The legislation provides for those loans made in 1980 and 1981 to have a permanent interest rate reduction to 1 percent effective December 23, 1985, to maturity. However, the interest rates on the loans made in 1983 and 1984 may remain the same as the original note rate.

(2) Loans made in 1983 and 1984 do not automatically qualify for a lower rate than the level of interest rates when the notes were first issued. Section 407 of Pub. L. 99–425 provides for a weighted average requirement that would affect those loans made in 1983 and 1984 to intermediary borrowers.

(3) In those cases where loans were made in RDLF intermediaries and the weighted average of all loans made by the RDLF intermediary after December 31, 1982, does not exceed the sum of 6 percent plus the interest rate to the intermediary (7 percent), the interest rate to be charged the RDLF intermediary will be the rate charged on such loans made in 1980, or 1 percent. Should the weighted average exceed 7 percent, the note rate will control.

(i) In order for FmHA to determine the weighted average of the loan portfolio, the RDLF intermediary will be required to complete a weighted loan average rate on its outstanding portfolio. The schedule prepared for FmHA's review should include:

(A) Calculations of the interest amount scheduled to accrue on each loan outstanding over a 1-year period based on the current interest rate of each ultimate recipient's loan.

(B) The sum total of interest on each individual loan will be added together to determine the total interest amount scheduled to accrue over a 1-year period.

(C) Divide the total of paragraph (a)(2) of this section by the total principal outstanding to determine the average interest percent yield in the intermediary's loan portfolio.

(D) The loans to be included in determining the weighted interest average will be those made from January 1, 1983, forward.

(E) FmHA will use the anniversary date of October 1 of each year to request the intermediary to complete a weighted interest average to determine the interest rate on its RDLF loan for the coming calendar year, January 1 through December 31. All loans made in 1980 and 1981 have had the interest rate permanently reduced by legislation to 1 percent, effective December 25, 1985.

(F) The weighted loan average interest rate on the outstanding loan portfolio as referenced in this section will be forwarded to FmHA along with sufficient documentation which should include calculations, list of outstanding loans, current interest rate being charged on the loan, etc.

(b) Interest rates charged by intermediaries to the ultimate recipients shall be at rates negotiated by those parties. Intermediaries are encouraged to make loans to ultimate recipients at the lowest possible rate, taking into account the cost of the loan funds to the intermediary and the cost of administering the loan portfolio.

§§ 1951.861–1951.865 [Reserved]

§ 1951.866 Security.

(a) *Loans from RDLF intermediaries to ultimate recipients.* Security requirements for loans from

intermediaries to ultimate recipients will be negotiated between the intermediaries and ultimate recipients. FmHA concurrence in the intermediary's security proposal is required only when security for the loan from the intermediary to the ultimate recipient will also serve as security for the FmHA loan.

(b) *Additional security.* The FmHA may require additional security at any time during the term of a loan to an intermediary if, after review and monitoring, an assessment indicates the need for such security.

(c) *Appraisals.* Real property serving as security for all loans to intermediaries and for loans to ultimate recipients serving as security for loans to intermediaries will be appraised by a qualified appraiser. For all other types of property, a valuation shall be made using any recognized, standard technique for the type of property involved (including standard reference manuals), and this valuation shall be described in the loan file.

§ 1951.867 Conflict of interest.

The intermediary will, for each proposed loan to an ultimate recipient, inform FmHA in writing and furnish such additional evidence as FmHA requests as to whether and the extent to which the intermediary or its principal officers (including immediate family) hold any legal or financial interest or influence in the ultimate recipient or the ultimate recipient or any of its principal officers (including immediate family) holds any legal or financial interest or influence in the intermediary. FmHA shall determine whether such ownership, influence or financial interest is sufficient to create potential conflict of interest. In the event FmHA determines there is a conflict of interest, the intermediary's assistance to the ultimate recipient will not be approved until such conflict is eliminated.

§ 1951.868-1951.870 [Reserved]

§ 1951.871 Post award requirements.

(a) RDLF intermediaries with undisbursed RDLF loan funds shall be governed by these regulations, the loan agreement, the approved work program, security interests, and other conditions which FmHA may require in awarding a loan.

(b) Unless otherwise specifically agreed to in writing by the FmHA, any loan funds held by an intermediary and any funds obtained from loaning FmHA-derived funds and recollecting them that are not immediately needed by the intermediary for an ultimate recipient should be deposited in an interest-bearing account in a bank or other financial institution which will be covered by a form of Federal deposit insurance. Any interest or income earned as a result of such deposits shall be used by the intermediary only for purposes authorized by FmHA.

(c) Intermediaries operating relending programs must maintain separate ledgers and segregated accounts for RDLF funds at all times.

(d) Reporting requirements shall be those delineated in the loan agreement between the United States and the intermediary and such subsequent requirements as FmHA deems appropriate. The intermediaries must document periodically the extent to which increased employment, income and ownership opportunities are provided to rural residents for each loan made by such intermediary.

(e) No intermediary may make a loan to an ultimate recipient who has applied for or received a loan from another intermediary unless FmHA provides prior written approval for such loan.

(f) All loan payments that are due on RDLF loans will be made payable to the Farmers Home Administration, using the number assigned, and mailed directly to: Farmers Home Administration, Finance Office, FC 35, 1520 Market Street, St. Louis, Missouri 63103.

§ 1951.872 Other regulatory requirements.

(a) *Intergovenmental consultation.* The RDLF program is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. For each ultimate recipient to be assisted with a loan under this Subpart and for which the State in which the ultimate recipient is to be located has elected to review the program under their intergovernmental review process, the State Point of Contact must be notified. Notification, in the form of a project description, can be initiated by the intermediary or the ultimate recipient. Any comments from the State must be included with the intermediary's request to use the loan funds for the ultimate recipient. Prior to FmHA's decision on the request, compliance with the requirements of intergovernmental consultation must be demonstrated for each ultimate recipient. These requirements should be carried out in accordance with FmHA Instruction 1940-J, "Intergovernmental Review of Farmers Home Administration Programs and Activities," available in any FmHA office.

(b) *Environmental requirements.* (1) Unless specifically modified by this section, the requirements of Subpart G of Part 1940 of this Chapter apply to this Subpart. FmHA will give particular emphasis to ensuring compliance with the environmental policies contained in §§ 1940.303 and 1940.304 in Subpart G of Part 1940 of this Chapter. Intermediaries and ultimate recipients of loans must consider the potential environmental impacts of their projects at the earliest planning stages and develop plans to minimize the potential to adversely impact the environment.

(2) As part of the intermediary's request to FmHA for concurrence to make a loan to an ultimate recipient, the intermediary will include for the ultimate recipient a properly completed Form FmHA 1940-20, "Request for Environmental Information," if it is classified as a Class I or Class II action. FmHA will complete the environmental review required by Subpart G of Part 1940 of this Chapter. The results of this review will be used by FmHA in making its decision on the request.

(c) *Equal opportunity and nondiscrimination requirements.*

(1) In accordance with Title V of Pub. L. 93-495, the Equal Credit Opportunity Act, neither the intermediary nor FmHA will discriminate against any applicant on the basis of race, color, religion, national origin, age, physical or mental handicap (provided that the applicant has the capacity to enter into a binding contract), sex or marital status with respect to any aspect of a credit transaction anytime Federal funds are involved.

(2) The regulations contained in Part 1901, Subpart E of this Chapter apply to loans made under this program.

(3) The Administrator will assure that equal opportunity and nondiscrimination requirements are met in accordance with Title VI of the Civil Rights Act of 1964, "Nondiscrimination in Federally Assisted Programs," 42 U.S.C. 2000d-2000d-4. If there is indication of noncompliance with these requirements, such facts will be reported in writing to the Administrator, ATTN: Equal Opportunity Officer.

§§ 1951.873-1951.876 [Reserved]

§ 1951.877 Loan agreements.

(a) A loan agreement will have been executed by the RDLF intermediary and OCS or HHS for each loan. The loan agreement ordinarily would contain the following provisions:

(1) The amount of the loan.

(2) The interest rate.

(3) The term and repayment schedule.

(4) The provisions for late charges.

(5) Provisions regarding default.

(6) Disbursement procedure.

(7) Insurance requirements.

(i) Hazard insurance with a standard mortgage clause naming the intermediary as beneficiary will be required on every ultimate recipient in an amount that is at least the lesser of the depreciated replacement value of the property being insured or the amount of the loan. Hazard insurance includes fire, windstorm, lightning, hail, business interruption, explosion, riot, civil commotion, aircraft, vehicle, marine, smoke, builder's risk, public liability, property damage, flood or mudslide, or any other hazard insurance that may be required to protect the security. The RDLF intermediary's interest in the insurance ordinarily will be assigned to the FmHA.

(ii) Ordinarily, life insurance, which may be decreasing term insurance, is required for the principals and key employees of the ultimate recipient and will be assigned or pledged to the RDLF intermediary and subsequently to FmHA. A schedule of life insurance available for the benefit of the loan will be included as part of the application.

(iii) Workmen's compensation insurance on ultimate recipients is required in accordance with State law.

(iv) The RDLF intermediary is responsible for determining if an ultimate recipient is located in a special flood or mudslide hazard area anytime Federal funds are involved. If the ultimate recipient is in a flood or mudslide area, then flood or mudslide insurance must be provided.

(b) The RDLF intermediary will agree:

(i) Not to make any changes in the RDLF intermediary's articles of incorporation, charter or bylaws without the concurrence of FmHA.

(ii) Not to make a loan commitment to an ultimate recipient without first receiving FmHA's written concurrence in the proposed use of loan funds.

§§ 1951.878–1951.880 [Reserved]

§ 1951.881 Loan servicing.

(a) These regulations do not negate contractual arrangements that were previously made by the HHS, Office of Community Services (OCS), or the intermediaries operating relending programs that have already been entered into with ultimate recipients under previous regulations. preexisting documents control when in conflict with these regulations. The loan is governed by terms of existing legal documents of each intermediary. The RDLF/IRP intermediary is responsible for compliance with the terms and conditions of the loan agreement.

(b) Each intermediary will be monitored by FmHA based on progress reports submitted by the intermediary, audit findings, disbursement transactions, visitations, and other contract with the intermediary as necessary.

(c) Loan servicing is intended to be preventive rather than a curative action. Prompt followup on delinquent accounts and early recognition of potential problems and pursuing a solution to them are keys to resolving many problem loan cases.

(d) Written notices on payments coming due will be prepared and sent to the intermediary by the FmHA Finance Office approximately 15 days in advance of the due date of the payments. A copy of the notice will be sent to the FmHA Administrator or designee.

(e) If the scheduled payment is not made by the intermediary within 30 days after the due date of the payment, the Finance Office will send a past due notice to the intermediary. The notice will show the late charge amount, if applicable, and the interest amount past due. The late charge amount, if applicable, and the interest past due amount will be capitalized as principal due 30 days after the due date of the monthly payment unless existing loan documents prior to this regulation state otherwise. If the loan documents state when late charge amounts or interest accruals are to be capitalized, the loan documents will prevail.

(1) A per diem amount will be shown on the late notice sent to the intermediary. The Finance Office will send this notice to the Administrator or designee 30 days after the past due notice has been sent to the intermediary and the account remains delinquent. Thereafter, further notices by FmHA designee will be sent to the intermediary on the late payments or any further payments until the account is in a current status.

(2) The Finance Office will notify the Administrator or designee on any payments due from the delinquent intermediary. It will be the responsibility of the Administrator or designee to follow up on delinquent payments to bring the account to a current status.

(3) A copy of any correspondence or notice generated by the Administrator or designee on any delinquent loan will be sent to the Finance Office.

(4) Interest will be computed on a 365-day basis unless legal documents state otherwise.

(f) It is the responsibility of the Finance Office to maintain complete accounting records for each intermediary. The Finance Office will:

(1) Coordinate with the Administrator or designee to assure that interest and principal payments received are in accordance with the promissory notes and its companion documents, and the effective amortization schedule. If the payments received appear to be incorrect, the Finance Office will advise the Administrator or designee. The Adminstrator or designee will take the necessary action to clear the issue and promptly advise the Finance Office of the proper accounting procedure.

(2) Send monthly statements to the National Office reflecting all payments received to date on each borrower.

(3) Send to the Administrator or designee a monthly summary of all intermediary loans as follows:

(i) Number and amount of all loans.

(ii) Total advanced on all loans.

(iii) Total interest and principal received on the loans.

(iv) Total outstanding balance on all loans.

(4) Prepare reamortization schedules needed as a reault of restructuring any loans and send to the Administrator or designee.

(5) Furnish in writing to the Administrator or designee a per diem amount on the actual interest amount due when requested by the Administrator.

(g) It is the responsibility of the Administrator or designee to:

(1) Review and analyze the semiannual report of the intermediaries and reconcile same to the annual audits.

(2) Review the annual audits of intermediaries.

(3) Review the semiannual reports of the intermediaries and take appropriate action when necessary.

(4) Follow up on delinquent intermediaries to bring the account current.

(5) Notify the Finance Office in writing when a loan is determined to be uncollectible in order for the Finance Office to make provisions for an appropriate timely entry to the loss account.

(6) Furnish to the Finance Office the necessary information to produce reamortization schedules.

(7) Provide the Finance Office a copy of any correspondence in regard to the restructuring of the loans.

(8) Review reamortization schedules, the schedule will then be forwarded to the intermediary.

(9) Confirm account balances. Payment history of loans and any other related matter will be furnished to the requesting party, (i.e. third party auditing firms) if warranted and proper If there are discrepancies in any loan

balances being confirmed, the Finance Office should be consulted before the Administrator or designee writes the requested parties.

(10) Furnish upon request by the Finance Office, the information necessary to help reconcile account balances, obtain evidence of payments made by the borrower, and any other related data necessary to keep the financial records correct and in balance.

(11) Answer Congressional and other correspondence.

(12) Review intermediary's plans, cash flow projections, balance sheets, and operating statements.

§ 1951.882 Field visits.

(a) During or in preparation for field visits to RDLF/IRP intermediaries by FmHA personnel, the following loan servicing activities are to be performed:

(1) Review what is being done to inform eligible applicants of the program's existence.

(2) Obtain current and proper financial information and analyze for trends on all RDLF/IRP intermediaries. Also determine if there is a sufficient interest rate spread between the interest rate charged the intermediary and the interest rate charged the ultimate recipients to cover the administrative costs, including bad debts of operating the program.

(3) Include in the writeups of the field visit any issues or problems not resolved from the last visitation in the agenda.

(4) Review credit elsewhere information (has the ultimate recipient been refused funds by other sources?) to determine if this information is in the files.

(5) Observe collateral and its condition, maintenance, protection and utilization by the intermediary or ultimate recipient.

(6) Review the process for handling loan proceeds to assure they are deposited in an interest-bearing account or time deposit in a bank or other financial institution fully protected by Federal or State insurance.

(7) Review materials to determine if the purpose of the program is being fulfilled; i.e., loan funds are being used in accordance with FmHA policies, procedures, the approved work plan and the Loan Agreement.

(8) A report of the visit will be made on "RDLF/IRP Review Summary Sheet," or otherwise documented and included in the loan file in the format of the "RDLF/IRP Review Summary Sheet." The report should include an opinion on the financial condition of the intermediary based upon the review of the annual audited financial statement, periodic financial statements, and observations made during the visit and other sources.

(9) Determine if the ultimate recipients' files are complete, organized, and current.

(10) Any instructions, directions, or corrective action should be confirmed by letter to the intermediaries.

(b) All intermediaries are required to provide an annual audited financial statement as well as a summary sheet of their lending program on each ultimate recipient receiving Federal funds. The summary sheet of their lending program on each ultimate recipient should include but not be limited to: the borrower's name and address, type of business, use of loan funds, loan amount, date of note, outstanding balance, date of final payment, interest rate, amount and type of collateral, insurance information, loan status, and the date of FmHA approval, if applicable.

(c) The intermediary should perform an analysis on its ultimate recipients and follow up in writing on any servicing action required. A copy of the analysis will be provided to FmHA for those ultimate recipients having Federal funds.

§ 1951.883 Reporting Requirements:

(a) Intermediaries are to provide FmHA with reports as required in their respective loan agreements, applicable statutes and as required by FmHA. The report shall include the following:

(1) An annual audit; dates of audit report period need not necessarily coincide with other reports on the RDLF/IRP. Audits shall be due 90 days following the audit period. Audits must cover all of the intermediary's activities. Audits will be performed by an independent certified public accountant or by an independent public accountant licensed and certified on or before December 31, 1970, by a regulatory authority of a State or other political subdivision of the United States. An acceptable audit will be performed in accordance with generally accepted auditing standards and include such tests of the accounting records as the auditor considers necessary in order to express an opinion on the financial condition of the intermediary. FmHA does not require an unqualified audit opinion as a result of the audit. Compilations or reviews do not satisfy the audit requirement.

(2) Quarterly reports for periods ending March 31, June 30, September 30, and December 31 (due 30 days after the end of the period). FmHA at its option may change this requirement to semiannual reports. These reports shall contain information only on the RDLF/IRP loan funds, or if other funds are included, the RDLF/IRP loan program portion shall be segregated from the others; and in the casw ehre the intermediary has more than one RDLF/IRP loan, from FmHA, a separate report shall be made for each of these RDLF/IRP loans. The reports will include:

(i) Form FmHA 1951–4, "Report of IRP/RDLF Lending Activity" (available in the FmHA National Office). This report will include information on the intermediary's lending activity, income and expenses, and financial condition and a summary of names and characteristics of the ultimate recipients the intermediary has financed.

(ii) Project Progress Review Narrative.

(3) An annual report on the extent to which increased employment income and ownership opportunities are provided to low-income persons, farm families, and displaced farm families for each loan made by such intermediary.

(4) Proposed budget for the following year.

(5) Other reports as FmHA may require from time to time.

(b) Intermediaries shall report to FmHA whenever an ultimate recipient is more than 90 days in arrears in the repayment of principal or interest.

§ 1951.884 Non-Federal funds.

Once all the FmHA-derived loan funds have been utilized by the intermediary for assistance to ultimate recipients according to the provisions of these regulations and the loan agreement, assistance to new ultimate recipients financed thereafter from the intermediary's revolving loan fund shall not be considered as being derived from Federal funds and the requirements of these regulations will not be imposed on those new ultimate recipients. Ultimate recipients assisted by the intermediary with FmHA-derived loan funds shall be required to comply with the provisions of these regulations and/or loan agreement.

§ 1951.885 Loan classifications.

All loans to intermediaries in the FmHA portfolio will be classified by FmHA at loan closing and again whenever there is a change in the loan which would impact on the original classification. No one classification should be viewed as more important than others. The uncollectibility aspect of Doubtful and Loss classifications is of obvious importance. However, the function of the Substandard classification is to indicate those loans that are unduly risky which may result in future losses. Substandard, Doubtful

and Loss are adverse classifications. The special mention classification is for loans which are not adversely classified but which require the attention and followup of FmHA. The loans will be classified as follows:

(a) *Seasoned loan classification.* To be classified as a seasoned loan, a loan must:

(1) Have a remaining principal loan balance of two-thirds or less of the original aggregate of all existing loans made to that intermediary.

(2) Be in compliance with all loan conditions and FmHA regulations.

(3) Have been current on the loan(s) payments for 24 consecutive months.

(4) Be secured by collateral which is determined to be adequate to ensure there will be no loss on the loan.

(b) *Current non-problem classification.* This classification includes those loans which have been current for less than 24 consecutive months and are in compliance with the loan conditions and FmHA regulations, and are not considered to pose a credit risk to FmHA. These loans would be classified as seasoned but for the "24 months" and "two-thirds" requirements for seasoned loans.

(c) *Special mention classification.* This classification includes loans which do not presently expose FmHA to a sufficient degree of risk to warrant a Substandard classification but do possess credit deficiencies deserving FmHA's close attention because the failure to correct these deficiencies could result in greater risk in the future. This classification would include loans that may be high quality, but which FmHA is unable to supervise properly because of an inadequate loan agreement, the condition or lack of control over the collateral, failure to obtain proper documentation or any other deviations from prudent lending practices. Adverse trends in the intermediary's operation or an imbalanced position in the balance sheet which has not reached a point that jeopardizes the repayment of the loan should be assigned to this classification. Loans in which actual, not potential, weaknesses are evident and significant should be considered for a Substandard classification.

(d) *Substandard classification.* This classification includes loans which are inadequately protected by the current sound worth and paying capacity of the obligor or of the collateral pledged, if any. Loans in this classification must have a well defined weakness or weaknesses that jeopardize the payment in full of the debt. If the deficiencies are not corrected, there is a distinct possibility that FmHA will sustain some loss.

(e) *Doubtful classification.* This classification includes those loans which have all the weaknesses inherent in those classified Substandard with the added characteristic that the weaknesses make collection or liquidation in full, based on currently known facts, conditions and values, highly questionable and improbable.

(f) *Loss classification.* This classification includes those loans which are considered uncollectible and of such little value that their continuance as loans is not warranted. Even though partial recovery may be effected in the future, it is not practical or desirable to defer writing off these basically worthless loans.

§§ 1951.886–1951.888 [Reserved]

§ 1951.889 Transfer and assumption.

(a) All transfers and assumptions must be approved in advance in writing by FmHA. Such transfers and assumptions must be to an eligible intermediary.

(b) Available transfer and assumption options to eligible intermediaries include the following:

(1) The total indebtedness may be transferred to another eligible intermediary on the same terms.

(2) The total indebtedness may be transferred to another eligible intermediary on different terms not to exceed those terms for which an initial loan can be made to an organization that would have been eligible originally.

(3) Less than total indebtedness may be transferred to another eligible intermediary on the same terms.

(4) Less than total indebtedness may be transferred to another eligible intermediary on different terms.

(c) The transferor will prepare the transfer document for FmHA's review prior to the transfer and assumption.

(d) The transferee will provide FmHA with a copy of its latest financial statement and a copy of its annual financial statement for the past 3 years if available; its Federal Tax Identification number; organizational charter; minutes from the Board of Directors authorizing the transaction; certification of good standing from the Secretary of State or whatever regulatory agency oversees nonprofit corporations for that State or Commonwealth where the entity is headquartered; and any other information that FmHA deems necessary for its review.

(e) The assumption agreement will contain the FmHA case nunber of the transferor and transferee.

(f) When the transferee makes a cash downpayment in connection with the transfer and assumption, any proceeds received by the transferor will be credited on the transferor's loan debt in inverse order of maturity.

(g) The Administrator or designee will approve or decline all transfers and assumptions.

§ 1951.890 Office of Inspector General and Office of General Counsel referrals.

When facts or circumstances indicate that criminal violations, civil fraud, misrepresentations, or regulatory violations may have been committed by an applicant or an intermediary, FmHA will refer the case to the appropriate Regional Inspector General for Investigations, OIG, USDA, in accordance with FmHA Instruction 2012–B (available in any FmHA office) for criminal investigation. Any questions as to whether a matter should be referred will be resolved through consultation with OIG and FmHA and confirmed in writing. In order to assure protection of the financial and other interests of the Government, a duplicate of the notification will be sent to the OGC. OGC will be consulted on legal questions. After OIG has accepted any matter for investigation, FmHA staff must coordinate with OIG in advance regarding routine servicing actions on existing loans.

§ 1951.891 Liquidation; default.

(a) In the event that FmHA takes over the servicing of the ultimate recipient of an intermediary, those loans will be serviced by this regulation and in accordance with the contractual arrangement between the intermediary and the ultimate recipient. Should the FmHA determine that it is necessary or desirable to take action to protect or further the interests of FmHA in connection with any default or breach of conditions under any loan made hereunder, the FmHA may:

(1) Declare that the loan is immediately due and payable.

(2) Assign or sell at public or private sale, or otherwise dispose of for cash or credit at its discretion and upon such terms and conditions as FmHA shall determine to be reasonable, any evidence of debt, contract, claim, personal or real property or security assigned to or held by the FmHA in connection with financial assistance extended hereunder.

(3) Adjust interest rates, use fixed or variable rates, grant moratoriums on repayment of principal and interest, collect or compromise any obligations held by FmHA and take such actions in

respect to such loans as are necessary or appropriate, consistent with the purpose of the program and this Subpart. The Administrator will notify the FmHA Finance Office of any change in payment terms, such as reamortizations or interest rate adjustments, and effective dates of any changes resulting from servicing actions.

(b) Failure by an ultimate recipient to comply with the provisions of these regulations and/or loan agreement shall constitute grounds for a declaration of default and the demand for immediate and full repayment of its loan.

(c) Failure by an intermediary to comply with the provisions of these regulations or to relend funds in accordance with an approved work plan or loan agreement shall constitute grounds for a declaration of default and the demand for immediate and full repayment of the loan.

(d) In the event of default, the intermediary will promptly be informed in writing of the consequences of failing to comply with loan covenant(s).

(e) Protective advances to the intermediary will not be made in lieu of additional loans, in particular working capital loans. Protective advances are advances made by FmHA for the purpose of preserving and protecting the collateral where the intermediary has failed to and will not or cannot meet its obligations. The Administrator or designee must approve in writing all protective advances.

(f) In the event of bankruptcy by the intermediary and/or ultimate recipient, FmHA is responsible for protecting the interests of the Government. All bankruptcy cases should be reported immediately to the Regional Attorney. The Administrator must approve in advance and in writing the estimated liquidation expenses on loans in liquidation backruptcy. These expenses must be considered by FmHA to be reasonable and customary.

(g) Liquidation, management, and disposal of inventory property will be handled in accordance with Subparts A, B, and C of Part 1955 of this Chapter.

§§ 1951.892–1951.893 [Reserved]

§ 1951.894 Debt settlement.

Debt settlement of all claims will be handled in accordance with the Federal Claims Collection Standards [4 CFR Parts 101–105].

§ 1951.895 [Reserved]

§ 1951.896 Appeals.

Any appealable adverse decision made by FmHA which affects the borrower may be appealed upon written request of the aggrieved party in accordance with Subpart B of Part 1900 of this Chapter.

§ 1951.897 Exception authority.

The Administrator may, in individual cases, grant an exception to any requirement or provision of this subpart which is not inconsistent with an applicable law or opinion of the Comptroller General, provided the Administrator determines that application of the requirement or provision would adversely affect the Government's interest. The basis for this exception will be fully documented. The documentation will: demonstrate the adverse impact; identify the particular requirement involved; and show how the adverse impact will be eliminated.

§§ 1951.898–1951.899 [Reserved]

§§ 1900 OMB Control Number.

The collection of information requirements in this regulation have been approved by the Office of Management and Budget and assigned OMB Control Number 0575.0131. In accordance with 5 CFR Part 1320, summarized below is the annualized public reporting burden for this regulation.

Sect. of regulations	Title	Form No. (if any)	Estimated No. of respondents	Report filed annually	Total annual responses (d) × (e)	Est. No. of man-hrs. per response	Est. total manhours (f) × (g)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
Reporting Requirements—No Forms							
1951.860(a)(3)(i)	Weighted average interest calculation	Written	12	1	12	3.0	36
1951.877(a)(7)(i)	Insurance	Assignment	36	On occasion	100	1.0	100
1951.882(a)	Intermediary visitations	Meeting	36	1	36	4.5	162
1951.882(b)	Audited financial statement	Written	36	1	36	.5	18
1951.883(a)(2)(ii)	Program narrative	Written					
	IRP borrower		10	4	40	4.0	160
	RDLF borrower		26	2	52	4.0	208
1951.833(a)(2)(iii)	Employment/income narrative	Written	36	1	36	1.5	54
1951.883(a)(2)(iv)	Proposed budget	Written	36	1	36	2.5	90
1951.883(c)	Intermediary's report of loans 90 days in arrears	Written	36	On occasion	50	1.0	50
1951.889(c)	Assumption Agreement	Written	2	1	2	3.5	7
1951.889(d)	Transferee financial statement	Written	2	1	2	.5	1
Form Approved with this Docket							
1951.883(a)(2)	IRP Lending Activity Report	1951–4					
	IRP borrower		10	4	40	20	800
	RDLF borrower		26	2	52	20	1040
Reporting Requirements Under Other Numbers							
1951.872(b)	Request for Environmental Information	1940–20 (0575–0094).			[1]494		[2]2,726

[1] Docket totals. [2] Total hours.

PART 1955—PROPERTY MANAGEMENT

6. The authority citation for Part 1955 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Liquidation of Loans Secured by Real Estate and Acquisition of Real and Chattel Property

7. Section 1955.3 is amended by revising paragraphs (b), (e), and (k) to read as follows:

§ 1955.3 Definitions.

* * * * *

(b) CONACT or CONACT property. Property acquired or sold pursuant to the Consolidated Farm and Rural Development Act. Within this subpart, it shall also be construed to cover property which secured loans made pursuant to the Agriculture Credit Act of 1978; the Emergency Agricultural Credit Adjustment Act of 1978; the Emergency Agricultural Credit Act of 1984; the Food Security Act of 1985; and other statutes giving agricultural lending authority to FmHA.

* * * * *

(e) *Loans to organizations.* Community Facility (CF); Water and Waste Disposal (WWD); Association Recreation; Watershed (WS); Resource Conservation and Development (RC&D); insured Business and Industrial (B&I) both to individuals and groups; Rural Development Loan Fund (RDLF); Intermediary Relending Program (IRP); Nonprofit National Corporations (NNC); loans to associations for Irrigation and Drainage (I&D) and other Soil and Water conservation measures; loans to Indian Tribes and Tribal Corporations; Shift-In-Land Use (Grazing Association); Economic Opportunity Cooperative (EOC); Rural Housing Site (RHS); Rural Cooperative Housing (RCH); Rural Rental Housing (RRH) and Labor Housing (LH) to both individuals and groups. The housing-type organization loans identified here are referred to in this subpart collectively as Multiple-family Housing (MFH) loans.

* * * * *

(k) *Servicing official.* For loans to individuals as defined in paragraph (d) of this section, the servicing official is the County Supervisor. For insured B&I loans, the servicing official is the State Director. For RDLF and IRP, the servicing official is the Director, Business and Industry Division. For NNC, the servicing official is the Director, Community Facility Division. For all other types of loans, the servicing official is the District Director.

* * * * *

Subpart B—Management of Property

8. Section 1955.53 is amended by revising paragraphs (a), (h), and (1) to read as follows:

§ 1955.53 Definitions.

* * * * *

(a) *CONACT or CONACT property.* Property acquired or sold pursuant to the Consolidated Farm and Rural Development Act (CONACT). Within this subpart, it shall also be construed to cover property which secured loans made pursuant to the Agriculture Credit Act of 1978; the Emergency Agricultural Credit Adjustment Act of 1978; the Emergency Agricultural Credit Act of 1984; the Food Security Act of 1985; and other statutes given agricultural lending authority to FmHA.

* * * * *

(h) *Loans to organizations.* Community Facility (CF), Water and Waste Disposal (WWD), Association Recreation, Watershed (WS), Resource Conservation and Development (RC&D), loans to associations for Irrigation and Drainage and other Soil and Water conservation measures, loans to Indian Tribes and Tribal Corporations, Shift-In-Land Use (Grazing Associations); Business and Industrial (B&I) both to individuals and groups, Rural Development Loan Fund (RDLF), Intermediary Relending Program (IRP), Nonprofit National Corporations (NNC), Economic Opportunity Cooperative (EOC), Rural Housing Site (RHS), Rural Cooperative Housing (RCH), Rural Rental Housing (RRH) and Labor Housing (LH) to both individuals and groups. The housing-type loans identified here are referred to in this subpart collectively as MFH loans.

* * * * *

(1) *Servicing official.* For loans to individuals as defined in paragraph (f) of this section, the servicing official is the County Supervisor. For insured B&I loans, the servicing official is the State Director. For Rural Development Loan Fund and Intermediary Relending Program loans, the servicing official is the Director, Business and Industry Division. For Nonprofit National Corporations loans, the servicing official is the Director, Community Facility Division. For all other types of loans, the servicing official is the District Director.

* * * * *

Subpart C—Disposal of Inventory Property

9. Section 1955.103 is amended by revising paragraphs (d) and (1) to read as follows:

§ 1955.103 Definitions.

* * * * *

(d) *CONACT or CONACT property.* Property acquired or sold pursuant to the Consolidated Farm and Rural Development Act (CONACT). Within this subpart, it shall also be construed to cover property which secured loans made pursuant to the Agriculture Credit Act of 1978; the Emergency Agricultural Credit Adjustment Act of 1978; the Emergency Agricultural Credit Act of 1984; the Food Security Act of 1985; and other statutes giving agricultural lending authority to FmHA.

* * * * *

(1) *Organization property.* Property for which the following loans were made is considered organization property. Community Facility (CF); Water and Waste Disposal (WWD); Association Recreation; Watershed (WS); Resource Conservation and Developemnt (RC&D); loans to associations for Shift-In-Land Use (Grazing Association); loans to associations for Irrigation and Drainage and other soil and water conservation measures; loans to Indian Tribes and Tribal corporations; Rural Rental Housing (RRH) to both groups and individuals; Rural Cooperative Housing (RCH); Rural Housing Site (RHS); Labor Housing (LH) to both groups and individuals; Business and Industry (B&I) to both individuals and groups or corporations; Rural Development Loan Fund (RDLF); Intermediary Relending Program (IRP); Nonprofit National Corporations (NNC); and Economic Opportunity Cooperative (EOC). Housing-type (RHS, RCH, RRH and LH) organization property is referred to collectively in this subpart as Multiple Family Housing (MFH) property.

* * * * *

10. Section 1955.105 is amended by revising paragraph (a) to read as follows:

§ 1955.105 Real property affected (CONACT).

(a) *Loan types* Sections 1955.106–1955.109 of this subpart prescribed procedures for the sale of inventory real property which secured any of the following type of loans (referred to as CONACT property in this subpart): Farm Ownership (FO); Recreation (RL); Soil and Water (SW); Operating (OL); Emergency (EM); Economic Opportunity

(EO); Economic Emergency (EE); Softwood Timber (ST); Community Facility (CF); Water and Waste Disposal (WWD); Resource Conservation and Development (RC&D); Watershed (WD); Association Recreation; EOC; Rural Renewal; Water Facility; Business and Industrial (B&I); Rural Development Loan Fund (RDLF); Intermediary Relending Program (IRP); Nonprofit National Corporations (NNC); Irrigation and Drainage; Shift-in-Land Use (Grazing Association); and loans to Indian Tribes and Tribal Corporations. Before property can be sold, § 1955.73 of Subpart B of this part concerning dwelling retention must be followed, if applicable.

* * * * *

Date: July 20, 1988.

Neal Sox Johnson,

Acting Administrator, Farmers Home Administration.

[FR Doc. 88-18395 Filed 8-12-88; 8:45 am]

BILLING CODE 3410-07-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 569c

[Docket No. 88-681]

Conservators and Receivers; Priority of Claims; Depositor Priority

Date: August 9, 1988.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final Rule.

SUMMARY: The Federal Home Loan Bank Board ("Board"), in its own right and as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC"), is promulgating as a final rule a revision to its receivership regulations at 12 CFR 569a.11(a)(6) to establish a priority for withdrawable deposits and accounts, including those of the FSLIC as subrogee or transferee, over unsecured claims of general creditors in receiverships of federally chartered associations or savings banks in States that provide such a priority for depositors in State-chartered savings and loan associations.

EFFECTIVE DATE: August 15, 1988.

FOR FURTHER INFORMATION CONTACT: Lawrence W. Hayes, Deputy General Counsel for FSLIC, (202) 377-6428; Ronald A. Brown, Associate General Counsel for FSLIC, (202) 377-7044; or Michael B. Phillips, Attorney, Office of General Counsel, (202) 377-6755; Federal Home Loan Bank Board, 1700 G Street NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Introduction—The Establishment of a Depositor Priority for Purposes of the Administration of FSLIC Receiverships

In a final rule published in the **Federal Register** of July 5, 1988 (53 FR 25129), the Board promulgated certain portions of the Proposed Receivership and Conservatorship Regulations that were published in the **Federal Register** of November 27, 1985 (50 FR 48970, 48995). The final rule established a priority structure for unsecured claims applicable to all FSLIC receiverships under a new Part 569c of Title 12 of the *Code of Federal Regulations*. Section 569c.11(a)(6) of that rule recognized State law priorities with respect to depositors for State-chartered institutions, including a provision in that section for depositor priority over claims of unsecured general creditors for FSLIC—insured institutions chartered by those States with depositor preference legislation.

The rule being promulgated today, published for comment on July 5, 1988 (53 FR 25169), amends § 569.11 to recognize a depositor priority for deposits registered at offices of federally chartered institutions located in States with depositor preference legislation.

The Board has determined that a primary benefit of the expansion of the depositor priority coverage in § 569c.11(a)(6) would be the enhancement of FSLIC's claims as subrogee to the claims of insured depositors up to the statutory maximum. Under the National Housing Act ("NHA") and the common law doctrine of equitable subrogation, the FSLIC is entitled to exercise the rights of depositors with respect to their insured accounts after making available transferred accounts. (For an explanation of the common law doctrine of equitable subrogation, see the introduction to the proposed rule that was published in the **Federal Register** of July 5, 1988 (53 FR 25169, 25170.)

Through its status as subrogee to the claims of insured depositors, under the depositor priority coverage of § 569c.11(a)(6), the FSLIC is placed in a stronger position to be compensated for its payment to insured depositors in the event of the Board's appointment of the FSLIC as receiver for an insolvent institution. Under the procedures of § 569c.11(d), all priority categories in paragraph (a) of § 569c.11 must be paid in full in their order of priority until the assets of the receivership are exhausted. As a result of the final rule now adopted, for purposes of the administration of a FSLIC receivership in a State with depositor preference legislation, FSLIC as subrogee of insured depositors will be entitled to a paid on a pro rate basis with uninsured depositors before any recovery by unsecured general creditors from the assets of the receivership.

Eight States have enacted legislation to recognize full depositor preference for their savings and loan associations. These States are: Georgia, Indiana, Nebraska, North Carolina, Oklahoma, Texas, Utah, and West Virginia.[1] (South Dakota, Tennessee, Washington State have enacted statutes providing an extremely limited and minimal depositor priority.)

The Board has received four public comments on the proposed rule that was published in the **Federal Register** of July 5, 1988. These comments are summarized in Part II of this preamble.

II. Statutory Authority for the Scope of this Rulemaking

Pursuant to section 5(d)(11) of the Home Owners' Loan Act of 1933 ("HOLA"), 12 U.S.C. 1464(d)(11), the Board has plenary authority to make rules and regulations for federally chartered associations in conservatorship or receivership, for the conduct of conservatorships and receiverships, and for the liquidation and dissolution of such associations. Pursuant to section 406(c)(3)(A) of the NHA, 12 U.S.C. 1729(c)(3)(A), the provisions of section 5(d)(11) of the HOLA are applicable to a State-chartered insured institution for which the Board has appointed the FSLIC as conservator or receiver "in the same manner and to the same extent as if such [State-chartered] institution were a Federal association . . ."

For a discussion of the Board's broad authority to regulate conservatorships and receiverships under section 5(d)(11) of the HOLA and section 406(c)(3) of the NHA, see the introduction to the Proposed Receivership and Conservatorship Regulations (50 FR 48970). Concerning the Board's authority to promulgate extensive rules for the receivership and liquidation of State-chartered associations for which the

[1] The following list presents citations for the eight State statutory sections recognizing full depositor preference for receivership involving FSLIC-insured institutions.

(1) *Georgia:* GA. CODE ANN. 7-1-202(a)(2);

(2) *Indiana:* IND. CODE 28-1-3.1-10(3);

(3) *Nebraska:* NEB. REV. STAT. 8-1, 110;

(4) *North Carolina:* N.C. GEN. STAT. 54B-70(m)(2), (3);

(5) *Oklahoma:* OKLA. STAT. ANN. tit. 18, 381.76(K)(1)(b);

(6) *Texas:* TEX. REV. CIV. STAT. ANN. art. 852a, 8.09(g)(3);

(7) *Utah:* UTAH CODE ANN. 7-2-15(d); and

(8) *West Virginia:* W. VA. CODE 31A-7-12(a)(3).

Board has appointed the FSLIC as receiver, see section 6 of the Bank Protection Act of 1968, Pub. L. No. 90–389, 82 Stat. 294. Congress based this extension of regulatory powers on the FSLIC's "vital interest in seeing that the liquidation of the [State-chartered] association proceeds in an orderly manner". S. Rep. No. 1263, 90th Cong., 2d Sess., *reprinted in* 1968 U.S. Code Cong. & Ad. News 2530, 2531.

Concerning the FSLIC's statutory obligations to insured depositors, section 405(b) of the NHA, 12 U.S.C. 1728(b), directs the FSLIC, in the event of a default by any insured institution, to pay each insured account in such insured institution that is "surrounded and transferred" to the FSLIC. Pursuant to section 406(b)(2) of the NHA, 12 U.S.C. 1729(b)(2), the FSLIC as receiver of a Federal association is directed to pay insurance in accordance with section 405 of the NHA. Section 406(b)(2) of the NHA also provides that the FSLIC, upon "surrender and transfer" of an insured account in any Federal association which is in default, shall become subrogated with respect to such account. The provisions of section 406(b)(2) of the NHA are applicable to the FSLIC as receiver of a State-chartered institution under appointment by the Board pursuant to section 406(c)(1)(B) of the NHA.

III. Summary of and Agency Response to Public Comments on the Proposed Revisions to Section 569c.11(a)(6)

The following discussion summarizes the four public comments on these proposed revisions to § 569c.11(a)(6) and presents the Board's response to these comments.

1. *Comments from a thrift industry trade association.* The focus of this organization's comments was on the final rule establishing § 569c.11 (priority of claims regulations), which was adopted by the Board on June 23, 1988 and published in the **Federal Register** of July 5, 1988. The trade association criticized the revisions to the specific regulatory language in proposed § 569c.11 as published in the **Federal Register** of November 27, 1985 (50 FR 48970, 48995), as substantially modifying the proposed rule and not in accordance with procedural due process considerations. It recommended that the effective date of the final rule of July 5, 1988, and the effective date of this rule be held in abeyance until either Congress or the United States Supreme Court addresses the appropriate scope of the statutory authority of the FSLIC as receiver. The organization was interested particularly in a stay of the effective date of § 569c.11 until the decision of the U.S. Supreme Court in *Coit Independence Joint Venure v. Firstsouth, F.A.*, 829 F.2d 563 (5th Cir. 1987), *cert. granted*, 108 S.Ct. 1105 (1988).

The Board continues to hold that: (1) § 569.c11 of the final rule of July 5, 1988, did not modify substantially proposed § 569c.11 as published in the **Federal Register** of November 27, 1985, and (2) the Board has sufficiently broad statutory authority to support the promulgation of § 569c.11 (*see* 53 FR 25129, 25130–25132).

2. *Comments from a savings and loan association headquartered in California.* This association recognized the potential benefit of the proposed rule to the FSLIC as subrogee to the claims of insured depositors, but cited certain effects arising from the rule that could be detrimental to the financial condition of affected savings and loan associations.

The association argued that the effect of this rule would be the lowering of the debt ratings of healthy thrift institutions. The comment asserted: "This would drive up the cost of public debt to those institutions and could reverse the trend of moving away from dependence upon Federal Home Loan Bank Borrowings." In addition, the association asserted that the effect of the rule would be detrimental to holders of existing public debt of thrift institutions.

The Board has determined that as a result of the expansion of depositor preference coverage under this rule, the benefit to the FSLIC as subrogee to the claims of insured depositors will be significant. The Board will monitor the impact of depositor preference coverage for the administration of FSLIC receiverships in States with depositor preference legislation, to determine its effect on the debt ratings of insured thrift institutions in those States.

3. *Comments from a securities firm headquartered in Connecticut.* This comment focused on the impact of depositor preference on transactions between thrift institutions and securities firms, stating:

> In the short run, the current and proposed rules are intended to reduce costs to FSLIC by improving the creditor position of depositors for whom the FSLIC is ultimately responsible. In the longer run, these rules will increase costs to FSLIC as securities firms and others withdraw their support from the thrift industry in the face of their dimished status as creditors of weak institutions. This reduced level of support will exacerbate liquidity problems and hurt the Board's efforts to find time to deal with these problems in an orderly manner.

According to this comment, securities firms will be more reluctant to deal with thrifts if the Board and the FSLIC exercise their authority to reject selectively certain executory securities contracts with thrifts in receivership. This comment stated that such selectivity (referred to in this comment as "cherry picking") would upset certain well established "netting and set off practices" by the securities industry and would increase the credit exposure of securities firms to thrifts.

This comment recommended that certain procedures be implemented by the FSLIC to protect broker/dealers' rights in the event of a FSLIC receivership in a State with depositor preference legislation. According to this comment, claims of unsecured general creditors should be placed on a par with depositors, and securities transactions with thrifts should be netted for credit purposes subject to the following protections: (1) The types of securities transactions for which a dealer claims rights of offset should be approved by the thrift in a Board of Directors resolution; (2) rights of offset should be permitted specifically in the written agreements supporting the transactions; and (3) rights of offset should be limited to netting between and among "trading type transactions" (forward sales, options, futures, interest rate swaps, or repurchase agreements).

The Board has determined that the FSLIC's financial interest as subrogee for insured depositors should be optimized where feasible, particularly where State legislatures have recognized depositor priority coverage for purposes of receiverships of State-chartered thrift institutions. The expansion of depositor priority coverage in this rule to include Federal associations is limited to the administration of FSLIC receiverships of thrift institutions in States with depositor priority legislation.

Under § 569c.11(d), unsecured claims under the priority categories in paragraphs (a)(1)–(10) of § 569c.11 must be paid in full (on a pro rata basis within the respective priority categories) in their order of priority until the assets of the receivership are exhausted. Hence, any FSLIC decision on the priority of certain unsecured claims of securities firms (including rights of offset) must be treated within the appropriate priority category under § 569c.11, *i.e.*, paragraph (a)(6).

With respect to concerns as to the effect of depositor priority on unsecured claims of securities firms (including on the right of offset by securities firms), the Bank Board will consider these concerns within the context of future rulemaking activities.

4. *Comments from a securities firm headquartered in New York.* This comment also focused on the potential negative effect of depositor priority coverage on the securities industry's willingness to enter into contracts with thrift institutions. This could, the comment argued, result in a reduction of an important liquidity source for the securitization of the assets of thrift institutions, and a demand by the securities industry for increased collateralization. This firm urged the following revisions to § 569c.11: (a) a receiver would not attempt to impair the exercise of "netting and set-off rights" in connection with covered transactions; and (b) a receiver would administer a liquidating receivership or would consummate a purchase and assumption transaction or other transaction only in a manner that such covered transaction is, immediately following the appointment of a receiver by the Board, either rejected or assumed. In conclusion, this firm stated:

> The Board's failure to provide such explicit comfort will likely result in increased collaterization requirements (thus further impairing the efforts of all Thrifts (and in particular weaker Thrifts) to liquefy their securities and mortgage portfolios) and may result in reduced access to the types of contracts that provide liquidity for Thrifts' portfolios and hedge their interest rate risk.

With respect to the limited scope of the proposed rule, this firm recommended that depositor preference coverage under the Board's receivership regulations only should apply to protect the FSLIC or the FDIC as subrogee to the claims of insured depositors, not to protect uninsured depositors. This firm advocated that uninsured depositors should be placed in the same priority category in § 569c.11(a) as unsecured general creditors.

The Board believes that the depositor priority coverage under this rule should be limited to the scope of the protected depositor category under the respective State depositor priority statutes. The Board has covered this firm's other concerns in the aforementioned response to the comments of the Connecticut firm.

IV. "Good Cause" Exception under Section 553(d)(3) of the Administrative Procedure Act (APA)

Section 553(d)(3) of the APA, 5 U.S.C. 553(d)(3), states that the publication of a final rule "shall be made not less than 30 days before its effective date", *except* as "provided by the agency *for good cause found* and *published with the rule*" (emphasis added). The Board has determined that such "good cause" exists to support this rule.

The implementation of the expanded deposit priority coverage in this rule is important for the consummation of certain FSLIC-assisted transactions pursuant to the Board's "Southwest Plan". The Board's Southwest Plan was initiated in February 1988 to resolve the financial and operational problems of more than one hundred forty financially impaired FSLIC-insured institutions in the Southwestern United States (particularly in Texas, which has depositor preference legislation).[2] Given the current efforts of the Board to resolve the financial condition of the FSLIC Insurance Fund and the significant opportunity costs for the FSLIC Insurance Fund in any delay in the consummation of transactions for the implementation of the Southwest Plan, it is important that where feasible, the FSLIC should benefit from its status as subrogee for the claims of insured depositors in Southwest Plan transactions.

According to the Deputy Executive Director of the FSLIC for the Southwest Plan, but for the waiver of the 30-day waiting period, there are at least three probable transactions under the Bank Board's Southwest Plan that would be significantly jeopardized or delayed. (These transactions include Federal associations that have been an important part of the respective Southwest Plan packages under review.)

These three probable transactions under the Southwest Plan would involve significant savings to the FSLIC Insurance Fund through its status as subrogee with respect to the claims of insured depositors up to the statutory maximum. Given the continuing financial deterioration of those insolvent Texas institutions that are included in these probable transactions, through the consummation of these transactions during the 30-day period following publication of the rule, FSLIC could avoid the significant costs to the Insurance Fund that otherwise would be incurred through a delay (or a resulting failure) in these transactions.

The Board has determined that the effect of this waiver of the 30-day waiting period on affected parties would be minimal. The Board only received four public comments on the proposed rule. No comments were received from entities headquartered in States with depositor priority legislation.

Another factor concerning the effect on affected parties of the waiver of the 30-day waiting period is that the final rule is identical to the proposed rule. Hence, those parties already have received substantial guidance on the probable content of the final rule. The legislative history to section 553(d)(3) of the APA indicates that the primary purpose of the "good cause" exception is to facilitate an adjustment by the affected parties of their business decisions to reflect the requirements of the final rule.

[2] *See* Board Resolution No. 88-68 (February 3, 1988).

V. Final Regulatory Flexibility Analysis

Pursuant to section 3 of the Regulatory Flexibility Act, 5 U.S.C. 603, the Board is providing the following regulatory flexibility analysis:

1. *Need for and objectives of the rule.* These elements are incorporated above in **"SUPPLEMENTARY INFORMATION"** regarding this final rule.

2. *Issues raised by comments and agency assessment and response.* These elements are incorporated above in **"SUPPLEMENTARY INFORMATION".**

3. *Significant alternatives minimizing small-entity impact and agency response.* The Small Business Administration defines a small financial institution as "a commercial bank or savings and loan association, the assets of which, for the preceding fiscal year, do not exceed $100 million." 13 CFR 121.13(a) (1988). This final rule treats all institutions in the same manner, and this rule will not have a substantial impact on small entities.

List of Subjects in 12 CFR Part 569c

Administrative practice and procedure, Reporting and recordkeeping requirements, Savings and loan associations.

Accordingly, the Board hereby amends Part 569c, Subchapter D, Chapter V, Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 569c—RECEIVERSHIP RULES

1. The authority citation for Part 569c continues to read as follows:

Authority: Sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); secs. 402, 406, 48 Stat. 1256, 1259, as amended (12 U.S.C. 1725, 1729); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–1948 Comp., p. 1071.

2. Section 569c.11 is amended by revising paragraph (a)(6) to read as follows:

§ 569c.11 Priorities.

(a) * * *

(6) Claims for withdrawable accounts, including those of the Corporation as subrogee or transferee, and all other claims which have accrued and become unconditionally fixed on or before the

date of default, whether liquidated or unliquidated, except as provided in paragraphs (a)(1) through (a)(5) of this section, provided, however, that if the association is chartered and was operated under the laws of a state that provided a priority for holders of withdrawable accounts over such other claims or general creditors, such priority within this paragraph (a)(6) shall be observed by the receiver; and provided further, that if deposits of a Federal association are booked or registered at an office of such association that is located in a State that provides such priority with respect to State-chartered associations, such deposits in a Federal association shall have priority over such other claims or general creditors, which shall be observed by the receiver;

* * * * *

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-18404 Filed 8-12-88; 8:45 am]

BILLING CODE 6720-01-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Definition of Small Business for Dredging

AGENCY: Small Business Administration (SBA).

ACTION: Final rule.

SUMMARY: The SBA is amending its size standard for the Dredging Industry from the present $9.5 million in annual gross receipts to $13.5 million. This is the size standard which was utilized over the December 9, 1985, to November 3, 1986 period. The $9.5 million size standard which has been utilized since November 3, 1986, resulted from an order from the District Court for the District of Columbia dated November 3, 1986, setting aside the then current dredging size standard of $13.5 million, but restoring the previous size standard of $9.5 million pending SBA's completion of a review of the remanded rulemaking effort. SBA has now completed its review as directed by the Court order and is restoring the size standard of $13.5 million which SBA has determined to be the appropriate size standard for the dredging industry.

EFFECTIVE DATE: September 14, 1988.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray, Economist, Size Standards Staff, (202) 653-6373.

SUPPLEMENTARY INFORMATION: On November 3, 1986, the United States District Court for the District of Columbia declared invalid the SBA's size standard for the dredging industry and remanded the administrative record of the rulemaking to the Agency for further consideration. The Court recognized that the previous size standard for the dredging industry of $9.5 million was not challenged and remained in effect pending SBA's completion of its review of the issues raised in the remanded rulemaking record. The Court cited SBA's failure to consider regional size standards, after first recognizing the presence of regional differences in structure and in procurement patterns, as sufficient cause in itself to invalidate the size standard.

In addition, on October 15, 1986 Congress passed the National Defense Authorization Act of 1987 (Pub. L. 99-661). Section 921 of this Act contained a mandate that SBA review the size standards of certain industries including dredging. The purpose of the review was to ensure that small business set-asides accounted for no more than approximately 30 percent of the total Federal contract dollar value for those industries. If SBA were to find as a result of its review that the 30 percent threshold was exceeded for any industry under review, the Agency was required to reduce the size standard for that industry accordingly.

The Act also authorized SBA to further divide industry categories when it received evidence that such division is warranted due to special capital needs, or special labor, or geographic requirements, or to recognize a new industry. New size standards would then be established for these new industry categories.

The Act, moreover, provided three prerequisites which Congress considered must all be present in order for segmentation on a regional basis to occur in an industry. These three prerequisites are: (1) The Government must typically designate the area where work for such contracts is to be performed; (2) Government purchases comprise the major portion of the entire domestic market for such goods and services; and (3) due to the fixed location of facilities, high mobilization costs, or similar economic factors, it is unreasonable to expect competition from business concerns located outside of the general areas where such concerns are located.

Using these three prerequisites, SBA examined the question as to whether the dredging industry merited segmentation of its size standard in an Advanced Notice of Proposed Rulemaking which was published on March 17, 1987 (52 FR 8261). This notice explored the possibility of segmenting the industry for light and heavy projects for the Northeast, Southeast, Gulf Coast, West Coast, and Greak Lakes regions.

A majority of those commenting on this notice did not support segmented size standards for dredging. The comments included one dredging firm and one association that favored the concept of a regional standard, while four firms, two associations, and the U.S. Corps of Engineers were opposed. The respondents raised several concerns regarding the proposed segmentation. The most important comment from the standpoint of complying with the legislation, however, opposed the idea of segmented size standards based on the nature of competition within the industry. In particular, several respondents argued that dredges are mobile, and therefore, the statutory prerequisite that competition could not be expected from outside the region was not met.

As a result of these comments, SBA examined the question further. Specifically, it requested the views of the Army Corps of Engineers, the agency responsible for the great majority of Federal procurement activities in this industry. The Corps responded by stating its view that this third requirement for segmentation was not present and that therefore, the concept of segmentation should not be applied to the dredging industry. SBA also reviewed available data sources to determine whether there is a pattern of dredging firms operating in more than one region of the nation. It discovered in Table 3 of its publication "Profile of the Dredging Industry for the Purpose of Setting a Size Standard" (June 4, 1984), a pattern in which both large and small firms in the industry often operate in more than one region of the nation. Of the 40 most active firms in the industry, for example, 17 firms operated to a significant degree in more than one region of the nation over the 1980-83 period. These 17 firms include both large and small firms. As a whole they were responsible for almost 55 percent of all Federal dredging contracts. Accordingly, there is strong statistical evidence for the view that competition does occur across regions and that firms in the activity of dredging are not inherently immobile.

After careful review of this issue SBA concluded that the third congressional requirement was not present in the dredging industry. Accordingly, it did not propose segmented size standards for this industry in its Proposed Rule of December 17, 1987 (52 FR 47937).

This process in which SBA in an advance notice of proposed rulemaking first solicited public response to the concept of regional size standards, and then rejected the idea after appropriate review in a proposed rule fulfills the Court's statutory requirement that the SBA seriously consider the viability of regional size standards in the dredging industry prior to making a decision on the proper size standard(s). SBA in this Final Rule is, therefore, focusing its attention on a nationally structured size standard. Specifically, it is reinstituting the $13.5 million size standard in preference to the present size standard of $9.5 million which was restored by Court Order.

The decision to move to a size standard of $13.5 million which was made during 1985 was based on a number of factors relating to the industry structure of the dredging industry. Some of these factors cannot be updated because the data at that time were obtained through a special survey of dredging firms which was costly and time consuming. However, some information is presently available from the Corps of Engineers, and therefore, SBA has evaluated whether the industry has changed significantly since the 1985 decision.

In the final dredging size standard rule of November 8, 1985, (50 FR 46418), SBA based its recommendation to raise the size standard in dredging on six factors. These are: concentration ratio (percent of Federal procurement dollars received by the four largest firms in the industry), average firm size, cost increases over time, the proportion of firms defined as small, the average size of Federal contracts, and the proportion of Federal contract dollars received by small firms. Of the six variables in question, four supported a higher size standard than the present $9.5 million. These four were average firm size, cost increases over time, the proportion of firms defined as small, and the average size of contracts. The remaining two factors—the concentration ratio and the proportion of contract dollars received by large firms—provided ambiguous results.

In reviewing more recent data, SBA was only able to gather information on the concentration ratio (proportion of sales in the industry generated by the four largest firms in the industry), the average size of Federal contract, and the proportion of contract dollars received by small firms. In general, SBA views high indexes for both the concentration ratio and average size of contract as indicators that an industry's size standard should be relatively high. Conversely, it views a relatively low proportion of contract dollars awarded to small firms as an indicator that an industry's size standard might be too low. In this case, SBA wanted to compare the situation in the dredging industry during 1987 with the situation in the earlier period to assure itself that a need continued for a higher size standard. Data for FY 1987 are compared with the 1984 study in the following table:

Factor	Dredging data from earlier study	FY 1987
Concentration ratio (percent of Federal contracts awarded the 4 largest firms in industry)	[1] 26	63
Average size of total Federal contracts (millions)	[2] 1.60	[2] $1.69
Proportion of Federal dollars awarded small firms (percent)	[2] 35.3	15.8

[1] Average over 1980–83 period. ($9.5 million size standard in effect.)
[2] 1983 data. ($9.5 million size standard in effect.)

These statistics indicate that the situation in the dredging industry involves a greater concentration of economic activity among a few large firms in the dredging industry than occurred in 1983. There is a need to restore the previous size standard of $13.5 million based on the fact that four very large firms received almost two-thirds of Federal contract dollars, while firms defined as small (less than $9.5 million in gross annual receipts) received only 16 percent of all Federal contract dollars. These low percentages for small firms in the industry also indicate that there is little likelihood that the 30 percent set-aside threshold incorporated in Section 921 of Pub. L. 99–661 would be exceeded by a restoration of the $13.5 million size standard.

Based on these considerations and the fact that SBA has extensively considered regional size standards in the dredging industry as directed by Court Order, SBA is restoring the national size standard of $13.5 million for dredging as appropriate for the reasons described in the published rule change in 1985 (50 FR 46418) and due to the results of the analysis of more current data.

This regulation is promulgated as a final rule without prior notice and opportunity to comment in accordance with 5 U.S.C. 553(b). Because SBA has already received and considered public comment on both the issue of geographical distribution (see 52 FR 8261 and 52 FR 47937), and the size standard increase (see 50 FR 46418 and 49 FR 47412), it is not in the public interest to delay the rule further in order to receive further public comment.

Compliance With Executive Order 12291, Regulatory Flexibility Act, and Paperwork Reduction Act

SBA certifies that this regulation is a major rule as defined by Executive Order 12291. Over the fiscal year 1987 period, annual Federal outlays for dredging activities exceeded $340 million. Thus the annual economic effect criteria of $100 million used to measure a major rule change could be exceeded as a result of this rule. Potentially, any firm in the industry could be affected in the future by a higher size standard, since the eligibility of a firm could impact on its competitive situation for any set-aside contract and on the decision whether or not to set-aside a contract. This regulation, however, is not likely to result in a major increase in costs, or prices, or in significant adverse effects on the United States economy.

This regulation is unlikely, however, to have a significant economic impact on a substantial number of small entities. (There are no known firms currently active in the dredging industry in the $9.5 to $13.5 million range and only five firms are estimated to be in the $7.0 to $9.5 million range.) Therefore, in compliance with Executive Order 12291, SBA offers this final regulatory impact analysis. SBA has considered regulatory action in this instance in response to intense public comment on the size standard in this particular industry. The purpose of this final rule is to update the size standard for the dredging industry, which has remained at the same level as 1974, to reflect both inflation and changes in industry structure over a 14-year time period. This final rule change is authorized by section 3(a) of the Small Business Act (15 U.S.C. 623(a)), which mandates that SBA define small business concerns on an industry-by-industry basis.

The dredging industry is comprised of approximately 250 companies of which 70 participated in the Federal procurement process during fiscal year 1987. Of these firms, however, only five would likely be significantly affected by a higher size standard. These are firms whose annual receipts usually fall in the $7.0 to $9.5 million range. Clearly, a higher size standard would remove a major constraining factor on expansion for these five firms.

Assuming these five firms are capable of and choose to expand into the $9.5 to $13.5 million range, other firms could be affected by the new higher size

standard. There could be some additional competition for contracts, since these five firms could bid for more contracts without exceeding the new size standard limitation of $13.5 million. Similarly, the competition for unrestricted contracts could be expected to be enhanced, since small firms would be less concerned that winning a contract would push them over the size standard. In addition, Federal contracting officials would be able to set aside some additional contracts, and thus a slightly higher proportion of contract dollars would probably be set aside. Although more contracts will probably be set aside, SBA considers it highly unlikely that the set-aside percentage would exceed 30 percent given the low incidence of set-asides in this industry during 1987 (10 percent), and the fact that only five firms are estimated to be in the $7.0 to $9.5 million range.

Overall, any one of the 250 firms active in the dredging industry might be affected by the increased size standard if it were to bid on a dredging procurement that was set aside for small business, or if the higher size standard freed small firms to bid on unrestricted contracts. The net benefits of this rule change, therefore, are a closer relationship between the size standard and the industry structure and an easing of constraints on expansion for firms within the industry.

In deciding that a size standard of $13.5 million most accurately reflects the current dredging industry, SBA also considered the alternatives of raising the size standard above $13.5 million, lowering it below $9.5 million, or maintaining it at $9.5 million. SBA rejected raising the standard above the $13.5 million level because of the concern that a higher size standard than $13.5 million would more likely result in a set-aside plus 8(a) percentage of Federal contracting in the industry which exceeds the 30 percent level prohibited by Public Law 99-661. Lowering the size standard was rejected because of the industry's dominance by large firms, the relatively large size of contracts in the industry, and the inflationary trends since 1974 when the $9.5 million size standard was established. Thus there are no significant alternatives which would accomplish the stated objectives of minimizing the economic impact on small firms.

SBA certifies that there are no relevant Federal rules which would duplicate, overlap, or conflict with this Final Rule. SBA also certifies that this regulation contains no reporting or recordkeeping requirements which are subject to the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Loan programs—business, Reporting and recordkeeping requirements, Small business.

Accordingly, SBA is amending Part 121 of 13 CFR as follows:

PART 121—[AMENDED]

1. The authority citation of Part 121 of 13 CFR is revised to read as follows:

Authority: Secs. 3(a) and 5(b)(6) of the Small Business Act, 15 U.S.C. 632(a) and 634(b)(6), and Public Laws 99-591 and 99-661.

§ 121.1 (Amended)

2. In table 2 in § 121.2(d)(2), for Major Group 16—Construction, Other Than Building Construction—General Contractors, the last item in the table, Item 1629—Dredging and Surface Cleanup Activities is revised to read as follows: (Item 1629 Heavy Construction, Except Dredging, N.E.C., is set forth for the convenience of the reader and is not changed).

Dated: May 24, 1988.

SIC	Description (N.E.C.=Not Elsewhere Classified)	Size standards in number of employees or millions of dollars—Final rule
1629	Heavy Construction, Except Dredging, N.E.C..	$17.0
1629	Dredging and Surface Cleanup Activities [2].	13.5

[2] To be considered small, a firm must perform the dredging of at least 40 percent of the yardage with its own dredging equipment or equipment owned by another small dredging concern.

James Abdnor,

Administrator, U.S. Small Business Administration.

[FR Doc. 88-18312 Filed 8-12-88; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 88-ASO-11]

Amendment to Control Zone, Augusta, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment changes the Augusta, Georgia, control zone from full-time to part-time due to a reduction in hours of operation of the local National Weather Service Office. Since June 23, 1988, no weather reports have been available for the Bush Field Airport, Augusta, Georgia, during the hours 1 a.m. until 6 a.m. local time. This action will allow the control zone hours to conform with the hours when aviation weather reporting service is available.

EFFECTIVE DATE: 0901 u.t.c., October 20, 1988.

FOR FURTHER INFORMATION CONTACT: James G. Walters, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

The Rule

This amendment to Part 71 of the Federal Aviation Regulations is to amend the Augusta, Georgia, control zone by changing the time of designation from full-time to part time. This action is necessary since weather reporting service is no longer available at the Bush Field Airport between 1 a.m. and 6 a.m. local time due to a reduction in operating hours by the local office of the National Weather Service, which is subject to further change by that agency. Current hours of operation will be published for user information.

I find that notice and public procedure under 5 U.S.C. 553(b) are unecessary because this action is a minor amendment in which the public would not be particularly interested. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6D dated January 4, 1988.

The FAA has determined that this regulation only involves an established body of the technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12991; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zone.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as amended 52 FR 46740, is further amended, as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

§ 71.171 [Amended]

2. Section 71.171 is amended as follows:

Augusta, Georgia [Amended]

By adding the following statement at the end of the present description:

This zone is effective during the specific dates and times established in advance by Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

Issued in East Point, Georgia, on August 4, 1988.

William D. Wood,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 88–18371 Filed 8–12–88; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 88–ASO–2]

Designation of Transition Area; Keystone Heights, FL; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction to final rule.

SUMMARY: This action corrects the description of the transition area Keystone Heights, Florida. The final rule action mistakenly contained a reference to Restricted Area R–2903B. The reference should have been R–2903A.

EFFECTIVE DATE: 0901 u.t.c., September 22, 1988.

FOR FURTHER INFORMATION CONTACT: James G. Walters, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763–7646.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 88–ASO–2 was published on June 23, 1988. This rule action was to establish the Keystone Heights, Florida, transition area (53FR23606). Inadvertently, reference was made to Restricted Area, R–2903B. The reference should have been R–2903A.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, transition area.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Federal Register Document 88–ASO–2, on page 23606 of the Federal Register on June 23, 1988, is corrected to read as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. Section 71.181 is amended to read as follows:

Keystone Heights, Florida [Amend]

By eliminating the phase, "* * * excluding that airspace that coincides with Restricted Area R–2903B," and substituting the following, "* * * excluding that airspace that coincides with Restricted Area R–2903A."

Issued in East Point, Georgia, on August 2, 1988.

William D. Wood,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 88–18372 Filed 8–12–88; 8:45 am]

BILLING CODE 4910–13–M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 5

Review of Contract Market Designation Applications; Adoption of Internal Processing Procedure

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: As a matter of administrative practice, the Commodity Futures Trading Commission ("Commission") publishes in the Federal Register notice of the availability of the terms and conditions of applications for contract market designation to obtain comment from the public on proposed applications. The Commission has determined that routine publication of designation applications is in the public interest. As a matter of informal practice, the Commission generally has published applications for designation of futures contract markets for a period of sixty days, designation of options on physicals for forty-five days and for options on futures for a period of thirty days. The Commission is hereby formalizing its internal processing procedure and establishing a uniform comment period for futures and both types of option designation applications. In order to provide more ready reference to this internal procedure, the Commission is including it as Appendix D to Part 5 of its regulations.

EFFECTIVE DATE: August 15, 1988.

FOR FURTHER INFORMATION CONTACT: J. Blake Imel, Deputy Director, or Paul M. Architzel, Chief Counsel, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581 (202) 254–3201, 254–6990, respectively.

SUPPLEMENTARY INFORMATION:

I. The Internal Processing Procedure

Since its formative period, the Commission has determined that obtaining public comment with respect to pending applications for contract market designation is in the public interest and therefore has provided the public with an opportunity to comment on such applications. Over time, an

informal practice evolved of providing a public comment period of sixty days for applications for designation of futures contract markets, forty-five days for options on physicals and thirty days for options on futures contract markets. On occasion, however, where an application was identical to an existing contract, or for other reasons, a shorter comment period was provided.

The Commission periodically reviews its procedures relating to the designation of new contract markets to make them as efficient as possible. For example, as part of its ongoing efforts to streamline and expedite the review process, the Commission in 1987 adopted an internal processing procedure under which applications for contract market designation are deemed to be withdrawn where no timely, written response or supplementation on the merits is received by the Commission. The procedure provides specifically that an application which is materially incomplete is deemed to be withdrawn where a response to a Commission letter or voluntary stay tolling the review period is not received by the Commission within a year. 52 FR 1444 (January 14, 1987). This internal processing procedure limits increases in the Commission's backlog of applications for designation which are no longer of interest to exchanges. As a result of this, and other Commission initiatives, the review of applications for contract market designation on average has been reduced to five and one-half months for futures and five months for options, well under the statutory period of one-year.[1]

The Commission's experience with its review of applications for contract market designation indicates that a uniform thirty-day period for comment generally will be sufficient to permit interested parties to submit their views concerning such applications. Moreover, a thirty-day comment period will aid the Commission in the expeditious processing of applications. Finally, such a period is consistent with the customary notice period for applications for designation of contract markets for options on futures and for most exchange rules submitted for Commission approval under section 5a(12) of the Commodity Exchange Act, 7 U.S.C. 7a(12), which have been determined by the Commission to be of major economic significance.

Of course, where an application for designation raises particularly complex or novel issues, a longer comment period may be appropriate. In addition, a longer comment period may be appropriate where the Commission must consider the merits of a petition for confidential treatment filed by an applicant exchange which covers significant, material portions of an application. Accordingly, in those instances, the Commission, in its discretion, may determine on a case-by-case basis to provide for a longer comment period.

In addition, the Commission has determined to formalize its practice with respect to publication in the **Federal Register** of notice of contract terms and conditions by memorializing this procedure and including it in the Code of Federal Regulations. Accordingly, the Commission is adopting this internal procedure as Appendix D to Part 5 of its rules.

II. Related Matters

A. Regulatory Flexibility Act

The Commission has previously determined that contract markets are not "small entities" for purposes of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* 47 FR 18618 (April 30, 1982). The requirements of the Regulatory Flexibilty Act, therefore, do not apply to contract markets. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the action taken herein will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, ("PRA") imposes certain requirements on Federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. In compliance with the PRA the Commission has submitted this rule and its associated information collection requirements to the Office of Management and Budget. The Commission has determined that because the proposed rule merely codifies and modifies existing Commission practice, and does not require the submission of information or reports to the Commission, the rule being adopted will not cause an increase in the paperwork burden.

Persons wishing to comment on the paperwork implications of the rule should contact Robert Neal, Office of Management and Budget (OMB), Room 3228, NEOB, Washington, DC 20503 (202) 395–7340. Copies of the information collection submission to the OMB are available from Joseph G. Sallazar, C.F.T.C. Clearance Officer, 2033 K St. NW.; Washington, DC 20581 (202) 254–9735.

C. Administrative Procedure Act

The Administrative Procedure Act requires that notice and an opportunity to comment be provided to the public before agencies adopt final regulations, except where interpretative rules, general statements of policy or rules relating to agency organization, procedure or practice are involved, or where the agency finds for good cause that such notice and comment is impractical, unnecessary or contrary to the public interest. 5 U.S.C. 553(b). The Commission is adopting a general statement of policy relating to internal agency procedure with respect to the processing of designation applications. The Commission believes that it is in the public interest to make this statement effective upon publication.

List of Subjects in 17 CFR Part 5

Contract markets, Designation application.

In consideration of the foregoing, pursuant to the authority contained in the Commodity Exchange Act, and in particular sections 4c, 5, 5a, 6, and 8a, 7 U.S.C. 6c, 7, 7a, 8, and 12a, the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations by amending Part 5 as follows:

PART 5—DESIGNATION OF AND CONTINUING COMPLIANCE BY CONTRACT MARKETS

1. The authority citation for Part 5 continues to read as follows:

Authority: 7 U.S.C. 6c, 7, 7a, 8, and 12a.

2. Appendix D is added to Part 5 to read as follows:

Appendix D—Internal Procedure Regarding Period for Public Comment

The Commission will seek public comment on applications for designation of futures and option contract markets by publishing a notice of availability of the terms and conditions of the proposed contract. Generally, the Commission will provide for a public comment period of thirty days on such applications for designation. The Commission, or its delegatee under § 140.96 of this chapter, in its discretion, may publish for comment the notice of availability for such longer period as appropriate.

[1] These periods are based upon the review of applications for designation during fiscal year 1987, and exclude the time during which the review periods were tolled either by the Commission or voluntarily by the exchanges because the applications were materially incomplete as filed.

Issued in Washington, DC this 9th day of August, 1988, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 88-18345 Filed 8-12-88; 8:45 am]

BILLING CODE 6351-01-orm

17 CFR Part 30

Foreign Option Transactions

AGENCY: Commodity Futures Trading Commission.

ACTION: Order.

SUMMARY: The Commodity Futures Trading Commission ("Commission") is authorizing option contracts on the Three-Year Australian Treasury Bond futures contracts traded on the Sydney Futures Exchange to be offered and sold to persons located in the United States. This order is issued pursuant to Commission Rule 30.3(a), 52 FR 28980, 28998 (August 5, 1987), which makes it unlawful for any person to engage in the offer and sale of a foreign option product until the Commission, by order, authorizes such foreign option to be offered in the United States, and the Commission's order dated July 20, 1988, 53 FR 28832 (July 29, 1988), promulgated thereunder.

EFFECTIVE DATE: September 14, 1988.

FOR FURTHER INFORMATION CONTACT: Jane C. Kang, Esq., or Robert H. Rosenfeld, Esq., Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581. Telephone: (202) 254-8955.

SUPPLEMENTARY INFORMATION: The Commission has issued the following Order:

United States of America before the Commodity Futures Trading Commission

Order Under CFTC Rule 30.3(a) Permitting Option Contracts on the Three-Year Australian Treasury Bond Futures Contract Traded on the Sydney Futures Exchange to be Offered and Sold in the United States Thirty Days after Notice to the Commission and Publication in the **Federal Register**

By order dated July 20, 1988 ("initial Order"), the Commission authorized, pursuant to Commission Rule 30.3(a),[1] certain option products traded on the Sydney Futures Exchange ("Exchange") to be offered and sold in the United States. 53 FR 28832 (July 29, 1988). Among other conditions, the initial Order specified that:

Except as otherwise permitted under the Commodity Exchange Act and regulations thereunder, that no offer or sale of any Exchange option product in the United States shall be made until thirty days after publication in the **Federal Register** of notice specifying the particular option(s) to be offered and sold pursuant to this Order.

By letter dated August 1, 1988, the Exchange requested that the Commission supplement its initial Order authorizing options on 90-Day Bank Accepted Bill, Ten-Year Treasury Bond and Australian Dollar Futures by also authorizing the Exchange's option contract on Three-Year Australian Treasury Bond futures to be offered and sold to persons in the United States. Upon due consideration, and for the reasons previously discussed in the initial Order, 53 FR 28832, the Commission believes that such authorization should be granted.

Accordingly, pursuant to Commission Rule 30.3(a), 52 FR 28980, 28998, the Commission's initial Order dated July 20, 1988, 53 FR 28832, and subject to the terms and conditions specified therein, the Commission hereby authorizes the Sydney Futures Exchange's option on the Three-Year Australian Treasury Bond futures contract to be offered and sold to persons located in the United States, thirty days after publication in the **Federal Register**:

Contract Specifications—Options on the Three-Year Australian Treasury Bond Futures Contract

Contract Unit: One Australian Three-Year Treasury Bond futures contract with a face value of $100,000.

Exercise Prices: Set at intervals of 0.25% per annum. New exercise prices are created automatically as the underlying futures contract price moves.

Premiums: Quoted in multiples of 0.005% per annum. The minimum fluctuation in the premium represents a change in the option value of approximately $10.00 to $13.00, varying with the exercise price.

Contract Months: The initial contract month will be September 1988.

Expiry: The last day of trading in the underlying Australian Three-Year Bond futures contract month. Trading ceases at 12:00 noon.

Exercise: Options may be exercised on any business day up to and including the day of expiry. In-the-money options are automatically exercised at expiry.

Trading Hours: 8:30 a.m. to 12:30 p.m.; 2:00 p.m. to 4:30 p.m.

List of Subjects in 17 CFR Part 30

Commodity futures, Commodity options, Foreign commodity options.

Amendment of Appendix B

In consideration of the foregoing, 17 CFR Part 30 is amended to read as follows:

PART 30—FOREIGN FUTURES AND FOREIGN OPTION TRANSACTIONS

1. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 2(a)(1)(A), 4, 4c and 8a of the Commodity Exchange Act, 7 U.S.C. 2, 4, 6, 6c and 12a (1982).

2. Appendix B is amended by adding the following entry alphabetically:

Appendix B—Option Contracts Permitted To Be Offered and Sold in the U.S. Pursuant to § 30.3(a)

Exchange	Type of contract	FR date and citation
* * * * *		
Sydney Furtures Exchange.	Options on Three-Year Australian Treasury Bond Futures Contracts.	53 FR ____
* * * * *		

Issued in Washington, DC, on August 9, 1988, by the Commission.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 88-18344 Filed 8-12-88; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Ch. I, Appendix

Extension of the Trust or Restricted Status of Certain Indian Lands

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Extension of Trust or Other Restrictions on Indian Land; Amendment to Appendix, Chapter I.

SUMMARY: Notice is hereby given that on February 23, 1988, the Secretary of the Interior issued an order extending the period of trust or other restrictions against alienation of certain Indian lands which would otherwise expire during the calendar years 1989 through 1993.

EFFECTIVE DATE: February 23, 1988.

FOR FURTHER INFORMATION CONTACT: Lee E. Maytubby, Realty Specialist, Bureau of Indian Affairs, Room 4521, Main Interior, 18th & C Streets, NW., Washington, DC 20240, telephone (202) 343-3837.

SUPPLEMENTARY INFORMATION: Various Executive Orders and orders of the Secretary of the Interior extended the trust periods on Indian lands expiring during the calendar years 1949 through 1988. Orders of the Secretary of the Interior issued pursuant to authority delegated by Executive Order No. 10250 of June 5, 1951, as amended by Executive Order No. 10732 of October 10, 1957, have in recent years been issued at five year intervals. On

[1] Commission Rule 30.3(a), 52 FR 28980, 28998 (August 5, 1987), makes it unlawful for any person to engage in the offer and sale of a foreign option product until the Commission, by order, authorizes such foreign option to be offered in the United States.

February 23, 1988, the Secretary issued the following order:

Trust Periods Expiring During Calendar years 1989 through 1993, Inclusive.

By virtue of and pursuant to the authority delegated by Executive Order No. 10250 of June 5, 1951, as amended by Executive Order 10732 of October 10, 1957, and pursuant to section 5 of the Act of February 8, 1887 (24 Stat. 388, 389), the Act of June 21, 1906 (34 Stat. 325, 326), and the Act of March 2, 1917 (39 Stat. 969, 976), and other applicable provisions of law, it is hereby ordered that the periods of trust or other restrictions against alienation contained in any patent applying to Indian lands, whether of a tribal or individual status, which, unless extended, would expire during the calendar years 1989 through 1993 inclusive, be, and the same are hereby extended until January 1, 1994.

This order is not intended to apply to any case in which Congress has specifically reserved to itself authority to extend that period of trust on tribal or individual Indian lands.

Ross O. Swimmer,

Assistant Secretary—Indian Affairs.

Chapter I—Notice is hereby given to extend the period of trust or other restrictions against alienation of Certain Indian lands.

Appendix to Chapter I—Extension of Trust or Restricted Status of certain Indian Lands [Amended]

The Appendix to 25 CFR Chapter I is amended as follows:

1. The following entry is added as the last entry in the last "General Orders" table:

GENERAL ORDERS

Order	Date	Per. of exten.	FR citation
• • •	• • •	• • •	•
Sec. Int.	Aug. 15, 1988	5 yrs	[Insert FR citation to this document]

2. The Note following the last "General Orders" table is amended by adding "; [Insert FR page citation and date of publication]" following "July 27, 1983" and by adding ", 1989—1993" following "1984—1988".

[FR Doc. 88-15055 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-02-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2619

Valuation of Plan Benefits in Single-Employer Plans; Amendment Adopting Additional PBGC Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This amendment to the regulation on Valuation of Plan Benefits in Single-Employer Plans contains the interest rates and factors for the period beginning September 1, 1988. The use of these interest rates and factors to value benefits is mandatory for some terminating single-employer pension plans and optional for others. The Pension Benefit Guaranty Corporation adjusts the interest rates and factors periodically to reflect changes in financial and annuity markets. This amendment adopts the rates and factors applicable to plans that terminate on or after September 1, 1988, and will remain in effect until the PBGC issues new interest rates and factors.

EFFECTIVE DATE: September 1, 1988.

FOR FURTHER INFORMATION CONTACT: John Foster, Attorney, Office of the General Counsel, Code 22500, Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006, 202-778-8824 (202-778-8859 for TTY and TDD only). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation's ("PBGC's") regulation on Valuation of Plan Benefits in Single-Employer Plans (29 CFR Part 2619) sets forth the methods for valuing plan benefits of terminating single-employer plans covered under Title IV of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). The recent amendments to Title IV made by the Pension Protection Act ("PPA"), a part of the Omnibus Budget Reconciliation Act of 1987, increase the amount of plan benefits for which an employer is responsible upon plan termination. These new termination rules apply to plan terminations with respect to which the 60-day advance notice to affected parties (the notice of intent to terminate) is issued after December 17, 1987. (For more detail, see the PBGC's Notice of Revised Termination Rules, 53 FR 1905 (January 22, 1988).) However, the PPA does not change the Title IV valuation rules.

Under amended ERISA section 4041(c), all plans wishing to terminate in a distress termination must value guaranteed benefits and "benefit liabilities", i.e., all benefits provided under the plan as of the plan termination date, using the formulas set forth in Part 2619. Plans terminating in a standard termination may, for purposes of the notice given to the PBGC, use these formulas to value benefit liabilities, although this is not required. (Such plans may value benefit liabilities that are payable as annuities on the basis of a qualifying bid obtained from an insurer.)

Plans that terminate on or after January 1, 1986 (the effective date of the Single-Employer Pension Plan Amendments Act of 1986) and issued notices of intent to terminate prior to December 18, 1987, or against which the PBGC instituted involuntary termination proceedings before that date, shall continue to be responsible for benefit commitments under the plan and to value guaranteed benefits and/or benefit commitments.

Appendix B in Part 2619 sets forth the interest rates and factors that are to be used in the formulas contained in the regulation. Because these rates and factors are intended to reflect current conditions in the financial and annuity markets, it is necessary to update the rates and factors periodically.

The rates and factors currently in use have been in effect since June 1, 1988 (53 FR 17025 (May 13, 1988)). Changes in the financial and annuity markets now require an increase in those rates. Accordingly, this amendment adds to Appendix B a new set of interest rates and factors for valuing benefits in plans that terminate on or after September 1, 1988, which set reflects an increase of ¼ percent in the immediate interest rate to 8¼ percent.

Generally, the interest rates and factors will be in effect for at least one

month. However, any published rates and factors will remain in effect until such time as the PBGC publishes another amendment changing them. Any change in the rates normally will be published in the **Federal Register** by the 15th of the month preceding the effective date of the new rates or as close to that date as circumstances permit.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest rates and factors promptly so that the rates can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans that will terminate on or after September 1, 1988, and because no adjustment by ongoing plans is required by this amendment, the PBGC finds that good cause exists for making the rates set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this is not a "major rule" under the criteria set forth in Executive Order 12291, because it will not result in an annual effect on the economy of $100 million or more, a major increase in costs for consumers or individual industries, or significant adverse effects on competition, employment, investment, productivity, or innovation.

List of Subjects in 29 CFR Part 2619

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, Part 2619 of Chapter XXVI, Title 29, Code of Federal Regulations, is hereby amended as follows:

PART 2619—[AMENDED]

1. The authority citation for Part 2619 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362, as amended by secs. 11004(a), 11007–11009, 11016(c)(12)–(c)(13) and 11011(a), Pub. L. 99–272, 100 Stat. 239–240, 244–252, 274 and 253–257 and by secs. 9312–13, Pub. L. 100–203, 101 Stat. 1330.

2. Rate Set 74 of Appendix B is revised and Rate Set 75 of Appendix B is added to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix B—Interest Rates and Quantities Used to Value Immediate and Deferred Annuities

In the table that follows, the immediate annuity rate is used to value immediate annuities, to compute the quantity "Gy" for deferred annuities and to value both portions of a refund annuity. An interest rate of 5% shall be used to value death benefits other than the decreasing term insurance portion of a refund annuity. For deferred annuities, k_1, k_2, k_3, n_1, and n_2, are defined in § 2619.45.

Rate set	For plans with a valuation date			Immediate annuity rate (percent)	Deferred annuities				
	On or after	&	Before		k_1	k_2	k_3	n_1	n_2
•	•	•	•	•	•	•	•		
74	June 1, 1988		Sept. 1, 1988	8.00	1.0725	1.0600	1.0400	7	8
75	Sept. 1, 1988			8.25	1.0750	1.0625	1.0400	7	8

Kathleen P. Utgoff,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 88–18348 Filed 8–12–88; 8:45 am]

BILLING CODE 7708–01–M

29 CFR Part 2676

Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal; Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR Part 2676). The regulation prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219(c)(1)(D) and 4281(b) of the Employee Retirement Income Security Act of 1974. Section 2676.15(c) of the regulation contains a table setting forth, for each calendar month, a series of interest rates to be used in any valuation performed as of a valuation date within that calendar month. On or about the fifteenth of each month, the PBGC publishes a new entry in the table for the following month, whether or not the rates are changing. This amendment adds to the table the rate series for the month of September 1988.

EFFECTIVE DATE: September 1, 1988.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Attorney, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington DC 20006; 202–778–8820 (202–778–8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The PBGC finds that notice of and public comment on this amendment would be impracticable and contrary to the public interest, and that there is good cause for making this amendment effective immediately. These findings are based on the need to have the interest rates in this amendment reflect market conditions that are as nearly current as possible and the need to issue the interest rates promptly so that they are available to the public before the beginning of the period to which they apply. (*See* 5 U.S.C. 533 (b) and (d).) Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

The PBGC has also determined that this amendment is not a "major rule" within the meaning of Executive Order 12291 because it will not have an annual effect on the economy of $100 million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 29 CFR Part 2676

Employee benefit plans, Pensions.

In consideration of the foregoing, Part 2676 of Subchapter H of Chapter XXVI of Title 29, Code of Federal Regulations, is amended as follows:

PART 2676—VALUATION OF PLAN BENEFITS AND PLAN ASSETS FOLLOWING MASS WITHDRAWAL

1. The authority citation for Part 2676 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1399(c)(1)(D), and 1441(b)(1).

2. In § 2676.15, paragraph (c) is amended by adding to the end of the table of interest rates therein the following new entry:

§ 2676.15 Interest.

* * * * *

(c) *Interest rates.*

For valuation dates occuring in the month:	The values of i_k are:															
	i_1	i_2	i_3	i_4	i_5	i_6	i_7	i_8	i_9	i_{10}	i_{11}	i_{12}	i_{13}	i_{14}	i_{15}	i_w
September 1988	.10125	.0975	.0925	.0875	.0825	.07625	.07625	.07625	.07625	.07625	.07	.07	.07	.07	.07	.06

Kathleen P. Utgoff,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 88-18347 Filed 8-12-88; 8:45 am]

BILLING CODE 7708-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 239a

[DoD Directive 5100.60]

Department of Defense Housing Referral Program

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This rule removes Part 239a in its entirety. The part is has served the purpose for which it was intended and is no longer required.

EFFECTIVE DATE: July 25, 1988.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Bynum, Directives Division, Office of the Director for Administration and Management, Washington, DC 20301-1155, telephone (202) 697-4111.

SUPPLEMENTARY INFORMATION:

List of Subject in 32 CFR Part 239a

Housing; Military personnel.

PART 239a-[REMOVED]

Accordingly, Title 32, Chapter I is amended to remove Part 239a.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 10, 1988.

[FR Doc. 88-18360 Filed 8-12-88; 8:45 am]

BILLING CODE 3810-01-M

32 CFR Part 239b

[DoD Instruction 4165.51]

Housing Referral Offices and Services

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This rule removes Part 239b in its entirety. The part has served the purpose for which it was intended and is no longer required.

EFFECTIVE DATE: July 25, 1988.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Bynum, Directives Division, Office of the Director for Administration and Management, Washington, DC 20301-1155, telephone (202) 697-4111.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 239b

Housing; Military personnel.

PART 239b—[REMOVED]

Accordingly, Title 32, Chapter I is amended to remove Part 239b

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 10, 1988.

[FR Doc. 88-18361 Filed 8-12-88; 8:45 am]

BILLING CODE 3810-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 6F3453/R978; FRL-3428-9]

Pesticide Tolerances For Bifenthrin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for the residues of the synthetic pyrethroid bifenthrin in or on the raw agricultural commodities (RACs) cottonseed; meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep; and milk. This regulation to establish the maximum permissible levels for residues of the chemical was requested pursuant to a petition by the FMC Corp. This regulation expires on October 31, 1992.

EFFECTIVE DATE: August 15, 1988.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 2708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 15, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 200, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-2400.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of November 19, 1986 (51 FR 41828), which announced that FMC Corp., Agricultural Chemical Group, 2000 Market St., Philadelphia, PA 19103, had submitted pesticide petition (PP) 6F3453 proposing to establish tolerances in or on the RACs cottonseed at 0.5 part per million (ppm); meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep at 0.1 ppm; and milk at 0.02 ppm for residues of the pesticide bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate).

No comments were received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data considered in support of the tolerance include a 12-month feeding study in dogs with a no-observed-effect level (NOEL) of 1.5 milligrams (mg)/per kilogram (kg)/per day; a 24-month rat feeding/oncogenicity study with dietary levels of 0, 12, 50, 100, and 200 ppm with a systemic NOEL of 50 ppm (2.5 mg/kg/day) and a lowest effect level (LEL) of 100 ppm (5.0 mg/kg/day) with no evidence of oncogenicity at 200 ppm (10 mg/kg/day), which was the highest dose tested (HDT); a mouse feeding oncogenicity study (87 weeks for males, 92 weeks for females) with dose levels of 0, 50, 200, 500, and 600 ppm in which there was a significantly elevated incidence of leiomyosarcoma of the urinary bladder of males at 600 ppm (30 mg/kg/day); a two-generation rat

reproduction study with a maternal toxicity NOEL of 30 ppm and reproduction toxicity and developmental toxicity NOELs greater than 100 ppm (HDT); a rat teratology study with maternal and developmental toxicity NOELs of 1 mg/kg/day; a rabbit teratology study with a maternal toxicity NOEL of 2.67 mg/kg/day and developmental toxicity NOEL greater than 8 mg/kg/day (HDT). Several of the genotoxicity studies submitted were negative, including a reverse mutation (Ames) assay in *Salmonella typhimurium;* a chromosome aberration study with Chinese Hamster ovary (CHO) cells; and an unscheduled DNA synthesis study with rat hepatocytes. A forward mutation study involving the thymidine kinase (TK) locus in mouse lymphoma cells showed dose-dependent increases in mutation frequency both with and without S–9 activation; bifenthrin is therefore mutagenic with and without S–9 activation in this assay.

On the basis of a statistically highly significant (P=0.00053) dose related trend of increased tumor incidence (as well as a significantly elevated increased incidence at the highest dose level) of leiomyosarcoma of the urinary bladder in male mice, the Agency has classified bifenthrin as a Class C (possible human) oncogen.

The decision supporting a Category C classification (rather than a Category B classification) was based primarily on the fact that only one sex was affected (male), only one species was affected (mouse), mutagenicity assays did not support upgrading to a B classification, and the structure-activity relationship of bifenthrin to other pyrethroids supported a C classification. In classifying bifenthin as a Category C oncogen, the Agency concluded that a quantitative estimation of the oncogenic potential for humans should be calculated because of the uncommon nature of the urinary bladder tumors. Thus, Q_1^* of 5.4×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents has been calculated. If we assume that 100% of all cotton is treated with bifenthrin and tolerance level residues are present on foods as eaten (meat, milk), the estimated dietary oncogenic risk to the general population would be 10^{-5}.

Although this estimate of potential oncogenic risk provided above may appear high, the Agency believes that actual exposure and risk would be lower. The basis for this is that the risk of 10^{-5} reflects a worst case dietary exposure because it assumes that 100% of the United States cotton crop is treated with bifenthrin and that all quantities of the food consumed will bear residue levels as high as the proposed tolerance. In reality the Agency knows that all cotton would not be treated with this pesticide. Based upon an analysis of the market penetration of currently registered pyrethroids and acaricides, the Agency expects the percent of crop treated with bifenthrin in a typical year to range from 1 to 26 percent, but would most likely be about 10 percent. Likewise the Agency believes that actual residues on meat and milk will be lower than tolerance levels since cottonseed (a feed item necessitating the establishment of the meat and milk tolerances) is a relatively minor component of most animal diets. Thus, if we assume that 10 percent of the cottom crop will have residues at the tolerance level (0.5 ppm), the estimated dietary oncogenic risk to the general population would be 10^{-6}.

In addition to assessing risk the Agency has determined that the use of bifenthrin is likely to result in smaller amounts of pesticide being applied to cotton to control spider mites, of tank mixing an insecticide and an acaricide to achieve the same result. Bifenthrin is the first pyrethroid with acaricidal properties and will be a valuable tool for growers in managing spider mite resistance, a major problem in many cotton-growing areas. The Agency's review of comparative yield data also demonstrate increased yields of cotton in bifenthrin-treated plots relative to test plots treated with currently used pyrethroids and acaricides. An Agency analysis determined that the observed yield increases could result in significant economic benefits even though the application costs of bifenthrin may be considerably higher than alternative pesticides.

The Agency has reviewed and evaluated the data submitted by the manufacturer in support of the tolerance for bifenthrin on cotton and considered information on the risks associated with the proposed use of bifenthrin. The Agency has also considered information on the social, economic, and environmental benefits of the proposed use of bifenthrin, including benefits information submitted by the manufacturer and comparative efficacy and yield data gleaned from the open literature.

Based on an assessment of the risk and benefits of the proposed use of bifenthrin, the Agency believes that the proposed use of bifenthrin on cotton will pose extremely small risks to humans and that the proposed tolerance levels are acceptable and should be established.

The acceptable daily intake (ADI), based on a NOEL of 1.5 mg/kg/day from a 1-year dog feeding study and a safety factor of 100 is 0.015 mg/kg body weight/day. The theoretical maximum residue contribution from the proposed tolerances is 0.000445 mg/kg body weight/day. This is equivalent to about 3 percent of the ADI.

The metabolism of the chemical in plants for this cotton use is adequately understood. An analytical method (gas liquid chromatography with an electron capture detector) is available for enforcement. Prior to its publication in the *Pesticide Analytical Manual,* Vol. II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from: By mail: Information Service Section (TS–757C), Program Management and Support Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)–557–3262.

The tolerances established by amending 40 CFR Part 180 are adequate to cover residues in or on cottonseed; milk; fat, meat, and meat by-products of cattle, goats, hogs, horses, and sheep.

There are currently no actions pending against the registration of this product. This pesticide is considered useful for the purpose for which the tolerances are sought.

On August 5, 1988, the Agency issued a condition registration for use of bifenthrin on cotton with a final expiration date of October 31, 1991. In order to evaluate the effects of bifenthrin on fish and aquatic organisms and its fate in the environment, several data requirements must be fulfilled during the period of the conditional registration. Such requirements include a fish life-cycle study (§ 72–5), which must be submitted by August 1988; a simulated or actual aquatic field test study (§ 72–7), which must be submitted by January 1989; a volatility (lab) study (§ 163–2), which must be submitted by August 1989; an aquatic invertebrate life cycle (fresh water) test (§ 72–4) and an aquatic invertebrate life cycle (estuarine) test (§ 72–4), which must be submitted by October 1989; a repeat soil dissipation study (§ 164–1), which must be submitted to the Agency by November 1990; and a repeat confined crop rotation study in wheat only (§ 165–1), which must be submitted to the Agency by October 1991. Because of the lack of these studies, the Agency is establishing the tolerances for this

pesticide on cottonseed at 0.5 ppm; meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep at 0.1 ppm; and milk at 0.02 ppm with an expiration date of October 31, 1992, to cover residues expected to be present during the period of conditional registration.

Based on the above information and data considered, the agency concludes that the tolerances would protect the public health. Therefore, the tolerances are established as set forth below with an expiration date of October 31, 1992. After receipt and evaluation of the data required to support the conditional registration of bifenthrin, the Agency will consider establishing a permanent tolerance.

Any person adversely affected by this regulation may, within 30 days after the date of publication in the **Federal Register**, file written objections with the Hearing Clerk (address above). Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164 (5 U.S.C. 601–612)), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from the tolerance requirements do not have a significant economic impact on a substantial number of small entitles. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950). (Sec. 408(c), 72 Stat. 1786 (21 U.S.C. 346(C)).)

List of Subjects In 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 5, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. New § 180.442 is added, to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

Tolerances, to expire October 31, 1992, are established for residues of the pyrethroid bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifeuoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following commodities:

Commodities	Part per million
Cottonseed	0.5
Meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep	0.1
Milk	0.02

[FR Doc. 88–18375 Filed 8–12–88; 8:45 am]

BILLING CODE 6560–50–M

LEGAL SERVICES CORPORATION

45 CFR Part 1607

Governing Bodies

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: This final rule revises § 1607.6 of 45 CFR Part 1607 of the Legal Services Corporation's regulations on recipient governing bodies. Section 1607.6 implements section 1007(c) of the Legal Services Corporation Act, which prohibits LSC program attorney board members from receiving compensation from "a recipient." 42 U.S.C. 2996f. Part 1607 as originally promulgated in 1976 substituted the definite article, "the recipient," for the indefinite article used in the Act, causing uncertainty as to the scope of the restriction. This revision, which makes the language in the regulation more closely comport with the letter and the meaning of the Act, is intended to reinforce the independence of recipient board members. The revision also more clearly defines what is included in the term "compensation."

EFFECTIVE DATE: September 14, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Timothy B. Shea, General Counsel, Office of the General Counsel, Legal Services Corporation, 400 Virginia Avenue SW., Washington, DC 20024–2751, (202) 863–1823.

SUPPLEMENTARY INFORMATION: Notice of proposed changes to 45 CFR Part 1607, LSC's regulations on recipient governing bodies, published at 52 FR 38900 (Oct. 19, 1987), was amended at 52 FR 42460 (Nov. 5, 1987) to extend the comment period to December 10, 1987, and, as a matter of discretion, until December 17, 1987, the day of the LSC Board's Operations and Regulations Committee meeting. The notice proposed several changes to Part 1607, including § 1607.6. A total of 567 comments from state and local bar associations, Members of Congress, LSC programs, and other interested individuals and groups has been received. Approximately 145 comments addressed the proposed changes to § 1607.6. In addition, the LSC Board's Operations and Regulations Committee met in Philadelphia, Pennsylvania, on November 20, 1987, in Charleston, South Carolina, on December 17 and 18, 1987, and in Washington, DC, on January 28 and 29, 1988, to hear public comment and consider the proposed changes. On January 29, 1988, the Board, at the recommendation of the Operations and Regulations Committee, adopted revisions to § 1607.6 as final.

Approximately 143 comments opposed and 2 favored the proposed revision of section 1607.6 to prohibit receipt of compensation from "any recipient," rather than the current prohibition on "the recipient." The comments urged that Congress did not mean "any" when it used the indefinite article "a" in section 1007(c). Comments also asserted that the revision would prevent recipient attorneys from serving on national support centers where their first-hand knowledge and experience are valuable.

Section 1007(c) of the LSC Act prohibits LSC program attorney board members from receiving compensation from "a recipient." 42 U.S.C. 2996f. When the implementing regulation, 45 CFR Part 1607, was promulgated in 1976, the definite article was substituted for the indefinite article without any accompanying explanation. *See* 41 FR 18526 (May 5, 1976) (proposed rule); 41 FR 25899 (June 23, 1976) (final rule). As evidenced by comments to the proposed changes to Part 1607, some commenters insisted that Congress meant "the" even though it used the indefinite article "a" to modify "recipient" in the Act.

If the provision is construed to mean "a" recipient, then attorney board members may not be compensated by any LSC-funded recipient program. If it is construed to mean "the" recipient, then attorney board members may receive compensation from any LSC program except the recipient on whose board the attorneys serve.

The prohibition is intended to assure that recipient board members are independent, dispassionate, and free from institutional or individual conflicts that detract from the primacy of the provision of effective and efficient client service. The potential for conflict for a staff member who holds a director

position for the same recipient is indisputable. These same concerns apply, though more remotely, in the case of a recipient staff member who sits on other recipient boards. More specifically, many state and national support centers have directors who receive salaries from the same recipient programs to which the support centers provide services. The governing bodies of support centers regularly make decisions on how and where to allocate training, technical assistance, co-counseling, and other substantial resources to the legal services community. Support center directors who are staff members at other programs have a potential conflict with regard to resource allocation decisions insofar as they may have the opportunity to influence decisions to benefit their own programs. Expanding the rule's prohibition from "the" recipient to "a" recipient will reinforce the strong interest in independent governance.

The use of the indefinite article "a" in the LSC Act is not ambiguous and should be given its plain meaning. *United States v. Public Utilities Commission of California*, 345 U.S. 295, 315 (1953), as Congress expresses its intent through the ordinary meaning of the words it uses. *Rubin v. United States*, 449 U.S. 424, 430 (1981). No facial ambiguity in the tenor of section 1007(c) itself has been urged. Conspicuously, use of the definite article in the rule adopted in 1976 is not accompanied by any explanation of the departure from the terms of the statute. Nevertheless, review of the legislative history persuasively demonstrates that the indefinite article was deliberately chosen.

S. Rep. No. 495, 93rd Cong., 1st Sess. 17 (1973), addressing a bill leading to the 1974 LSC Act, S. 2686, 93rd Cong., 1st Sess. (1973), constitutes the main authority for the proposition that "a" should be deemed to mean "the," according to the commenters. The proposed Senate language prohibited compensation from "such" recipient, meaning "the" recipient. It is clear from both the proposed Senate language and the accompanying explanation that the Senate originally contemplated restricting compensation of attorney board members from only those programs on whose boards the attorneys served. S. Rep. No. 495, 93rd Cong., 1st Sess. 17 (1973). The House bill, H.R. 7824, 93rd Cong., 1st Sess. (1973), included a similar prohibition on receipt of compensation by attorneys from recipients. The proposed House language, however, used the indefinite article and was clearly intended to prevent compensation from any LSC recipient. H.R. Rep. No. 247, 93rd Cong., 1st Sess. 12, 20 (1973).

The House version prevailed in conference. The Senate dropped its use of the word "such" in deference to the House use of "a." H.R. Conf. Rep. No. 1039, 93rd Cong., 2d Sess. 10, 28 (1974) and S. Conf. Rep. No. 84, 93rd Cong., 2d Sess. 10, 28 (1974). Though no explanation is given, the change was certainly deliberate.

Subsequent legislative deliberations, H. Rep. No. 201, 98th Cong., 1st Sess. 34 (1983) and H. Rep. No. 448, 99th Cong., 1st Sess. 38 (1985), some nine years after the LSC Act, on amendments that were never adopted, assumed that the prohibition against compensation from "a" recipient ran to "that" recipient. These suggestions, which were unaccompanied by any textual or legislative analysis, apparently were influenced by the regulation, § 1607.6, promulgated by the Corporation in 1976, which, of course, limited the prohibition to "the" recipient. The Supreme Court has consistently warned that the views of a subsequent Congress from a hazardous basis for inferring the intent of an earlier one. *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102, 117–18 (1980). Subsequent legislative history will rarely override a reasonable interpretation of a statute that is gleaned from its language and contemporaneous legislative history. *Id.* at 118 n. 13.

In short, review of the legislative history supports the conclusion that the indefinite article "a" was intended when Congress used it in section 1007(c) of the LSC Act.

Concern was expressed to the LSC Board that the revision would preclude healthy exchanges between support centers and their principal clients, the field programs. Certainly, the staffs of support centers and field officers have frequent contact. Nevertheless, to the degree that board level exchanges are deemed necessary, local program board members may still serve on the support center boards, as no restriction exists in this regard.

Section 1607.6 is also revised to clarify that "compensation" includes salary, per diem, or other like payments that constitute remuneration for services rendered, whether in salary, fees, commissions, or per diem. Payment for normal travel and other out-of-pocket expenses required for fulfillment of the obligations of board membership is excluded. The commenter registered no opposition to this change.

Language in the most recent LSC appropriations act, the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–202, 101 Stat. 1329 (1987), imposes certain constraints on the regulation by LSC of recipient governing bodies. The proposed change to § 1607.6, however, does not fall within the constraints of the appropriations act's language. The appropriations act prohibits the Corporation from imposing any requirements on governing bodies that are additional to, or more restrictive than, the provisions of Pub. L. 99–180 and section 1007(c) of the LSC Act. As set out above, the purpose of the change is to revise the language in section 1607.6 to comport more closely with the letter and the meaning of the Act. The change will thus not impose any requirement on governing bodies that goes beyond requirements already delineated in the Act.

Pursuant to Pub. L. 100–201, 101 Stat. 1329–39 (1987), the Corporation is required to give 15 days notice to the appropriations committees of both Houses of Congress prior to publishing revisions to its regulations as final. Reprogramming letters were duly sent to the appropriate committees, and a response expressing disapproval of the proposed revisions based on subsequent legislative deliberations was received from the Senate committee. After careful analysis, set out above, the Corporation concluded that the subsequent deliberations were far outweighed by the express language of the LSC Act and the contemporaneous legislative history. An expression of disapproval, while respectfully considered, does not affect the authority of LSC to publish its revisions as final, as only notice, and not approval, is statutorily required. *See* Pub. L. 99–180, 99 Stat. 1165 (1985), incorporated by reference in Pub. L. 100–202, 101 Stat. 1329 (1987); 130 CONG. REC. S8588–8589 (daily ed. June 28, 1984); and *Principles of Federal Appropriations Law* 2–29 (GAO ed. 1982).

List of Subjects in 45 CFR Part 1607

Legal services.

For reasons set out above, 45 CFR Part 1607 is amended as follows:

1. The authority citation for Part 1607 is revised to read as follows:

Authority: Sec. 1007(c); 42 U.S.C. 2996f(c); Pub. L. 97–377; 96 Stat. 1830; Pub. L. 100–202; 101 Stat. 1329.

2. Section 1607.6 is revised to read as follows:

§ 1607.6 Compensation.

While serving on the governing body of a recipient, no board member shall

receive compensation from any recipient of the Corporation, whether such compensation is termed salary, per diem, or otherwise. A board member may receive payment for normal travel and other out-of-pocket expenses required for fulfillment of the obligations of board membership.

Timothy B. Shea,

General Counsel.

Date: August 9, 1988.

[FR Doc. 88-18351 Filed 8-12-88; 8:45 am]

BILLING CODE 7050-01-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 88-05, Notice 2]
RIN 2127-AC47

Federal Motor Vehicle Safety Standards Air Brake Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: Standard No. 121, *Air Brake Systems*, specifies braking requirements for trucks, buses and trailers equipped with air brake systems. Some vehicles which fall within one of those vehicle classes are excluded from the standard because their attributes, typically those relating to configuration, speed or weight, result in restricted highway operation. This notice amends Standard No. 121 by eliminating the exclusion of vehicles based on width, except for trailers that have a width of more than 102.36 inches with extendable equipment in the fully retracted position and are equipped with two short track axles in a line across the width of trailer.

DATES: The amendment is effective September 14, 1988. Petitions for reconsideration must be received on or before September 14, 1988.

ADDRESSES: Petitions for reconsideration should be submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mr. George Soodoo, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (202-366-5892).

SUPPLEMENTARY INFORMATION: Standard No. 121, *Air Brake Systems*, specifies braking requirements for trucks, buses and trailers equipped with air brake systems. Certain vehicles are excluded by section S3 from the standard's applicability because they have unusual physical or operational characteristics that result in restricted highway operation (e.g., low speed, permit requirements, daytime operation) which limits hazards and the possibility of accidents. Also, the unusual configurations and low production volumes of these vehicles sharply increase compliance costs.

On January 21, 1988, NHTSA published in the **Federal Register** (53 FR 1643) a notice of proposed rulemaking (NPRM) to eliminate from Standard No. 121 a provision which excludes vehicles that have an overall vehicle width of more than 102 inches. The notice was issued in response to a petition for rulemaking submitted by Corpac Industries, Inc.

Corpac stated in its petition that the Surface Transportation Assistance Act of 1982 prevents states from establishing a maximum width of more than or less than 102 inches for commercial motor vehicles operating on the National Network and that this was subsequently interpreted by the Federal Highway Administration as including its approximate metric equivalent, i.e., 2.6 meters (102.36 inches). The petitioner submitted information showing that thousands of trailers are now being produced which are 102.36 inches wide. Corpac argued that Standard No. 121 does not technically apply to these vehicles and urged that the 102-inch exclusion be eliminated to prevent the production of vehicles with possibly markedly inferior braking performance.

NHTSA noted in the January 1988 NPRM that one issue raised by Corpac's petition was whether new 102.36-inch trailers are excluded from Standard No. 121 by virtue of the provision, set forth in section S3(a), that excludes vehicles that have "an overall vehicle width of more than 102 inches with extendable equipment in the fully retracted position." The agency concluded that these vehicles are not excluded from Standard No. 121.

Section 416(a) of the Surface Transportation Assistance Act of 1982 states that "(n)o state, other than the State of Hawaii, shall establish, maintain, or enforce any regulation of commerce which imposes a width limitation of *more or less than 102 inches* on any segment of the National System of Interstate and Defense Highways, or any other qualifying Federal-aid highway as designated by the Secretary of Transportation, with traffic lanes designed to be a width of twelve feet or more * * * " (Emphasis added.) Thus, a state may not prohibit vehicles with a width of 102 inches or less, or permit vehicles with a width greater than 102 inches, on these highways. (States are permitted under section 416(b) to grant special use permits to vehicles that exceed 102 inches in width.)

In proposing regulations under the statute, the Federal Highway Administration (FHWA) stated the following:

> The American National Metric Council and the Truck Trailer Manufacturers Association have called attention to the practices of some Canadian trailer manufacturers to construct their trailers 2.6 meters wide. This dimension is equivalent to 102.36 inches. The FHWA is interested in knowing the advantages and disadvantages of allowing trailers of 102.36-inch widths on the roads as perceived by the State and the public, in general. The FHWA solicits comments on the question of allowing 102.36-inch wide trailers on the National Network. 48 FR 41280, September 14, 1983.

In issuing a final rule, the FHWA stated:

> Commenters on the subject of recognizing the approximate metric width equivalent of 2.6 meters (102.36 inches), on trailers were strongly in favor of such a position. Standardization of truck width on an international basis is seen as an important objective, which will serve to enhance international trade. The FHWA concurs in that assessment. The final rule as contained in Section 658.15 establishes the maximum width as 102 inches or its approximate metric equivalent of 2.6 meters. The FHWA believes the States can accommodate the rule without changing laws or violating congressional intent. 49 FR 23312, June 5, 1984.

The FHWA regulation, set forth at 23 CFR § 685.15, states:

> No State shall impose a width limitation of more or less than 102 inches, or its approximate metric equivalent, 2.6 meters (102.36 inches) on a vehicle operating on the National Network, except for the State of Hawaii * * *

Thus, 102.36 inches is defined in the FHWA regulation as the "approximate metric equivalent" of 102 inches, and was determined by FHWA as being consistent with Congressional intent as not being "more or less" than 102 inches. Particularly given this background, it is NHTSA's opinion that the 102.36 inch trailers being produced in light of the FHWA regulation are not considered to have a width of "more than 102 inches" within the meaning of Standard No. 121's applicability section. Also, previous **Federal Register** notices make it clear that NHTSA did not intend the criteria in section S3 to exclude typical configuration vehicles from Standard

No. 121. For example, in establishing the 102-inch width exclusion, the agency stated that, in all states other than Hawaii, vehicles exceeding this width were allowed to operate on the highway only by permit. See 42 FR 42208, August 22, 1977.

NHTSA stated in the January 1988 NPRM that while it is the agency's opinion that the 102.36-inch vehicles are not excluded from Standard No. 121, it agreed that it should clarify the applicability of the standard to those vehicles. The agency stated that while such clarification could be achieved through amending S3(a) to expressly refer to the 102.36-inch trailers, it believed that a better approach would be to eliminate the exclusion altogether. The agency tentatively concluded that it was not necessary to retain the width exlcusion. NHTSA stated that it was unaware of any vehicles wider than 102 inches or 102.36 inches that do not come within one of the section S3's other exclusions, and that it believed that those exclusions are sufficiently comprehensive to continue to exclude all vehicles whose function or construction result in restricted highway operation and for which compliance would be very difficult. The agency accordingly proposed to delete section S3's width exclusion.

NHTSA received four comments on the January 1988 NPRM. General Motors stated that it supports the proposed amendment to eliminate the exclusion based on vehicle width on the basis that the other criteria stated in section S3 are sufficiently comprehensive to exclude the vehicles that should be excluded from the applicability of Standard No. 121. The Insurance Institute for Highway Safety also supported the proposal, stating that any exclusion from a Federal motor vehicle safety standard should be limited to specific and unusual circumstances. A comment supporting the proposal was also submitted by Corpac.

The Truck Trailer Manufacturers Association (TTMA) commented that if the width exclusion is eliminated from Standard No. 121, a new exclusion should be added. That commenter stated that the elimination of the width exclusion would make some trailers with trunnion or dual oscillating suspension/axle assemblies subject to the standard. According to TTMA, these trailers have a unique undercarriage in that there are two short track axles across the trailer's width instead of one, and do not have sufficient space for brakes that can meet Standard No. 121. That commenter stated that this construction results in a trailer which is typically 120 inches wide, but that some trailers may expand to 120 inches in width when loaded but are less than 102 inches wide when empty. According to TTMA, these trailers often travel at highway speeds when used on the road, but under permit due to their width. That commenter stated that while most of these trailers are excluded from Standard No. 121 by having a gross axle weight rating greater than 29,000 pounds, some of the trailers are excluded only because they have a width greater than 2.6 meters (102.36 inches). TTMA recommended that a new exclusion be added for any trailer equipped with two short track axles in a line across the width of the trailer.

After considering the comments, NHTSA has declined to eliminate Standard No. 121's width exclusion, except for trailers that have a width of more than 102.36 inches with extendable equipment in the fully retracted position and are equipped with two short track axles in a line across the width of trailer. NHTSA has concluded that the trailers with trunnion or dual oscillating suspension/axle assemblies identified by TTMA are vehicles whose function or construction result in restricted highway operation and for which compliance would be very difficult. The agency indicated in the NPRM that it did not intend to extend the applicability of Standard No. 121 to such vehicles. NHTSA is retaining a width provision in the revised exclusion to make it clear that it does not exclude any vehicles not previously excluded by the old width exclusion.

The effective date is 30 days after publication of a final rule in the **Federal Register**. NHTSA has determined that there is a good cause for an effective date within that time period since the amendment clarifies the standard's applicability and is not believed to affect the applicability of the standard to any vehicles currently being produced.

The agency has analyzed the economic and other effects of this amendment and determined that it is neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation's regulatory policies and procedures. As indicated above, the amendment clarifies Standard No. 121's applicability to vehicles of 102.36 inches and is not believed to affect the applicability of the standard to any vehicles currently being produced. The agency has also determined that the effects of the amendment are so minimal that a full regulatory evaluation is not required.

In accordance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this action on small entities. I certify that the amendment will not have a significant economic impact on a substantial number of small entities. For the reasons stated in the preceding paragraph, neither small businesses, small organizations, nor small governmental units will be affected by the amendment.

The agency has analyzed this rule for the purposes of the National Environmental Policy Act, and determined that it will not have any significant impact on the quality of the human environment.

Finally, this rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The agency has determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

A regulatory information number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires.

PART 571—[AMENDED]

In consideration of the foregoing, 49 CFR Part 571 is amended as follows:

1. The authority citation for Part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.121 [Amended]

2. S3 is revised to read as follows:

S3. *Application.* This standard applies to trucks, buses, and trailers equipped with air brake systems. However, it does not apply to:

(a) Any trailer that has a width of more than 102.36 inches with extendable equipment in the fully retracted position and is equipped with two short track axles in a line across the width of the trailer.

(b) Any vehicle equipped with an axle that has a GAWR of 29,000 pounds or more;

(c) Any truck or bus that has a speed attainable in 2 miles of not more than 33 mph;

(d) Any truck that has a speed attainable in 2 miles of not more than 45 mph, an unloaded vehicle weight that is not less than 95 percent of its GVWR, and no capacity to carry occupants other than the driver and operating crew;

(e) Any trailer that has a GVWR of more than 120,000 pounds and whose body conforms to that described in the definition of "Heavy hauler trailer" set forth in S4;

(f) Any trailer that has an unloaded vehicle weight which is not less than 95 percent of its GVWR; and

(g) Any load divider dolly.

Notwithstanding any language to the contrary, sections S5.3.1, S5.3.1.1, S5.3.2, S5.3.2.1, S5.3.2.2, S5.7.1, S5.7.3(a) and S5.7.3(b) of this standard are not applicable to trucks and trailers, and section S5.3.1 of this standard is not applicable to buses.

Issued on August 10, 1988.

Diane K. Steed,

Administrator.

[FR Doc. 88-18367 Filed 8-12-88; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF INTERIOR

Fish and Wildlife Service

50 CFR Part 23

Export of American Alligators Harvested in 1988

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Convention on International Trade in Endangered Species of Wild Fauna and Flora (Convention) regulates international trade in certain animal and plant species. As a general rule, exports of animals and plants listed on Appendix II of the Convention may occur only if a Scientific Authority has advised a permit-issuing Management Authority that such exports will not be detrimental to the survival of the species, and if the Management Authority is satisfied that the animals or plants were not obtained in violation of laws enacted for their protection.

This rule by the U.S. Scientific Authority and Management Authority approves the export of alligators harvested in Florida, Georgia, and South Carolina in 1988. These final findings also stipulate that monitoring procedures previously established for other States including Florida, be extended to include Georgia, and South Carolina.

EFFECTIVE DATE: August 15, 1988.

ADDRESSES: Please send correspondence concerning this rule to the Office of Scientific Authority; Mail Stop: Room 527, Matomic Building; U.S. Fish and Wildlife Service; Washington, DC 20240. Materials received will be available for public inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, at the Office of Scientific Authority, Room 537, 1717 H Street NW., Washington, DC or at the Office of Management Authority, Room 400, 1375 K Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Scientific Authority Finding—Dr. Charles W. Dane, Office of Scientific Authority, U.S. Fish and Wildlife Service, Washington, DC 20240, telephone (202) 653-5948

Management Authority Findings—Mr. Marshall P. Jones, Office of Management Authority, U.S. Fish and Wildlife Service, Washington, DC 20240, telephone (202) 343-4968

Export Permits—Mr. Richard K. Robinson, Office of Management Authority, U.S. Fish and Wildlife Service, Washington, DC 20240, telephone (202) 343-4955

State Export Programs—Mr. S. Ronald Singer, Office of Management Authority, U.S. Fish and Wildlife Service, Washington, DC 20240, telephone (202) 343-4963.

SUPPLEMENTARY INFORMATION: On September 2, 1986, **Federal Register** (51 FR 31130), the U.S. Fish and Wildlife Service (Service) published a rule granting export approval for American alligator (*Alligator mississipiensis*) from specified States for the 1986-88 harvest seasons. The purpose of this rule now being published is to add Georgia and South Carolina to the list of States for which alligator export would be approved, and to issue Service findings on a revised harvest program in Florida to enable continued export of alligators from that State.

Scientific Authority Findings

Article IV of the Convention requires that an export permit for any specimen of a species included in Appendix II shall only be granted when certain findings have been made by the Scientific Authority and Management Authority of the exporting country. The Scientific Authority must advise "that such export will not be detrimental to the survival of that species" before a permit can be granted by the Management Authority.

The American alligator is listed in Appendix II to respond both to problems of potential threat to the survival of American alligators [Convention Article II.2(a)] and its similarity in appearance to other crocodilians that are threatened with possible extinction [Convention Article II.2(b)].

The marking of hides, meat, and parts with specified tags and documentation of shipments, as well as the issuance of export permits, is considered sufficient to address the issue of identification due to the similarity in appearance between American alligators and other listed species (see Management Authority findings for export program and tag specifications).

Inasmuch as the alligator is also listed because of a potential threat to its survival, the Service must determine if exports will not be detrimental to the survival of the American alligator itself.

Guidelines developed for Scientific Authority advice on exports of American alligators under the provisions of Convention Article II.2(a), are summarized as follows:

A. Minimum requirements for biological information

(1) Information on the condition of the population, including trends (the method of determination to be a matter of State choice), and population estimates where such information is available;

(2) Information on total harvest of the species;

(3) Information on distribution of harvest; and

(4) Habitat evaluation.

B. Minimum requirements for a management program

(1) There should be a controlled harvest, methods and seasons to be a matter of State choice;

(2) All hides should be registered and marked; and

(3) Harvest level objectives should be determined annually by the State.

The Service's Office of Scientific Authority finds that current information on population status, management, and harvest submitted by the States of Florida, Georgia, and South Carolina, as well as information collected by the Service fully support a finding that the export of alligators taken in accordance with State regulations in these States during the 1988 harvest season will not be detrimental to the survival of the species in the listed States. Tagging of hides by the States and documentation of shipments by the U.S. Management Authority provide assurance that export will not reduce the effectiveness of the Convention in controlling trade in other species of crocodilians. Documents containing information that provided the basis for the Service's findings are available for public inspection at the

Office of Scientific Authority (address given above).

Management Authority Findings

Exports of Appendix II species are to be allowed under the Convention only if the Management Authority is satisfied that the specimens were not obtained in contravention of laws enacted for the protection of the involved species. The Service, therefore, must be satisfied that alligator hides, meat or products were not obtained in violation of State or Federal law in order to allow export. Evidence of legal taking for American alligator is provided by Service-approved State tagging programs. The Service annually contracts for the manufacture and delivery of special Convention animal-hide tags for export-qualified States. In a **Federal Register** notice, published on April 24, 1986 (52 FR 15548), the Service announced the introduction, use, and protection of a US-CITIES tag symbol. This symbol appers on every Service-approved export tag to provide legal evidence of export approval for certain Convention Appendix II listed species.

Guidelines developed for Management Authority findings on State American alligator export programs, slightly modified from the 1986–1988 rule, under provisions of Convention Article IV.2(b), are summarized as follows:

(1) Current State alligator trapping and tagging, meat, and parts processing regulations must be on file with the Office of Management Authority;

(2) Sample reporting forms, export tag, meat packing seal, and parts tag must be on file with the Office of Management Authority;

(3) The export tag must be durable and permanently locking, and must show U.S.-CITIES logo, State of origin, year of take, species, and be serially unique;

(4) The export tag, meat seal, and parts tag must be applied to all hides, meat or parts, within a minimum time after take or processing, as specified by State law, and such time should be as short as possible to minimize movement of untagged hides, meat, or parts;

(5) The tags or seals must be permanently attached, as mandated by the State;

(6) All alligator harvesters and processors must be State registered;

(7) All hide, meat, and parts dealers are to be State registered;

(8) All State-registered alligator harvesters, processors, and dealers must make available their alligator harvest and commerce data to the State on at least an annual basis, as specified by the State;

(9) State-registered alligator dealers and licensed harvesters allowed to attach export tags to the hides must account for all tags received and must return unused tags to the State within a specified time after the harvest period closes; and

(10) Fully manufactured alligator hide products may be exported from the United States when the State-hide Covention export tags, removed from hides contained in manufactured products, are surrendered to the Service prior to export.

The Service's Office of Management Authority has reviewed the alligator export tagging programs of Florida, Georgia, and South Carolina and has found that they fully meet the guidelines listed above. Documents containing information that provide the basis for the Service's findings are available for public inspection at the Office of Management Authority (address given above).

The Service approves exports of 1988 alligators harvested in Florida, Georgia, and South Carolina on the grounds that both Scientific Authority and Management Authority export requirements are satisfied.

Public Comment

No comment was received concerning the proposed rule published on July 15, 1988 (53 FR 26799).

This final rule is issued under authority of the Endangered Species Act of 1973 as amended (16 U.S.C.1531 *et seq.*). The authors are S Ronald Singer, Office of Management of Authority, and Dr. Charles W. Dane, Office of Scientific Authority.

Note.—The Department had previously determined that the export of alligators of various States taken in the 1986–1988 harvest seasons, was not a major Federal action that would significantly affect the quality of the human environment within the meaning of section 102(1)(c) of the National Environmental Policy Act, therefore, the preparation of an Environmental Impact Statement was not required (48 FR 37494). Because these findings do not significantly differ from the previous export findings, the previous determination not to prepare and Environmental Impact Statement on export of alligators taken during the 1986–1988 harvest seasons in certain States (51 FR 31130) remains appropriate. The Department had also previously determined that such harvest was not a major rule under Executive Order 12291 and did not have a significant economic affect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601). Because the existing rule treats exports on a State-by-State basis and approves export in accordance with a State management/export program, the rule will have little effect on small entities in and of itself. This rule does not contain any information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

This rule adds Georgia and South Carolina to those States already permitted to export this species and authorizes the expansion of the already existing program in Florida. The export of American alligator is a necessary portion of a State's alligator management program as the foreign markets for this species are dependent upon this final rule. The buying season is now underway in the already permitted States. The rule announced in this notice is to become effective upon publication so that export can begin in these additional States as soon as possible. This will enable these new States their share of the export market, enable the alligator farmers and trappers to realize a monetary return for their product, and infuse the resulting State share of export monies into State alligator programs.

List of Subjects in 50 CFR Part 23

Endangered and threatened wildlife, Exports, Fish, Imports, Plants (agriculture), Treaties.

PART 23—ENDANGERED SPECIES CONVENTION

Accordingly, the Service amends Part 23 of Title 50, Code of Federal Regulations, as set forth below:

1. The authority citation for Part 23 continues to read as follows:

Authority: Convention on International Trade in Endangered Species of Wild Fauna and Flora, TIAS 8249; and Endangered Species Act of 1973, 87 Stat. 884, 16 U.S.C. 1531–43 *et. seq.*

Subpart F—Export of Certain Species

2. In § 23.57 American alligator (*Alligator mississippiensis*), paragraphs (a) and (b) are revised, and paragraphs (c) through (g) are removed, to read as follows:

§ 23.57 [Amended]

* * * * *

(a) 1979–1988 harvests (wild and captive bred for each year unless otherwise noted).

	Florida	Georgia	Louisiana	South Carolina	Texas
1979(*)	+	–	+	–	–
1980	+	–	+	–	–
1981	+	–	+	–	–
1982	+	–	+	–	–
1983	+	–	+	–	–
1984	+	–	+	–	+
1985	+	–	+	–	+

	Florida	Georgia	Louisiana	South Carolina	Texas
1986	+	–	+	–	+
1987	+	–	+	–	+
1988	+	+	+	+	+

LEGEND
+ export approved.
– export not approved.
* and prior years.

(b) Conditions on export:

(1) Each hide must be clearly identified as to species, Country and State of origin, and season of taking, and must be marked by a permanently attached, serially numbered tag of a type approved by the Service that is attached under conditions established by the Service. Fully manufactured hide products may be exported from the United States when State hide export tags, removed from hides contained in the products, are surrendered to the Service prior to export.

(2) Meat from legally harvested and tagged alligators shall be packed in uniform containers, permanently sealed and labeled as required by State law. Bulk meat containers shall be marked with a State "parts tag" or "bulk meat tag" permanently attached indicating, at a minimum, State and country of origin, year of take, species, original hide export tag number, weight of container, and identification of State-licensed processor or packer.

(3) Large individual parts shall have a "parts tag" permanently attached, while smaller parts may be packed with a "parts tag" permanently attached to the package. "Parts tags" shall supply the same information as described for such tags used to mark alligator meat. Alligator skulls shall carry a "parts tag" and also be marked with the number of the original U.S.-CITES export tag used for the hide of that individual, and other markings, as required by State law.

Susan Recce,

Assistant Secretary for Fish and Wildlife and Parks.

Dated: August 3, 1988

[FR Doc. 88-18407 Filed 8-12-88; 8:45 a.m.]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register
Vol. 53, No. 157
Monday, August 15, 1988

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Grain Inspection Service

7 CFR Part 68

United States Standards for Whole Dry Peas

AGENCY: Federal Grain Inspection Service, USDA.[1]

ACTION: Proposed rule.

SUMMARY: The Federal Grain Inspection Service (FGIS or Service) is proposing to revise the United States Standards for Whole Dry Peas to make the current rounding procedures for percentages consistent with rounding performed by calculators, computer applications and other standards.

DATE: Comments must be submitted on or before September 14, 1988.

ADDRESSES: Comments must be submitted in writing to Lewis Lebakken, Jr., Resources Management Division USDA, FGIS, Room 0628 South Building, P.O. Box 96454, Washington, DC, 20090–6454.

Telemail users may respond to [IRSTAFF/FGIS/USDA] telemail. Telex users may respond as follows: To: Lewis Lebakken Jr., TLX:7607351, ANS:FGIS UC.

All comments received will be made available for public inspection at Room 0628 South Building, 1400 Independence Avenue, SW., Washington, DC, during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Lewis Lebakken, Jr., address as above, telephone (202) 475–3428.

[1] The authority to exercise the functions of the Secretary of Agriculture contained in the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), concerning inspections and standardization activities related to grain and similar commodities and products thereof has been delegated to the Administrator, Federal Grain Inspection Service (7 U.S.C. 75a; 7 CFR 68.5).

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This proposed rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512–1. This action has been classified as nonmajor because it does not meet the criteria for a major regulation established in the Order.

Regulatory Flexibility Act Certification

W. Kirk Miller, Administrator, FGIS, has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities because those persons that apply the standards and most users of the inspection service do not meet the requirements for small entities as defined in the Regulatory FlexibilityAct (5 U.S.C. 601 *et seq.*). Further, the standards are applied equally to all entities.

Proposed Action

The current rounding procedures for percentages provides that when a figure to be rounded is followed by a figure greater than 5, the figure is rounded up to the next higher figure, e.g. 0.46 is reported as 0.5; when a figure to be rounded is followed by a figure less than 5, the figure is to be retained, e.g., 0.54 is reported as 0.5; when figures that are even are followed by the figure 5, the even figure is retained; and when a figure is odd and followed by the figure 5 the figure is rounded to the next higher even figure, e.g., 0.45 is reported as 0.4, 0.35 is reported as 0.4.

The proposed rounding rules simply stated provide that a figure to be rounded followed by a 5 or a figure greater than 5 be rounded up to the next higher figure, e.g., report 0.35 as 0.4, 6.46 as 6.5. If the figure is followed by a number less than 5, the figure is retained, e.g., report 8.34 as 8.3. This procedure is consistent with rounding performed by calculators and in computer applications. It is also a more generally accepted mathematical rounding procedure and would facilitate the understanding and usage of the standards.

List of Subjects in 7 CFR Part 68

Administrative practice and procedure, Agricultural commodities, Whole dry peas.

For reasons set forth in the preamble, 7 CFR Part 68 is proposed to be amended as follows:

Subpart F—United States Standards for Whole Dry Peas

1. The authority citation for Part 68 continues to read as follows:

Authority: Secs. 202–208, 60 Stat. 1087, as amended (7 U.S.C. 1621 *et seq.*).

2. The heading for Part 68 is revised to read as follows:

PART 68—REGULATIONS AND STANDARDS FOR INSPECTION AND CERTIFICATION OF CERTAIN AGRICULTURAL COMMODITIES AND THEIR PRODUCTS

3. Section 68.405 Percentages, is revised to read as follows:

§ 68.405 Percentages.

(a) *Rounding.* Percentages are determined on the basis of weight and are rounded as follows:

(1) When the figure to be rounded is followed by a figure greater than or equal to 5, round to the next higher figure; e.g. report 6.36 as 6.4, 0.35 as 0.4, and 2.45 as 2.5.

(2) When the figure to be rounded is followed by a figure less than 5, retain the figure; e.g., report 8.34 as 8.3, and 1.22 as 1.2.

(b) *Recording.* All percentages shall be stated in whole and tenth percent to the nearest tenth percent.

Date: July 28, 1988.

W. Kirk Miller,

Administrator.

[FR Doc. 88–18368 Filed 8–12–88; 8:45 am]

BILLING CODE 3410-EN-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 210a

[INS Number: 1119–88]

Admission or Adjustment of Status of Replenishment Agricultural Workers

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice of availability.

SUMMARY: Section 210A of the Immigration Reform and Control Act of 1986 (IRCA) provides for the admission or adjustment of replenishment agricultural workers (RAWs) to

temporary residence. This notice announces the availability to the public of a preliminary working draft of the proposed regulations for the admission or adjustment of a RAW to temporary resident status. This action is taken to communicate the availability of the preliminary working draft to interested parties and ensures that the public has an opportunity to provide comments at the preliminary working draft step in the formulation process for the Service's proposed regulations. Interested parties may call (202) 786–5723 to request a copy of the preliminary working draft.

DATES: Written comments on the preliminary working draft must be received by close of the business day (5:00 p.m.) on or before September 14, 1988.

ADDRESSES: Written comments should be mailed in triplicate to Aaron Bodin, Deputy Assistant Commissioner, Special Agricultural Workers, Office of Legalization, Immigration and Naturalization Service, 452 "I" Street, NW., Washington, DC 20536, or delivered to Room 5250 at the same address.

FOR FURTHER INFORMATION CONTACT: Aaron Bodin, Deputy Assistant Commissioner, Special Agricultural Workers, at the above address, (202) 786–5723.

SUPPLEMENTARY INFORMATION: The Immigration Reform and Control Act of 1986 (IRCA), Pub. L. 99–603, was enacted on November 6, 1986. On January 20, 1987, the Service took the unprecedented step of publishing in the **Federal Register** a notice making available to the public the preliminary working draft regulations to implement the Special Agricultural Worker (SAW), Legalization, and Employer Sanctions provisions of IRCA. More than 6,800 copies were requested and responses were received from 164 organizations and individuals relative to the SAW program. The Service was pleased with the amount of constructive comments received. The comments were reviewed and contributed to the proposed regulations published in the **Federal Register** on March 19, 1987 (52 FR 8745).

The Service feels that it would be beneficial to repeat the preliminary working draft step in the formulation process for the regulations for the admission or adjustment of a replenishment agricultural worker to temporary residence. Therefore, the Service invites interested parties to request a copy of preliminary working draft and provide applicable comments.

Date: August 9, 1988.

Alan C. Nelson,

Commissioner.

[FR Doc. 88–18303 Filed 8–12–88; 8:45 am]

BILLING CODE 4410–01–M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 523

[No. 88–671]

Readmission of Federal Home Loan Bank Members Terminating Their Status as Insured Institutions

Date: August 5, 1988.

AGENCY: Federal Home Loan Bank Board.

ACTION: Proposed rule.

SUMMARY: The Federal Home Loan Bank Board (the "Board") is proposing to amend its regulations governing applications for membership in the Federal Home Loan Bank ("FHLBank") System by institutions that have been removed from membership under section 407(i) of the National Housing Act, as amended ("NHA"), 12 U.S.C. 1730(i), by virtue of the termination of Federal Savings and Loan Insurance Corporation ("FSLIC") insurance of their accounts. Specifically, the proposal would amend Part 523 of the Board's Rules and Regulations for the Federal Home Loan Bank System ("FHLBank Regulations"), 12 CFR Part 523, to provide that an FHLBank member that terminates its status as an FSLIC-insured institution and is thereby removed from FHLBank membership (as well as any other member whose membership is terminated pursuant to section 6(i) of the Federal Home Loan Bank Act ("FHLBank Act")) may be readmitted as a member only after the expiration of a five-year period following its departure from the FHLBank System.

DATE: Comments must be received by October 14, 1988.

ADDRESSES: Send comments to Director, Information Services Section, Office of the Secretariat, Federal Home Loan Bank Board, 1700 G Street NW., Washington, DC 20552. Comments will be available for public inspection at the Board's Information Services Office, 801—17th Street NW., Washington, D.C. 20006.

FOR FURTHER INFORMATION CONTACT: John A. Buchman, Deputy Director for Industry Structure, (202) 377–6963; V. Gerard Comizio, Director, (202) 377–6411; Corporate and Securities Division; or Julie L. Williams, Deputy General Counsel for Securities and Corporate Structure, (202) 377–6459; Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

Background

During the past five years, various FSLIC-insured institutions that had been members of the FHLBank System have converted to state-chartered savings banks, the accounts of which are insured by the Federal Deposit Insurance Corporation ("FDIC"). In connection with this type of conversion the FSLIC-insured status of the institution is necessarily terminated, a consequence of which is the automatic removal of the institution from membership in the FHLBank System pursuant to section 407(i) of the NHA.[1] However, § 523.3–1 of the FHLBank Regulations provides that a member institution that has been removed from FHLBank membership as a result of its conversion to a state-chartered savings bank and termination of FSLIC-insured status—

> shall be deemed, as of the effective date of [its] conversion, to be automatically approved by the Board as a member, provided that such institution, acting by its board of directors or board of trustees, has made written requests to the [FHL]Bank of the district in which it is located for such membership and such Bank has approved such request.

12 CFR 523.3–1 (1988).[2] Accordingly, under the Board's FHLBank Regulations, FSLIC-insured institutions that have converted to savings banks insured by the FDIC have been able to gain readmission to their FHLBanks immediately upon conversion.

In the context of recent applications involving the conversions of Federally-chartered, FSLIC-insured thrifts to state-chartered, FDIC-insured savings banks, the Board was advised by the staff that serious questions exist as to the continuing validity of § 523.3–1 of the FHLBank Regulations as well as the Board's legal authority to readmit as FHLBank members such converting institutions. The bases for these

[1] Section 407(i) provides, in pertinent part, that "termination under (section 407) or otherwise of the status of an institution as an insured institution shall automatically constitute a removal under (section 6(i)) of the Federal Home Loan Bank Act of the institution from [FHLBank] membership, if at the time of such termination such institution is a member of (an FHLBank) * * *." 12 U.S.C. 1730(i).

[2] The regulation also provides that, in the case of an automatically approved application, all loan, deposit, stock and other relationships existing between the converting member and the FHLBank shall continue in effect without interruption. *Id.*

concerns are discussed below. The Board did not act at that time to prevent the readmission to FHLBank membership of the savings bank applicants;[3] however, the Board did make known these concerns to the public in a January 22, 1988, release and, in order to elicit public comment on this issue, directed the staff to draft a proposed amendment to the FHLBank Regulations that would revoke § 523.3–1. As a result of these concerns, on July 11, 1988, the Board also issued an order to the FHLBanks [4] pursuant to section 17(a) of the FHLBank Act directing them (1) to treat any FSLIC-insured institution that henceforth terminates its FSLIC insurance of accounts as having been removed from FHLBank membership, (2) to refrain from approving any application by such an institution for admission to Federal Home Loan Bank membership pursuant to §§ 523.3–1 or 523.3–3 of the Board's FHLBank Regulations, and (3) to submit all such applications to the Board for its determination until such time as the Board makes a final decision regarding § 523.3–1.[5]

Discussion of the Proposal

In section 102 of the Financial Institutions Supervisory Act of 1966 ("FISA"), Pub. L. No. 89–695, section 102, 80 Stat. 1028, 1036–45, Congress amended section 407 of the NHA by adding a new subsection (i). As noted above, section 407(i) provides in part that an institution's termination of FSLIC insurance of accounts shall constitute an automatic removal of the institution from FHLBank membership under section 6(i) of the FHLBank Act, 12 U.S.C. 1426(i).[6] The legislative history of FISA seems to indicate that the membership removal provisions of section 407(i) were aimed primarily at those institutions whose FSLIC insurance was terminated involuntarily pursuant to section 407(b) of the NHA.[7] However, in view of the broad language in the statute referring to all instances in which an institution's FSLIC-insured status was terminated, it became evident that under section 407(i), an association insured by the FSLIC that converted to an FDIC-insured savings bank would automatically lose its FHLBank membership.

In apparent recognition of this fact, the Board in 1970 amended its FHLBank Regulations by adding § 523.3–1.[8] The new provision has not only enabled an institution that had been removed pursuant to section 407(i) s a result of its conversion to a state-chartered savings bank to regain FHLBank membership upon the approval of the FHLBank in whose district the institution was located, but has also made it clear that where such an institution is readmitted as a FHLBank member, all of its preexisting loan and other relationships with the FHLBank would continue without interruption, as if the thrift had never left the FHLBank System.

In the Board's view, the continuing legal validity of § 523.3–1 is called into question by the enactment of section 6(m) of the FHLBank Act, 12 U.S.C. 1426(m), in § 355 of the Garn-St Germain Depository Institutions Act of 1982 ("Garn-St Germain Act"), Pub. L. No. 97–320, section 355, 96 Stat. 1469, 1508. Section 6(m) generally prohibits "an institution which withdraws from [FHLBank] membership" from being readmitted to the FHLBank System until the expiration of a five-year period after its withdrawal.[9] To the extent that this provision applies to institutions that are removed from FHLBank membership pursuant to section 407(i) of the NHA, the Board's regulation—which permits immediate readmission of institutions that have converted to FDIC-insured savings banks—would appear to be preempted by the statute.

The Board is aware that one possible arguments against preemption could hinge on the use of the term "withdraws" in section 6(m) and a distinction being made between "withdrawals" and "removals" from FHLBank membership, with the result that the five-year bar on FHLBank readmissions contained in section 6(m) would only be imposed in the case of a voluntary "withdrawal" from FHLBank membership and not in a situation in which the institution is involuntarily "removed" from membership pursuant to section 407(i) of the NHA or otherwise.[10] However, the Board is not convinced that Congress, by drafting section 6(m) in this manner, intended to restrict its application to a limited type of voluntary departure from the FHLBank System.

As an initial matter, the Board notes that the types of transactions at issue, where an institution terminates FSLIC insurance and in so doing causes its removal from FHLBank membership pursuant to section 407(i) of the NHA, are voluntarily undertaken. Arguably, it would be semantic hair splitting, contrary to the statutory purpose, to say that termination of FHLBank membership under a linked, two-step sequence voluntarily begun by the affected institution should be treated differently from situations where the instituion simply takes the second step without the first. Accordingly, the Board believes that terminations of FHLBank membership in the context of conversions to FDIC insurance are most properly viewed as voluntary withdrawals well within the scope of section 6(m).

Moreover, the Board is of the view that a termination of FHLBank membership need not be independently volitional at each step in order to be subject to the statute. In this vein, the Board first notes that, whereas the prepayment penalty provision of section 6(i) of the FHLBank Act—which were also adopted in section 355 of the Garn-St Germain Act—make reference to "voluntary withdrawals" from FHLBank membership, section 6(m) applies to all membership withdrawals. In order to give independent meaning to the use of the term "voluntary" in section 6(i), it would seem to the Board that the "withdraws" language of section 6(m) must be read to include not only terminations of FHLBank membership that are voluntarily effected by an institution but also cessations of membership that are less directly the

[3] This decision was based in part on the fact that the converting institutions in question had received prior approval from their FHL Banks to be readmitted as members upon conversion.

[4] Board Resolution No. 88–575, dated July 11, 1988.

[5] Section 523.3–3 authorizes the Principal Supervisory Agent ("PSA") of an FHLBank to approve unprotested applications for FHLBank membership by entities that satisfy the criteria for membership. 12 CFR 523.3–3.

[6] Section 6(i) also provides that an institution may withdraw from membership in an FHLBank six months after notifying the bank of its intent to do so and that an institution may be removed by the Board if, after a hearing, the Board determines that the institution either (i) has failed to comply with the FHLBank Act or any Board regulation thereunder, or (ii) is insolvent.

[7] *See, e.g.*, S. Rep. No. 1482, 89th Cong., 2d Sess. 18–19 (1966).

[8] Board Resolution No. 70–47, dated July 14, 1970, 35 FR 11616 (July 21, 1970).

[9] In section 355 of the Garn-St Germain Act, Congress also amended section 6(i) of the FHLBank Act to provide that in the case of a "voluntary withdrawal" from district bank membership, the withdrawing institution must pay prepayment penalties in connection with liquidating any indepetedness owed to its district bank if its advances agreement with such FHLBank so provides. 12 U.S.C. 1426(i).

[10] This interpretation of the "withdraws" language in section 6(m) is also supported by the view that the Congressional intend in adopting section 355 of the Garn-St Germain Act was merely to prevent an FHLBank member with substantial high-interest advances outstanding from avoiding prepayment penalties on those advances by terminating its FHLBank membership, liquidating its indebtedness to its FHLBank (without penalty), and thereafter being readmitted as an FHLBank member. However, the Board is aware of no legislative history supporting such a narrow reading of section 355.

result of the member institution's own international act.

The Board also notes that section 6(m) contains exceptions from its disqualification provisions for withdrawals that are either as a consequence of a transfer of membership on a non-interrupted basis between FHLBanks or in connection with a member's obtaining a charter from the Federal Home Loan Bank Board. The inclusion of exceptions in the statute for withdrawals under these circumstances constitutes evidence that Congress thought that, in the absence of the exceptions, such withdrawls would be subject to section 6(m), and provides further support for the view that Congress intended that the disqualification provisions of the statute would apply to cessations of FHLBank membership that are not themselves intended but are incidental to or a consequence of other voluntarily undertaken actions by a member.

In addition to the language of the statute, the legislative history of section 6(m) is also consistent with a broad interpretation of this provision. As the Senate Committee on Banking, Housing, and Urban Affairs stated in its Report on S. 2879 (the Senate version of the Garn-St Germain Act), "[new § 6(m)] would prevent institutions leaving the FHLBank System from reentering for five years thereafter except in connection with receiving a federal charter."[11] Both the express language as well as the legislative history of section 6(m) would therefore appear to support the view that terminations of FHLBank membership that occur in connection with voluntary departures from the FSLIC insurance system are covered by the statute.

In sum, the Board has serious concerns as to whether the provisions of § 523.3–1 of the Board's FHLBank Regulations have been overridden by section 6(m) of the FHLBank Act, whether the Board and the FHLBanks are empowered to readmit institutions removed from membership under section 407(i) of the NHA upon their conversions to FDIC-insured savings banks, and whether the readmissions pursuant to § 523.3–1 that have taken place since the Garn-St Germain Act was enacted on October 15, 1982, are legally valid.

In view of these concerns, the Board is today proposing to remove current § 523.3–1 and to adopt a new provision that would generally prohibit readmission of any institution whose FHLBank membership is terminated pursuant to the provisions of section 6(i) of the FHLBank Act for a period of five years following the date of such institution's departure from the FHLBank system. In connection with the issuance of this proposal, the Board is also soliciting the views of the public with respect to the issues discussed above. Specifically, the Board requests comment on whether the adoption of section 6(m) of the FHLBank Act in 1982 precludes the Board and the FHLBanks from readmitting as members for a five-year period those FSLIC-insured institutions that convert to state-chartered savings banks insured by the FDIC. Noting that a number of the institutions that have effected such conversions since October 15, 1982, have been readmitted as FHLBank members pursuant to § 523.3–1, the Board also requests the public's views as to whether the Board could allow such institutions to continue to be treated as FHLBank members in the event that it is ultimately determined that § 523.3–1 has been preempted by section 6(m), and under what legal theory it could do so.

[11] S. Rep. No. 536, 97th Cong., 2d Sess. 59 (1982).

Initial Regulatory Flexibility Analysis

Pursuant to section 3 of the Regulatory Flexibility Act, 5 U.S.C. 603, the Board is providing the following initial regulatory flexibility analysis:

1. *Reasons, objectives and legal bases underlying the proposed rules.* These elements have been discussed elsewhere in the SUPPLEMENTARY INFORMATION regarding the proposal.

2. *Small entities to which the proposed rules would apply.* The Small Business Administration defines a small financial institution as "a commercial bank or savings and loan association, the assets of which, for the preceding fiscal year, do not exceed $100 million." 13 CFR 121.13(a) (1988). Accordingly, the small entities to which the proposed rule would apply are all institutions insured by the FSLIC that had assets totalling $100 million or less as of December 31, 1987.

3. *Impact of the proposed rules on small institutions.* The proposed rule would not have a disproportionate effect on small institutions, nor is it expected that the rule will have a significant economic impact on a substantial number of small institutions.

4. *Overlapping or conflicting federal rules.* There are no federal rules that duplicate, overlap or conflict with the proposed rule.

5. *Alternatives to the proposed rule.* No alternative to the proposed would better attain the objectives of the proposal.

List of Subjects in 12 CFR Part 523

Federal home loan banks, Flood insurance, Mortgages, Reporting and recordkeeping requirements.

Accordingly, the Federal Home Loan Bank Board hereby proposes to amend part 523, Subchapter B, Chapter V, Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER B—FEDERAL HOME LOAN BANK SYSTEM

PART 523—MEMBERS OF BANKS

1. The authority citation for Part 523 continues to read as follows:

Authority: Sec. 5, 47 Stat. 727, as amended (12 U.S.C. 1425); sec. 5A, 47 Stat. 727, as added by sec. 1, 64 Stat. 256, as amended (12 U.S.C. 1425a); sec. 5B, 47 Stat. 727, as added by sec. 4, 80 Stat. 824, as amended (12 U.S.C. 1425b); sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1437); sec. 2, 48 Stat. 128, as amended (12 U.S.C. 1462); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); secs. 401–403, 405–407, 48 Stat. 1255–1257, 1259–1260, as amended (12 U.S.C. 1724–1726, 1728–1730); sec. 408, 82 Stat. 5, as amended (12 U.S.C. 1730a); sec. 503, 88 Stat. 1521, as amended (12 U.S.C. 1691, 1691a); sec. 202(b), 87 Stat. 982, as amended (42 U.S.C. 4106(b)); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1947 Supp., 1943–48 Comp., p. 1071.

§ 523.3–1 [Removed]

§§ 523–3–2 and 523.3–3 [Redesignated as §§ 523.3–1 and 523.3–2]

2. Amend part 523 by removing § 523.3–1; by redesignating existing §§ 523.3–2 and 523.3–3 as new §§ 523.3–1 and 523.3–2, and by adding a new § 523.32, to read as follows:

§ 523–32 Restrictions on readmission of members.

A member whose membership in a Bank ceases pursuant to section 6(i) of the Federal Home Loan Bank Act may not acquire membership in any Bank for a period of five years thereafter, except where such termination of membership is a consequence of a transfer of membership on a non-interrupted basis between Banks or in connection with obtaining a charter from the Federal Home Loan Bank Board.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88–18405 Filed 8–12–88; 8:45 am]

BILLING CODE 6720–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR PART 121

Small Business Size Standards for Surveying and Mapping Services

AGENCY: Small Business Administration.

ACTION: Supplementary Notice of Proposed Rulemaking.

SUMMARY: On October 15, 1986, Congress passed the National Defense Authorization Act of 1987 (Pub. L. 99–661). Section 921 of that Act contained a mandate that SBA review the size standards of certain industries including Surveying and Mapping Services. The purpose of this review was to ensure that small business set-aside plus 8(a) contracts together account for no more than approximately 30 percent of the total value of Federal contracts for each industry covered by the legislation. To implement this statutory requirement and to correct an earlier proposed adjustment to the size standard for surveying and mapping services, SBA is now proposing that the size standard for both services in Standard Industrial Classification (SIC) code 8713 be $.75 million in gross annual receipts.

DATE: Comments to be submitted September 14, 1988.

ADDRESS COMMENTS TO: Gary M. Jackson, Director, Size Standards Staff, U.S. Small Business Administration, 1441 'L' Street, NW.—Room 601, Washington, DC 20416.

Data utilized in this notice can be reviewed at the above address.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray, Economist, Size Standards Staff, (202) 653–6373.

SUPPLEMENTARY INFORMATION: On October 15, 1986, Congress passed the National Defense Authorization Act of 1987 (Pub. L. 99–661) which required SBA to complete a review of its size standards in four industry groups: Construction (all codes in Major Groups 15, 16, and 17 of the SIC system); Architecture and Engineering Services, including Surveying and Mapping Services (SIC codes 8711, 8712, and 8713); Shipbuilding and Ship Repair (SIC code 3731); and Refuse Systems and Related Services (SIC code 4953 and a component of SIC code 4212). The SIC code designations in parentheses above were SBA's interpretations of the industries to which the statutory language applied.

The purpose of the review is to ensure that small business set-aside plus 8(a) awards together account for no more than approximately 30 percent of the total Federal contract dollars awarded in those industries. If SBA finds as a result of its review that the 30 percent threshold is exceeded for any industry under review, the Agency is required to adjust the size standard for that industry accordingly.

In response to this directive, SBA published a proposed rule (52 FR 47937) on December 17, 1987 in which the size standards of a number of construction industries were lowered. In that notice, SBA also proposed lowering the size standard in the surveying services industry (SIC code 8713) from $2.5 million to $.25 million. Due to data limitations, however, SBA did not adjust the size standard for mapping services, a component of which is classified in SIC code 8713 and another component in Business Services, Not Elsewhere Classified (SIC code 7389).

The SIC code system defines mapping activities primarily in SIC code 8713 (surveying). This industry is defined to include land, water and aerial surveying, and photogrammetric engineering and services.

The activity of land surveying—cadastral services, for example, is a combination of both surveying and mapping activities and it would be categorized entirely in SIC code 8713, Surveying Services. Thus in setting a size standard for SIC code 8713—surveying services—using the 30 percent guidelines, SBA would also be setting a size standard for those mapping services which are closely related to surveying. However, a significant proportion of all mapping activities is also included in SIC code 7389, Business Services, Not Elsewhere Classified. These include aerial mapping, mapping drafting services and photogrammetric mapping services (not professional engineers). SBA now believes that the activities in this industry must be considered separately from SIC code 8713, because the legislation has been interpreted to prohibit combining SIC codes.

Contract award data for surveying and mapping services were obtained form the Federal Procurement Data Center (FPDC). Contracts for surveying and mapping services are categorized in six FPDC service codes; Aerial Photographic Services (code T009); Land Surveys, Cadastral Services (code R404); Cartography Services (code T002); Charting Services (code T004); Photogrammetry Services (code T008); and Topography Services (code T014). the FPDC also classified individual contracts into SIC code 8713 (Surveying Services) or SIC code 7389 (Business Services, Not Elsewhere Classified) according to the SIC classification of the firm receiving the contract (prior to 1987, SIC codes 8911 and 7389, respectively). From the contract data, surveying mapping contracts from the six FPDC product and service codes were separated into either SIC code 8713 or SIC code 7389. Contract data in each SIC industry were independently analyzed to determine the percentage of surveying and mapping contracts that were awarded as set-aside or 8(a) contracts and to develop a size standard if the set-aside and 8(a) percentage exceeded 30 percent.

The classification of surveying and mapping contracts by FPDC product and service codes and SIC industries resulted in some data being unusable for analysis since any contract which did not contain both codes was discarded. As a result, data reported for SIC code 8713 for this study is composed of fewer records than included in the analysis of surveying and mapping contracts for the December 17, 1987 proposed rule. In the previous rule, all contracts included in FPDC product and service code R404 were used in the analysis since the SIC classification of the winning firm was not needed.

In determining whether mapping activities within SIC code 7389 needed to be addressed with a different size standard from the present size standard of $3.5 million covering all activities in the industry, SBA calculated the percent of Federal mapmaking contracts in that industry which was identified as set-aside or 8(a). During 1984 and 1986, this percentage totaled 23.5 percent (see table below). This is considerably below the threshold of 30 percent required by Pub. L. 99–661. As a result, SBA is not recommending a separate size standard revision for mapping services in SIC code 7389.

SIC	Present size standard	Set-aside plus 8(a) procurement dollars	Total Federal procurement dollars	Percent set-aside and 8(a) awards	Percent in excess of 30 percent	Dollars targeted to be shifted to unrestricted category by lowering the size standard
7389	$3.5M	$1.7M	$7.4M	23.5	0.0	$0.0M

For SIC code 8713 (surveying services), however, SBA evaluated the entire industry as covered by the 30 percent requirement associated with Pub. L. 99–661. In general, virtually all contract actions within this industry generally involve either surveying and/or mapping activities. Moreover, the activities of surveying and mapping are often so interrelated as to be indistinguishable. Therefore, SBA believes that it can simply evaluate the size standard for all of SIC code 8713, surveying services (including most mapping activities), while excluding mapping activities in SIC code 7389 (in which the set-aside plus 8(a) share is less than 30 percent) in fulfilling the statutory mandate to review surveying and mapping.

This approach resulted in SBA not having to break the surveying industry into a surveying component and a mapping component for size standards purposes.

SBA's previous calculation of the set-aside and 8(a) levels for surveying services was based only on contract award data in the FPDC category of Land Surveys, Cadastral Services (code R404). A recalculation was made which includes all set-aside and 8(a) contracts in six FPDC surveying and mapping product and service codes that were awarded to firms in the architectural, engineering and surveying SIC code (1972 SIC code 8911) in which the data were tabulated. SBA recalculated the percentages in the following tabulation:

SIC	Present size standard	Set-aside plus 8(a) procurement dollars	Total Federal procurement dollars	Percent set-aside and 8(a) awards	Percent in excess of 30 percent	Dollars targeted to be shifted to unrestricted category by lowering the size standard
8713	$2.5M	$11.1M	$13.7M	80.6	50.6	$7.0M

The last two columns of this table provide information relating to the targets which the statute requires SBA to consider when lowering its size standards. The goal in revising the standard is to reduce the present size standard of $2.5 million (first column) to a level that is likely to reduce set-asides to 30 percent. This would be achieved by shifting 50.6 percent (fifth column) of Federal revenues in the industry from the set-aside to unrestricted category. Based on contract data over the 1984–86 period, $7.0 million dollars a year in Federal contracts (sixth column) would have to move from the set-aside to unrestricted category for this industry to meet the 30 percent level.

The method utilized to set the size standard assumes that by eliminating from eligibility the larger small firms winning 8(a) or set-aside contracts it will be more difficult to set aside contracts. Consequently, the proportion of set-asides as a percent of total Federal procurement dollars would become lower. A size standard was calculated which will eliminate from eligibility those larger small firms which have cumulatively been awarded in set-aside and/or 8(a) contracts which sum to the targeted amount.

TABLE 1.—HYPOTHETICAL EXAMPLE

[Firms receiving set-aside and/or 8(a) contracts ranked by size of firm (M = million of dollars)]

Firm	Firm size	Total amount of receipts awarded as firm's set-aside and/or 8(a) contracts over the year	Cumulative receipts
A	$6.9M	$4M	$4M
B	6.7M	1M	5M
C	6.5M	5M	10M
D	6.3M	3M	13M
E	6.1M	3M	16M
F	5.9M	4M	[1] 20M
G	5.7M	3M	23M

[1] Set the size standard to eliminate firms generating the targeted level of $20.0M in set-aside or 8(a) contracts by lowering the size standard from $7.0 to $5.8 million.

Table 1 illustrates this approach. All firms which received a set-aside or 8(a) contract in a hypothetical industry are ranked by firm size (receipts from all sources). In the example, the largest small firm in the distribution had $6.9 million in sales with $4 million of its sales from set-aside and/or 8(a) contracts. In order to achieve the desired 30 percent, $20 million in set-aside and/or 8(a) contracts in the example would have to become unrestricted contracts. This is achieved by lowering the size standard to $5.8 million. This eliminates the largest small firms which have cumulatively been awarded set-aside and/or 8(a) contracts totaling $20 million.

In order to calculate size standards using this method, SBA obtained microdata information from SBA's United States Establishment and Enterprise Data Base in which each contract awarded for surveying and mapping services in SIC code 8713 was identified with the size of firm winning the contract. SBA ranked firms participating in the set-aside market by size of firm and these firms were cross-tabulated with awarded set-aside and 8(a) contracts to develop a table, similar to Table 1 for SIC code 8713. In the case of SIC code 8713, the dollar value counted down to achieve a 30 percent set-aside and 8(a) contract level was $7.0 million.

Using this approach, SBA calculated that the size standard to achieve a 30 percent share in SIC code 8713, Surveying Services, was $.75 million. This is significantly higher than the $.25 million proposed on December 17, 1987, which was based on incomplete data and did not incorporate mapping information. As a result SBA believes that the proposed size standard of $.75 million is a significant improvement over the previously proposed size standard of $.25 million in attempting to

satisfy the statutory requirement of Pub. L. 99–661.

Compliance With Regulatory Flexibility Act, Executive Order 12291 and the Paperwork Reduction Act

SBA certifies that this regulation will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. Section 601 *et seq.* SBA estimates that a size standard of $.75 million compared to the present one of $2.5 million would result in 752 firms out of 6,226 in the industry losing small business status. While these firms would lose small business status, the actual number of firms impacted by the size standard change would be less than the 752 firms, because not all of these firms participate in Federal procurement or SBA's financial assistance programs. Under a size standard of $.75 million, 80 percent of the firms in the industry would be considered eligible as small firms.

SBA also certifies that this regulation is a nonmajor rule as defined by Executive Order 12291, in that it is not expected to have an impact of over $100 million per year. A total of $7.0 million of Federal procurement expenditures is targeted to shift from the set-aside to unrestricted category under this size standard. In addition, this regulation is not likely to result in a major increase in cost or prices, or have a significant adverse impact on the economy. It contains no reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35. There are no Federal rules which duplicate, overlap, or conflict with this rule.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs-business, Loan programs-business, Reporting and recordkeeping requirements, Small business.

Accordingly, the SBA proposes to amend Part 12 of 13 CFR as follows:

PART 121—[AMENDED]

§ 121.2 [Amended]

1. The authority citation for Part 121 of 13 CFR is revised to read as follows:

Authority: Section 921 of Pub. L. 99–591 and Pub. L. 99–661, Secs. 3(a) and 5(b) of the Small Business Act, 15 U.S.C. 632(a) and 634(b)(6).

§ 121.2 [Amended]

2. In §121.2(d)(2), table 2, Division I—Services is proposed to be amended by changing SIC code 8713 to read as follows:

DIVISION I.—SERVICES

[Major group 87—miscellaneous services]

SIC	Description (* * * * = New SIC Code in 1987, not used in 1972)	Size standards * * *
8713	Surveying services	$.75 million.

James Abdnor,

Administrator.

Date: June 15, 1988.

[FR Doc. 88–18311 Filed 8–12–88; 8:45 am]

BILLING CODE 8025-01-M

13 CFR Part 121

Size Standard for Refuse and Garbage Collection Services

AGENCY: Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The Small Business Administration (SBA) is proposing to establish a size standard of $1.5 million for "Refuse and Garbage Collection Services" within Standard Industrial Classification (SIC) code 4212 (Local Trucking, Without Storage) and SIC code 4953 (Refuse Systems). A size standard revision for this category of services is proposed in compliance with section 921(f) of Pub. L. 99–591 and Pub. L. 99–661, which directs the SBA to revise its size standards for Refuse Systems and Related Services if the total dollar value of small business set-aside and SBA's Minority Small Business and Capital Ownership Development Assistance (Section 8(a)) Program awards for these activities exceed 30 percent of the dollar value of overall Federal procurements for these activities.

DATE: Comments must be submitted on or before September 14, 1988.

ADDRESS: Send comments to: Monika Edwards Harrison, Chairperson, Size Policy Board, U.S. Small Business Administration, 1441 'L' Street NW.—Room 600, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray (202) 653–6373.

SUPPLEMENTARY INFORMATION: Section 921(f) of Pub. L. 99–591 (an Act making continuing appropriations for fiscal year 1987) and an identical provision of Pub. L. 99–661 (National Defense Authorization Act for Fiscal Year 1987) requires the SBA to complete a review of its size standards in four industry groups: Construction (all Standard Industrial Classification (SIC) codes in Major Groups 15, 16, and 17 of the SIC system); Architecture and Engineering Services, including Surveying and Mapping Services (SIC codes 8711, 8712, and 8713); Shipbuilding and Ship Repair (SIC code 3731); and Refuse Systems and Related Services (SIC code 4953 and a component of SIC code 4212). If SBA finds that the total dollar value of small business set-aside and SBA's 8(a) awards in any industries in these categories exceed 30 percent of the value of overall Federal procurement awards, the laws require SBA to lower the relevant industry size standard to a level that will likely reduce the total of small business set-aside and 8(a) awards to approximately 30 percent of total Federal procurements.

In the proposed rule published on December 17, 1987, SBA did not disaggregate the activities of refuse systems and related services beyond the four-digit Standard Industrial Classification (SIC) code level. This was due to SBA's interpretation of refuse systems and related services in Section 921 to mean SIC code 4953. As a result, the response to the directive in Pub. L. 99–591 and Pub. L. 99–661 for refuse systems and related services was a decision not to lower the size standard in SIC code 4953 (Refuse Systems) because the set-aside and 8(a) share of that entire industry was less than 30 percent, and not to include the refuse and garbage collection component of SIC code 4212, Local Trucking, Without Storage in the calculations.

Concerned parties involved in the collection of refuse and garbage (a component of refuse and related services) submitted public comments to the proposed rule of December 17, 1987. The respondents argued that refuse and garbage collection activities within SIC code 4953 (refuse systems) and SIC code 4212 (local trucking, without storage) should be evaluated separately from the remainder of their respective SIC codes to determine whether set-aside and 8(a) contracts together exceed 30 percent of total procurement dollars for that category. The Conference Report to Accompany H.R. 1748 provides support for combining refuse and garbage collection data in SIC code 4212 with similar data in SIC code 4953 when adjusting the size standard to accommodate Pub. L. 99–591 and Pub. L. 99–661. Moreover, Subsection 921(a) of the laws also permits SBA to limit industry categories to a greater extent than that provided for by the four-digit SIC classification system "if the Administration [SBA] receives evidence indicating that further segmentation is warranted due to special capital

equipment needs, or special labor or geographic requirements."

A review of the activities in SIC codes 4212 and 4953 supports the need to segment certain activities within these two SIC codes, especially the common activity of garbarge and refuse collection. The special segmentation criteria in Pub. L. 99-591 are met for this activity, since it has different labor and equipment (truck) needs than the other activities in SIC codes 4212 and 4953. Specifically, refuse and garbage collection activities employ different labor and equipment than other activities in the refuse systems industry such as the operation of dumps, landfills, sledge disposal sites, and the collection and disposal of acid waste, and radioactive and hazardous waste. These other activities involve special treatment and handling operations; whereas, refuse and garbage collection require intensive use of labor and specially designed trucks. Similarly, refuse and garbage collection activities in the industry of trucking without disposal require specially designed trucks, with unique requirements tailored to accomplish that task. Thus the special segmentation criteria addressed in Pub. L. 99-591 are met for this activity, and SBA is justified in seeking more than one size standard for activities within these SIC codes.

Procurement data needed to evaluate the dollar value of set-aside and 8(a) contracts as a percentage of total dollar value of Federal prime contracts for refuse and garbage collection activities within SIC codes 4212 and 4953 were not analyzed below the four-digit SIC industry level in prior rulemaking. Secondary data sources do exist, however, which allow refuse and garbage collection activities to be evaluated separately from the SIC codes of which they are a component. The Federal Procurement Data Center (FPDC) collects procurement data on a product and service code basis, including the activity of refuse and garbage collection, service code S205. These data allow the garbage and refuse component of refuse related activities in SIC codes 4212 and 4953 to be analyzed independently as discussed in the following section.

Setting a Size Standard for the Activity of Refuse and Garbage Collection

In order to accommodate the need to set a size standard for refuse services while conforming with Section 921's requirement that SIC codes not be combined, the SBA calculated date relating to refuse and garbage collection activities within SIC code 4212 separately from those activities within SIC code 4953. The following table illustrates the relevant percentages:

TABLE 1

[In million of dollars]

SIC	Present size standard	Set-aside plus 8(A) procurement dollars involved in refuse and garbage collection (annual average, 1984 and 1986 figures)	Total Federal procurment dollars involved in refuse and garbage collection (annual average, 1984 and 1986 figures)	Percent set-aside and 8(A) awards	Percent in excess of 30 percent	Dollars targeted to be shifted to unrestricted category by lowering the size standard
4212	$6.0M	$16.810M	$19.831M	84.8	54.8	$10.867M
4953	6.0M	11.367M	15.920M	71.4	41.4	6.591M
Both Industries Combined	6.0M	28.177M	35.751M	78.8	48.8	17.458M

Based on this table, SBA gathered the necessary microdata to calculate the appropriate size standard to achieve a 30 percent level for the refuse and garbage collection component of each industry using the same countdown procedure used in its December 17, 1987 proposed rule. This methodology for adjusting size standard was developed by considering how set-aside contracts are selected. The method assumes that by reducing the size standard, thereby, eliminating from eligibility the larger small firms winning 8(a) or set-aside contracts, it will be more difficult to set aside contracts, since there will be fewer firms capable of satisfying contract obligations. Consequently, the proportion of set-asides as a percent of total Federal procurment dollars would decline.

A size standard was calculated within each industry which eliminated from eligibility a sufficient number of larger small firms such that the percentage level in the activity of refuse and garbage collection would decrease to 30 percent. Table 2 illustrates this approach for refuse and garbage collection activities within the two industries using tabulations in which data for five firms are grouped together. The table applies to acutal firm and contract data for refuse collection in SIC code 4212 for 1984.

TABLE 2.—FIRMS RECEIVING SET-ASIDE AND/OR 8(A) Contracts in Refuse Collection in SIC Code 4212 Ranked by Size of Firm—Targeted Level $10.9 MILLION

Firm size classification (in employees)	Number of firms in class	Total amount of receipts awarded as firms' set-aside and/or 8(A) contracts over the year (1984) (in thousands of dollars)	Cumulative receipts
65-180	5	$1,077	$1,077
40-64	5	2,227	3,304
35-39	5	1,977	5,281
30-34	5	990	6,271
23-29	5	3,487	9,758
20-22	5	757	10,515
17-19	5	227	10,742
16	1	1,792	12,534
0-15	47	3,616	16,150
Total	83	$16,150	$16,150

The above table ranks firms participating in the set-aside and/or 8(a) activity of the industry by size of firm in employees (annual receipts for size of firms were not used due to unavailable data). Each firm's receipts awarded as set-aside or 8(a) contracts were also calculated (column 3). The far right column summed all set-aside or 8(a) receipts received by firms of a given size or higher during 1984 on a cumulative basis. Counting down by the targeted amount of $10.9 million calculated in Table 1 resulted in a size standard of 16 employees in this case.

An identical exercise for the same activity during 1986 resulted in a size standard of 25 employees. Averaging the 2 years together (1985 data were not available) resulted in a size standard of 20.5 employees. This figure was then multiplied by $54,000 (representing receipts per employee in SIC code 4212 during 1984), and an inflationary adjustment factor of 1.13 to produce a dollar based size standard of $1.25 million.

A similar process was applied to the activity of refuse collection in SIC code 4953. The targeted dollars for this industry were $6.6 million (see Table 1). Applying this figure using the countdown procedure represented in Table 2 to the ranked lists of firms winning refuse contracts in this industry during 1984 and 1986 produced desired size standards of 25 and 30 employees, respectively. Averaging these two figures together produced a desired size standard in employees of 27.5 employees. This figure was then multiplied by $55,000 (representing receipts per employee in SIC code 4953 during 1984) and an inflationary adjustment factor of 1.13 to produce a dollar based size standard of $1.75 million.

By calculating the size standards for refuse and garbage collection activities separately within each industry, the SBA is satisfying the statutory requirement that size standards be established by four-digit SIC industry codes, while utilizing the segmentation provision to limit an industry to a greater extent when warranted by selected criteria. Since section 921 of Pub. L. 99–591 and 99–661 does not permit the combining of the SIC codes, SBA did not combine all refuse and garbage collection activities in one table, count down the necessary dollars to achieve a 30 percent 8(a) and set-aside share, and set a common size standard for all refuse collection activities within the two industries based on the 30 percent provision. Instead it calculated separate size standards for refuse and garbage collection activities within each industry using the 30 percent directive. This resulted in a size standard of $1.25 million for refuse and garbage collection services within SIC code 4212 and $1.75 million for refuse and garbage collection services in SIC code 4953.

Having estimated these separate size standards, however, SBA was concerned that contracting officers are indifferent in designating refuse and garbage collection contracts between the two industries for size standard purposes. A contracting officer would not likely be concerned with the method of disposal of refuse products that separates refuse and garbage collection into one of the two SICs. Instead, a contracting officer would likely focus entirely on the price and quality of service at the point of collection only, while usually assigning the relevant SIC code to the activity with the higher size standard. SBA viewed such a situation in which a contracting officer faces different size standards for an identical activity as having a potential for disputes over classification. It views the distinctions between the two SIC codes to be artificial, since refuse haulers in both industries tend to compete with each other regardless of method of disposal, or SIC code to which they belong. Rarely is there a practical difference between activities in the two SIC codes from a Federal procurement outlook. Therefore, it has adopted a common size standard for all refuse and garbage collection services in the two industries.

In calculating a common size standard, SBA averaged the two size standards in question—$1.25 million for SIC 4212 and $1.75 million for SIC code 4953—to produce a common size standard of $1.50 million for refuse and garbage collection activities within each SIC industry. Averaging the two size standards together is considered appropriate, since refuse and garbage collection activities are incorporated in approximately equal amounts in the two industries (see Table 1). (Moreover, this figure would be identical to the size standards which would result from aggregating all refuse collection activities into one table and setting a single size standard for all refuse and garbage collection activities regardless of primary SIC). This averaging procedure satisfied SBA's desire to have a common size standard for all refuse collection activities regardless of method of disposal, while still maintaining the integrity of the SIC system as well as adhering to the 30 percent directives of Pub. L. 99–591 and 99–661.

In separating out the category of refuse and garbage collection activities from other activities in SIC codes 4212 and 4953 as outlined above, it then become necessary to determine the set-aside and 8(a) share of the residual activities in SIC code 4953, Refuse Systems. This is because Pub. L. 99–591 and 99–661 require an adjustment of the size standard if the set-aside and 8(a) dollar value exceeds 30 percent of the value of overall Federal procurement for refuse systems and related services. SBA was concerned that removing a component of SIC code 4953 as proposed might result in the residual activities in the industry exceeding the 30 percent threshold required by law. (SBA is not concerned with the residual activities in SIC code 4212 after the component of refuse and garbage collection activities is removed since SIC code 4212, local trucking, without storage, is not covered by the legislation).

Table 3 illustrates the situation in the residual activities of SIC code 4953 after the refuse and garbage disposal activities (S205) are removed. This table indicates that the set-aside and 8(a) share of the residual activities of SIC code 4953 declines to 9 percent after refuse and garbage collection activities are analyzed separately. Thus the size standard for those activities in SIC code 4953 would not be affected by a separate treatment of refuse and garbage collection services in conjunction with the 30 percent requirement.

TABLE 3.—PROCUREMENT STATISTICS FOR REFUSE SYSTEMS AND RELATED SERVICES

Activity	Total procurement dollars (average of 1984 and 1986 figures)	Set-aside plus 8(a) dollars (average of 1984 and 1986 figures)	Percent
SIC–4953	$74.1M	$16.8M	22.6
S205 in SIC–4953	15.9M	11.4M	71.7
Residual in SIC–4953 after subtracting S205	58.2M	5.4M	9.2

Source: Federal Procurement Data Center.

Compliance With Regulatory Flexibility Act, Executive Order 12291 and the Paperwork Reduction Act.

This proposed rule if made final would have a significant effect on a substantial number of small firms as described in the Regulatory Flexibility Act. It would not, however, constitute a

major rule under Executive Order 12291. The preceeding information describes the reasons for this proposed rule, why it is being made, its objectives, and how it is to be implemented. The legal basis for this proposed rule is section 3 and 5(b) of the Small Business Act, 15 U.S.C. 632 and 634(b) and section 921 of Pub. L. 99–591 and 99–661. There are no significant alternatives to the proposed rule which would accomplish the stated objective.

In analyzing the effect of this proposed rule, SBA is heavily dependent on its procurement statistics. All available national data are structured on an industry-wide-basis only, and the smaller national activity of refuse and garbage collection is simply a component of the larger SIC industries. Thus data relating to firms in refuse and garbage collection activities are hidden in the larger SIC codes of 4212 and 4953, and SBA is limited, when appraising the relative importance of firms involved in refuse and garbage collection activities in these two industries, to inferences drawn from the procurement statistics relating to garbage collection activities in these SICs.

The procurement data available to SBA indicates that out of 140 firms in SIC code 4953 which were awarded contracts in the activity of refuse and garbage collection over the 1984–86 period, 46 firms or 33 percent would be removed from eligibility under a $1.5 million size standard. Out of 158 firms in SIC code 4212 winning 8(a) or set-aside contracts over the same period, 61 firms or 39 percent would be excluded from eligibility if a $1.5 million size standard were established. Summing refuse and garbage collection activities in both industries, about $17 million in Federal purchases on a yearly basis would move from the set-aside to unrestricted categoreis under a $1.5 million standard. This figure is much less than the $100 million threshold figure required for a major rule for purposes of Executive Order 12291.

Table 4 below provides estiamtes of the numbers of firms in the two industries which could be impacted by the proposed rule change. Estimates were derived from the relative importance of refuse and garbage collection activities in Federal procurement in the two industries and the relative importance of firms losing status that have been active in the past in Federal procurement. SBA is aware, for example, that in SIC code 4212, 43.3 percent of Federal procurement dollars during the 1984–86 period were awarded for refuse collection activity. Its estiamte of 14,447 firms engaged in refuse and garbage collection activities, therefore, was derived by mutiplying the known number of 34,047 firms in the entire industry by .433. Moreover, if all of SIC code 4212 were affected by the proposed revision, 1,663 firms would lose eligibility. The index of .433 was applied to these 1,663 firms to produce an estimate of 720 refuse firms losing eligibility. A similar calculation was incorporated for SIC code 4953 using the same procedure but different indexes.

TABLE 4.—INDUSTRIES AND FIRMS AFFECTED BY PROPOSED SIZE STANDARDS

SIC	Description	Number of firms in industry	Number of firms engaged in refuse and garbage collection activities (estimated)	Number of firms losing small business status (estimated)
4212	Local Trucking, Without Storage.	34,057	14,747	720
4953	Refuse Systems.	2,794	601	70

While almost 800 firms would lose small business status in both industries, the actual number of firms directly impacted is estimated at less than 100. This stems from the fact that most firms do not participate in Federal procurment or SBA's financial assistance programs in any one year.

SBA certifies that this proposed regulation contains no change, or special reporting, or recordkeeping requirement which are subject to the Paperework Reduction Act, 44 U.S.C. Chapter 35. There are no Federal rules which duplicate, overlap or conflict with the proposed rule.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs-business, Loan programs-business, Reporting and recordkeeping requirements, Small business.

Accordingly, SBA proposes to amend Part 121 of 13 CFR as follows:

PART 121—[AMENDED]

1. The authority citation of Part 121 of 13 CFR continues to read as follows:

Authority: Sections 3(a) and 5(b)(6) of the Small Business Act, 15 U.S.C. 632(a) and 634(b)(6) and Pub. L. 99–591 and Pub. L. 99–661.

§ 121.2 [Amended]

2. In § 121.2(d)(2) table 2, "Division E—Transportation, Communication, Electric, Gas, and Sanitary Services" is proposed to be amended by removing Footnote 7 from SIC code 4212, "Local Trucking, Without Storage", and by adding the "Refuse and Garbage Collection Activities, Without Disposal" component to SIC code 4212, with a proposed standard of $1.5 million in annual receipts to read as follows: (Item 4212 Local Trucking, Without Storage is set forth for the convenience of the reader, however, the size standard is not changed).

SIC	Description * * *	Size standards * * *
	Major Group 42 — Motor Freight Transportation and Warehousing	
4212	Local Trucking Without Storage	$12.5
4212	Refuse and Garbage Collection Activities Without Disposal.	$1.5

3. Also, in § 121.2(d)(2) Table 2, "Division E—Transportation, Communication, Electric, Gas, and Sanitary Services" is amended by removing Footnote 11 from SIC code 4953, Refuse Systems, and by adding the "Refuse and Garbage Collection Activities, With Disposal", component to SIC code 4953, with a size standard of $1.5 million in annual receipts to read as follows: (Item 4953, Refuse Systems, is set forth for the convenience of the reader—the size standard is not changed).

SIC	Description * * *	Size standards * * *
	Major Group 49—Electric, Gas, and Sanitary Services	
4953	Refuse Systems	$6.0
4953	Refuse and Garbage Collection Activities Without Disposal.	$1.5

James Abdnor,

Administrator, U.S. Small Business Administration.

Dated: May 24, 1988.

[FR Doc. 88–18310 Filed 8–12–88; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 88-ANM-2]

Proposed Alteration of VOR Federal Airway V-220—CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to alter the description of Federal Airway V-220 located in the vicinity of Meeker, CO. The C-220 extension from Meeker to Grand Junction, CO, would improve the flow of traffic in Aspen, CO, area and other snow belt area airports. This action would improve flight planning and provide controlled airspace in mountainous territory.

DATE: Comments must be received on or before September 29, 1988.

ADDRESSES: Send comments on the proposal in triplicate to: Director, FAA, Northwest Mountain Region, Attention: Manager, Air Traffic Division, Docket No. 88-ANM-2, Fedral Aviation Administration, 17900 Pacific Highway South, C-68966, Seattle, WA 98168.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue SW., Washington, DC.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Lewis W. Still, Airspace Branch (ATO-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-9250.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written date, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, econmic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to ackonwledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 88-ANM-2." The postcard will be date/time stamped and returned to the commenter. Alll communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Ruelmaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2 which describes the application prodecure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the description of VOR Federal Airway V-220, located in the vicinity of Meeker, CO. We propose to extend V-220 from Meeker to Grand Junction, CO, via a south dogleg. This action would improve traffic flow in snow country airports located in the vicinity of Aspen, CO. These changes also support terminal procedures by providing missed approach routes to holding on en route fixes. This action improves flight planning and increases airport capacity during instrument weather conditions. Section 71.123 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6D dated January 4, 1988.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, VOR Federal airways.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.123 [Amended]

2. Section 71.123 is amended as follows:

V-220 [Amended]

By removing the words "From Meeker, CO;" and substituting the words "From Grand Junction, CO, 25 miles, 90 MSL, 28 miles, 120 MSL, INT Grand Junction 075°T(060°M) and Meeker, CO, 167°T(152°M) radials; Meeker;"

Issued in Washington, DC, on August 8, 1988.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 88-18394 Filed 8-12-88; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

Electronic Release Notification to Certain Vessel and Air Carriers and Bonded Facilities that Are Not Part of the Automated Manifest System (AMS)

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

ACTION: Proposed rule; solicitation of comments.

SUMMARY: This document proposes to amend the Customs Regulations to reflect a change in the procedure by which certain vessel and air carrier and bonded facilities are notified of Customs decision to release certain shipments of their cargo. At present, carriers which are participants in the Automated Manifest System (AMS) receive this notification electronically for their shipments entered in the system. Such electronic release notification is not available to vessel carriers which are not participants in AMS or to air carriers and bonded facilities. These parties have been notified of release of their shipments by receipt of paper copies of the documents authorizing release of each shipment.

No changes are contemplated in the release notification procedure to AMS participants. As to non–AMS carriers and bonded facility operators, Customs intends to discontinue the practice of providing separate copies of release documents with respect to transactions which meet certain Customs criteria. Instead, each Customs district will post at the start of each business day, a computer generated list of the shipments which have been authorized for release from Customs custody.

This new procedure wil reduce the administrative burden on Customs of notifying carriers or bonded facility operators of the release of merchandise in their custody.

DATE: Comments must be received on or before October 14, 1988.

ADDRESS: Comments (preferably in triplicate) may be addressed to and inspected at the Regulations and Disclosure Law Branch, U.S. Customs Service, 1301 Constitution Avenue NW., Room 2324, Washington, DC 20229 (202–566–8237).

FOR FURTHER INFORMATION CONTACT: Steven Knox, Office of Cargo Enforcement and Facilitation, (202) 566–8151.

SUPPLEMENTARY INFORMATION:

Background

For nearly four years, Customs has had under development a system known as the Automated Commercial System (ACS). The ultimate goal of the ACS is to automate all phases of the Customs entry processing of imported merchandise into a single automated system.

Customs has developed an Automated Manifest System as an integral module of the ACS. The manifest module is, in essence, both an imported merchandise inventory control system and a cargo release notification system. By comparing information provided in the manifest with automated Customs entry data, Customs is able to make more informed decisions with respect to the allocation of resources for the inspection of merchandise. The AMS module is operational and contains approximately 35% of the bills of lading filed nationwide.

Customs is formulating an Air Manifest module which will perform the same functions and extend the same benefits for air cargo shipments. It is planned that testing of the Air Module will commence in two months.

One of the advantages AMS provides to participating carriers is the providing of electronic notification of Customs action authorizing the release of the cargo and its delivery to the consignee. Electronic release notification will also be available to those air carriers which participate in the Air Module. At present, carriers which are not participating in AMS and bonded facility operators receive notification of the release from a hard copy of a Customs document (usually the Customs form 3461) for each shipment which has been authorized for release.

Another module of the ACS is the Automated Broker Interface (ABI). The ABI is a system which allows customhouse brokers and importers to interface directly with Customs computer and transmit entry and entry summary data on imported merchandise. When Customs makes its determination to release a shipment, a message identical to that which is sent to the carrier is electronically transmitted to the entry filer through ABI.

The determination as to the type of examination, whether general or intensive, is performed by Customs through the Cargo Selectivity Module of the ACS. This determination is based on both national and local criteria as to the risk of the importer, the nature of the commodity, the country of origin, etc.

Customs has decided to change the procedure by which carriers and bonded facility operators which are not interfaced with Customs are notified of the release of certain of their shipments. This change in procedure is limited to those shipments for which entry data is furnished via ABI and which based on Customs analysis represent the most minimal risk to violation of the Customs laws. To accomplish this goal, Customs proposes to amend the Customs Regulations to provide for the daily posting of a report of all such transactions to all non-AMS carriers and bonded facility operators.

The report will contain the following information or data elements:

Vessel Cargo

1. Vessel Name or Code;
2. Voyage Number;
3. Bill of Lading Number;
4. Quantity Released; and
5. Entry Number (including filer code).

Air Cargo

1. Air Waybill Number;
2. Quantity Released; and
3. Entry Number (including filer code).

Cargo Moving in Bond

1. Immediate Transportation Bond Number;
2. Bill of Lading Number or Air Waybill Number;
3. Quantity Released; and
4. Entry Number (including filer code).

These reports will be posted in a public area of each U.S. Customs District office at the beginning of each business day.

Comments

Consideration will be given to any written comments timely submitted to Customs. Commenters are invited to address any business-related concerns and specifically indicate whether they believe that disclosure of the above-described data elements would cause competitive harm to their business. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations and Disclosure Law Branch, Room 2324, U.S. Customs Service Headquarters, 1301 Constitution Avenue NW., Washington, DC 20229.

Regulatory Flexibility Act

The proposal will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified by E.O. 12291. Accordingly, no regulatory analysis has been prepared.

Drafting Information

The principal author of this document was Harold M. Singer, Regulations and Disclosure Law Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 4

Carriers, Vessels, Release of merchandise.

Amendments to the Regulations

It is proposed to amend Part 4, Customs Regulations (19 CFR Part 4), as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The authority citation for Part 4, Customs Regulations (19 CFR Part 4), continues to read as follows:

Authority: 19 U.S.C 66, 1624, 46 U.S.C. 2, 3, General Hdnote. 11, Tariff Schedules of the U.S.

2. It is proposed to revise § 4.38(a) to read as follows:

§ 4.38 Release of cargo.

(a) No imported merchandise shall be released from Customs custody until a permit to release such merchandise has been granted. Such permit shall be issued by the district director only after the merchandise has been entered and, except as provided for in § 141.102(d) or Part 142 of this chapter, the duties thereon, if any, have been estimated and paid. Generally, the permit shall consist of a document authorizing delivery of a particular shipment or an electronic equivalent. Alternatively, the permit may consist of a report which lists those shipments which have been authorized for release. This alternative cargo release notice may be used when the manifest is not filed by the carrier through the Automated Manifest System, the entry has been filed by a designated electronic importer, and the cargo qualifies for electronic processing. The report shall be posted in an area to which the public has access.

(1) Where the cargo arrives by vessel, the report shall consist of the following data elements:

(i) Vessel Name or Code;

(ii) Voyage Number;

(iii) Bill of Lading Number (at the lowest level of detail—Master, House, Subhouse);

(iv) Quantity Relesed; and

(v) Entry Number (including filer code).

(2) Where the cargo arrives by air, the report shall consist of the following data elements:

(i) Air Waybill Number;

(ii) Quantity Released; and

(iii) Entry Number (including filer code).

(3) In the case of merchandise traveling via in-bond movement, the report will contain the following data elements:

(i) Immediate Transportation Bond Number;

(ii) Bill of Lading Number or Air Waybill Number;

(iii) Quantity Released; and

(iv) Entry Number (including filer code).

When merchandise is released without proper permit before entry has been made, the district director shall issue a written demand for redelivery. The carrier or facility operator shall redeliver the merchandise to Customs within 30 days after the demand is made. The district director may authorize unentered merchandise brought in by one carrier for the account of another carrier to be transferred within the port to the latter carrier's facility. Upon receipt of the merchandise the latter carrier assumes liability for the merchandise to the same extent as though the merchandise had arrived on its own vessel.

* * * * *

Michael H. Lane,

Acting Commissioner of Customs.

Approved: July 25, 1988.

Salvatore R. Martoche,

Assistant Secretary of the Treasury.

[FR Doc. 88-18302 Filed 8-12-88; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 201

[Docket No. R-88-1397; FR-2370]

Mortgage and Loan Insurance Programs; Title I Property Improvement and Manufactured Home Loans; Miscellaneous Amendments

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: The Department proposes to amend various provisions in the regulations governing its property improvement loan and manufactured home loan insurance programs under Title I, section 2 of the National Housing Act. Some amendments would make substantive changes; others would clarify existing provisions, correct typographical errors, and/or make editorial changes.

The substantive changes that would be made are:

- Title I manufactured home loan proceeds would be prohibited from being used for the purchase of furniture.
- The number of years of hazard insurance coverage that may be financed with Title I manufactured home loan proceeds would be reduced and the amount of hazard insurance coverage required for manufactured homes financed with loans insured under Title I would be changed.
- The manner in which the Department assesses and collects insurance preimum charges in connection with manufactured home loans would be changed.
- The maximum amount of an unsecured property improvement loan would be increased from $2,500 to $5,000.
- Manufactured home site certification requirements would be simplified.

Other changes that are proposed in this rule would clarify that—

- Late charges prescribed in the Title I regulations may be assessed by the lender unless applicable State law prescribes standards more beneficial to the borrower; also, late charges may not be assessed if interest on the loan is charged on a daily basis.
- Appurtenances to the manufactured home may be financed with the proceeds of a manufactured home purchase loan only with the approval of the Secretary, and subject to the lender obtaining a first lien on such appurtenances as well as on the manufactured home, its furnishings, equipment, and accessories.
- Certain fees and charges that cannot be financed would be permitted to be paid by the lender.
- A proof of claim would not have to be filed by the lender in certain bankruptcy or probate proceedings; also, the lender would be required to take all steps necessary to protect the interest of the note holder in any such

proceeding until a Title I insurance claim is paid by the Department.

• Appraisals of repossessed manufactured homes would be required to reflect the retail value of comparable homes in the geographic area where the repossession occurred.

• Premiums for hazard insurance on a foreclosed or repossessed manufactured home financed with a combination home and lot loan would be eligible for inclusion as part of the lender's Title I insurance claim.

DATE: Comments must be received by September 29, 1988.

ADDRESS: Interested persons are invited to submit comments regarding this rule to the Office of the General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Communication should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Robert J. Coyle, Director, Title I Insurance Division, Room 9160, 451 Seventh Street, SW., Washington, DC 20410. Telephone number (202) 755–6880. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The current Title I regulations were published as a final rule in the **Federal Register** on October 25, 1985 (50 FR 43516) and became effective on January 15, 1986 (51 FR 1495). The regulations have been amended several times subsequent to January 15, 1986 to rectify problems encountered by HUD and/or lenders. Experience by both HUD and lenders in operating under the current regulations has led the Department to conclude that additional substantive changes in the regulations are necessary. Some of the changes being proposed concern basic policy, while others would merely clarify ambiguities in current provisions. Editorial changes would also be made in several other provisions.

Financing of Furniture

Prior to the effective date of the current regulations, there was no specific limit on the amount of loan proceeds that could be used to finance furniture in connection with the purchase of a manufactured home. The current regulations, in § 201.10, placed a cap on the financing of furniture with the proceeds of a manufactured home loan, as follows: Loan proceeds may include an amount equal to the *wholesale (base) price* of any furniture package supplied by the manufacturer, subject to a maximum amount not to exceed the lesser of $2,000 or 10 percent of the wholesale (base) price of the home.

The Department estimates that furniture adds 7 to 13 percent ($1,500 to $2,500) to the *retail price* of the average manufactured home financed with a loan insured under Title I. In most instances of borrower default, the furniture is in poor condition or has been removed before the lender repossesses the home. In such cases, the furniture, which is part of the loan security, has little or no value and both lenders and the Department lose a great deal of money. Faced with these losses, the Department has concluded that the proceeds of manufactured home loans should no longer be used for the purchase of furniture.

Accordingly, the Department proposes to amend §§ 201.2(p), (kk)(2), and (ll), 201.10(b)(1), and 201.26(b)(4)(iii)(C), (b)(6)(i) and (b)(7)(ii) by deleting all references to furniture as part of the loan transaction. In addition, § 201.21(b)(3) would be amended to specifically state that the proceeds of a manufactured home loan shall not be used to purchase furniture. The definition of "furniture" in § 201.2(k) would be retained so as to enable program participants to know what is eligible and what is not eligible for inclusion in the loan.

Hazard Insurance and Single-Interest Insurance

Section 201.25(b)(2)(ii) allows Title I manufactured home purchase loans and combination loans to include the cost of premiums paid by the borrower for comprehensive and extended hazard insurance and vendor's single-interest insurance coverage for three years. The Department proposes to change this provision with regard to both types of insurance.

First, the Department proposes to reduce the number of years of hazard insurance coverage that may be financed with the proceeds of a Title I manufactured home loan from three years to one year. Premiums for this type of insurance coverage are extremely costly—frequently adding $900 to $2,400 to the loan, without adding to the value of the property. The typical manufactured home loan is for 15 years, and very little of the premium is amortized for several years. If a default occurs during the early years of the loan, the unpaid loan balance attributable to the premium is usually not recovered from the proceeds of the sale of the home. Both the lender and HUD share in this loss.

The regulations in effect prior to January 15, 1986 permitted a manufactured home loan to include the costs of hazard insurance for up to five years. The proposed rule published in July 5, 1984 provided for a reduction in the maximum term of a hazard insurance policy financed with the proceeds of a manufactured home loan to three years. In adopting the three-year limitation in the final rule that was published on October 25, 1985, the Department announced that it was contemplating a further reduction to one year in the term of hazard insurance premiums that may be financed. The Department concluded at that time that financing multiple years of hazard insurance coverage was, in the long run, more expensive to borrowers and increased the amount of insurance claims paid by the Department. However, since the 1984 proposed rule had not addressed the possibility of less than three years' coverage, any further reduction would require proposed rulemaking and an opportunity for public comment.

Accordingly, the Department now proposes to amend § 201.25(b)(2)(ii) to provide that hazard insurance premiums financed with Title I loan proceeds be limited to one year. For subsequent years of coverage, the borrower would be expected to pay for insurance either directly out-of-pocket or through monthly payments into an escrow account established by the lender for that purpose.

Secondly, we believe that 201.25(b)(2)(ii), as it relates to vendor's single-interest insurance premiums, is based upon a misconception as to how such insurance works and how premiums for such insurance are charged. Vendor's single-interest coverage protects the secured creditor, although the premium is usually paid by the borrower. Coverage is conditioned on default on the loan and repossession of the collateral by the lender, with payment being the lesser of the cost of repair, the remaining amount of the unpaid loan, or actual cash value. The premium is a one-time premium, unlike the premium for hazard insurance. Therefore, a limitation on the number of years' premiums for vendor's single-interest insurance that can be financed has no meaning.

Accordingly, the Department proposes to further amend § 201.25(b)(2)(ii) to change the term "vendor's single-interest insurance" to "single-interest insurance" in recognition of the fact that this insurance protects the secured creditor, which is usually not the vendor. In addition, the Department would clarify that the premium for single-interest insurance is a one-time premium and therefore it is not subject to the one-year limitation on other financed insurance premiums.

Because single-interest insurance is not subject to subrogation, benefits paid under such insurance coverage result in lenders obtaining double recoveries for such amounts if they are not accounted for in Title I insurance claims as post-default payments. Permitting lenders to retain single-interest insurance benefits without deducting them from the unpaid loan balance would result in lenders bearing less than their statutorily-required 10 percent coinsurance risk. Another result of exclusion of single-interest insurance benefits from Title I claims is that borrowers are liable to the Secretary for these amounts, even though they would not be liable to the lender or the lender's single-interest insurance carrier. The Department does not believe that this is legally permissible, and therefore proposes to amend § 201.55(b)(1)(ii) to include single-interest insurance benefits in the enumerated post-default receipts to be deducted from the unpaid loan balance in calculating the Title I insurance claim.

Section 201.28(b) of the Title I regulations now requires the borrower to obtain and maintain hazard insurance on a manufactured home financed with a Title I insured loan "in an amount at least equal to the unpaid balance of the loan or the actual cash value of the home, or home and lot in combination, whichever is lesser." Lenders and borrowers have pointed out that the requirement for insurance coverage in connection with a combination loan reflects the value of the lot, which should not be insured because neither the lender nor the borrower would be able to recover more than the home's value in the event of a total loss. The Department agrees with that position. In addition, the Department is concerned that requiring insurance coverage equal to the lesser of the unpaid balance of the loan or the actual cash value of the home does not adequately protect the lender's interest when the value of the home has depreciated to a level below the unpaid balance of the loan.

Accordingly, the Department proposes to amend § 201.28(b) to require that hazard insurance coverage on a manufactured home be maintained in an amount at least equal to the unpaid loan balance. This amendment will assure that there is sufficient coverage to pay off the loan in the event that the home is a total loss. Where the manufactured home is appreciating in value, lenders would be well-advised to require additional coverage to assure that both the borrower and the lender are adequately protected in instances of either full or partial loss on the home.

Loan Insurance Charges

In recent years, the Title I manufactured home loan program has sustained major underwriting losses. During the period 1984–1986, manufactured home claims exceeded loan insurance charges by more than $104 million. The Department has concluded that this shortfall has been caused in part by the manner in which the loan insurance charges have been assessed and collected.

To determine whether the present system of collecting loan insurance charges is actuarially sound, the Department conducted a study of 15-year manufactured home loans made under the Title I program, including a detailed analysis of loan survivorship, claims, and non-claim terminations. The study methodology was then evaluated by a private consultant who confirmed its validity. As a result of the study, which took into account the more-stringent underwriting criteria for loans made in 1986 and 1987, the Department concluded that the present system should be modified so that a higher percentage of the total loan insurance charge is collected in the early years of the loan, when the risks of default are greatest. Conversely, loan insurance charges in the later years of the loan term, when risks of default are minimal, would be eliminated.

The loan insurance charge for each Title I loan is set when the loan is registered for insurance, in the following manner: The loan amount is multiplied by the applicable rate, and that result is multiplied by the number of years of the loan term. The loan insurance charge is payable in advance, *i.e.*, when the loan is registered, but may be paid at such time and in such manner as may be prescribed by the Secretary. It has been the Department's policy that the insurance charge be paid in equal annual installments for the term of the loan. The present rates are 0.50 percent for a property improvement loan and 0.54 percent for a manufactured home loan.

The Department proposes to amend § 201.31 to (a) reduce the insurance charge rate for a manufactured home loan from 0.54 percent to 0.50 percent of the loan amount for the term of the loan, (b) change the system of collecting the loan insurance charge for a manufactured home loan, and (c) clarify that the late charges that can be assessed are in fact penalty charges and interest due from the lender when loan insurance charges are not paid in a timely manner.

The manner in which the insurance charge for a manufactured home loan would be collected is as follows:

1. For a loan with a term in excess of two years but not more than 12 years, the loan insurance charge would be 1.00 percent of the loan amount for each of the first three years, 0.75 percent for each of the next two years, and 0.50 percent for each succeeding year until the total loan insurance charge, calculated in the manner described above, is paid.

2. For a loan with a term in excess of 12 years but not more than 16 years, the loan insurance charge would be 1.00 percent of the loan amount for each of the first four years, 0.75 percent for each of the next three years, and 0.50 percent for each succeeding year until the total loan insurance charge is paid.

3. For a loan with a term in excess of 16 years, the loan insurance charge would be 1.00 percent of the loan amount for each of the first five years, 0.75 percent for each of the next four years, and 0.50 percent for each succeeding year until the total loan insurance charge is paid.

This change in the method of collecting the loan insurance charge will result in a slightly lower total income charge in the case of a manufactured home loan that is amortized over the full term of the loan, since the insurance charge rate would be reduced from 0.54 percent to 0.50 percent of the loan amount. However, since a higher percentage of the total insurance charge would be collected in the early years of the loan, and since manufactured home loans are typically paid out in an average of 7 to 8 years, the overall impact of this change would be to increase the amount of loan insurance charges collected on most manufactured home loans.

It is important for property improvement lenders to note that the insurance charge rate for a property improvement loan would remain at 0.50 percent and the loan insurance charge would continue to be collected in the present manner.

All loan insurance charges are considered earned when paid; therefore, if a loan is terminated by default or prepayment, all loan insurance charges

already paid would be retained by the Department, except in the circumstances described in § 201.31(e).

Maximum Amount of an Unsecured Property Improvement Loan

On December 30, 1982, the Department published in the **Federal Register** at 47 FR 58240 a final rule requiring that all Title I property improvement loans in excess of $2,500 be secured by a recorded lien upon the improved property. By notice published in the **Federal Register** on March 10, 1983 at 48 FR 10058, the final rule was given on effective date of April 1, 1983. Prior to April 1, 1983, the requirement that a property improvement loan be secured by a recorded lien applied only to loans in excess of $7,500. The change was deemed to be necessary "because of the significant increase in personal bankruptcy filings and the adverse treatment afforded unsecured property improvement loans in such proceedings", and because "[l]ien security will also enhance the collectibility of loans and reduce credit insurance claims by insured lenders."

The $2,500 ceiling for unsecured property improvement loans has been in effect for approximately five years, and the Department has concluded that the desired results of a lower threshold for secured loans, as enunciated above, have not been achieved. The Department's security interest in a Title I loan is usually in second or even lower position, so that foreclosure on the secured property after default is often not practical because it involves buying out the senior lienholder(s), and property values have not usually supported such action, whether or not the debtor is in bankruptcy. Also, because of the expenses connected with a foreclosure, it has not been cost-effective in most cases involving loans under $5,000.

Criticisms in 1982 by public commenters with regard to the reduced amount for unsecured loans were that (a) there would be increased costs, in time and expenses, associated with having to file liens for a greater number of loans; (b) because the expense of recording a lien is essentially fixed, the required recordation may render smaller loans not cost-effective and may disqualify moderate- and low-income borrowers; and (c) $2,500 is too low a threshold, and any reduction should allow loans of less than $5,000 to remain unsecured. Experience now shows that there was merit to these comments and, coupled with increased costs to improve property as a result of inflation, the Department now is of the opinion that the limit for unsecured loans should be increased to $5,000.

This change in the maximum amount of an unsecured loan would be made by amending § 201.24(a)(1) and (2).

Manufactured Home Site Certification Requirements

Section 201.21(e)(3) of the Title I regulations implements the site suitability requirements in section 2(a) of the National Housing Act by requiring that, for leased home sites in manufactured home parks, lenders obtain certifications of site compliance with standards for such parks. The certifications are required to be from the State or local authority which licenses such parks. Many States do not license manufactured home parks, and therefore lenders have had to obtain the certifications from registered civil engineers, often at great expense. The Department if proposing to simplify the certification process by amending § 201.21(e)(3) to require certifications of site suitability from the appropriate State or local government officials, such as a local planning or building official or public health official. This provision would also be amended to eliminate the requirement that the park comply with minimum standards on site location, storm drainage and landscaping, since most local jurisdictions do not establish or enforce minimum standards for these aspects of park development.

Section 201.21(e)(4) of the regulations requires similar certifications of site suitability and compliance with applicable standards for manufactured homes that are placed on individual lots or other sites owned or leased by borrowers. One of the currently required certifications is that the site is zoned to permit the placement of the manufactured home. Lenders have advised the Department that there are cases where either the land is not affirmatively zoned for manufactured homes, but the zoning does not prohibit their placement, or there are no local zoning requirements. Accordingly, the Department proposes to amend § 201.21(e)(4)(i) to change the required certification, from one stating that the site is zoned to permit the placement of a manufactured home, to a more general statement that the site complies with local zoning ordinances and regulations, if any. In addition, the Department proposes to eliminate the requirement that minimum storm drainage standards be met, in recognition of the lack of such standards in most local jurisdictions, and substitute a more general certification that any other minimum local standards and requirements for site suitability are met. A certification from a registered civil engineer would be required only when local standards for water supply and sewage disposal are not established or enforced.

Clarifying and editorial changes that would be made by this rule relate to the following matters:

Late Charges

Section 201.15 states that, subject to State law, the note may provide for certain late charges. The phrase "subject to State law" was intended to assure that borrowers would be assessed late charges in accordance with the Title I regulations or applicable State law, in the following manner: If State law provides for assessment of late charges after 10 days in arrears, the Title I regulations (providing for assessment of late charges after 15 days in arrears) would apply; if State law provides for assessment of late charges after 20 days in arrears, it would apply. Similarly, if the maximum amount of a late charge authorized by State law is less than that authorized by the Title I regulations, the former would apply; if the maximum amount authorized by State law is more than that authorized by the Title I regulations, the latter would apply. The Department proposes to amend § 201.15 to clarify the application of State law in regard to late charges.

Another requirement of § 201.15 with regard to late charges is that the borrower must be billed for any late charges imposed, and evidence of such billing must be in the loan file if an insurance claim is made. The Department's concern with late charges is not so much whether or not a late charge is imposed upon a delinquent borrower by a separate billing—many lenders provide payment coupons to their borrowers which state how much of a late charge is to be added to a late payment, so that separate billing is not needed—but how the late charge is paid. Late charges should not be collected by deducting them from borrowers' monthly payments for principal and interest, and therefore the Department proposes to amend § 201.15 by (a) clarifying the requirement for billings for late charges, and (b) adding a requirement that late charges, if imposed, must be paid by the borrower and may not be deducted from the borrower's monthly payment for principal and interest.

Section 201.15 also states that the note may provide for daily interest charges based on the interest rate in the note in lieu of late charges. This was not intended to permit an additional charge based upon the note rate, but to mean that interest would accrue daily on the

outstanding balance of the loan. The Department proposes to clarify this by further amending § 201.15 to provide that if interest is charged on a daily basis, late charges may not be assessed by the lender.

Appurtenances to Manufactured Homes

Section 201.2(u) defines a manufactured home purchase loan as "a loan for the purchase of a manufactured home exclusive of any lot or site, and may also include a garage, patio, carport or other comparable appurtenance." However, in prescribing the various items that may be included in the maximum loan amount for such a loan in § 201.10(b), no provision was made for appurtenances. The Department has nevertheless permitted the financing of such items, but only with the approval of the Secretary and at their actual cost to the borrower (see Notice published at 51 FR 9785, 9786, March 21, 1986).

The Department proposes to amend §§ 201.10(b), 201.21(b)(4), and 201.24(b) to provide, respectively, that (a) the cost of appurtenances may be included in the maximum amount of a manufactured home purchase loan under the conditions set forth in the above-cited Notice, (b) manufactured home purchase loan proceeds may be used for the purchase, construction or installation of appurtenances, and (c) any appurtenance that is financed with the proceeds of a manufactured home purchase loan must be secured by a first lien.

Fee and Charges Which Cannot Be Financed

Section 201.25(c) specifies fees and charges which cannot be financed with the loan proceeds. The first sentence of § 201.25(c) states, in relevant part, that these fees ". . . may be collected in the initial payment by the borrower prior to loan disbursement, but may not be included in the loan amount or otherwise financed or advanced" by other parties to the loan transaction. The Department's intention in promulgating this provision was to prevent the financing of these fees, but not to prevent the lender from paying these fees as a cost of doing business. The Department proposes to clarify that lenders can pay such fees by revising the first sentence of § 201.25(c) accordingly.

Proofs of claim in bankruptcy and probate

Section 201.42 requires a lender to file a proof of claim with the court having jurisdiction in cases where the lender has timely information that a borrower is involved in bankruptcy or insolvency proceedings, or is deceased, and the loan is in default and subject to acceleration. The Department has experienced cases in which borrowers have gone into bankruptcy or have died without being in default on their Title I obligations. Lenders should be required to file proofs of claim in such cases, and the Department proposes to amend this section accordingly.

In addition, lenders have frequently questioned the Department as to the necessity of filing a proof of claim in a bankruptcy proceeding when the court has identified it as a "no asset" case and has stated that proofs of claim should not be filed. The Department's policy is that a proof of claim need not be filed in such situations, and the Department proposes to amend § 201.42 to clarify the policy. This would be the only exception to the requirement in § 201.42 for filing a proof of claim in a bankruptcy proceeding.

Many Title I insurance claims have been submitted following deaths or bankruptcies of borrowers. Frequently in such a case, the lender has filed a proof of claim and then notified the court that the loan obligation has been assigned to HUD; the lender has then considered itself to have no further involvement after such notification. The Department, on the other hand, has taken the position that the assignment of a loan obligation is not accepted until payment is made on the insurance claim, and the lender must continue to exercise its rights as a creditor until the claim is paid. The Department proposes to further amend § 201.42 to clarify this position by requiring lenders to take all steps necessary to protect the interests of the creditor, until the Secretary has paid the claims. Following payment, the Secretary will notify the appropriate court of the assignment of the obligation and request that the United States be substituted as the creditor.

Appraisals of repossessed manufactured homes

The first sentence of § 201.51(b)(3) of the regulations requires lenders to obtain a HUD-approved appraisal for each repossessed manufactured home. The second sentence states that the appraisal "should reflect the retail value of comparable manufactured homes in similar condition and in the same geographic area . . . ." The Department's view is that "same geographic area" clearly refers to the area where the home is repossessed. However, some lenders have argued that this provision permits the manufactured home to be appraised on the basis of comparables in the area where the home is located for purposes of resale, which may be different from the area where the home was repossessed.

The Department recognizes that it is sometimes necessary for the home to be moved to another geographic area to obtain a better resale price, but we are concerned about the potential for abuses that can occur when the home is moved from the area where it was repossessed without first obtaining an appraisal. We have found instances where homes have been moved mainly for the purposes of obtaining lower appraisals, with the result that the Department's claim exposure is increased. One means of minimizing this type of program abuse is to require that an appraisal be obtained in the same area where the home was repossessed before moving it to another geographic area. Accordingly, the Department proposes to amend the second sentence of § 201.51(b)(3) to explicitly state that the appraisal must be based upon comparables in the same geographic area where the repossession occurred.

Hazard Insurance in Combination Loan Claims

Section 201.55(b)(3) of the regulations allows a lender to include the cost of premiums for hazard insurance on a repossessed manufactured home in its insurance claim for a manufactured home purchase loan. In § 201.55(b)(5) of the regulations, relating to insurance claims for manufactured home lot loans and combination loans where both the foreclosed manufactured home and the lot are classified as realty, the lender's cost of premiums for hazard insurance on the home was inadvertently omitted from the final rule as an eligible item for inclusion in the insurance claim, although the proposed rule published at 49 FR 27533 on July 5, 1984 did provide for inclusion of hazard insurance premiums in a combination loan claim. The Department proposes to amend § 201.55(b) by redesignating § 201.55(b)(5)(iii) as § 201.55(b)(5)(iv) and adding a new §201.55(b)(iii) to allow an insurance claim on a combination home and lot loan to include the cost of hazard insurance on the home, prorated to the date of disposition of the property.

Corrections

In the third sentence of § 201.13, the second "of" should have been "for". The Department proposes to make this change by revising the sentence accordingly.

Section 201.51(a)(2) provides that "if a lender holds one or more mortgages or other security instruments senior to a

secured property improvement loan, and if the borrower defaults on any such instrument or on the property improvement loan, the lender may both proceed against the secured property under such senior security instrument and later submit a claim under its Title I contract of insurance" if the lender follows certain procedures. The quoted revision contains a typographical error; it should have stated that the lender may proceed against the property under the senior security instrument and file a Title I claim only if the borrower defaults on *both* instruments. The Department proposes to make the appropriate correction.

A further correction is required in § 201.51(a)(2)(iv), which contains a reference to § 201.55(b). This reference should have been to § 201.55(a), and the Department proposes to amend § 201.51(a)(2)(iv) accordingly.

Applicability of Proposed Amendments

In accordance with § 201.3 of the Title I regulations, which provides that some provisions of the current regulations are applicable to all Title I loans, and others are only applicable for those loans for which loan applications were approved on or after the January 15, 1986 effective date, some of these proposed amendments would apply to all loans reported before, on, or after the effective date of the final rule; others would only apply to loans for which loan applications are approved on or after the effective date of the rule.

The amendments that would apply to all loans, whether reported for insurance before, on, or after the effective date of the final rule, would be the changes to §§ 201.10 (item #3), 201.13 (item #4) 201.15 (item #5), 201.21(b)(4) (item #6), 201.24(b) (item #7), 201.25(c) (item #8), 201.31(c) (item #11), 201.42 (item #12), 201.51 (item #13), and 201.55 (items #14 and #15). Amendments that would only apply to loans for which loan applications are approved on or after the effective date of the final rule would be the changes to §§ 201.2 (item #1), 201.10 (item #2), 201.21 (b)(3) and (e)(3) and (4) (item #6), 201.24(a) (item #7), 201.25(b) (item #8), 201.26 (item #9), 201.28 (item #10), and 201.31 (a) and (b) (item #11).

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street SW., Washington, DC 20410.

Regulatory Impact

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulations. Analysis of the rule indicates that it would not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect 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.

Regulatory Flexibility Act

Under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the undersigned hereby certifies that this rule would not have a significant economic impact on a substantial number of small entities because the majority of financial institutions participating in the Title I program are large depository institutions and none of the proposed changes pose undue burdens for small entities seeking to conduct title I loan transactions.

Regulatory Agenda

This rule was listed as item number 902 in the Department's Semiannual Agenda of Regulations published on April 25, 1988 (53 FR 13868) under Executive Order 12291 and the Regulatory Flexibility Act.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers are:

14.110 Manufactured Home Loan Insurance—Financing Purchase of Manufactured Homes as Principal Residences of Borrowers;
14.142 Property Improvement Loan Insurance for Improving All Existing Structures and Building of New Nonresidential Structures; and
14.162 Mortgage Insurance—Combination and Manufactured Home Lot Loans.

List of Subjects in 24 CFR Part 201

Health facilities, Historic preservation, Home improvement, Mobile homes, Manufactured homes and lots, Reporting and recordkeeping requirements.

Accordingly, the Department proposes to amend 24 CFR Part 201 as follows:

PART 201—TITLE I PROPERTY IMPROVEMENT AND MANUFACTURED HOME LOANS

1. The authority citation for 24 CFR Part 201 continues to read as follows:

Authority: Sec. 2, National Housing Act (12 U.S.C. 1703); sec. 7(d), Department of Housing and Urban Development (42 U.S.C. 3535(d)).

2. Section 201.2 would be amended by revising paragraphs (p), (kk)(2), and (ll) to read as follows:

§ 201.2 Definitions.

* * * * *

(p) "Manufacturer's invoice" means a document issued by a manufacturer and provided with a manufactured home to a retail dealer which separately details the wholesale (base) prices at the factory for specific models or series of manufactured homes, itemized options (large appliances, built-in items and equipment), and specific specialty items, plus actual itemized charges for freight (including any rental of wheels and axles) from the factory to the dealer's lot or the homesite and for any sales taxes to be paid by the dealer. The invoice may recite such prices and charges on an itemized basis or by stating an aggregate price or charge, as appropriate, for each category. The manufacturer shall certify in the invoice as follows:

The undersigned certifies under applicable criminal and civil penalties for fraud and misrepresentation that: (1) The wholesale (base) prices for the manufactured home, itemized options, and specialty items as detailed, the charges for freight and dealer-paid sales taxes, and all other statements in this invoice are true and accurate; (2) all such prices reflect the actual dealer costs at the factory, as quoted in the applicable current manufacturer's wholesale (base) price list; and (3) except for any payments of volume incentives or special benefits related to this transaction, all such prices and charges exclude any costs of—and the manufacturer will make no payments to or for the benefit of the dealer and/or home purchaser concerning—trade association fees or charges, discounts, bonuses, refunds, rebates, prizes, loan discount points or other financing charges, or anything else of more than a nominal value of $10 which will inure to the benefit of the dealer and/or home purchaser at any date.

* * * * *

(kk) * * *

(2) Whether or not available on an optional basis do not increase or decrease the wholesale (base) prices for the sale of a specific home, itemized

options, or specialty items, or the charges for freight and dealer-paid sales taxes as detailed in the manufacturer's invoice for a specific sale to a retail dealer;

* * * * *

(ll) "Wholesale (base) price list" means the price list(s), as periodically amended, which are published and distributed by a home manufacturer to all retail dealers in a given maketing area, quoting the actual wholesale (base) prices at the factory for specific models or series of manufactured homes, itemized options, and specialty items offered for sale to such dealers during a specified period of time. The wholesale (base) prices may include the manufacturer's projected costs of providing volume incentives and special benefits related to sales to dealers during the period. All such wholesale (base) prices shall exclude any costs of trade association fees or charges, discounts, bonuses, refunds, rebates, prizes, loan discount points or other financing charges, or anything else of more than a nominal value of $10 which will inure to the benefit of a dealer and/or home purchaser at any date. Each price list and amendment shall be retained by the manufacturer for a minimum period of six years from the date of publication so as to be available to HUD and other Federal agencies upon request.

* * * * *

§ 201.10 [Amended]

3. Section 201.10 would be amended by removing paragraph (b)(1)(ii) and redesignating paragraphs (b)(1)(iii) through (vi) as paragraphs (b)(1)(ii) through (v).

4. Section 201.10 would be amended further by adding a new paragraph (b)(1)(vi) to read as follows:

§ 201.10 Loan amounts.

* * * * *

(b) * * *

(1) * * *

(vi) The actual cost to the borrower of a garage, carport, patio or other comparable appurtenance to the manufactured home, as stated in the retail purchase contract and as approved by the Secretary;

* * * * *

5. Section 201.13 would be amended by revising the third sentence to read as follows

§ 201.13 Interest and discount points.

* * * The lender also may negotiate with the dealer the amount of discount points, if any, to be paid by the dealer from its own resources for the benefit of the borrower before or at the time of the borrower's initial payment to the lender.

* * *

6. Section 201.15 would be revised to read as follows:

§ 201.15 Late charges to borrowers.

(a) *Imposition of late charge.* The note may provide for imposition of a late charge unless precluded by State law. The late charge may be imposed only for installments of principal and interest which are in arrears for the greater of 15 calendar days or the number of days required by applicable State law before such a charge may be imposed. Late charges must be billed to the borrower or reflected in the payment coupon, and evidence that they have been paid must be in the loan file if an insurance claim is made.

(b) *Amount of late charge.* The late charge shall not exceed the lesser of (1) five percent of each installment of principal and interest, up to a maximum of $10 per installment for any property improvement loan and $15 per installment for any manufactured home loan, or (2) the maximum amount permitted by applicable State law.

(c) *Method of payment.* Payment of any late charge connot be deducted from the monthly payment for principal and interest, but must be an additional charge to the borrower.

(d) *Daily interest in lieu of late charges.* In lieu of late charges, the note may provide for interest to accrue on installments in arrears on a daily basis at the interest rate in the note.

7. Section 201.21 would be amended by revising paragraphs (b)(3) and (4) and paragraphs (e)(3) and (4) to read as follows:

§ 201.21 Manufactured home loan eligibility.

* * * * *

(b) * * *

(3) The proceeds of a manufactured home loan shall not be used to purchase furniture.

(4) The proceeds of a manufactured home purchase loan may be used for the purchase, construction or installation of a garage, carport, patio or other comparable appurtenance to the manufactured home, as stated in the retail purchase contract and as approved by the Secretary. The proceeds of a combination loan may be used for the purchase, construction or installation of a permanent foundation, garage, carport, patio or other comparable appurtenance to the manufactured home.

* * * * *

(e) * * *

(3) Where the manufactured home is to be placed on a leased site in a manufactured home park, the lender shall obtain certifications from the appropriate State or local government officials that the park complies with minimum standards relating to vehicular access, water supply, sewage disposal, utility connections, and other aspects of park development. Where minimum State or local standards for park development are not established or enforced, the lender shall obtain a certification from a registered civil engineer tht the park meets minimum standards for park development prescribed by the Secretary.

(4) When the manufactured home is to be placed on an individual manufactured home lot or other site owned or leased by the borrower (or on an Indian land site under paragraph (e)(1) of this section), the lender shall obtain certifications from the appropriate local government officials that:

(i) The site complies with local zoning ordinances and regulations, if any;

(ii) Adequate vehicular access from a public right-of-way is available to the site;

(iii) Adequate water supply and sewage disposal facilities are available to or on the site; and

(iv) Any other minimum local standards and requirements for site suitability are met. Where minimum local standards for water supply and sewage disposal are not established or enforced, the lender shall obtain a certification from a registered civil engineer that the site meets minimum standards for water supply and sewage disposal prescribed by the Secretary.

8. Section 201.24 would be amended by revising the first sentence of paragraph (a)(1), paragraph (a)(2), and the first sentence of paragraph (b) to read as follows:

§ 201.24 Security requirements.

(a) *Property improvement loans.* (1) Any property improvement loan in excess of $5,000 shall be secured by a recorded lien on the improved property.* * *

(2) Any property improvement loan for $5,000 or less (other than a manufactured home improvement loan) shall be similarly secured if, including such loan, the total amount of all Title I property improvement loans obtained by the borrower is more than $5,000.

(b) *Manufactured home loans.* Any manufactured home loan shall be secured by a recorded lien on the home (or lot or home and lot, as appropriate), its furnishings, equipment, accessories, and appurtenances.* * *

* * * * *

9. Section 201.25 would be amended by revising paragraph (b)(2)(ii)— and the introductory text of paragraph (c) to read as follows:

§ 201.25 Charges to borrower to obtain loan.

* * * * *

(b) * * *

(2) * * *

(ii) Premiums paid by the borrower for the first year of comprehensive and extended hazard insurance coverage, including premiums for flood insurance where applicable, and premiums for single-interest insurance;

* * * * *

(c) *Fees and charges which may not be financed.* Except for any discount points to be paid by a dealer to a lender under § 201.13, the following fees and charges incurred in connection with a loan insured under this part may be collected in the initial payment made by the borrower or may be paid by the lender, but may not be included in the loan amount or otherwise financed or advanced by the dealer, the manufacturer, if any, or any other party to the loan transaction:

* * * * *

10. Section 201.26 would be amended by revising paragraph (b)(4)(iii)(C), the first sentence of paragraph (b)(6)(i), and paragraph (b)(7)(ii) to read as follows:

§ 201.26 Conditions for loan disbursement.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

(C) The dealer has performed the inspection and tests required under § 201.21(c)(3) and, as installed or erected on the homesite, the manufactured home has sustained no structural damage or other defects, and all plumbing, mechanical and electrical systems are fully operational; and

* * * * *

(6) * * *

(i) In the absence of information to the contrary, the lender may accept and rely upon a certification by the dealer or seller under applicable criminal and civil penalties for fraud and misrepresentation that the manufactured home, any options (large appliances, built-in items and equipment), and any specialty items included in the purchase price of the home or to be financed with loan proceeds have been delivered to and properly installed or erected on the site, and any other work to be accomplished at the site and financed with loan proceeds has been completed.* * *

(7) * * *

(ii) The manufactured home, any options, and any specialty items included in the purchase price of the home or to be financed with loan proceeds have been delivered and completed;

* * * * *

11. Section 201.28 would be amended by revising the second sentence of paragraph (b) to read as follows:

§ 201.28 Flood and hazard insurance, and Coastal Barriers properties.

* * * * *

(b) *Hazard insurance.* * * * Such insurance shall be maintained by the borrower for the full term of the loan or until the property is repossessed or foreclosed by the lender, and in an amount at least equal to the unpaid balance of the loan. * * *

* * * * *

12. Section 201.31 would be amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 201.31 Insurance charge.

(a) *Insurance charge.* For each eligible property improvement loan and manufactured home loan reported and acknowledged for insurance, the lender shall pay to the Secretary an insurance charge equal to the loan amount multiplied by 0.50 percent, multiplied by the number of years of the loan term. The insurance charge shall be paid in the manner prescribed in paragraph (b); however, no charge shall be made for a period of 14 days or less, and a charge for a full month shall be made for a period of more than 14 days. There shall be no abatement or refund of an insurance charge except as provided in paragraph (e).

(b) *Payment of insurance charge.* (1) For any loan having a maturity of 25 months or less, payment of the entire insurance charge prescribed in paragraph (a) is due on the 25th calendar day after the date the Secretary acknowledges the loan report.

(2) For any loan having a maturity in excess of 25 months, payment of the insurance charge shall be made in annual installments, with the first installment due on the 25th calendar day after the date the Secretary acknowledges the loan report, and the second and succeeding installments due on the 25th calendar day after the date of billing by the Secretary. Annual installments shall be paid according to the following schedule:

(i) For any property improvement loan having a maturity in excess of 25 months, payment shall be made in annual installments of 0.50 percent of the loan amount until the insurance charge is paid.

(ii) For any manufactured home loan having a maturity in excess of 25 months but not more than 144 months, payment shall be made in annual installments of 1.00 percent of the loan amount for the first three years of the loan term, 0.75 percent of the loan amount for the next two years, and 0.50 percent of the loan amount for all succeeding years until the insurance charge is paid.

(iii) For any manufactured home loan having a maturity in excess of 144 months but not more than 192 months, payment shall be made in annual installments of 1.00 percent of the loan amount for the first four years of the loan term, 0.75 percent of the loan amount for the next three years, and 0.50 percent of the loan amount for all succeeding years until the insurance charge is paid.

(iv) For any manufactured home loan having a maturity in excess of 192 months, payment shall be made in annual installments of 1.00 percent of the loan amount for the first five years of the loan term, 0.75 percent of the loan amount for the next four years, and 0.50 percent of the loan amount for all succeeding years until the insurance charge is paid.

(3) All insurance charges are considered earned when paid.

(c) *Penalty charge and interest.* Insurance charges not received from the lender by the due date specified in paragraph (b) shall be assessed a penalty charge of four percent of the amount of the payment. Insurance charges received from the lender more than 30 days after the due date specified in paragraph (b) shall also be assessed daily interest at the current United States Treasury value of funds rate, as published periodically in the **Federal Register.** However, no penalty charge or daily interest shall be assessed if the Secretary fails to acknowledge receipt of the loan report or fails to issue a proper billing to the lender for the insurance charges.

* * * * *

13. Section 201.42 would be revised to read as follows:

§ 201.42 Bankruptcy, insolvency or death of borrowers.

(a) *Bankruptcy, insolvency.* The lender shall file a proof of claim with the court having jurisdiction when the lender has timely information that a borrower is involved in bankruptcy or insolvency proceedings, except that a proof of claim need not be filed if the court notifies the lender that the borrower has no assets and a proof of claim should not be filed. The notice of bankruptcy and a copy of the proof of

claim (or the notice from the court that a proof of claim is not required) shall be retained in the loan file.

(b) *Death of a borrower.* The lender shal file a proof of claim with the court having jurisdiction when the lender has timely information that a borrower is deceased, unless the lender determines that there will not be a probate proceeding. A copy of the proof of claim (or documentation as to why a proof of claim was not filed) shall be retained in the loan file.

(c) *Responsibility of the lender after insurance claim is filed.* After the Secretary pays an insurance claim, the Secretary will notify the bankruptcy or probate court, as appropriate, that the loan has been assigned to the United States and will request substitution as the party to whom the claim is owed. Until the insurance claim is paid, the lender shall take all steps necessary to protect the interests of the holder of the note in any bankruptcy or probate proceeding.

14. Section 201.51 would be amended by revising paragraphs (a)(2) introductory text and (a)(2)(iv) and the second sentence of paragraph (b)(3) to read as follows:

§201.51 Proceeding against the loan security.

(a) * * *

(2) If a lender holds one or more mortgages or other security instruments senior to a secured property improvement loan, and the borrower defaults on both the senior security instrument and the property improvement loan, the lender may proceed against the secured property under the senior security instrument and later submit a claim under the Title I contract of insurance only if:

* * * * *

(iv) The lender calculates its claim for loss on the property imnprovement loan in accordance with §201.55(a).

* * * * *

(b) * * *

(3) * * * The appraisal should reflect the retail value of comparable manufactured homes in similar condition and in the same geographic area where the repossession occurred, as listed in a current value rating publication acceptable to the Secretary.

* * *

§201.55 [Amended]

15. Section 201.55 would be amended by removing "and" from paragraph (b)(5)(ii) and by redesignating paragraph (b)(5)(iii) as paragraph (b)(5)(iv).

16. Section 201.55 would be further amendd by revising paragraph (b)(1)(ii) and by adding a new paragraph (b)(5)(iii) to read as follows:

§201.55 Calculation of insurance claim payment.

* * * * *

(b) * * *

(1) * * *

(ii) All amounts to which the lender is entitled after the date of default from any source relating to the property, including but not limited to such items as rent, other income, recourse recovery against the dealer, hazard insurance benefits, single-interest insurance benefits, and rebates on prepaid insurance premiums; and

* * * * *

(5) * * *

(iii) Premiums for hazard insurance on the manufactured home, prorated to the date of disposition of the property; and

* * * * *

Dated: July 7, 1988.

James E. Schoenberger,

General Deputy, Assistant Secretary for Housing - Federal Housing Commissioner.

[FR Doc. 88-18316 Filed 8-12-88; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Safety and Pollution-Prevention Equipment

AGENCY: Minerals Management Service, Interior.

ACTION: Reopening of comment period.

SUMMARY: Current rules governing offshore oil and gas operations require that safety and pollution-prevention equipment (i.e., surface safety valves, underwater safety valves, and subsurface safety valves) be manufactured in accordance with a quality assurance program specified in the rule. On July 6, 1988, the Minerals Management Service (MMS) issued a Notice of Proposed Rulemaking which would amend existing rules to update the American National Standard Institute/American Society of Mechanical Engineers (ANSI/ASME) SPPE-1 quality assurance standard from the 1985 edition to the 1988 edition and to provide for the recognition of the Amerian Petroleum Institute's (API) quality assurance program, API Spec Q1 in combination with API Spec 14A and Spec 14D, as an acceptable alternate or optional quality assurance program for the manufacture of safety and pollution-prevention equipment. This Notice reopens the comment period for an additional 45 days to allow additional time for the public to review applicable documents and to prepare and submit comments.

DATES: Comments must be received or postmarked by September 29, 1988.

ADDRESSES: Comments should be mailed or hand delivered to the Department of the Interior; Minerals Management Service; Mail Stop 646, Room 6A110; 12203 Sunrise Valley Drive; Reston, Virgina 22091; Attention: Gerald D. Rhodes.

FOR FURTHER INFORMATION CONTACT: M.L. Courtois; Chief, Offshore Inspection and Enforcement Division; Minerals Management Service; Mail Stop 647, Room 6A200; 12203 Sunrise Valley Drive; Reston, Virgina 22091; (703) 648-7750.

SUPPLEMENTARY INFORMATION: The current relations requires that safety and pollution-prevention equipment be manufactured under the 1985 edition of the ANSI/ASME SPPE-1 quality assurance program. On July 6, 1988, MMS issued a Notice of Proposed Rulemaking (53 FR 25349) to amend the regulations to recognize the API quality assurance program using API Spec Q1 in combination with API Spec 14A and Spec 14D as an acceptable alternative to the ANSI/ASME quality assurance program using ANSI/ASME SPPE-1. The proposed rule also would incorporate by reference the 1988 edition of ANSI/ASME SPPE-1 in place of the 1985 edition of ANSI/ASME SPPE-1.

Comments received in response to the proposed rule have noted that response to the proposed rule requires that interested parties obtain copies of and review referenced documents prior to commenting and that the 30-day comment period included in the Notice of Proposed Rulemaking was insufficient. The MMS recognizes the importance of these documents and the complexities of determining the implications of not only the new documents but also of a new quality assurance program. Accordingly, MMS is reopening the comment period for an additional 45 days. This will provide interested parties with an additional 45 days to complete any analyses started during the original 30-day comment period and to prepare and submit comments.

Comments submitted during the original comment period need not be resubmitted. The MMS will consider all written comments received between July 6, the date of publication of the Notice of Proposed Rulemaking, and the close of

this new comment period. Persons wishing to comment on the proposed rule should send written comments to the address identified above by September 29, 1988.

Date: August 8, 1988.

Thomas A. Readinger,

Acting Associate Director for Offshore Minerals Management.

[FR Doc. 88-18355 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-MR-M

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 201-1, 201-2, 201-23, 201-24

Implementation of Title VIII, Paperwork Reduction Reauthorization Act of 1986, Pub. L. 99-500 Regarding Automatic Data Processing Equipment

AGENCY: Information Resources Management Service, GSA.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed final rule implements certain selected portions of the Paperwork Reduction Reauthorization Act of 1986 in the Federal Information Resources Management Regulations (FIRMR). Among other changes, the amendment clarifies the applicability of the FIRMR in FIRMR Part 201-1 to the management, acquisition, and use of various information resources by Federal agencies. In this regard, key phrases in the statute such as "making significant use" and "incidental to the performance" have been clarified.

FIRMR Part 201-2 is revised to establish an umbrella term for ADP and telecommunications resouces—Federal information processing (FIP) resources. The term and related definitions, is an efficient means for prescribing uniform programs, policies, and procedures for ADP and telecommunications resources. The term "commercial items" is defined and used in place of "general purpose, commercially available, mass-produced" to indicate which FIP resources should be managed and acquire under FIRMR provisions.

The amendment also prescribes policies and procedures in FIRMR Part 201-24 for use in determining whether any particular procurement must be conducted under GSA's exclusive procurement authority.

In addition, the amendment streamlines the Delegations Program by establishing uniform procedures, uniform blanket delegations of procurement authority, and uniform agency procurement requests (APRs) for all FIP resources. The effect of these changes to FIRMR Part 201-23 is to set a single competitive regulatory blanket delegation of procurement authority of $2.5 million for most ADP and telecommunications resources. The change allows GSA to focus review activities on agencies' overall IRM programs under the Procurement Management Review Program and on the most significant agency acquisitions under the Delegations Program.

The amendment also adopts continuing relevant portions of FIRMR Temporary Regulation 13 (51 FR 45887) that immediately addressed the impact of the same statute, and consolidates or eliminates certain portions of that rule. This amendment supersedes and cancels FIRMR Part 201-39, Major Changes and New Installations of Telecommunication Resources. (**Note.**—It also supersedes Subpart 201-38.2 of a proposed FIRMR rule, Revisions of FIRMR Telecommunications Policies, (Project No. 86.75) that was announced in a notice of proposed rulemaking appearing in the **Federal Register** on September 23, 1987 (52 FR 35736).)

DATE: Comments are due September 14, 1988.

ADDRESS: Comments should be submitted to the General Services Administration (Project KMP-87-7), Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Phillip R. Patton, Regulations Branch, (KMPR), Office of Information Resources Management Policy, (202) 566-0194, or FTS 566-0194. The full text of the proposed rule is available upon telephone request.

SUPPLEMENTARY INFORMATION: (1) On December 23, 1986, FIRMR Temporary Regulation 13 was published in the **Federal Register** and was effective that day. It implemented applicable portions of the Paperwork Reduction Reauthorization Act of 1986 by incorporating the statutory definition of ADPE in the FIRMR. It further provided blanket regulatory delegations of procurement authority for those cases where the amended Brooks Act became applicable to the acquisition. This amendment codifies relevant portions of FIRMR Temporary Regulation 13 and incorporates additional changes from the aforementioned statute as described in the succeeding paragraphs.

(2) Explanation of the changes being made by this issuance are shown below:

(a) In Part 201-1, the following changes will be made.

(i) Section 201-1.000-1 will be amended by revising paragraph (c) by removing language from the Paperwork Reduction Act of 1980 identifying "information management activities" and substituting the definition of "information resources management" that was provided in Pub. L. 99-500 (the Paperwork Reduction Reauthorization Act of 1986).

(ii) Section 201-1.102-2 will be amended by removing outdated language that reflected the prior review function of the Office of Management and Budget under Pub. L. 89-306.

(iii) Section 201-1.102-3 will be amended by removing the language included in that section. Exclusions from the Paperwork Reduction Reauthorization Act of 1986 that reflected the exclusions set forth in Pub. L. 97-86 (10 U.S.C. 2315) will now be more appropriately addressed in § 201-1.103, Applicability.

(iv) Section 201-1.103 will be amended by revising the section completely. This section will set forth in much greater detail the extent of FIRMR's applicability to Federal agencies. It will address management and use of records by Federal agencies, management, acquisition, and use of Federal information processing (FIP) resources by Federal agencies, and management, acquisition, and use of radio equipment. The inapplicability of the FIRMR will be set forth including those instances when the use of FIP resources is incidental to the acquisition. The statutory exceptions to Pub. L. 99-500 will be stated as well as the exclusions for telecommunications resources that were set forth in § 201-1.103(c)(4). A note will be added that provides a regulatory blanket delegation of GSA's exclusive procurement authority and a waiver of FIRMR provisions for non-commercial FIP resources.

(b) In Part 201-2, the folloiwng changes will be made.

(i) A new definition of "Federal information processing resources" will be added.

(ii) A new definition of "Federal information processing equipment" will be added.

(iii) A new definition of "Federal information processing software" will be added.

(iv) A new definition of "Federal information processing services" will be added.

(v) A new definition of "Federal information processing support services" will be added.

(vi) A new definition of "Federal information processing related supplies" will be added.

(vii) A new definition of "Federal information processing system" will be added.

(viii) A new definition of "Telecommunications resources" will be added.

(ix) A new definition of "Commercial items" will be added.

(x) A new definition of "Radio equipment" will be added.

(xi) A new definition of "Information" will be added.

(xii) A new definition of "Data" will be added.

(xiii) A new definition of "Television equipment" will be added.

(xiv) A new definition of "Radar equipment" will be added.

(xv) A new definition of "Sonar equipment" will be added.

(xvi) A new separate definition of "Executive agency" will be added.

(c) Part 201–23 will be amended and revised.

(i) Section 201–23.000 will be amended and revised to more fully describe the scope of the part.

(ii) Subpart 201–23.1 will be amended and revised to address delegations of GSA's exclusive procurement authority for FIP resources.

(iii) Section 201–23.100 will be amended and revised to more accurately describe the scope of the subpart.

(iv) Section 201–23.101 will be amended and revised to prescribe newly established policies regarding GSA's exclusive procurement authority for FIP resources.

(v) Section 201–23.102 will be amended and revised to set forth the policies and procedures regarding accountability for acquisition of FIP resources delegated under GSA's exclusive procurement authority.

(vi) Section 201–23.103 will be amended and revised to describe the methods of obtaining delegations of GSA's exclusive procurement authority for FIP resources.

(vii) Section 201–23.103–1 will be amended and revised to describe the policies and procedures regarding regulatory blanket delegations of GSA's exclusive procurement authority for FIP resources. It will provide a regulatory blanket delegation of GSA's exclusive procurement authority for non-commercial FIP resources and waive FIRMR provisions for such resources.

(viii) Section 201–23.103–2 will be amended and revised to provide policies and procedures regarding the establishment of agency blanket delegations of GSA's exclusive procurement authority for FIP resources.

(ix) Section 201–23.103–3 will be amended and revised to provide a single method for submitting an agency procurement request and obtainig a delegation of procurement authority for acquiring FIP resources.

(x) Subpart 201–23.2 will be amended and revised to address delegations of GSA's multi-year contracting authority for telecommunications resources.

(xi) Section 201–23.200 will be amended and revised to more accurately describe the scope of the subpart.

(xii) Section 201–23.201 will be amended and revised to describe GSA's authority to enter into multi-year contracts for telecommunications resources.

(xiii) Section 201–23.202 will be amended and revised to set forth more accurately the agency's accountability for acquisitions made under delegation of GSA's multi-year contracting authority for telecommunications.

(xiv) Section 201–23.203 will be amended and revised to more accurately prescribe policies and procedures relating to GSA's blanket multi-year contracting authority for telecommunications resources delegated to Executive agencies.

(d) In Part 201–24, the following changes will be made.

(i) Section 201–24.107 will be added to prescribe new policies and procedures regarding FIP resources that are included within general procurement requirements. It is designed to ensure that FIP resources are acquired under GSA's exclusive procurement authority unless such resources are incidental to the performance of general procurement requirements. It further provides a procedure so that Federal agencies may request a deviation to conduct procurements outside the provisions of the FIRMR even though the requirement meets the definition of incidental as set forth in § 201–1.103(c)(2)(ii)(A).

(ii) Section 201–24.202 will be retitled and modified to incorporate the policy that was in § 201–1.103(b)(2). This addition rquires Federal agencies to include in solicitations and resultant contracts terms, conditions, and clauses which apply the full and open competition objective to the procurement of ADP resources by Federal contractors in certain situations.

(b) The General Services Administration has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981. GSA actions are based on adequate information concerning the need for, and the consequences of the rule. The rule is written to ensure maximum benefits to Federal agencies. This is a Governmentwide regulation that will have little or no net cost effect on society. It is therefore certified that this rule will not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

List of Subjects in 41 CFR Part 201–1, 201–2, 201–23, and 201–24

Computer technology, Government procurement, Government property management, Telecommunications, Information resources activities, Government records management, Hearing and appeal procedures, Competition.

(4) This amendment supersedes and cancels FIRMR Temporary Regulation 13 upon its effective date.

Dated: February 10, 1988.

Francis A. McDonough,

Deputy Commissioner for Federal Information Resources Management.

[FR Doc. 88–18341 Filed 8–12–88; 8:45 am]

BILLING CODE 6820–25–M

Notices

Federal Register
Vol. 53, No. 157
Monday, August 15, 1988

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 COMMERCE

National Technical Information Service

Intent To Grant Exclusive Patent License; Qualimetrics Inc.

The National Technical Information Service (NTIS), U.S. Department of Commerce, intends to grant to Qualimetrics Inc., having a place of business in Sacramento, California, an exclusive license in the United States and certain foreign countries under the rights of the United States of America to manufacture, use, and sell products embodying the invention entitled "Quad Disk Static Pressure Probe," United States Patent Application Serial Number 7–210,546. The patent rights in this inventiion have been assigned to the United States of America, as represented by the Secretary of Commerce, and to The University of Colorado Foundation, Inc. NTIS has been authorized to license all of the patents rights in this invention.

The proposed exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The proposed license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the proposed license would not serve the public interest.

Inquiries, comments and other materials relating to the intended license must be submitted to Charles A. Bevelacqua, Office of Federal Patent Licensing, NTIS, Box 1423, Springfield, VA 22151.

Douglas J. Campion,

Associate Director, Office of Federal Patent Licensing, National Technical Information Service, U.S. Department of Commerce.

[FR Doc. 88–18343 Filed 8–12–88; 8:45 am]

BILLING CODE 3510–04–M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1988; Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to procurement list.

SUMMARY: This action adds to Procurement List 1988 commodities to be produced by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: September 14, 1988.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202–3509.

FOR FURTHER INFORMATION CONTACT: E.R. Alley, Jr. (703) 557–1145.

SUPPLEMENTARY INFORMATION: On June 3, 1988, the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (53 FR 20359) of proposed additions to Procurement List 1988, December 10, 1987 (52 FR 46926). The intent of the notice was to add the GSA Zone 1 requirements for NSN 8540–00–530–3770 to the Procurement List. The state of Rhode Island, which is in Zone 1, was inadvertently omitted from the states listed. The current contractor, the only commenter, addressed the addition of the GSA Zone 1 requirements. Accordingly, the entire GSA Zone 1 requirements for this commodity, including Rhode Island, are being added to the Procurement List by this final rule. However, comments relative to the inclusion of Rhode Island in this addition action will be considered if received prior to the effective date of this notice.

Comments were received from the current contractor for one of the items of toilet paper proposed for addition to the Procurement List. The issues raised in the comments concerned the continuation of competitive bidding for these items in order for the Government to obtain the lowest price, the ability of the workshop to effectively comply with GSA contracting procedures, the impact on subcontractors who are small and small disadvantaged businesses, and the cumulative effect of future additions of additional portions of the Government's requirements for these items.

Best Price for Government

The commenter stated that the market for paper and paper tissue is very competitive which results in the prices submitted to the Government being very low. He indicated that the items should continue to be purchased on a competitive basis in order to obtain the best price for the Government.

Under the Committee's Act, the Committee is responsible for determining "fair market prices" for commodities and services on the Procurement List (41 U.S.C. 47(b)). The Committee considers that the reasonable bids received by the Government for the item under consideration are the best measure of the market for that item. Under its longstanding pricing policy, the initial fair market prices for items being added to the Procurement List, which have been recently procured by the Government, are based on the median of the reasonable bids which were received on the most recent procurement, or the award price increased by 5%, whichever is greater. Thus, the workshop is not required to produce this toilet paper at the award prices.

The fair market prices established by the Committee for these items are considered to be reflective of the market for the toilet paper and are fair market prices within the policies and procedures of the Committee.

Compliance with GSA Contracting Procedures

The commenter questioned the ability of the workshop to effectively comply with GSA contracting procedures. He indicated that his firm has refined the necessary procedures and organized the essential administrative support for servicing Government contracts efficiently.

The workshop proposed to produce this toilet paper received the most recent contract to produce NSN 8540–01–055–6094. That item is identical to the other item NSN 8540–00–530–3770 except for packaging. The workshop was inspected by the procuring activity and determined capable of producing the items involved in compliance with the Government's requirements. The National Industries for the Blind has performed an on-site inspection of the workshop and has indicated that it is

capable of complying with the Government's commercial item description and delivery requirements for the items involved. Based on the preceding, the Committee has determined that the workshop is capable of producing the toilet paper in compliance with the commercial item description and within the time frames required by the Government.

Impact on Small Business Subcontractors

The commenter stated that the addition of the toilet paper to the Procurement List will not only affect the prime contractor, but also small and small disadvantaged businesses with which such suppliers conduct business in relation to GSA contracts. The workshop is the most recent contractor for one of the two items included in the proposal. These items are procured twice each year and cover the requirements of the Government for a six-month period. In determining impact, the Committee considered awards made for the items for the annual period. The value of the commenting firm's contract for one of these items represents 1/10 of one percent of its annual sales and about 1.6% of the annual sales of the other competitive contractor for the item. This is not considered to be serious impact. Regarding the effect of the addition on small and small disadvantaged businesses, the workshop is required by Committee regulations (41 CFR 51–4.4(b)) to accomplish the maximum subcontracting to small business concerns that it finds consistent with efficient performance in producing commodities on the Procurement List. Thus, the addition of the items to the Procurement List should have little, if any, effect on the small business subcontractors since the workshop will be utilizing those firms when possible and necessary for the efficient production of these items.

Cumulative Effect of Future Additions

The commenter expressed a concern with the cumulative effect of future additional which would expand the workshop's production of these items under the Committee's program.

The paramount issue is whether or not the addition of this toilet paper severely impacts the current contractors. In deciding whether or not a proposed addition to the Procurement List would have a serious adverse impact on the current or most recent contractor, the Committee is required by regulation (41 CFR 51–2.6(d) to give particular attention to the possible impact on that contractor's sales, including any cumulative impact as a result of other recent Committee actions. This regulation would also apply to a future decision to add another portion of the Government's requirements for this toilet paper to its Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.6.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered were:

a. The actions will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The actions will not have a serious economic impact on any contractors for the commodities listed.

c. The actions will result in authorizing small entities to produce the commodities procured by the Government.

Accordingly, the following commodities are hereby added to Procurement List 1988:

Paper, Toilet Tissue

8540–00–530–3770

(Requirements for GSA Zone 1 only)

8540–01–055–6094

E.R. Alley, Jr.,

Acting Executive Director.

[FR Doc. 88–18294 Filed 8–12–88; 8:45 am]

BILLING CODE 6820–33–M

DEPARTMENT OF DEFENSE

Office of the Secretary

DIA Scientific Advisory Committee; Meeting

AGENCY: Defense Intelligence Scientific Advisory Committee, DOD.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of subsection (d) of section 10 of Pub. L. 92–463, as amended by section 5 of Pub. L. 94–409, notice is hereby given that a closed meeting of the DIA Scientific Advisory Committee has been scheduled as follows:

DATES: Wednesday and Thursday, September 7–8, 1988, 9:00 a.m. to 5:00 p.m. each day.

ADDRESS: The DIAC, Bolling AFB, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel John E. Hatlelid, USAF, Executive Secretary, DIA Scientific Advisory Committee, Washington, DC 20340 (202/373–4930).

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(1), Title 5 of the U.S. Code and therefore will be closed to the public. The Committee will receive briefings on and discuss several current critical intelligence issues and advise the Director, DIA on related scientific and technical intelligence matters.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Office, Department of Defense.

August 10, 1988.

[FR Doc. 88–18363 Filed 8–12–88; 8:45 am]

BILLING CODE 3810–01–M

Performance Review Board; Membership Appointments

AGENCY: Defense Mobilization Systems Planning Activity, DOD.

ACTION: Announce membership of Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board (PRB) of the Defense Mobilization Systems Planning Activity (DMSPA). The publication of the PRB membership is required by 5 U.S.C. 4314(c)(4).

The Performance Review Board provides fair and impartial review of Senior Executive Service performance appraisals and makes recommendations regarding performance and performance awards to the Director.

FOR FURTHER INFORMATION CONTACT: Ms. Lorna J. D. Jons, Resource Management and Support Services, Defense Mobilization Systems Planning Activity, c/o OASD(FM&P), Correspondence & Control Division, The Pentagon, Room 3E–759, Washington, DC 20301, (703) 756–7913.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the following register constitutes members of the Defense Mobilization Systems Planning Activity PRB who will serve one-year renewable terms effective August 22, 1988.

Mr. John W. Beach

Mr. Bruce J. Campbell

Dr. Michael L. Ioffredo

Dr. David T. Signori, Jr.

Mr. Thomas M. Stanners

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 10, 1988.

[FR Doc. 88-18362 Filed 8-12-88; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[ERA Docket No. 88-11-NG]

Northeast Gas, Inc.; Order Extending Blanket Authorization To Import Natural Gas

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Order extending blanket authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice that it has issued an order granting Northeast Gas, Inc. (NGI), an extension of its existing blanket authorization to import up to 100 Bcf of Canadian natural gas over a two-year term which expired March 31, 1988. The order authorizes NGI to import up to 100 BCF of natural gas over a two-year term beginning on date of first delivery after expiration of NGI's existing import authorization. The gas is for resale to 20 local distribution companies in the U.S. Northeast.

A copy of this order is available for inspection and copying in the Natural Gas Division Docket Room, GA-076, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC August 8, 1988.

Constance L. Buckley,

Acting Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88-18397 Filed 8-12-88; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 88-43-NG]

Tennessee Gas Pipeline Co.; Application To Extend an Authorization To Import Natural Gas From Canada

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of application to extend authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of receipt on July 20, 1988, of an application from Tennessee Gas Pipeline Company (Tennessee) to amend its existing blanket authority to import up to 75,000 Mcf per day of "special purchase gas" from its Canadian supplier, ProGas Ltd. (ProGas) by extending such authority through October 31, 2000.

The application is filed with the ERA pursuant to Section 3 of the Natural Gas Act and DOE Delegation Order No. 0204-111. Protests, motions to intervene or notices of intervention, and written comments are invited.

DATE: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are due to be filed no later than September 14, 1988.

FOR FURTHER INFORMATION CONTACT:

Edward J. Peters, Jr., Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Forrestal Building, Room GA-076, 1000 Independence Ave, SW., Washington, DC 20585, (202) 586-8162.

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E-042, Washington, DC 20585, (202) 586-6667.

SUPPLEMENTARY INFORMATION:

Tennessee is currently authorized under DOE/ERA Opinion and Order No. 131 (Order 131), issued June 19, 1986, to import up to 75,000 Mcf per day of Canadian natural gas through October 31, 2000, in accordance with the provisions of its November 25, 1985, gas purchase agreement, as amended, with ProGas. Order 131 also permitted Tennessee to assign its rights and obligations with respect to the purchase, receipt and payment for any and all of the gas designated as "special purchase gas" to third parties through spot sales for a period of two years from the date of the first such sale. Special purchase gas is Canadian natural gas that ProGas may offer for sale to Tennessee from time to time under their gas purchase contract at a commodity charge less than the commodity charge otherwise in effect. Tennessee can buy that gas for its system supply or assign its right to purchase that gas to a third party without forfeiting its rights to credit such volumes toward its take-or-pay obligation. Tennessee asserts that this arrangement provides a more expeditious mechanism for adjusting prices to meet changing market conditions than provided for by the quarterly adjustment provisions of the contract authorized in Order 131. Tennessee's first take of special purchase gas was in August 1986, according to its first quarterly report to the ERA covering its third quarter activity under Order 131. To date, Tennessee has reported three takes of special purchase gas totaling 2,088,750 Mcf.

Tennessee requests the ERA to amend its import authorization under Order 131 by extending its authority to import special purchase gas from August 1988, through October 31, 2000, without amending any other terms and conditions of Order 131. In support of its request for a long-term extension of its blanket authorization, Tennessee asserts that ERA's justification for denial of its original request for a concurrent term with its regular supply arrangement on the basis of the experimental nature of the blanket authorization concept is no longer valid. Tennessee claims that the short-term blanket import authorization program is not as experimental as when Order 131 was issued and that it has worked well since its inception. In support of this claim, Tennessee cites an instance in 1986 when it purchased gas under its special purchase contract provision at a commodity charge of $1.30 per MMBtu that enabled Tennessee to liquidate a sizable take-or-pay obligation resulting in an actual cost of its special purchase gas of less than the $.94 per MMBtu paid for its regular purchase gas during the same period. Tennessee also claims that in March of 1988, it released up to 5,000 Mcf per day of gas to ProGas for sale to others which resulted in a $.06 per Mcf credit to Tennessee by ProGas for gas sold under that release. Tennessee further states that the availability of its special purchase gas enhances competition in the market it serves and notes that two Federal Courts of Appeals have upheld the ERA's blanket import authorization program.

The decision on this application will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of the import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. Tennessee has asserted that the volumes are needed over the requested term and that its contract provision for special gas

purchases is competitive. Parties opposing the amended arrangement bear the burden of overcoming this assertion.

All parties should be aware that, in accordance with its present policy and past practice, if the ERA approves the requested extension of the blanket authorization, it may limit the term to two years.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene, or notice of intervention, as applicable, and written comments. Any person wishing to become a party to this proceeding and to have written comments considered as a basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590.

Protests, motions to intervene, notices of interventions, requests for additional procedures, and written comments should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA–076, RG–23, Forrestall Building, 1000 Independence Ave., SW., Washington, DC 20585, (202) 586–9478. They must be filed no later than 4:30 p.m. e.d.t., September 14, 1988.

The Administrator intends to develop a decisional record on the application through responses to the notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law or policy at issue, show that it is material and relevant to a decision on the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, a final opinion and order may be issued based upon the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Tennessee's application is available for inspection and copying in the Natural Gas Division Docket Room, GA–076, at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on August 8, 1988.

Constance L. Buckley,

Acting Director, Office of Fuels Programs Economic Regulatory Administration.

[FR Doc. 88–18398 Filed 8–12–88; 8:45 am]

BILLING CODE 6450–01–M

[ERA Docket No. 88–22–NG]

Western Gas Marketing U.S.A. Ltd.; Order Granting Blanket Authorization To Import and Export Natural Gas

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Order Granting blanket authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice that it has issued an order granting Western Gas Marketing U.S.A. Ltd. (Western) blanket authorization to import natural gas from Canada and to export natural gas to Canada. The order issued in ERA Docket No. 88–24–NG authorizes Western to import up to 300 Bcf of natural gas and to export up to 100 Bcf over a two-year period for sale in the North American spot markets.

A copy of this order is available for inspection and copying in the Natural Gas Division Docket Room, GA–076, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, August 8, 1988.

Constance L. Buckley,

Acting Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88–18399 Filed 8–12–88; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. G–11587–002, et al.]

ARCO Oil and Gas Co., Division of Atlantic Richfield Co., et al.; Applications for Certificates, Abandonment of Service and Amendment of Certificates [1]

August 9, 1988.

Take notice that each of the Applicants listed herein has filed an application pursuant to section 7 of the Natural Gas Act for authorization to seel natural gas in interstate commerce, to abandon service or to amend certificates as described herein, all as more fully described in the respective applications which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before August 31, 1988, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or to be represented at the hearing.

Lois D. Cashell,

Acting Secretary.

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[1] This notice does not provide for consolidation for hearing of the several matters covered herein.

[Filing Code: A—Initial Service; B—Abandonment; C—Amendment to add acreage; D—Amendment to delete acreage; E—Total Succession; F—Partial Succession]

Docket No. and Date Filed	Applicant	Purchaser and Location	Description
G-11587-002, D, July 18, 1988	ARCO Oil and Gas Company, Division of Atlantic Richfield Company, P.O. Box 2819, Dallas, TX 75221.	Natural Gas Pipeline Company of America, Twin Field, Hansford County, Texas.	(1)
G-19544-000, B, July 18, 1988	Phillips 66 Natural Gas Company, 990-G Plaza Office Building, Bartlesville, OK 74004.	Panhandle Eastern Pipe LIne Company, South Guyman and Hugoton Fields, Sherman and Hansford Counties, Texas, and Texas County, Oklahoma.	(2)
CI63-1491-001, D, July 25, 1988	ARCO Oil and Gas Company, Division of Atlantic Richfield Company.	Panhandle Eastern Pipe LIne Company, Putnam (N.E. Trail) Field, Dewey County, Oklahoma.	(3)
CI66-701-001, CF, July 13, 1988	Tenneco Oil Company, P.O. Box 2511, Houston, TX 77252.	Tennesee Gas Pipeline Company, Urschel Field, Starr County, Texas.	(4)
CI75-227-002, D, July 20, 1988	OXY USA Inc. (formerly: Cities Service Oil and Gas Corporation), P.O. Box 300, Tulsa, OK 74102.	KN Energy, Inc., Bradshaw Field, Hamilton County, Kansas.	(5)
CI76-761-001, D, June 24, 1988	Amoco Production Company, P.O. Box 3092, Houston, TX 77253.	El Paso Natural Gas Company, Spraberry Field, Midland County, Texas.	(6)
CI78-654-001, E, July 15, 1988	Conoco Inc., P.O. Box 2197, Houston, TX 77252	Transcontinental Gas Pipe Line Corporation, East Cameron Block 57, Offshore Louisiana.	(7)
CI80-138-002, E, July 13, 1988	Conoco Inc	United Gas Pipe Line Company, High Island Block A-490, Offshore Texas.	(7)
CI88-512-000, B, June 27, 1988	TXO Production Corp., First City Center, 1700 Pacific Ave., Dallas, TX 75201.	Transcontinental Gas Pipe Line Corporation, Dunn Field, Live Oak County, Texas.	(8)
CI88-519-000 (CI66-808), B, July 7, 1988.	ARCO Oil and Gas Company, Division of Atlantic Richfield Company.	El Paso Natural Gas Company, West Waha Field, Reeves County, Texas.	(9, 10)
CI88-520-000 (CI66-639), D, July 8, 1988.	Tenneco Oil Company	Williams Natural Gas Company, Waynoka NE Field, Woods and Woodward Counties, Oklahoma.	(11)
CI88-521-000 (CI61-1429) B, July 8, 1988.	Sun Exploration and Production Company, P.O. Box 2880, Dallas, TX 75221-2880.	El Paso Natural Gas Company, Jalmat Field, Lea County, New Mexico.	(12)
CI88-522-000 (CI71-679), D, July 8, 1988.	Mobil Exploration and Producing North America Inc., Nine Greenway Plaza—Suite 2700, Houston, TX 77046-0957.	Trunkline Gas Company, OCS-G-1043, Ship Shoals 274, Field, Offshore Louisiana.	(13)
CI88-523-000 (CI69-321), D, July 11, 1988.	Sohio Petroleum Company, P.O. Box 4587, Houston, TX 77210.	Phillips Petroleum Company, West Panhandle Field, Hutchinson County, Texas.	(14)
CI88-524-000 (CI65-665), D, July 11, 1988.	....do	Panhandle Producing Company, West Panhandle Field, Hutchinson County, Texas.	(14)
CI88-525-000 (CI65-662), D, July 11, 1988.	....do	Colorado Interstate Gas Company, West Panhandle Field, Hutchinson County, Texas.	(14)
CI88-526-000 (CI65-664), D, July 11, 1988.	....do	Colorado Interstate Gas Company, West Panhandle Field, Hutchinson, Moore & Potter Counties, Texas.	(14)
CI88-527-000 (CI65-667), D, July 11, 1988.	....do	Panhandle Producing Company, *et al.*, West Panhandle Field, Hutchinson County, Texas.	(14)
CI88-528-000 (CI65-666), D, July 11, 1988.	....do	Phillips Petroleum Company, Hugoton Field, Sherman County, Texas.	(14)
CI88-529-000 (CI68-1428), D, July 11, 1988.	....do	Phillips Petroleum Company, West Pandhandle Field, Hutchinson County, Texas.	(14)
CI88-530-000 (CI69-333), D, July 11, 1988.	Sohio Petroleum Company	Phillips Petroleum Company, West Panhandle Field, Hutchinson County, Texas.	(14)
CI88-531-000 (CI69-307), D, July 11, 1988.	....do	....do	(14)
CI88-532-000 (CI69-308), D, July 11, 1988.	....do	....do	(14)
CI88-533-000 (CI78-955), B, July 14, 1988.	Tenneco Oil Company	El Paso Natural Gas Company, Reydon Field, Roger Mills County, Oklahoma.	(15)
CI88-534-000 (CI79-436), D, July 14, 1988.	Tenneco Oil Company	Lone Star Gas Company, a Division of Enserch Corporation, Golden Trend, Garvin County, Oklahoma.	(16)
CI88-536-000 (CI80-84-000), D, July 18, 1988.	GEO Oil & Gas Company of Houston, P.O. Box 2511, Houston, TX 77252.	Williston Basin Interstate Pipeline Company, Pavillion Field, Fremont County, Wyoming.	(17)
CI88-537-000 (CI80-86-000), D, July 18, 1988.	....do	KN Energy, Inc., Alkali Butte Field, Fremont County, Wyoming.	(18)
CI88-538-000 (CI80-85-000), D, July 18, 1988.	GEO Oil & Gas Company of Houston	Williston Basin Interstate Pipeline Company, Pavillion Field, Fremont County, Wyoming.	(19)
CI88-539-000 (CI76-357), B, July 18, 1988.	ARCO Oil and Gas Company, Division of Atlantic Richfield Company.	Tennessee Gas Pipeline Company, Grand Isle Block 45, Offshore Louisiana.	(20)
CI88-540-000 (CI62-1234), B, July 18, 1988.	Sun Exploration and Production Company	Phillips Petroleum Company, Amacker-Tippett Field, Upton County, Texas.	(21)
CI88-542-000 (CI68-495), D, July 26, 1988.	Tenneco Oil Company	Arkla Energy Resources, a division of Arkla, Inc., James Worth Unit and Midwest-Quick #1 well, Mansfield Field, Logan & Scott Counties, Kansas.	(22)
CI88-544-000 (CI76-331), D, July 20, 1988.	ARCO Oil and Gas Company, Division of Atlantic Richfield Company.	El Paso Natural Gas Company, Parkway West Unit, Eddy County, New Mexico.	(9)
CI88-547-000 (G-19728), D, July 22, 1988.	Tenneco Oil Company	El Paso Natural Gas Company, Andrews (Wolfcamp) South Field, Andews County, Texas.	(23, 24)
CI88-548-000 (CI66-101), D, July 22, 1988.	....do	....do	(24)

[1] ARCO assigned undeveloped acreage to Walker Exploration Company, effective December 1, 1987.
[2] The Mayers No. 1 well located in section 3-2N-17ECM, Texas County, Oklahoma, has been plugged and abandoned.
[3] ARCO assigned its interest in certain acreage under the April 18, 1963, contract comprising its FERC Gas Rate Schedule No. 274 to Meadowbrook Oil Corporation, effective October 26, 1987.
[4] Tenneco is filing to amend its certificate to add acreage acquired from Conoco Inc., effective November 1, 1986, by assignment dated January 19, 1988.
[5] Cities Service Oil and Gas Corporation, predecessor to OXY, assigned all of its remaining interest except the W/2 of section 32-22S-41W, Hamilton County, Kansas, to Ladd Petroleum Company, effective June 1, 1986.

[6] Amoco assigned its interest in the Neta Crawford lease, being all of section 43, Block A, G.G. Gray Survey, Midland County, Texas, from the surface of the earth to the base of the Wolfcamp Formation, to Five States Limited-1987, effective August 1, 1987, by assignment executed December 18, 1987.
[7] Conoco acquired certain interests from Shell Offshore, Inc., effective January 1, 1988.
[8] Dunn "B" #1 well was plugged on November 24, 1987.
[9] ARCO assigned certain acreage to Hondo Oil & Gas Company, by assignment executed February 27, 1987.
[10] The remaining leases have expired.
[11] Tenneco sold certain interests, effective December 1, 1986, to Vanguard Oil & Gas, Inc., and effective April 1, 1986, to Redgate Petroleum, Inc.
[12] All wells in this area have been plugged and abandoned. No active wells remain.
[13] Mobil assigned its interest in OCS-G-1043, covering all of Block 293, Ship Shoal Area, South Addition, Offshore Louisiana, to Shell Offshore Inc. effective September 1, 1987, by assignment executed October 5, 1987.
[14] Sohio Petroleum Company assigned certain acreage to Kim Petroleum Company, by assignment executed June 24, 1988.
[15] The only producing well was plugged and abandoned on June 9, 1983. The lease expired under its own terms.
[16] Tenneco Oil Company assigned certain acreage to Exxon Company, USA, effective December 1, 1987.
[17] GEO assigned its interest in acreage attributable to the Blankenship 4-8 well, being the E/2 Section 4-T3N-R2E, W.R.M., to Quinoco Oil and Gas Income Program 1983-2, Quinoco Oil and Gas Income Program 1983-3 and Quinoco Oil and Gas Income Program 1983-4, effective January 1, 1984, by assignment executed March 2, 1984.
[18] GEO assigned its interest in acreage attributable to the Federal #1 well, being the S/2 S/2 section 23-T34N-R95W, to Quinoco Oil and Gas Income Program 1983-2, Quinoco Oil and Gas Income Program 1983-3 and Quinoco Oil and Gas Income Program 1983-4, effective January 1, 1984, by assignment executed March 2, 1984.
[19] GEO assigned its interest in acreage attributable to the Tribal #1-22 well, being all of section 22-T3N-R2E, W.R.M., to Quinoco Oil and Gas Income Program 1983-2, Quinoco Oil and Gas Income Program 1983-3 and Quinoco Oil and Gas Income Program 1983-4, effective January 1, 1984, by assignment executed March 2, 1984.
[20] The subject lease expired April 30, 1988.
[21] All leases expired in 1963.
[22] Tenneco sold the James Worth Unit to B. J. Brown effective April 6, 1970. Tenneco surrendered the Midwest-Quick No. 1 lease to the landowners in July 1976.
[23] The W/2 of Section 30, Block 1, University Lands, Andrews County, Texas, reverted to the landowners.
[24] Tenneco assigned certain acreage to Prudential-Bache Energy Income Production Partnership IIIP-12, IIIP-13, IIIP-14, IIIP-15, VP-18, VP-19, IVP-16 and IVP-17, and Prudential-Bache Energy Production Inc., effective January 29, 1987.

[FR Doc. 88-18391 Filed 8-12-88; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. CP88-623-000]

North Penn Gas Co. v. Tennessee Gas Pipeline Co.; Complaint

August 9, 1988.

Take notice that on July 18, 1988, North Penn Gas Company (North Penn), 76-80 Mill Street, Port Allegany, Pennsylvania 16643, filed a complaint and request for summary disposition in Docket No. CP88-623-000 pursuant to Rules 206 and 217 of the Commission's Rules of Practice and Procedure (18 CFR 385.206 and 18 CFR 385.217, respectively), alleging that Tennessee Gas Pipeline Company (Tennessee) has refused to implement North Penn's request for CD reduction under § 284.10 of the Commission's Regulations.

North Penn states that on December 10, 1986, Tennessee initiated transportation under section 311 of the Natural Gas Policy Act of 1978. North Penn further states that as a result of such transportation and pursuant to then existing § 284.10 of the Commission's Regulations, North Penn formally requested Tennessee to reduce by 15 percent North Penn's sales (or CD) entitlements on the Tennessee system as of June 23, 1987.

North Penn maintains that under then existing § 284.10 of the Commission's Regulations, Tennessee was required to implement North Penn's CD reduction as of June 23, 1987, as North Penn requested. Instead, North Penn states, Tennessee notified North Penn by letter, dated July 13, 1987, of its refusal to implement the reduction request because of Tennessee's stated belief that the D.C. Circuit decision in *Associated Gas Distribution* v. *FERC*, 824 F.2d 981 (D.C. Cir. 1987) rendered ineffective North Penn's CD reduction request.

North Penn maintains that in *Interstate Pipeline Co.* v. *Natural Gas Pipeline Co.*, 41 FERC ¶61,096 (1987) and 42 FERC ¶61,049 (1988), the Commission rejected the very justification proffered by Tennessee for refusing to implement North Penn's CD reduction request. North Penn states that by letter to Tennessee, dated December 4, 1987, North Penn cited the *Interstate* decision, repeated its request for a CD reduction and asked that Tennessee refund the overcharges associated with Tennessee's failure to provide the requested reduction. North Penn states that it has on several occasions repeated its request for a CD reduction with appropriate refunds, but, to date, Tennessee has refused to comply with North Penn's request.

North Penn states that on January 29, 1988, Tennessee filed in Docket No. CP88-172, a request inter alia to abandon 15,000 Dth per day of existing firm sales service to North Penn. It is stated that Tennessee sought to condition that request on North Penn's relinquishing its right to the 15 percent reduction effective as of June 23, 1987. North Penn states that it has never agreed to give up its rights to a 15 percent reduction as of June 23, 1987; rather, it has an immediate need for substantial reductions in its Tennessee contract obligations.

In addition, North Penn states that Tennessee may soon be filing a general rate case to allow for a 5-month suspension that terminates February 1, 1989, which is the end of the 36-month period by which Tennessee must have new rates in effect pursuant to the Commission's regulations. North Penn states that it is important that Tennessee is on formal notice that North Penn's billing determinants should reflect the 15-percent CD reduction.

North Penn stresses that despite ample opportunity, Tennessee has never argued that North Penn did not qualify under Section 284.10 of the Commission's Regulations as that section existed when Tennessee became an open-access transporter and when North Penn requested a 15-percent CD reduction.

It is stated that North Penn's existing CD corresponds to its D-1 and D-2 billing determinants of 37,139 Dth and 13,555,910 Dth, respectively on the Tennessee system. It is further stated that a 15 percent reduction would reduce North Penn's D-1 and D-2 determinants to 31,568 Dth and 11,522,524 Dth, respectively. North Penn maintains that the Commission should require Tennessee to reduce North Penn's entitlement by 15 percent, effective June 23, 1987, and refund, with interest, the money Tennessee has collected since June 23, 1987, for D-1 and D-2 charges set at billing determinants in excess of 31,568 Dth and 11,522,524 Dth.

Any person desiring to be heard or to make any protest with reference to said complaint should on or before September 8, 1988, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or 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.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 88-18392 Filed 8-12-88; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3428-7]

Proposed Administrative Penalty Assessment and Opportunity to Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed administrative penalty assessment and opportunity to comment.

SUMMARY: EPA is providing notice of a proposed administrative penalty assessment for alleged violations of the Clean Water Act. EPA is also providing notice of opportunity to comment on the proposed assessment.

Under 33 U.S.C. 1319(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue such orders after the commencement of either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessments pursuant to 33 U.S.C. 1319(g)(4)(a).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment or Civil Penalties and the Revocation and Suspension of Permits, 40 CFR Part 22. The procedures through which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the procedures by which a respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty days after issuance of public notice.

On the date identified below, EPA commenced the following Class II proceeding for the assessment of penalties:

In the Matter of the County of Kauai, Department of Public Works, Wailua Sewage Treatment Plant, Wailua, Kauai, Hawaii; EPA Docket No. IX-FY88-38; filed on August 5, 1988, with James Casuscelli, Regional Hearing Clerk, U.S. EPA, Region 9, 215 Fremont St., San Francisco, California 94105, (415) 974-0718; proposed penalty up to $120,000 for discharging to Waters of the United States in violation of an NPDES permit.

FOR FURTHER INFORMATION CONTACT: Persons wishing to receive a copy of EPA's Consolidated Rules, review the complaint or other documents filed in this proceeding, comment upon a proposed assessment, or otherwise participate in the proceeding should contact the Regional Hearing Clerk identified above. The administrative record for this proceeding is located in the EPA Regional Office identified above, and the file will be open for public inspection during normal business hours. All information submitted by the respondent is available as part of the administrative record, subject to provisions of law restricting public disclosure of confidential information. In order to provide opportunity for public comment, EPA will issue no final order assessing a penalty in these proceedings prior to thirty days after the date of publication of this notice.

Dated: August 5, 1988.

Harry Seraydarian,

Director, Water Managment Division.

[FR Doc. 88-18377 Filed 8-12-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL HOME LOAN BANK BOARD

[No. 88-655]

FSLIC Statement of Policy and Criteria on Assistance to Insured Institutions Absent a Requirement for an Immediate Merge Acquisition by a Third Party

Date: August 4, 1988.

AGENCY: Federal Home Loan Bank Board.

ACTION: The Federal Home Loan Bank Board (the "Board"), as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC"), is adopting a Policy Statement setting forth the criteria that will be used in providing assistance to certain insured institutions under circumstances where an immediate merger with or acquisition by a third party is not required. This Policy Statement is intended to provide guidance regarding the Board's policy in this area, the eligibility requirements for this type of assistance, and the administration of this policy.

EFFECTIVE DATE: August 12, 1988.

FOR FURTHER INFORMATION CONTACT: James A. Meyer, Financial Assistance Division, (202) 254-2427, Federal Savings and Loan Insurance Corporation, 801 17th Street, NW., Washington, DC 20006; or Richard B. Foley, Attorney, Office of General Counsel, (202) 377-7393, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: The Board as the operating head of the FSLIC is authorized, pursuant to section 406(f) of the National Housing Act ("NHA"), 12 U.S.C. 1729(f), including but not limited to the amendments to NHA Section 406(f) made by section 405 of the Competitive Equality Banking Act of 1987, Pub. L. No. 100-86, 101 Stat. 552, 613-614 (1987), to provide various types of assistance to FSLIC-insured institutions under certain conditions. Assistance may be provided directly to the institution to prevent its default or to facilitate the merger/acquisition of an association by another entity financially able to acquire the failing institution. In order for the FSLIC to provide assistance, either the amount of the assistance must be less than the cost of liquidating, including paying the insured accounts of the institution, or the FSLIC must determine that the continued operation of the institution is essential to provide adequate savings or home financing services in its community. The Board is publishing the following Statement of Policy and Criteria to provide guidance regarding this type of assistance under certain conditions.

Statement of policy and criteria: This Statement of Policy and Criteria is issued to set out the general terms and conditions the Board believes are appropriate if the FSLIC is to provide assistance to an operating FSLIC-insured institution to prevent its default or to minimize the risk to the FSLIC, absent an immediate merger/acquisition by a third party. The objectives of providing assistance to an operating institution are as follows:

A. For an institution near insolvency, where FSLIC financial assistance will be necessary to prevent a default and the problems of the institution have been identified and are containable, to facilitate earlier resolution of the problem to lessen the cost to FSLIC; and

B. For an already insolvent institution, where a determination has been made that FSLIC assistance is necessary to resolve the case and an immediate acquisition by a third party is not feasible, to provide assistance to stabilize the institution pending a subsequent resolution action or to facilitate the rehabilitation of the institution. The rehabilitation option will include appropriate ownership incentives for approved management that will be undertaking the recovery effort in conjunction with the FSLIC. The Board anticipates approval of assistance to insolvent institutions will often be

accompanied by consolidations in order to take advantage of economies of scale.

Assistance intended for near insolvent institutions should meet the following guidelines unless the Board determines that there are compelling reasons justifying the contrary:

(1) The estimated cost to the FSLIC clearly must be less than other readily available options. The cost analyses should reflect the future risk each available case resolution option represents for the FSLIC.

(2) Adequate managerial resources, sufficient projected capitalization, and a reasonable assurance of the future profitability of the institution must be provided for. A key determinant of sufficient projected capitalization should be compliance with the Board's capital regulations at a specified future date.

(3) Assistance must be accompanied by significant capital infusions from the stockholders and/or other non-FSLIC sources.

(4) Assistance must benefit the institution and the FSLIC and not be diverted to other purposes.

(5) The review, renegotiation, or termination of management contracts should be expected prior to the granting of assistance. Continued service of all directors, officers serving in a policy-making role, and other officers of the assisted institution, as may be designated by the FSLIC, will be subject to approval by the FSLIC. Further, the FSLIC will review and must approve any or all parts of any new compensation packages or termination agreements covering these individuals throughout the period assistance is outstanding.

(6) Common shareholders and holders of subordinated debt and/or preferred stock of the failing institution must agree to subordinate to the interests of the FSLIC represented by its direct financial assistance until it has been repaid. Until the assistance has been repaid, no dividends or payments on subordinated debt/preferred stock will be permitted absent FSLIC approval. FSLIC approval for dividends in advance of total repayment of assistance would generally be limited to new capital and equity positions taken by the FSLIC.

(7) If acceptance of an equity position (such as preferred stock) is necessary, the FSLIC will receive a return on equity satisfactory to the FSLIC. The FSLIC is not permitted to own voting or common stock of an insured institution.

(8) Any direct FSLIC assistance should be repaid with interest. As additional compensation or repayment for the assistance and risk, the FSLIC will expect to receive warrants to purchase common stock or some other appropriate form of compensation.

(9) If the assisted institution is a subsidiary of a holding company, dividends, interest payments, compensation, etc., would not be permitted to flow from the insured institution to the holding company without prior FSLIC approval until all assistance has been repaid in full. The holding company should make a significant contribution toward minimizing the financial exposure of the FSLIC.

(10) The FSLIC and the Office of Regulatory Activities ("ORA"), or their designee, have the right to approve/disapprove the institution's business plans and budgets.

(11) The institution would agree to accept FSLIC notes and/or other assets of the FSLIC for the payment of assistance.

(12) The institution must execute a "pre-nuptial" or net worth maintenance agreement with the FSLIC consenting to a merger/acquisition or the appointment of a receiver/conservator should the assistance efforts fail to restore the institution to viability.

(13) The institution would be expected to pursue claims against individuals or entities associated with or performing services for the institution to the satisfaction of the FSLIC and with the guidance of the Board's Office of General Counsel, including, without limitation, claims against directors, officers, employees, agents, stockholders, controlling persons, bonding and insurance companies, accountants, appraisers, attorneys, investment bankers or brokers, and securities dealers. However, the association must provide the FSLIC with the option of assuming and pursuing at any time, on its own initiative, such claims of the institution. Recoveries by the FSLIC would be used to offset assistance paid to the institution and other costs, including costs incurred in pursuing such claims.

(14) Fee arrangements for attorneys, investment bankers, consultants, and other advisors incident to requests for FSLIC assistance pursuant to this statement of policy must be disclosed to the FSLIC and will be evaluated in determining the cost of assistance to the FSLIC. Excessive fees must be avoided, and in no instance should the payment of any fee be contingent upon the level of financial assistance approved by the FSLIC.

Assistance necessary to stabilize the institution pending a subsequent resolution action or to facilitate the rehabilitation of insolvent institutions when an immediate merger/acquisition by a third party is not feasible should meet the following guidelines unless the Board determines that there are compelling reasons justifying the contrary:

(1) The estimated cost to the FSLIC clearly must be less than other readily available options. The cost analyses should reflect the future risk each available case resolution option represents for the FSLIC.

(2) The FSLIC would be appointed as receiver and substantially all of the institution's assets and liabilities would be transferred by the receiver to a *de novo* institution. The receiver would transfer to the FSLIC in its corporate capacity claims against individuals or entities associated with or performing services for the institution, including, without limitation, claims against directors, officers, employees, agents, stockholders, controlling persons, bonding and insurance companies, accountants, appraisers, attorneys, investment bankers or brokers, and securities dealers.

(3) Adequate managerial resources, sufficient projected capitalization, and a reasonable assurance of the future profitability of the institution once the assistance effort is complete must be provided for. The key determinant of sufficient projected capitalization should be that the rehabilitated institution meet the Board's regulatory capital requirements at the conclusion of the rehabilitation assistance program.

(4) The resulting *de novo* institution would be operated under safeguards designed for the protection of the FSLIC. Incentives should be structured for management undertaking the recovery effort in conjunction with the FSLIC that mirror the interests of the FSLIC. For example, management could be rewarded by an ownership interest in the institution that grows as the rehabilitation program progresses. Additionally, management would be encouraged to invest a nominal amount of their own funds in the institution.

(5) If the resulting *de novo* is a stock institution, the FSLIC would retain an substantial equity position in the institution via warrants and/or convertible preferred stock (the FSLIC cannot own voting or common stock). The FSLIC would be able to sell its ownership position to third parties at a later date. The rehabilitation should encourage the infusion of new private capital through private or public offerings of common stock and/or the sale of the FSLIC's equity interests as a way to expedite the rehabilitation of the institution with private capital.

(6) The FSLIC and the ORA, or their designee, have the right to approve/disapprove officers, directors, compensation, business plans, and budgets of the institution during the term of the rehabilitation assistance agreement.

(7) The institution would accept FSLIC notes and/or other assets of the FSLIC for the payment of assistance.

(8) The rehabilitation effort should involve the consolidation of other insolvent institutions to achieve the benefits of economies of scale.

(9) Management responsible for the institution's insolvency shall be replaced with new management approved by the FSLIC.

(10) The institution must execute a "pre-nuptial" agreement with the FSLIC consenting to a merger/acquisition or the appointment of a receiver/conservator should the assistance efforts fail to restore the institution to viability.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-18406 Filed 8-12-88; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86P-0510]

Canned Green Beans Deviating From Identity Standard; Extension and Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension and amendment of a temporary permit issued to Truitt Bros., Inc., to market test experimental packs of canned green beans containing added zinc chloride. These actions will allow the permit holder to continue experimental market testing of the product while the agency takes action on the permit holder's petition to amend the standard of identity for canned green beans.

DATE: The new expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

FOR FURTHER INFORMATION CONTACT: Catharine R. Calvert, Center for Food Safety and Applied Nutrition (HHF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0121.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Truitt Bros., Inc., P.O. Box 309, Salem, OR 97308, to market test canned green beans containing added zinc chloride to retain the color of the test product (up to 75 parts per million of zinc in the finished food). The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Truitt Bros., Inc., was published in the **Federal Register** of January 21, 1987 (52 FR 2297).

Truitt Bros., Inc., has requested that the temporary permit be extended so the market test period can continue while agency action on a petition to amend the standard of identity for canned green beans proceeds. The permit holder also requested that their existing temporary permit be amended to provide for market testing on an annual basis of 50,000 cases containing six No. 10 (603 X 700) cans each of the test product. These quantities are in addition to the 50,000 cases of No. 10 cans of the test product provided for by the existing permit, but which have not been distributed.

Truitt Bros., Inc., in accordance with 21 CFR 130.17(i), submitted a petition to amend 21 CFR 155.120 at the same time the application for extension was submitted. FDA is inviting interested persons to participate in the market test under the conditions that apply to Truitt Bros., Inc., including the labeling requirements and the amounts of test product to be distributed, except that the designated area of distribution shall not apply.

Any person who wishes to participate in the extended market test must notify, in writing, the Acting Director, Division of Food Chemistry and Technology (HHF-410), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The notification must include the amount of test product to be distributed, the area of distribution, and the labeling that will be used for the test product (i.e., a label for each size of container and each brand of product to be test marketed).

Therefore, under the provisions of 21 CFR 130.17(i), FDA is extending the expiration date of the permit such that the permit expires either on the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking. All other conditions and terms of this permit remain the same.

Dated: July 29, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-18328 Filed 8-12-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86P-9369]

Canned Pacific Salmon Deviating From Identity Standard; Extension of Temporary Marketing Permit

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the expiration date of a temporary permit to market test canned skinless and boneless chunk salmon packed in water is being extended. This extension will allow the permit holder to continue experimental market testing of the product while the agency takes action on the permit holder's petition to amend the standard of identity for canned Pacific salmon.

DATE: The new expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Bumble Bee Seafoods, Inc., San Diego, CA 92123, to market test canned skinless and boneless chunk salmon packed in water to test consumer acceptance of the new style pack. The permit was issued to facilitiate market testing of foods that deviate from the requirements of the standard of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Bumble Bee Seafoods, Inc., was published in the **Federal Register** of September 16, 1986 (51 FR 32844).

Bumble Bee Seafoods, Inc., has requested that the temporary permit be extended so the market test period can continue while agency action on a

petition submitted by the National Food Processors Association (NFPA) to amend the canned Pacific salmon standard proceeds. The petition was submitted by NFPA on behalf of Bumble Bee Seafoods, Inc., and the other salmon packers holding temporary permits. FDA has concluded that it is in the interest of consumers to issue the extension. FDA is inviting interested persons to participate in the market test under the conditions that apply to Bumble Bee Seafoods, Inc., including the labeling requirements and the amounts of test product to be distributed, except that the designated area of distribution shall not apply. Any interested person who wishes to participate in the market test must notify, in writing, the Acting Director, Division of Food Chemistry and Technology (HFF–410), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The notification must include the amount of test product to be distributed, the areas of distribution, and labeling that will be used for the test product.

Therefore, FDA is extending the expiration date of the permit such that the permit expires either in the effective date of a final rule for any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal. All other conditions and terms of this permit remain the same.

Dated: July 29, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–18330 Filed 8–12–88; 8:45 am]

BILLING CODE 4160–01–M

Salmonella Enteritidis in Shell Eggs; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to exchange information on the problem of egg-associated *Salmonella enteritidis* infections in the United States.

DATE: Thursday, September 15, 1988, 1 p.m. to 5 p.m.

ADDRESS: Auditorium, Hubert H. Humphrey Bldg., 200 Independence Avenue, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Thomas L. Schwarz, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–485–0140.

SUPPLEMENTARY INFORMATION: FDA is announcing a public meeting to provide a forum for exchanging information on the problem of egg-associated *Samonella enteritidis* infections in the United States. This meeting will primarily focus on public health issues. Consideration will be given to domestic and worldwide epidemiologic data, scientific knowledge about the *Salmonella enteritidis* organism, analytical methodology, safe food handling and cooking recommendations, and related topics.

Salmonella enteritidis outbreaks have been concentrated in the Northeastern United States, but now appear to be spreading to other areas. FDA needs to learn more about this geographic change. FDA also needs information about affected groups or individuals in order to consider appropriate intervention programs in the future. Additionally, the agency is seeking data relative to the producing hens, such as information on the transmission of *Salmonella enteritidis* between birds, serological testing of laying hens, and various sampling protocols.

FDA is inviting representatives of the egg industry and other interested parties to participate. FDA anticipates that the information presented at this meeting will enable the agency to more full understand all of the public health issues associated with *Salmonella enteritidis* in shell eggs.

Dated August 8, 1988.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–18329 Filed 8–12–88; 8:45 am]

BILLING CODE 4160–01–M

Health Resources and Services Administration

Program Announcement and Proposed Funding Priorities for Grants for Graduate Training in Family Medicine

The Health Resources and Services Administration announces that applications for Fiscal Year 1989 Grants for Graduate Training in Family Medicine are being accepted under the authority of section 786(a) of the Public Health Service Act, as amended by Pub. L. 99–129 and invites comments on the proposed funding priorities stated below.

Section 786(a) authorizes the Secretary to make grants to public or nonprofit private hospitals, accredited schools of medicine or osteopathy, and other public or private nonprofit entities to assist in meeting the cost of planning, developing and operating or participation in approved graduate trraining programs in the fields of family medicine. In addition, section 786(a) authorizes assistance in meeting the cost of supporting trainees in such programs who plan to specialize or work in the practice of family medicine.

Legislative authorization for this program expires September 30, 1988. For FY 1989 the Administration is proposing to consolidate the various health professions categorical programs into a single, flexible authority. This announcement is being made in the event that the Graduate Training in Family Medicine Program is reauthorized and funds are made available in FY 1989. Publication of this notice is a contingency measure that will assure that grants can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year.

In addition, programmatic changes may result from currently pending legislative action. Should such changes be necessary, all applicants will be notified at a later date.

To receive support, programs must meet the requirements of regulations as set forth in 42 CFR Part 57, Subpart Q.

Review Criteria

The review of applications will take into consideration the following criteria:

(1) The degree to which the proposed project provides for the project requirements;

(2) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner; and

(3) The potential of the project to continue on a self-sustaining basis.

Proposed Funding Priorities

In determining the order of funding of approved applications it is proposed to give a funding priority to the following:

(1) Projects which satisfactorily demonstrate a net increase in enrollment of underrepresented minorities in proportion or more to their numbers in the general population or can document extent of demonstration net increase of underrepresented minorities (i.e. Black, Hispanic and American Indian/Alaskan Native) over average enrollment of the past three years in postgraduate year (PGY) trainee.

These population groups continue to be underrepresented in the medical profession and have insufficient access to primary medical care. Their representation should be increased to

ensure equitable opportunities to a career in medicine and equal access to health care services. Studies show that minority physicians provide a greater proportion of health care for medically underserved populations than other United States physicians. Therefore, this funding priority is designed to increase the number of underrepresented minority physicians.

(2) Projects in which the substantial training experience is in a PHS 332 health manpower shortage area and/or PHS 329 migrant health center, PHS 330 community health center or PHS 781 funded Area Health Education Center or State designated clinic/center serving an underserved population. Section 329 authorizes support for migrant health facilities nationwide and comprises a network of health care services for migrant and seasonal farm workers. Section 330 of the Public Health Service Act is the authority which supports community health centers providing primary health services to persons located in rural and urban areas with financial and/or geographic barriers to care. Section 781 authorizes a national program to support area health education centers and projects to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system. There are estimated 1,931 health manpower shortage areas with an estimated underserved population of 12,847,023. An estimated 4,139 primary medical practitioners are needed to remove these areas from the shortage designation.

These designations include geographic areas, population groups and facilities. The proposed funding priority is designed to provide trainees with substantial training in health manpower shortage areas, community health centers, migrant health centers, and State facilities serving underserved population. An applicant applying for this priority through a State or local designation must have written documentation from the appropriate State or local authority responsible for designating health personnel shortages for geographic areas, population groups and/or facilities. This documentation must indicate that the designated geographic areas, population groups, and/or facilities are part of a State or local plan to increase service access to underserved populations. These experiences are expected to have a positive influence on the selection of practice locations of such trainees. The application of this funding priority is also to provide a more integrated federal strategy to the implementation of health professions assistance and primary health service programs.

(3) Applications proposing to develop, expand or implement curricula concerning ambulatory and impatient case management of HIV/AIDS patients.

Health professionals are increasingly required to provide a wide range of services to HIV-infected persons. However, widespread organized curricula offerings for these trainees are not in place. The proposed priority is designed to encourage new offerings.

(4) Applications which are innovative in their educational approaches to quality assurance/risk management activities, monitoring and evaluation of health care services and utilization of peer-developed guidelines and standards. Assuring quality in the health care system is increasingly becoming the responsibility of health care providers. The proposed funding priority is designed to encourage increased emphasis on the principles and methods of health care quality assurance and risk management in the continuum of the health professions educational process.

(5) Applications proposing to provide substantial multidisciplinary geriatric training experiences in multiple ambulatory settings and inpatient and extended care facilities.

The population 65 years of age and over will increase about 2 percent a year between now and 2020 (compared to an increase of less than 1 percent for younger persons). The oldest old (85-plus) segment of the population will experience the most rapid growth before 200. The youngest old (65–74) segment will increase fastest between 2000 and 2020. The older population will require expansion of a wide range of health services, including preventive, primary, long-term, hospice, and rehabilitation care. However, health providers lack adequate training needed to care for this aging population.

The proposed funding priority is designed to provide increased emphasis on geriatrics training for all health professions trainees in the continuum of their training.

Interested persons are invited to comment on the proposed funding priorities. Normally, the comment period would be 60 days. However, due to the need to implement any changes for the Fiscal Year 1989 award cycle, this comment period has been reduced to 30 days. All comments received on or before September 14, 1988 will be considered before the final funding priorities are established. No funds will be allocated or final selections made until a final notice is published stating whether the final funding priorities will be applied.

Written comments should be addressed to: Director, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 4C–25, 5600 Fishers Lane, Rockville, Maryland 20857.

All comments received will be available for public inspection and copying at the Division of Medicine, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

Requests for application materials and questions regarding grants policy should be directed to: Grants Management Officer (D–15), Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C–22, Rockville, Maryland 20857, Telephone (301) 443–6960.

If additional programmatic information is needed, please contact: Primary Care Medical Education Branch, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 4C–04, Rockville, Maryland 20857, Telephone (301) 443–6820.

The standard application form PHS 6025–1, HRSA Competing Training Grant Application, General Instructions and supplement for this program have been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915–0060.

The deadline date for receipt of applications is September 30, 1988. 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 and received in time for submission to the independent review group. 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.

Applications received after the deadline will be returned to the applicant.

This program is listed at 13.379 in the *Catalog of Federal Domestic Assistance*. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR Part 100).

Dated: August 9, 1988.

John H. Kelso,

Acting Administrator.

[FR Doc. 88-18332 Filed 8-12-88; 8:45 am]

BILLING CODE 4160-15-M

Program Announcement and Proposed Funding Priority for Grants for Predoctoral Training in Family Medicine

The Health Resources and Services Administration announces that applications for Fiscal Year 1989 Grants for Predoctoral Training in Family Medicine are being accepted under the authority of section 786(a) of the Public Health Service Act, as amended by Pub. L. 99-129 and invites comments on the proposed funding priority stated below.

Section 786(a) of the Public Health Service Act authorizes the award of grants to assist in meeting the cost of planning, developing and operating or participating in approved predoctoral training programs in the field of family medicine. Grants may include support for the program only or support both the program and the trainees.

Legislative authorization for this program expires September 30, 1988. For FY 1989 the Administration is proposing to consolidate the various health professions categorical programs into a single, flexible authority. This announcement is being made in the event that the Predoctoral Training in Family Medicine Program is reauthorized and funds are made available in FY 1989. Publication of this notice is a contingency measure that will assure that grants can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year.

In addition, programmatic changes may result from currently pending legislative action. Should such changes be necessary, all applicants will be notified at a later date.

To receive support, programs must meet the requirements of regulations as set forth in 42 CFR Part 57, Subpart Q. Eligible applicants are accredited public or nonprofit private schools of medicine or osteopathic medicine.

Review Criteria

The review of applications will take into consideration the following criteria:

(1) The potential effectiveness of the proposed project in carrying out the training purposes of section 786(a) of the Act;

(2) The degree to which the proposed project adequately provides for the project requirements;

(3) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner; and

(4) The potential of the project to continue on a self-sustaining basis after the period of grant support.

Proposed Funding Priority

In determining the order of funding of approved applications, it is proposed to give a funding priority to:

Projects in which substantial training experience is in a PHS 332 health manpower shortage area and/or PHS 329 migrant health center, PHS 330 community health center or PHS 781 funded Area Health Education Center or State designated clinic/center serving an underserved population. Section 329 authorizes support for migrant health facilities nationwide and comprises a network of health care services for migrant and seasonal farm workers. Section 330 of the Public Health Service Act is the authority which supports community health centers providing primary health services to persons located in rural and urban areas with financial and/or geographic barriers to care. Section 781 authorizes a national program to support area health education centers and projects to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system.

There are an estimated 1,931 health manpower shortage areas with an estimated underserved population of 12,847,023. An estimated 4,139 primary medical practitioners are needed to remove these areas from the shortage designation. These designations include geographic areas, population groups and facilities. The proposed funding priority is designed to provide trainees substantial training in health manpower shortage areas, community health centers, migrant health centers, and State facilities serving underserved populations. An applicant applying for this priority through a State or local designation must have written documentation from the appropriate State or local authority responsible for designating health personnel shortages for geographic areas, population groups and/or facilities. This documentation must indicate that the designated geographic areas, population groups, and/or facilities are part of a State or local plan to increase service access to underserved populations.

These experiences are expected to have a positive influence on the selection of practice locations of such trainees. The application of this funding priority is also to provide a more integrated federal strategy to the implementation of health professions assistance and primary health service programs.

Interested persons are invited to comment on the proposed funding priority. Normally, the comment period would be 60 days. However, due to the need to implement any changes for the Fiscal Year 1989 award cycle, this comment period has been reduced to 30 days. All comments received on or before September 14, 1988, will be considered before the final funding priority is established. No funds will be allocated or final selections made until a final notice is published stating whether the final funding priority will be applied.

Written comments should be addressed to: Director, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 4C-25, 5600 Fishers Lane, Rockville, Maryland 20857.

All comments received will be available for public inspection and copying at the Division of Medicine, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

Requests for application materials and questions regarding grants policy should be directed to: Grants Management Officer (D-15), Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C-22, Rockville, Maryland 20857, Telephone: (301) 443-6960.

If additional programmatic information is needed, please contact: Primary Care Medical Education Branch, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 4C-04, Rockville, Maryland 20857, Telephone: (301) 443-6820.

The standard application form PHS 6025-1, HRSA Competing Training Grant Application, General Instructions and supplement for this program have been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915-0060.

The deadline date for receipt of applications is October 14, 1988. Applications should be considered as meeting the deadline date if they are either:

(1) *Received on* or before the deadline date, or

(2) *Postmarked on* or before the deadline and received in time for submission to the independent review group. 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. Applications received after the deadline will be returned to applicant.

This program is listed at 13.986 in the *Catalog of Federal Domestic Assistance.* It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR Part 100).

Dated: August 9, 1988.

John H. Kelso,

Acting Administrator.

[FR Doc. 88-18331 Filed 8-12-88; 8:45 am]

BILLING CODE 4160-15-M

Public Health Service

Privacy Act of 1974; New System of Records

AGENCY: Public Health Service, HHS.

ACTION: Notification of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) is publishing a notice of a proposal to establish a new system of records: 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/OHA." The purposes of this system of records are to determine the public health impact of exposure or potential exposure to toxic and hazardous substances, and to establish and maintain registries of such exposed persons and the serious diseases associated with these exposures. We are also proposing routine uses for this system of records.

DATES: PHS invites interested parties to submit comments on the proposed internal and routine uses on or before September 14, 1988. PHS has sent a Report of a New System to the Congress and to the Ofice of Management and Budget (OMB) on August 8, 1988. PHS has requested that OMB grant a waiver of the usual requirement that the system of records not be put into effect until 60 days after the report is sent to OMB and Congress. If this waiver is granted, PHS will publish a notice to that effect in the **Federal Register.** The routine uses will be effective September 14, 1988, unless PHS receives comments which would result in a contrary determination.

ADDRESS: Comments should be addressed to the Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Privacy Act Coordinator at the address listed below. Because CDC provides administrative support to ATSDR, the CDC Privacy Act Coordinator also serves as the ATSDR Privacy Act Coordinator. Comments received will be available for inspection Monday through Friday, between 9 a.m. and 3 p.m. in the Buckhead Facility, Room 500, at that address.

FOR FURTHER INFORMATION CONTACT: Joseph E. Salter, Alternate Privacy Act Coordinator, Centers for Disease Control/Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, Buckhead, Room 500, Mailstop E11, Atlanta, Georgia 30333, (404) 842-6720. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: ATSDR proposes to establish a new system of records: 09-19-0001 "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/OHA."

Records in this system will assist ATSDR in fulfilling its legislated public health functions by:

(1) Employing pilot studies [1] (including exposure studies, symptom and disease prevalence studies, cluster investigations), epidemiologic studies, and other public health investigations to identify the possible deleterious effects on humans of exposure to toxic and hazardous substances; and

(2) Establishing and maintaining national registries [2] of persons exposed to toxic substances and persons with serious diseases associated or potentially associated with exposure to toxic substances, informing them of pertinent health information, and serving as a focal point for toxic exposure research data.

Death certificate information will be used to evaluate the possible relationship of cause of death to exposure to hazardous substances. The data may also be examined to validate reported causes of death. If it is determined that excess mortality is occurring among individuals exposed to toxic or hazardous substances, similarly exposed persons will be notified. State or local health departments may provide physician records or private physicians themselves may seek consultation with ATSDR. This information would be used to evaluate the morbidity or mortality experience of persons exposed to hazardous substances, validate self-reported cases of disease, or to determine numbers of cases of a disease occurrence. Other previously collected medical information may also be provided by State or local health departments, the Environmental Protection Agency (EPA), and other Federal agencies. This information may have been collected as part of a health study or investigation for which ATSDR is being requested to provide assistance.

Approximately 8,000 individuals will probably take part in pilot studies each year. Of these, 2,000 will be involved in exposure studies, 5,000 in symptom and disease prevalence studies, and 1,000 in cluster investigations. There will be approximately 5,000 persons in epidemiologic studies. A portion of individuals involved in pilot studies or epidemiologic studies along with other cohorts [3] identified by other Federal and State investigations will participate in ATSDR registries.

At present, the National Exposure Registry is planned with data collection to begin at two sites (approximately 500 persons per site) in 1988. In 1989, six sites and updating of previous sites are planned. The sites likely to be considered for the establishment of a subregistry include all sites listed on EPA's National Priorities List (NPL), non-NPL sites on which epidemiologic/pilot studies may have been conducted, landfills, sites with contaminated drinking water or soil, and sites of emergency activities.

ATSDR, and its contractors, working with State and local health professionals, will identify eligible participants for the subregistry on the basis of documented environmental exposure to the toxicants of interest. Potentially exposed persons (current and past) will be identified using tax rolls, city directories, telephone books, school enrollment, rental and employment records, and self-reporting. Individuals with documented exposures will be contacted and asked to voluntarily participate in the subregistry and to agree to routine releases of data.

The records will include, at a minimum, core demographic information (i.e., name, sex, length of time at current address, current and past occupations, life style factors such as smoking history), the level and length of exposure for each substance, the pathway of

[1] Pilot studies are limited evaluations of a defined population to determine if the extent of exposure to hazardous substances and possible adverse health effects warrant a comprehensive epidemiologic investigation or establishment of a subregistry.

[2] A registry is defined as a system for collecting and maintaining in a structured record, information on specific persons from a defined population.

[3] A *cohort* is defined as a group of individuals having a statistical factor in common in a demographic study, i.e., exposure to a specific substance, geographic area of residence, etc.

exposure (i.e., air, water, soil, etc.), the route of exposure (i.e., inhalation, ingestion, etc.), and additional existing data or medical records that may be available. The specific study or subregistry will determine the specific types of records collected and maintained.

Pilot studies and registry establishment will involve scientists on the staff of ATSDR, the Centers for Disease Control (CDC), and other researchers working under contracts awarded by ATSDR. These contracts may include: (1) Locating exposed or potentially exposed individuals; (2) conducting interviews; and (3) collecting blood and urine specimens, or performing medical examinations. In addition, Registry contracts will entail providing for annual followup of registrant participants to update information on file and to possible advise of new scientific information regarding health effects, preventive measures, or breakthroughs in treatment of environmentally caused illnesses unavailable at the time the registry was originally established. CDC staff will participate in collaborative efforts and may perform statistical analysis.

ATSDR will collect and manage all data in a manner to safeguard any identifying information. Stringent safeguards will be developed to prevent inadvertent disclosure of any data, as described in the system notice.

ATSDR will require that Privacy Act provisions appear in any contracts which involve the collection of identifying information. Such contracts will specify the appropriate safeguards to be employed in the performance of the contract, and the disposition of records when the contract is completed.

ATSDR has examined a number of alternative means of accomplishing the program requirements, including the option to maintain no Privacy Act system of records. Considering the potentially large number of individual records that may be involved in carrying out the environmental mandates of ATSDR, it was concluded that it would be impossible to carry out the required activities without collecting individual identifiers. Name and Social Security number (supplied voluntarily) will be some of the indices used to retrieve records from the system. Other retrieval methods (such as by toxic substance) may be used as individual survey or subregistry dictates.

ATSDR is proposing seven routine uses which will support ATSDR's efforts to carry out its legislative mandate efficiently and effectively. Proposed routine use #1 which permits disclosure of information to contractors to enable them to locate, interview, collect biological samples from or perform medical examinations on individuals will be necessary to gather information about the potential exposure of persons to toxic and hazardous substances. This routine use will also be necessary to enable ATSDR to establish and maintain national registries of persons exposed to toxic substances and of persons with diseases associated with such exposures.

Proposed routine use #2 which permits disclosures of records to other Federal agencies and State or local health officials for collaborative efforts is intended to enable ATSDR to more effectively conduct its studies, to avoid duplication of study efforts and to facilitate the location of individuals for followup surveys and any necessary treatment. This routine use will also satisfy mandatory reporting requirements when applicable. These disclosures are compatible with the system's purposes to identify the extent of the health threat posed by exposure to hazardous substances.

Proposed routine use #3 permitting disclosure of records to other Federal agencies is intended to aid in locating individuals exposed to hazardous substances. The frequent relocation of families mandates that all sources of information be utilized to ensure an adequate assessment of initially exposed individuals who may no longer be residing near the contaminated site.

Proposed routine use #4 permits data sharing for research purposes. It is anticipated that data from pilot studies, epidemiologic studies, and establishment of subregistries will be of significant interest to members of the research community interested in the possible connection between health problems and exposure to hazardous substances. While ATSDR wishes to share data and avoid duplication of study efforts, the agency is also committed to protecting the integrity of the data collected.

Proposed routine use #5 permits disclosure to members of Congress for the purpose of allowing subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure will be made only at the explicit request of the individual.

Proposed routine use #6 permits ATSDR to disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department of Justice to effectively represent the agency. This disclosure would be necessary in the event of litigation initiated at the request of EPA in collaboration with ATSDR to recover costs of cleanup operations associated with Superfund or Resource Conservation and Recovery Act enforcement.

Proposed routine use #7 which permits disclosure of records to the Department of Justice for litigation defense purposes will enable the Department of Justice to represent ATSDR in litigation arising from program activities/operations related to investigations of the health effects of exposure to hazardous substances.

The following notice is written in the present, rather than the future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: August 9, 1988.

Wilford J. Forbush,

Deputy Assistant Secretary for Health Operations and Director, Office of Management.

09-19-0001

SYSTEM NAME:

Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/OHA.

SYSTEM CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Health Assessment (OHA), Agency for Toxic Substances and Disease Registry, Chamblee Building 28N, 1600 Clifton Road, Atlanta, GA 30333;

Office of External Affairs (OEA) Agency for Toxic Substances and Disease Registry, Chamblee Building 2 S, 1600 Clifton Road, Atlanta, GA 30333; and

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

Data are also located at contractor sites. A list of contractor sites where individually identified data are currently located is available upon request to the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals exposed or potentially exposed to toxic or hazardous substances may include the following: (1) Selected persons living or having lived near a hazardous waste site; (2) Persons exposed or potentially exposed to environmental hazards resulting from ingestion of contaminated drinking water, persons exposed to contaminated soil, persons living on mining wastes, persons inhaling toxic substances (all of which may or may not be the result of

contamination by a specified waste site); (3) Participants in pilot studies (including exposure studies, symptom and disease prevalence studies, cluster investigations), and epidemiologic studies to determine the public health threat of exposure to hazardous or toxic substances; (4) Registry participants with exposures associated with sites listed on the Environmental Protection Agency's (EPA) National Priorities List (NPL), non-NPL sites on which epidemiologic or pilot studies may have been conducted, sites of emergency activities, and other toxic waste sites proposed by concerned citizens; (5) Registry participants with diseases associated or potentially associated with exposure to toxic or hazardous substances; (6) Persons working or having worked in response actions at hazardous waste sites or other occupational settings where exposure to hazardous substances occurred. The first five categories of persons above may include children as well as adults.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, address, (including length of time at current address), telephone number, date of birth, Social Security number, sex, current and past occupations, dates, pathways and routes of toxic or hazardous substance exposure or potential exposure, smoking history, results of medical and laboratory tests, records on biological specimens (e.g. blood, urine, etc.), and related documents such as questionnaire responses. The specific type of records collected and maintained is determined by the needs of the individual registry or study.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Comprehensive Environmental Response, Compensation, and Liability Act of 1980" as amended by "Superfund Amendments and Reauthorization Act of 1986" (42 U.S.C. 9601, 9604); and the "Resource Conservation and Recovery Act of 1976" as amended in 1984 (42 U.S.C. 6901).

PURPOSES:

Records in this system are used to carry out the legislated environmental public health mandates of the Agency for Toxic Substances and Disease Registry (ATSDR). Specifically this information is used to: (1) Identify the public health threat caused by exposure to toxic and hazardous substances utilizing pilot studies, epidemiologic studies, and other health effects studies; and (2) establish and maintain national registries of persons exposed to toxic substances and persons with serious diseases and illnesses associated or potentially associated with exposure to toxic substances. Registries will have the additional purposes of tracking exposed individuals, keeping them informed of health effects of exposure, preventive measures and possible breakthroughs in treatment, along with serving as a centralized location for research data on these exposed individuals.

Records may be disclosed to the Center for Environmental Health and Injury Control, Centers for Disease Control, for laboratory analysis of samples and for collaborative efforts (i.e., providing staff, performing statistical analysis, etc.) in coordinating investigations. Records (i.e., name, Social Security number, date of birth) may be disclosed to the National Center for Health Statistics to obtain a determination of vital status. Death certificates with the cause of death will then be obtained from Federal, State, or local agencies to enable ATSDR (1) to determine whether excess mortality is occurring among individuals exposed to toxic or hazardous substances, and (2) to notify similarly exposed persons. Records may also be disclosed to the Social Security Administration for additional sources of locating information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Records may be disclosed to Department of Health and Human Services contractors to locate individuals exposed or potentially exposed to toxic or hazardous substances (e.g., in the establishment of the National Exposure Registry), conduct interviews, perform medical examinations, collect and analyze biological specimens, evaluate and interpret data, and perform followup health investigations so that the research purposes for which the records are collected may be accomplished. The contractor must comply with the requirements of the Privacy Act with respect to such records.

2. Records may be disclosed to Federal agencies such as the Environmental Protection Agency (EPA), State and local health departments, and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with exposures to hazardous or toxic substances, and to satisfy mandatory reporting requirements when applicable.

3. Records (i.e., name, Social Security number) may be disclosed to other Federal agencies and to missing person location agencies to obtain information to aid in locating individuals involved in these studies.

4. Records may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identified form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Disclosures may be made to a congressional office from the records of an individual, in response to a verified inquiry from the congressional office made at the written request of that individual.

6. In the event of litigation initiated by EPA in collaboration with ATSDR, ATSDR may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent ATSDR. The types of litigative proceedings that ATSDR may request include the recovery of expenses incurred in cleanup operations at Superfund or Resource Conservation and Recovery Act sites, including program and staff costs.

7. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, computer tapes and disks (hard and floppy).

RETRIEVABILITY:

By name or Social Security number.

SAFEGUARDS:

The following special safeguards are provided to protect the records from inadvertent disclosure:

1. Authorized Users: Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of ATSDR or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. A list of authorized users will be maintained by the system manager.

2. Physical Safeguards. Questionnaires, log books, and other source data are maintained in locked cabinets in locked rooms, 24-hour guard service in buildings, personnel screening of visitors, electronic anti-intrusion devices in operation at the Federal Records Center (FRC), fire extinguishers, overhead sprinkler system, and card-access control equipment in the mainframe computer room (Clifton Road facility), computer terminals, lockable personal computers, and automated records located in secured areas.

3. Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code, account code and password prior to acceptance of a terminal session or job submission, computer software to control access, frequently changed passwords, and Fault Management System.

Knowledge of individual tape passwords is required to access tapes, and acces to systems is limited to users obtaining prior supervisory approval. When Privacy Act tapes are scratched, a special "certified" process is performed in which tapes are completely written over to avoid inadvertent data disclosure. When possible, a backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Selected safeguards will be applicable to specific elements of the system, as appropriate. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the specific data set.

ATSDR and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either ATSDR or contractor sites is restricted to specifically authorized personnel.

Appropriate Privacy Act provisions are included in contracts and the ATSDR Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to ATSDR or destroyed, as specified by the contract.

4. Implementation Guidelines: The safeguards outlined above are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13; Part 66, "Automated Information Systems Security," of the HHS Information Resources Management Manual; the National Bureau of Standards Federal information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31). FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B-Archives and Records.

RETENTION AND DISPOSAL:

ATSDR retains records in accordance with the CDC Records Control Schedule Item 37, which allows the system manager to keep the records for 20 years unless needed for further study. Registry records will be actively maintained as long as funding is provided for by legislation. Contractors will retain the records only as long as necessary to complete data collection and verify ATSDR's receipt of the data in usable form. Record copy of study reports is maintained in the agency from two to three years in accordance with retention schedules. Source documents for computer tapes or disks are disposed of when no longer needed in the study as determined by the system manager, and as provided in the signed consent form, as appropriate.

Records may be transferred to a Federal Records Center for storage when no longer needed for evaluation or analysis. Disposal methods include the paper recycling process, burning or shredding hard copy records, and erasing computer tapes and disks.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Health Assessment, Agency for Toxic Substances and Disease Registry, Chamblee Building 28N, 1600 Clifton Road, Atlanta, GA 30333;

Director, Office of External Affairs, Agency for Toxic Substances and Disease Registry, Chamblee Building 28S, 1600 Clifton Road, Atlanta, GA 30333;

Policy coordination is provided by: Deputy Associate Administrator, Agency for Toxic Substances and Disease Registry, Chamblee Building 29, 1600 Clifton Road, Atlanta, GA 30333.

NOTIFICATION PROCEDURES:

An individual may learn if a record exists about himself/herself by contacting the appropriate system manager at the address above. Persons who knowingly and willfully request or acquire a record pertaining to an individual under false pretenses are subject to criminal prosecution. Requesters in person must provide photo identification (such as driver's license) or other positive identification that would authenticate the identity of the individual making the request. Individuals who do not appear in person must submit a request which has been notarized to verify their identity. A parent or guardian who requests notification of, or access to, a minor's medical record must provide a birth certificate (or notarized copy), court order, or other competent evidence of guardianship. An individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative (who may be a physician, other health professional, or other responsible individual) who will be willing to review the record and inform the subject individual of its

contents at the representative's discretion.

In addition, the following information should be provided when requesting notification: (1) Full name and Social Security number; (2) nature of the study, or probable exposure or disease subregistry which might include the requester.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may also be requested.

CONTESTING RECORD PROCEDURES:

Contact the system manager at the address specified above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Subject individuals, families of deceased individuals, concerned citizens associated with a particular site, State and local health departments, physican records, hospital records, Social Security Administration, Environmental Protection Agency and other agencies responsible for environmental public health.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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BILLING CODE 4160-70-M

Privacy Act Of 1974; New System of Records

AGENCY: Public Health Service, HHS.

ACTION: Notification of a new system or records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) is publishing a notice of a proposal to create a new system or records, 09-17-0003, "Indian Health Service Medical Staff Credentials and Privileges Records; HHS/IHS/OHP." We are also proposing routine uses for this new system.

DATES: PHS invites interested persons to submit comments on the proposed new system of records on or before September 14, 1988. PHS has sent a Report of A New System of Records to the Congress and to the Office of Management and Budget (OMB) on August 8, 1988. The new system of records will be effective 60 days from the date submitted to OMB, unless PHS receives comments which result in a contrary determination.

ADDRESS: Address comments to the IHA Privacy Act Coordinator, Department of Health and Human Services, Room 6A-30, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. We will make comments received available for public inspection at the above address during normal business hours, 8:30 a.m.-5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Olson, Office of Health Programs, Indian Health Service, Room 6A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-4644. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Indian Health Service (IHS) proposes to establish a new system of records. Records will be maintained in this system to ensure that members of IHS medical staffs are qualified, competent and capable of delivering quality health services consistent with those of the medical community at large. A medical staff includes physicians (M.D. and D.O.) and dentists and may include other health care practitioners such as psychologists, optometrists, podiatrists, audiologists, and in some states, certified nurse midwives. Personnel included are those who have applied for active, provisional, temporary or courtesy membership on an IHS medical staff as IHS employees or under contract to IHS. Records of current and former members of the IHS medical staff will be included in this system of records. Included in the proposed system will be records of personnel who have applied for specific IHS medical staff privileges and the recommendations of specific IHS medical staff members concerning these applications.

These records will be used by IHS staff (i.e., Clinical Directors and Credentials and Privilege Committee at each Service Unit, Governing Body and Physician and other Health Professions Recruiters at IHS Area Offices) to make recommendations with regard to retention, promotion, transfer, reassignment and release of IHS medical staff. Through use of these records the credentials and privileges of IHS medical staff will be evaluated, re-evaluated and re-certified on a recurring and standardized basis.

The confidentiality of all records contained in this system of records will be strictly maintained. The following safeguards will be introduced into the operation of this system of records. Access will be limited to authorized personnel for use in the performance of their official duties. (Authorized personnel include: Physician and other Health Professions Recruitment Branch staff and Area Governing Board Members at IHS Area Offices, Service Unit Directors, Clinical Directors and members of the Credentials and Privileges Committees of each IHS Service Unit). At each location where records in this system will be maintained, a list of personnel or catetories of personnel having a demonstrable need for access to the records in the performance of their official duties will be developed and maintained. In addition, physical and procedural safeguards (as specified in the proposed system notice) will be in place to maintain the confidentiality of records contained in this system. Thus, only those IHS employees who have assigned responsibilities for carrying out the system's purpose of ensuring that IHS medical staff are qualified, competent, and capable of delivering quality health services to the population served will be granted access to these records.

The Privacy Act of 1974 permits disclosure of information without the consent of the subject individual for "routine uses," that is, disclosure for purposes which are compatible with the purposes for which the data are collected. Accordingly, we are establishing seven routine uses for information in this system. The relationship between each of these seven routine uses to the purpose of the system follows.

The first routine use provides for disclosure to organizations authorized to conduct evaluation studies concerning the delivery of health care services by the Indian Health Service. Thus, disclosure may be made to organizations such as the Joint Commission on the Accreditation of Healthcare Organizations to evaluate the adequacy or effectiveness of the IHS health care delivery program.

The second routine use provides for disclosure to an entity which maintains records relating to the issuance, retention or revocation of licenses or registrations necessary to practice a health prefessional occupation or specialty. The purpose of this disclosure is to inform health profession licensing boards or other appropriate entities about the health care practices of a current, terminated, resigned, or retired IHS medical staff member whose professional health care activity so

significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of members of the general public. This will be done within the guidelines for notice, hearing, and review as delineated in the medical staff bylaws of the IHS facility.

The third routine use provides for disclosure to references provided by IHS medical staff applicants for the purpose of evaluating the applicants' professional qualifications, experience, and suitability, and disclosure to an entity for the purpose of verifying that all claimed background and employment data are valid and all claimed credentials are current and in good standing.

The fourth routine use provides for disclosure to other Federal agencies, to State and local governmental agencies and to organizations in the private sector to which the subject individual has applied for clinical privileges, membership or licensure for the purpose of documenting the qualifications and competency of the subject individual to provide health services in his/her health profession based on the individual's professional performance while employed by the IHS.

The fifth routine use provides for disclosure to the Department of Justice for litigation purposes when HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

The sixth routine use provides for disclosure to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

In the event that a system of records maintained by the IHS to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the seventh routine use provides for the disclosure of the relevant records to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

For the reasons stated above, IHS believes that the routine uses of this system of records are compatible with the purpose of this system of records. The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the notice becomes effective.

Dated: August 9, 1988.

Wilford J. Forbush,

Deputy Assistant Secretary for Health Operations and Director, Office of Management.

09-17-0003

SYSTEM NAME:

Indian Health Service Medical Staff Credentials and Privileges Records, HHS/IHS/OHP.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Each Indian Health Service (IHS) Area Office and each IHS Service Unit (Appendix 1).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, current and former Indian Health Service (IHS) medical staff members. The term IHS medical staff includes fully licensed individuals permitted by law to provide patient care services independently and without concurrent professional direction or supervision, within the scope of his/her license and in accordance with individually granted clinical privileges. The IHS medical staff includes physicians (M.D. and D.O.) and dentists and may include other health care practitioners such as psychologists, optometrists, podiatrists, audiologists, and, in some states, certified nurse midwives.

Types of assignment categories of current and former IHS medical staff members include the following:

Provisional—Those new members of the medical staff who are serving a required initial probationary period, as specified in the local medical staff bylaws. During this time, their qualifications for membership on the active or courtesy IHS medical staff are assessed.

Active—Those members who are either IHS employees or employees of P.L. 93-638 Tribal Contractors who spend at least 50 percent of their professional time within the IHS facility and/or IHS Service Unit. They have served their probationary period and have been found to be fully qualified for membership on the IHS medical staff.

Temporary—Those members who provide services on a short-term basis.

Courtesy or Associate—Those members who generally provide services on a periodic or episodic basis (e.g., specialty clinics) and are usually not IHS employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains name, Social Security Number, IHS medical staff membership and privileges applications and associated forms, employment data, liability insurance coverage, credentialing history of licensed health professionals, personal, educational, and demographic background information, professional performance information consisting of continuing education, performance awards, and adverse or disciplinary actions, and evaluations and approvals completed by IHS medical staff reviewers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Indian Self Determination and Education and Assistance Act (25 U.S.C. 450), Snyder Act (25 U.S.C. 13), Indian Health Care Improvement Act (25 U.S.C. 1601 et. seq.), Indian Health Service Transfer Act (42 U.S.C. 2001-2004).

PURPOSE(S):

The purposes of this system are:

1. To ensure that IHS medical staff members are qualified, competent and capable of delivering quality health services consistent with those of the medical community at large and that they are granted privileges commensurate with their training and competence and with the ability of the facility to provide adequate support equipment, services, and staff.

2. To inform health care practitioner(s) and staff of health care facilities, state or county health professional societies or licensing boards to whom the subject individual may apply for clinical privileges, membership or licensure, of the subject individual's professional competence, character and ethical qualifications. This may include information regarding drug or alcohol abuse or dependency. Within the Department such releases may be made to personnel staffs of DHHS Regional Offices.

3. To provide adverse health care practice information to the data bank established under Title IV of Pub. L. 99-660, the Health Care Quality Improvement Act of 1986. The purpose of such a release is to provide information concerning a current or former IHS medical staff member whose professional health care activity failed to conform to generally accepted

standards of professional medical practice.

4. To provide health care practice information concerning current or former members of the IHS medical staff with Commissioned Corps status to the Division of Commissioned Personnel, U.S. Public Health Service, so that an informed decision may be made concerning the promotion, retention, or reassignment of the subject individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Records may be disclosed to organizations authorized to conduct evaluation studies concerning the delivery of health care services by the Indian Health Service (e.g., Joint Commission on the Accreditation of Healthcare Organizations).

2. IHS may disclose records consisting of name, Social Security Number, employment history and any professional qualification information concerning medical staff membership and privileges, professional competence, clinical judgment and personal character to a State or local government health profession licensing board, to the Federation of State Medical Boards, to the data bank established under Title IV of Pub. L. 99–660 and/or to a similar entity which has the authority to maintain records concerning the issuance, retention or revocation of licenses or registrations necessary to practice a health professional occupation or specialty. The purpose of this disclosure is to inform medical profession licensing boards and appropriate entities about the health care practices of a current, terminated, resigned, or retired IHS medical staff member whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of members of the general public. This will be done within the guidelines for notice, hearing, and review as delineated in the medical staff bylaws for the IHS facility and/or within other HHS or IHS regulations or policies.

3. IHS may disclose biographic data and information supplied by potential applicants to (a) references listed on the IHS medical staff and/or privileges application and associated forms for the purpose of evaluating the applicant's professional qualifications, experience, and suitability, and (b) a State or local government health profession licensing board, to a health-related professional organization, to the Federation of State Medical Boards, and to the data bank established under Title IV of Pub. L. 99–660 or a similar entity for the purpose of verifying that all claimed background and employment data are valid and all claimed credentials are current and in good standing.

4. Records may be disclosed to other Federal agencies (including the Office of Personnel Management for subject individuals applying for or maintaining Civil Service appointments), to State and local governmental agencies, and to organizations in the private sector to which the subject individual applies for clinical privileges, membership or licensure for the purpose of documenting the qualifications and competency of the subject individual to provide health services in his/her health professional based on the individual's professional performance while employed by the IHS.

5. The Department may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof, or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

6. Records may disclosed to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

7. In the event that a system of records maintained by the IHS to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Indexed and retrieved by name, Social Security Number, and any other identifying numbers necessary to establish the identity of an individual whose record is maintained in the system of records.

SAFEGUARDS:

1. Authorized Users:

Access is limited to authorized personnel for use in the performance of their official duties. Authorized personnel include: Physician Recruitment and other Health Professions Branch Staff and Area Governing Board Members at IHS Area Offices, and Service Unit Directors, Clinical Directors and members of the Credentials and Privilege Committee of each IHS Service Unit. At each location where records in this system will be maintained, a list of personnel or categories of personnel having an official need-to-know has been developed and is maintained.

2. Physical Safeguards:

Records are kept in locked metal filing cabinets or in locked desk drawers in secured rooms at all times when not actually in use during working hours and at all times during non-working hours. Record storage areas, including file cabinets and desks, are not left unattended or unlocked during office hours, including lunch hours.

3. Procedural Safeguards:

Persons who have an official need-to-know are entrusted with records from this system of records and are instructed to safeguard the confidentiality of these records and to destroy all copies or to return such records when the need to know has expired. Instructions include the statutory penalties for noncompliance. Proper charge-out procedures are followed for the removal of records from the area in which they are maintained. Before an employee who will control disclosure of records can work with the records (i.e., employees who report to the system manager) the system manager or designee ensures that the employee has received training in the safeguards applicable to the records and is aware of the actions to take to restrict disclosure. When copying records for authorized purposes, care is taken to ensure that any imperfect pages are not left in the reproduction room where they

can be read but are destroyed or obliterated.

4. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS.hf:45–13 of the General Administration Manual.

RETENTION AND DISPOSAL:

Records are maintained by IHS for at least five years after the individual's termination of employment or association with IHS. Records of unsuccessful applicants for medical staff membership will be retained for three years after his/her rejection. After these periods of retention expire, records are destroyed by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

See Appendix 1.

Policy Coordinating Official: Director, Patient Care Professional Affairs and Support IHS, 5600 Fishers Lane, Room 6A–55, Rockville, Maryland 20857.

The IHS Clinical Directors at all IHS Service Units listed in Appendix 1 are System Managers. The original IHS medical staff credentials and privileges files are stored at these locations. Other addresses listed in Appendix 1 are locations at which copies of all or parts of these records may be stored (Physician Recruiter at IHS Area Offices). Post Office Box designations appearing in Appendix 1 should be specified when making requests by mail.

NOTIFICATION PROCEDURE:

Requests must be made to the appropriate System Manager (Clinical Director for the appropriate Service Unit) listed in Appendix 1.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain, at a minimum, the name, signature, Social Security Number, and address of the requester, and for unsuccessful applicants the date when the application was submitted, and for current or former IHS health care providers the dates and locations of service.

We may request additional identification when we hold records for different persons with the same name or where an apparent discrepancy exists between information contained in the record and that provided by the individual requesting access to the record.

Other names used: Where an individual is seeking to obtain information about himself/herself which may be retrieved by a different name than his/her current name, he/she shall be required to produce evidence to verify that he/she is the person whose record he/she seeks.

Requests in person: A subject individual who appears in person at a specific location (where he or she currently works or formerly worked) seeking access or disclosure of records contained in this system of records relating to him/her shall provide the information described in "Requests by mail" (above) and at least one piece of tangible identification such as a driver's license or passport.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

RECORD ACCESS PROCEDURES:

Same as Notification Procedure. Requesters should also provide a reasonable description of the record being sought.

Requesters may also request an accounting of disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the appropriate Service Unit Clinical Director at the address specified in Appendix 1 and reasonably identify the record, specify the information being contested, and state the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Subject individual, IHS health care personnel, references supplied by the subject individual, professional societies or associations, specialty boards, colleges and universities attended by the subject individual, former employers, health facilities or health providers with which the subject individual was associated, liability insurance carriers, organizations providing cardiopulmonary resuscitation (CPR) training to the subject individual, State and local health and health care licensing or certifying organizations, and organizations which serve as repositories of information on health care professionals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix 1—System Managers

Director, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Avenue, SE. Aberdeen, South Dakota 57401

Clinical Director, Rapid City Service Unit, Rapid City Indian Hospital, Rapid City, South Dakota 57701

Clinical Director, Cheyenne River Service Unit, Eagle Butte Indian Hospital, Eagle Butte, South Dakota 57625

Clinical Director, Fort Berthold Service Unit, Minni-Tohe Indian Health Center, New Town, North Dakota 58763

Clinical Director, Fort Totten Service Unit, Fort Totten Indian Health Center, Fort Totten, North Dakota 58335

Clinical Director, Pine Ridge Service Unit, Pine Ridge Indian Hospital, Pine Ridge, South Dakota 57770

Clinical Director, Rosebud Service Unit, Rosebud Indian Hospital, Rosebud, South Dakota 57570

Clinical Director, Sisseton-Wahpeton Service Unit, Sisseton Indian Hospital, Sisseton, South Dakota 57262

Clinical Director, Standing Rock Service Unit, Fort Yates Indian Hospital, Fort Yates, North Dakota 58538

Clinical Director, Turtle Mountain Service Unit, Belcourt Indian Hospital, Belcourt, North Dakota 58316

Clinical Director, Omaha-Winnebago Service Unit, Winnebago Indian Hospital, Winnebago, Nebraska 68071

Clinical Director, Yankton-Wagner Service Unit, Wagner Indian Hospital, Wagner, South Dakota 57380

Clinical Director, Pierre Service Unit, Ft. Thompson Indian Health Center, Ft. Thompson, South Dakota 57339

Director, Bemidji Area Office, Indian Health Service, 203 Federal Building, Bemidji, Minnesota 56601

Clinical Director, Eastern Michigan Service Unit, Kincheloe Indian Health Center, Kincheloe, Minnesota 49788

Clinical Director, Greater Leach Lake Service Unit, Cass Lake Indian Hospital, Cass Lake, Minnesota 56633

Clinical Director, Red Lake Service Unit, Red Lake Indian Hospital, Red Lake, Minnesota 56671

Clinical Director, White Earth Service Unit, White Earth Indian Health Center, White Earth, Minnesota 56591

Director, Alaska Area Native Health Service, 250 Gambell Street, Anchorage, Alaska 99510

Clinical Director, Anchorage Service Unit, PHS, Alaska Native Medical Center, P.O. Box 7–741, Anchorage, Alaska 99510

Clinical Director, Barrow Service Unit, Barrow Alaska Native Hospital, Barrow, Alaska 99723

Clinical Director, Kotzebue Service Unit, Kotzebue Alaska Native Hospital, Kotzebue, Alaska 99752

Clinical Director Annette Island Service Unit, Metlakatla Alaska Native Health Center, Box 428, Metlakatla, Alaska 99926

Clinical Director, Yukon-Kuskokwim-Delta Service Unit, Yukon-Kuskokwim-Delta Regional Hospital, Indian Health Service, Bethel, Alaska 99559

Director, Albuquerque Area Indian Health Service, 505 Marquette N.W. Suite 1502, Albuquerque, New Mexico 87102–0097

Clinical Director, Albuquerque Service Unit, Albuquerque Indian Hospital, 801 Vassar Drive, NE., Albuquerque, New Mexico 87106

Clinical Director, Mescalero Service Unit, Mescalero Indian Hospital, P.O. Box 210, Mescalero, New Mexico 88340
Clinical Director, Southern Colorado-Ute Service Unit P O. Box 778, Ignacio, Colorado 81137
Clinical Director, Zuni-Ramah Service unit, Zuni Indian Hospital, Zuni, New Mexico 87327
Clinical Director, Acoma-Canoncito-Laguna Service Unit, Acoma-Canoncito-Laguna Indian Hospital, P.O. Box 130, San Fidel, New Mexico 87049
Director, Billings Area Indian Health Service, P.O. Box 2143, Billings, Montana 59103
Clinical Director, Blackfeet Service Unit, Browning Indian Hospital, Browning, Montana 59417
Clinical Director, Crow Service Unit, Crow Indian Hospital, Crow Agency, Montana 59022
Clinical Director, Flathead Service Unit, St. Ignatius Indian Health Center, St. Ignatius, Montana 59865
Clinical Director, Fort Belknap Service Unit, Harlem Indian Hospital, Harlem, Montana 59526
Clinical Director, Fort Peck Service Unit, Poplar Indian Health Center, Poplar, Montana 59255
Clinical Director, Wind River Service Unit, Fort Washakie Indian Health Center, Fort Washakie, Wyoming 82514
Clinical Director, Northern Cheyenne Service Unit, Lame Deer Indian Health Center, Lame Deer, Montana 59043
Clinical Director, Rocky Boy's Service Unit, Rocky Boy's Indian Health Center, Box Elder, Montana 59521
Clinical Director, Navajo Area Indian Health Service, P.O. Box G, Window Rock, Arizona 86515
Clinical Director, Chinle Service Unit, Chinle, Comprehensive Health Facility, P.O. Box P.H., Chinle, Arizona 86503
Clinical Director, Crownpoint Service Unit, Crownpoint Indian Hospital Crownpoint, New Mexico 87313
Clinical Director, Fort Defiance Service Unit, Fort Defiance Indian Hospital, Fort Defiance, Arizona 86504
Clinical Director, Gallup Service Unit, Gallup Indian Medical Center, Gallup, New Mexico 87301
Clinical Director, Kayenta Service Unit, Kayenta Indian Health Center, Kayenta, Arizona 86033
Clinical Director, Shiprock Service Unit, Shiprock Indian Hospital, Shiprock, New Mexico 87420
Clinical Director, Tuba City Service Unit, Tuba City Indian Hospital, Tuba City, Arizona 86045
Clinical Director, Winslow Service Unit, Winslow Indian Health Center, P.O. Box 40, Winslow, Arizona 86047
Director, Oklahoma City Area Indian Health Service, 215 Dean A. McGee Street NW., Oklahoma City, Oklahoma 73102-3477
Clinical Director, Ada Service Unit, Carl Albert Comprehensive Indian Health Facility, 1001 North Country Club Drive, Box 1564, Ada, Oklahoma 74820
Clinical Director, Claremore Service Unit, Claremore Comprehensive Indian Health Facility, Claremore, Oklahoma 74017
Clinical Director, Clinton Service Unit, Clinton Indian Hospital, Clinton, Oklahoma 73601
Clinical Director, Kansas Service Unit, Holton Indian Health Center, Holton, Kansas 66436
Clinical Director, Lawton Service Unit, Lawton Indian Hospital, Lawton, Oklahoma 73501
Clinical Director, Pawnee Service Unit, Pawnee Indian Health Center, Pawnee, Oklahoma 74058
Clinical Director, Shawnee Service Unit, Shawnee Indian Health Center, Shawnee, Oklahoma 74801
Clinical Director, Tahlequah Service Unit, W.W. Hastings Indian Hospital, 100 S. Bliss, Tahlequah, Oklahoma 74464
Director, Phoenix Area Indian Health Service, 3738 N. 16th Street, Suite A, Phoenix, Arizona 85016-5981
Clinical Director, Colorado River Service Unit, Parker Indian Hospital, Route 1, P.O. Box 12, Parker, Arizona 85344
Clinical Director, Fort Yuma Service Unit, Winterhaven Indian Hospital, P.O. Box 1368, Yuma, Arizona 85364
Clinical Director, Keams Canyon Service Unit, Keams Canyon Indian Hospital, P.O. Box 98, Keams Canyon, Arizona 86034
Clinical Director, Owyhee Service Unit, Owyhee Indian Hospital, P.O. Box 212, Owyhee, Nevada 89832
Clinical Director, Phoenix Service Unit, Phoenix Indian Medical Center, 4212 North 16th St., Phoenix, Arizona 85016
Clinical Director, Sacaton Service Unit, Sacaton Indian Hospital, Sacaton, Arizona 85247
Clinical Director, San Carlos Service Unit, San Carlos Indian Hospital, San Carlos, Arizona 85550
Clinical Director, Schurz Service Unit, Schurz Indian Hospital, Schurz, Nevada 89427
Clinical Director, Unitah and Ouray Service Unit, Fort Duchesne Indian Health Center, P.O. Box 160, Fort Duchesne, Utah 84026
Clinical Director, Whiteriver Service Unit, Whiteriver Indian Hospital, Whiteriver, Arizona 85941
Director, Portland Area Indian Health Service, Room 476, Federal Building, 1220 Southwest Third Avenue, Portland, Oregon 97204-2892
Clinical Director, Colville Service Unit, Colville Indian Health Center, Nespelem, Washington 99155
Clinical Director, Fort Hall Service Unit, Fort Hall Indian Health Center, P.O. Box 317, Fort Hall, Idaho 83203
Clinical Director, Northern Idaho Service Unit, Northern Idaho Indian Health Center, P.O. Drawer 367, Lapawai, Idaho 83540
Clinical Director, Warm Springs Service Unit, Warm Springs Indian Health Center, Warm Springs, Oregon 97761
Clinical Director, Puget Sound Service Unit, Kitsap Indian Health Center, 1212 South Judkins, Seattle, Washington 98144
Clinical Director, Yakima Service Unit, Yakima Indian Health Center, Route 1, Box 1104, Toppenish, Washington 98948
Clinical Director, Umatilla Service Unit, Yellowhawk Indian Health Center, P.O. Box 159, Pendleton, Oregon 97801
Clinical Director, Taholah Service Unit, Taholah Indian Health Center, P.O. Box 219, Taholah, Washington 98587
Clinical Director, Neah Bay Service Unit, Neah Bay Indian Health Center, P.O. Box 418, Neah Bay, Washington 98357
Clinical Director, Northwest Washington Service Unit, Lummi Indian Health Center, 2592 Kwina Road, Bellingham, Washington 98225
Clinical Director, Wellpinit Service Unit, Wellpinit Indian Health Center, P.O. Box 391, Wellpinit, Washington 99040
Director, Tucson Area Office, Indian Health Serevice, P.O. Box 11340, Tucson, Arizona 85734
Clinical Director, Sells Service Unit, Sells Indian Hospital, Sells, Arizona 85634
Director, Nashville Area Office, Indian Health Service, Oak Towers Building, 1101 Kermit Drive, Suite 810, Nashville, Tennessee 37217-2191
Clinical Director, Cherokee Service Unit, Cherokee Indian Hospital, Cherokee, North Carolina 28719
Director, California Area Office, Indian Health Service, 2999 Fulton Avenue, Sacramento, California 95821

[FR Doc. 88-18327 Filed 8-12-88; 8:45 am]
BILLING CODE 4160-70-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. N-88-1843]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESS: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal

for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: August 8, 1988.

David S. Cristy,

Deputy Director, Information Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Interim Rule Amending 24 CFR Part 970: Demolition/Disposition of Public Housing Projects (FR-2463).

Office: Public and Indian Housing.

Description of the Need for the Information and its Proposed Use: The interim rule amending 24 CFR Part 970 requires additional replacement housing plan requirements for Public Housing Agencies' (PHAs') applications for HUD approval of demolition/disposition of public housing units. This information will be used by HUD in application reviews.

Form Number: None.

Respondents: Individuals or Households, State or Local Governments, and Federal Agencies or Employees.

Frequency of Submission: On Occasion.

Reporting Burden:

	Number of Respondents	×	Frequency of Response	×	Hours per Response	=	Burden Hours
Application	70		1		4		280

Total Estimated Burden Hours: 280

Status: Revision.

Contact:

Wayne Hunter, HUD, (202) 755-6713

John Allison, OMB, (202) 395-6880

Dated: August 8, 1988.

[FR Doc. 88-18380 Filed 8-12-88; 8:45 am]

BILLING CODE 4210-01-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

[Billing No. 6116-01]

Housing Guaranty Program; Investment Opportunity

The Agency for International Development (A.I.D.) has authorized the guaranty of a loan to Guatemala as part of A.I.D.'s development assistance program. The proceeds of this loan will be used to finance shelter projects for low-income families in Guatemala. Central Park of Guatemala has authorized A.I.D. to request proposals from eligible investors. The name and address of the Borrower's representative to be contacted by interested U.S. lenders or investment bankers, and the amount of the loan and project number are indicated below:

Government of Guatemala

Project: 520-HG-004—$10,000,000

Attention: Lic. Fernando Figueroa Amado, General Manager, Banco de Guatemala, 7a Avenida 22-01, Zona 1, Guatemala City, Guatemala, Telex No.: 5231 (answer back GUABAN-DU), Telefax No.: 202/22-85-09. Telephone No.: 502/28-16-35.

Interested investors should submit their bids to the Borrower's representative on August 24, 1988 no later than 5:00 p.m. New York Time. Bids should remain open for 48 hours. Copies of all bids should be simultaneously sent to the following:

Mr. Mario Pita, Assistant Director, Central America, RHUDO/Tegucigalpa, USAID/Tegucigalpa, APO Miami 34022, (street address: Edificio Castillo Poujol, Colonia Palmira, 4 Calle, #2401, Tegucigalpa, DC Honduras). Telephone No.: 504/32-2120. Telefax No.: 9-001-504-32027.

USAID/Guatemala, c/o American Embassy, Guatemala City, Guatemala, (street address: 7-01 Avenida de la Reforma, Zone 10). Telephone No.: 502/(2)31-15-41.

Michael G. Kitay/Barton Veret, Agency for International Development, GC/PRE, Room 3328 N.S., Washington, DC 20523. Telex No.: 892703 AID WSA. Telefax No.: 202/647-4958 (preferred communication).

Each proposal should consider the following terms:

(a) *Amount:* U.S. $10 million.

(b) *Term:* Up to 30 years

(c) *Grace Period on Principal:* 10 years

(d) *Amortization:* 40 equal semi-annual principal payments.

(e) *Interest Rate:* Variable rate based on six-months U.S. Treasury Bills, with options of interest rate cap and options to convert to fixed rate.

(f) *Draw Down:* Full disbursement expected by September 30, 1988.

(g) *Prepayment:* Proposals should include the option of prepayment of the loan by Borrower.

(h) *Fees:* Payable at closing from proceeds of loan.

Selection of investment bankers and/or lenders and the terms of the loan are initially subject to the individual discretion of the Borrower and thereafter subject to approval by A.I.D. The lender and A.I.D. shall enter into a Contract of Guaranty covering the loan. Disbursements under the loan will be subject to certain conditions required of the Borrower by A.I.D. as set forth in agreements between A.I.D. and the Borrower.

The full repayment of the loans will be guaranteed by A.I.D. The A.I.D. guaranty will be backed by the full faith and credit of the United States of America and will be issued pursuant to authority in Section 222 of the Foreign

Assistance Act of 1961, as amended (the "Act").

Lenders eligible to receive an A.I.D. guaranty are those specified in section 238(c) of the Act. They are: (a) U.S. citizens; (2) domestic U.S. corporations, partnerships, or associations substantially beneficially owned by U.S. citizens; (3) foreign corporations whose share capital is at least 95 percent owned by U.S. citizens; and, (4) foreign partnerships or associations wholly owned by U.S. citizens.

To be eligible for an A.I.D. guaranty, the loans must be repayable in full no later than the thirtieth anniversary of the disbursement of the principal amount thereof and the interest rates may be no higher than the maximum rate established from time to time by A.I.D.

Information as to the eligibility of investors and other aspects of the A.I.D. housing guaranty program can be obtained from: Peter M. Kimm, Director, Office of Housing and Urban Programs, Agency for International Development, Room 315, SA-18C, Washington, DC 20523. Telephone: 703/875-4808.

William Gelman,

Acting Director, Agency for International Development, Office of Housing and Urban Programs.

Date: August 11, 1988.

[FR Doc. 88-18524 Filed 8-12-88; 9:28 am]

BILLING CODE 6116-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-330-08-4211-02]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget, Interior Department Desk Officer, Washington, DC 20503, telephone number 202-395-7340.

Title: Right-of-Way Cost Recovery Procedures, 43 CFR 2808.

Abstract: Respondents supply identifying information and data on monetary value of the rights and privileges sought by the applicant, costs incurred for the benefit of the general public interest rather than for the exclusive benefit of the applicant, and public services provided which are necessary to determine who may be entitled to a set-off against reimbursement of costs to the government.

Bureau Form Number: None Required.

Frequency: Once from about 17 applicants per year.

Description of Respondents: Right-of-way applicants for which the authorized officer determines that the Bureau's application processing activities will require gathering of original data to comply with the National Environmental Policy Act and other statutes, and three or more field examinations.

Annual Responses: 17.

Annual Burden Hours: 850.

Estimated Average Completion Time: 50 hours.

Bureau Clearance Officer: Rick Iovaine 202-653-8853.

Dated: August 2, 1988.

Dean E. Stepanek,

Assistant Director, Land and Renewable Resources.

[FR Doc. 88-18336 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-84-M

[AAA220-08-4322-02]

Bureau Forms Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the requirements should be made directly to the Bureau's Clearance Officer and to the Office of Management and Budget, Interior Department Desk Officer, Washington, DC 20503, Telephone (202) 395-7340.

Title: Actual Grazing Use Report, 43 CFR 4130.1-2.

OMB Approval Number: 1004-0051.

Abstract: This form is used by permittees to provide information on the actual amount of livestock grazing use made on the public lands within a specified time to the Bureau of Land Management for billing purposes and resource monitoring.

Bureau Form Number: 4130-5.

Frequency: Annually.

Description of Respondents: Grazing permittees required to report actual livestock use on the public lands.

Estimated Completion Time: 24 minutes.

Annual Responses: 15,000.

Annual Burden Hours: 6,000.

Bureau Clearance Officer (alternate): Rick Iovaine (202) 653-8853.

Dated: August 4, 1988.

Dean Stepanek,

Assistant Director, Renewable Resources.

[FR Doc. 88-18337 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-84-M

[AA220-08-4322-02]

Bureau Forms Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau of Land Management (BLM) Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the BLM's Clearance Officer and to the Office of Management and Budget, Interior Department Desk Officer, Washington, DC 20503, Telephone (202) 395-7340.

Title: Grazing Application—Grazing Schedule, 43 CFR 4130.1.

OMB Approval Number: 1004-0005.

Abstract: This form is used by permittees to apply for annual authorization to graze livestock on the public lands.

Bureau Form Number: 4130-1.

Frequency: Annually.

Description of Respondents: Applicants requesting authorization to graze livestock on the public lands.

Estimated Completion Time: 20 minutes.

Annual Responses: 6,000.

Annual Burden Houres: 2,000.

BLM Clearance Officer (alternate): Rick Iovaine (202) 653-8853.

Dated: August 4, 1988.

Dean Stepanek,

Assistant Director, Renewable Resources.

[FR Doc. 88-18338 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-84-M

[AA220-08-4322-02]

Bureau Forms Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau's clearance officer and and to the Office of Management and Budget, Interior Department Desk Officer, Washington, DC 20503, telephone (202) 395-7340.

Title: Cooperative Agreements for Range Improvements, 43 CFR 4120.3-2.

OMB Approval Number: 1004-0068.

Abstract: Respondents supply information to obtain authority to construct and/or maintain range improvements on the public lands in cooperation with Bureau programs.

Bureau Form Number: 4120-6.

Frequency: Occasionally.

Description of Respondents: Permittees or lessees authorized to graze livestock on the public lands.

Estimated Completion Time: 10 minutes.

Annual Responses: 600.

Annual Burden Hours: 102.

Bureau Clearance Officer (alternate): Rick Iovaine (202) 653-8853.

Dated: August 4, 1988.

Dean Stepanek,

Assistant Director, Renewable Resources.

[FR Doc. 88-18339 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-84-M

Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

PRT-720930

Applicant: Gibbon and Gallinaceous Bird Center, Saugus, CA

The applicant requests an amendment to a previously-issued permit to import one newborn dark-handed gibbon (*Hylobates agilis*) from the Perth Zoo, Australia. This animal is the offspring of a pair of gibbons that were previously authorized for import.

PRT-730152

Applicant: National Wildlife Health Research Cntr, U.S. Fish & Wildlife Service, Madison, WI

The applicant requests a permit to import serum, blood smears, cloacal and tracheal swabs, fecal samples and ectoparasites collected from captive live cranes and fixed or frozen tissues samples from cranes that died. The speciemens will be imported from the Moscow Zoo and Okisky Preserve, USSR. Cranes from which the samples will be obtained are the following: Manchurian crane (*Grus japonensis*), Siberian crane (*G. leucogeranus*), hooded crane (*G. monacha*), black-necked crane (*G.nigricollis*) and white-naped crane (*G. vipio*). the specimens will be tested for evidence of exposure to or presence of avian disease agents. Fixed tissues will be used for histopathology to determine cause of death.

PRT-730276

Applicant: Hawthorn Corporation, Grayslake, IL

The applicant requests a permit to import one captive born female tiger (*Panthera tigris*) from Parc Safari, Quebec, Canada, for breeding and exhibition purposes. This tiger is the result of a breeding loan agreement between applicant and Parc Safari. It will be used in applicant's own breeding program and will be exported/re-imported for exhibition purposes.

PRT-730153

Applicant: Cincinnati Zoo, Cincinnati, OH

The applicant requests a permit to import one pair of captive born cheetahs (*Acinoyx jubatus*) from the De Wildt Cheetah Research Centre, De Wildt, South Africa, for purposes of scientific research, propagation, exhibition, and education.

PRT-730325

Applicant: Dr. Neil Carey, San Diego, CA

The applicant requests a permit to import the sport-hunted trophy of a male bontebok (*Damaliscus dorcas dorcas*), to be culled from the captive herd maintained by Mr. E.L. Pringle, Huntley Glen, Bedford, Republic of South Africa, for the purpose of enhancement of survival of the species.

PRT-730327

Applicant: International Animal Exchange, Inc., Ferndale, MI

The applicant requests a permit to export one male and two female captive-born Andean condors (*Vultur gryphus*) to the Nagasaki Biopark, Nagasaki, Japan, for purposes of public display and possible captive breeding.

PRT-730329

Applicant: International Wildlife Veterinary Services, Orangevale, CA

The applicant requests a permit to import serum samples taken from black rhinos (*Diceros bicornis*) captured for relocation in Zimbabwe. The samples are to be imported for purposes of scientific research.

PRT-730352

Applicant: Philadelphia Zoological Garden, Philadelphia, PA

The applicant requests a permit to purchase in foreign commerce and import on male captive-born drill *(Papio leucophaeus)* held Hannover Zoo, Hannover, West Germany for enhancement of propagation and survival of the species.

PRT-730381

Applicant: New York Zoological Society, Bronx, NY

The applicant requests a permit to import frozen plasma samples taken from giant pandas (*Ailuropoda melanoleuca*) held in captivity at Calgary Zoo, Calgary, Canada for analyses of nutritional deficiencies and development of optimal diet, thereby enhancing the propagation and survival of the species.

PRT-730364

Applicant: Zoo Atlanta, Atlanta, GA

The applicant requests a permit to import 2 male and 2 female captive white collared (sooty) mangabeys (*Cercocebus torquatus torquatus*) from Zoologischer Garten Hannover, Hannover, West Germany for the purposes of propagation and exhibit. One male and one female are of unkonwn origin and one male and one female were born at Hannover Zoo.

PRT-730447

Applicant: U.S. Fish & Wildlife Service, Patuxent Wildlife Research Center, Laurel, MD

The applicant requests a permit to sacrifice 10 wild-caught masked bobwhites (*Colinus virginianus ridgwayi*) that were imported from Mexico in 1986. The applicant proposes to sacrifice the birds for genetic studies that will be carried out at the University of Texas System Cancer Center, Smithville, Texas, by Dr. Donald Morizot.

PRT-730473

Applicant: Alfred Cito, Staten Island, NY

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus dorcas dorcas*) to be culled from the captive herd maintained by Mr. Frank Bowker,

Jr., Grahamstown, Republic of South Africa, for the purpose of enhancement of survival of the species.

PRT-730471

Applicant: Edmond Wolf Sancturary, Edmond, OK

The applicant requests a permit to purchase three captive born male wolf (*Canis lupus*) cubs from Mr. Jim Rieder, Timber Wolf Preservation Society, Inc., of Greendale, Wisconsin, for the purpose of educational display.

PRT-730378

Applicant: Martin Rigoletti, Jr., Denville, NJ

The applicant requests a permit to import the sport-hunted trophy of a male bontebok (*Damaliscus dorcas dorcas*) to be culled from the captive-herd maintained by F.W.M. Bowker Jr. Thornkloof, Grahamstown, Rupblic of South Africa, for the purpose of enhancement of survival of the species.

PRT-703575

Applicant: Moscow Circus (Soyuzgoscirk), c/o Circus Productions, inc., New York, NY

The applicant requests a permit to import and reexport 21 captive-born tigers (*Panthera tigris*) from the Soviet Union via Canada for the purpose of exhibition and conservation education. The circus proposes to tour the United States then return to the Soviet Union early in 1989.

Documents and other information submitted with these applications are available to the public during normal business hours (7:45 am to 4:15 pm) Room 403, 1375, K Street NW., Washington DC 20005, or by writing to the Director, U.S. Office of Management Authority, P.O. Box 27329, Washington, DC 20038-7329.

Interested persons may comment on any of these applications within 30 days of the date of this publication by submitting written views, arguments, or data to the Director at the above address. Please refer to the appropriate applicant and PRT number when submitting comments.

Dated: August 11, 1988.

R.K. Robinson,

Chief, Branch of Permits, U.S. Office of Management Authority.

[FR Doc. 88-18408 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-AN-M

Minerals Management Service

Outer Continental Shelf Advisory Board; South Atlantic Regional Technical Working Group

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of Meeting of South Atlantic Regional Technical Working Group Committee.

SUMMARY: The Atlantic Outer Continental Shelf (OCS) Region has scheduled a meeting of its South Atlantic Regional Technical Working Group (SARTWG) Committee. The meeting agenda includes the following topics:

September 7, 1988

Election of State Cochair
Summary of State OCS-Related Programs and Activities
Status of Proposed Exploratory Well Sale 108 (South Atlantic) Area Identification
MMS Environmental Studies Program
MMS Participation on the Oil Spill Response Team
State Environmental Studies Programs Impacting on the Federal Offshore Leasing Program

September 8, 1988

Recent Developments in Nonenergy Minerals Activities in the South Atlantic
The Role of the RTWG in the Federal Nonenergy Minerals Program
Public Comment

DATES: September 7-8, 1988.

ADDRESSES: The meeting will begin at 9 a.m. at the following: Radisson Plaza Hotel Raleigh, 420 Fayetteville Street Mall, Raleigh, North Carolina 27601

The Atlantic OCS Region is at the following location: Minerals Management Service, Atlantic OCS Region, 1951 Kidwell Drive, Suite 601, Vienna, Virginia 22180.

FOR FURTHER INFORMATION CONTACT: Marsha Polk, RTWG Coordinator, Atlantic OCS Region, at the Virginia address above; telephone (703) 285-2165, (FTS) 285-2165.

SUPPLEMENTARY INFORMATION: The SARTWG is part of the OCS Advisory Board and was established to advise the Minerals Management Service (MMS) Director on technical matters of regional concern regarding offshore prelease and postlease sale activities in the South Atlantic. The SARTWG membership consists of representatives from Federal Agencies, the Coastal States of Virginia through Florida, the petroleum industry, and other private interests.

(Federal Advisory Committee Act (Pub. L. No. 92-463))

Date: August 5, 1988.

Bruce G. Weetman,

Regional Director, Atlantic OCS Region.

[FR Doc. 88-18335 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-MR-M

National Park Service

Information Collection Submitted for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comment and suggestions on the requirement should be made directly to the Bureau clearance officer and the Office of Management and Budget reviewing official, Washington, DC 20503, Telephone 202-395-7313.

Title: Special Use Permit.

Abstract: The National Park Service uses the Special Use Permit to document and authorize special uses of public land that are otherwise restricted. Permits are necessary to determine whether a proposed activity is authorized by law and to evaluate the potential effects on park resources.

Bureau Form Number: 10-114.

Frequency: On occasion.

Description of Respondents: Individuals or households, businesses, or organizations.

Annual Responses: 496,975.

Annual Burden Hours: 138,933.

Bureau Clearance Officer: Russell K. Olsen, 202-523-5133.

Russell K. Olsen,

Information Collection Clearance Officer.

[FR Doc. 88-18379 Filed 8-12-88; 8:45 am]

BILLING CODE 4310-70-M

Bureau of Reclamation

Department of Agriculture

Soil Conservation Service

Colorado River Water Quality Improvement Program, Price-San Rafael Rivers Salinity Control Unit, UT

AGENCY: Bureau of Reclamation, Interior, Soil Conservation Service USDA.

ACTION: Notice of intent to prepare a joint Draft Enviromental Impact Statement.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, the Department of the Interior and the Department of Agriculture intend to prepare a joint

Draft Environmental Impact Statement (DEIS) for the Price-San Rafael River Unit of the Colorado River Water Quality Improvement Program. Reclamation will also integrate the DEIS with a planning report for the salinity control unit. The DEIS will address the environmental impacts of and the alternatives to reducing salt loading to the Colorado River through irrigation systems improvements.

FOR FURTHER INFORMATION CONTACT: The Bureau of Reclamation contact for this DEIS is Larry W. Fluharty, Chief, Planning Division, Bureau of Reclamation, Utah Projects Office, P.O. Box 1338, Provo, Utah 84603, telephone (801) 379–1155.

The Soil Conservation Service contact for the DEIS is Gary R. Gross, Assistant State Conservationist, Soil Conservation Service, Utah State Office, P.O. Box 11350, Salt Lake City, Utah 84147, telephone (801) 524–5054.

SUPPLEMENTARY INFORMATION:

The Price-San Rafael River Unit is located in east-central Utah, 120 miles southeast of Salt Lake City, encompassing Carbon and Emery counties. The Price and San Rafael Rivers and their tributaries deliver approximately 425,000 tons of salt annually to the Colorado River. Of this amount approximately 60 percent is the result of deep percolation or irrigation water into salt-bearing ground formations. This salt causes economic problems for municipal, industrial, and agricultural water users downstream. The purpose of the Price-San Rafael Rivers Unit is to decrease this salt loading in a cost-efficient manner.

Numerous alternatives have been evaluated for the unit including irrigation systems improvements, using irrigation return flows for powerplant cooling, treatment of disposal of return flows, using return flows for other industrial purposes, selective withdrawal and treatment or disposal of return flows, retiring farmland, using fresh water for other beneficial purposes, and no Federal action. Of these alternatives, all but the Irrigation Systems Improvements and No Federal Action Alternatives were determined to be nonviable and have been eliminated from further consideration.

Prior to 1986 the Bureau of Reclamation and the Soil Conservation Service were independently investigating methods of reducing salt loading within the study area. However, in March 1986, it was determined that greater effectiveness and economic efficiency could be achieved by both agencies jointly developing a salinity control project.

The Irrigation Systems Improvement Alternative would reduce deep percolation of irrigation water through development of more efficient irrigation systems. Under the alternative, pressurized sprinkler irrigation systems would be developed to serve approximately 26,600 acres of presently irrigated farmland. Additionally, surface irrigation improvements would be developed for 10,000 acres of existing farmland. Canal seepage due to winter water practices could be eliminated by providing winter for livestock through existing culinary systems, enlarging and lining existing stockponds in remote areas, making improvements to the existing Cottonwood Creek livestock watering system to improve its reliability, and constructing a pipeline to deliver raw water to the Orangeville and Castledale water treatment plants. Implementation of these measures would reduce salt loading by about 100,000 tons per year.

Measures to replace lost wildlife habitat caused by off-farm developments would be provided by Reclamation by development of new habitat in the vicinity of Three Forks on the San Rafael Rivers. Measures to replace lost wildlife habitat onfarm would be provided voluntarily by individual farmers in accordance with the Colorado River Salinity Control Act of 1974 (Pub. L. 93–320) and as amended (Pub. L. 98–569) in 1984.

The Bureau of Reclamation and the Soil Conservation Service have each conducted their own separate scoping activities for the DEIS. No further formal scoping activities are planned.

The DEIS is scheduled to be circulated for public review during the summer of 1989.

Dated: August 5, 1988.

Joe D. Hill,

Deputy Commissioner of Reclamation.

Dated: August 1, 1988.

Norman W. Priest,

Deputy State Conservationist, Soil Conservation Service.

[FR Doc. 88–18346 Filed 8–12–88; 8:45 am]

BILLING CODE 4310–09–M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB–290 (Sub-NO. 13X)]

Southern Railway Co.; Exemption for Abandonment Between Troutman and Statesville, NC

Applicant has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon its 3.43-mile line of railroad between milepost 0–39.07 at Troutman, NC and milepost 0–42.5 at Statesville, NC.

Applicant has certified (1) that no local traffic has moved over the line for at least 2 years and that overhead traffic is not moved over the line or may be rerouted, and (2) that no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court, or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.-Abandonment-Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on September 14, 1988 (unless stayed pending reconsideration). Petitions to say regarding matters that do not involve environmental issues [1] and formal expressions of intent to file an offer of financial assistance under 49 CFR 1152.27(c) [2] must be filed by August 25, 1988, and petitions for reconsideration, including environmental energy, and public use concerns, must be filed by September 4, 1988 with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: F. Blair Wimbush, Norfolk Southern Corporation, One Commercial Place, Norfolk, VA 23510–2191.

If the notice of exemption contain false or misleading information, use of the exemption is void *ab initio.*

[1] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by party or by the Section of Energy and Environment in its indepent investigation) cannot be made prior to the effective date of the notice of exemption. *See* Ex Parte No. 274 (Sub-No. 8), *Exemption of Out-of-Service Rail Lines* (not printed), served March 8, 1988.

[2] *See Exemption of Rail Abandonments of Discontinuance—Offers of Financial Assistance*, 4 I.C.C. 2d 164 (1987), and final rules published in the **Federal Register** on December 22, 1987 (52 48440–48446).

Applicant has filed an environmental report which addresses environmental or energy impacts, if any, from this abandonment.

The Section of Energy and Environment (SEE) will prepare an environmental assiessment (EA). SEE will serve the EA on all parties by August 20, 1988. Other interested persons may obtain a copy of the EA from SEE by writing to it (Room 3115, Interstate Commerce Commission, Washington, DC 20423) or by calling Carl Bausch, Chief, SEE at (202) 275–7316.

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use conditions.

Decided: August 8, 1988.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 88–18263 Filed 8–12–88; 8:45 am]

BILLING CODE 7035–01–M

NATIONAL SCIENCE FOUNDATION

Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978, Pub. L. 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act of 1978 at title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to these permit applications by September 14, 1988. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESS: Comments should be addressed to Permit Office, Room 627, Division of Polar Programs, National Science Foundation, Washington, DC 20550.

FOR FURTHER INFORMATION CONTACT: Charles E. Myers at the above address or (202) 357–7934.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), has developed regulations that implement the "Agreed Measures for the Conservation of Antarctic Fauna and Flora" for all United States citizens. The Agreed Measures, developed in 1964 by the Antarctic Treaty Consultative Parties, recommended establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Specially Protected Areas and Sites of Special Scientific Interest. Additional information was published in the **Federal Register** on June 21, 1988.

The application received is as follows:

1. *Applicant:* Gerald L. Kooyman, Physiological Research Laboratory, University of California, San Diego, La Jolla, California 92093.

Activity for Which Permit Requested

Taking; Import into the U.S.A. The applicant is conducting a study of diving physiology in vertebrates. The applicant proposes to collect Emperor penguins and Weddell seals, attach blood and muscle electrodes, temperature thermistors, ECG electrodes, and microprocessor/recorders. After the experiments the instrumentation will be removed and the animals will be released.

In a second set of experiments, the applicant proposes to collect four live Emperor penguin chicks and return the specimens to the Sea World laboratories in San Diego. The birds will be used in studies of the energetics, hydrodynamics and physiology of graded swimming exercises. The birds will be held at the Sea World penguin facility after the experiments.

Location: McMurdo Sound, Antarctica.

Dates: October 1988—February 1989.

Charles E. Myers,

Permit Office.

[FR Doc. 88–18334 Filed 8–12–88; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards Subcommittee on Safety Philosophy, Technology, and Criteria; Meeting

The ACRS Subcommittee on Safety Philosophy, Technology, and Criteria will hold a meeting on September 1, 1988, Room P–110, 7920 Norfolk Avenue, Bethesda, MD. The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, September 1, 1988—8:30 a.m. Until the Conclusion of Business

The Subcommittee will discuss the Staff's proposed implementation plan for the Safety Goal Policy Statement.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Dean Houston (telephone 202/634–3267) between 7:30 a.m. and 4:15 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: August 8, 1988.

Morton W. Libarkin,

Assistant Executive Director for Project Review.

[FR Doc. 88–18385 Filed 8–12–88; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 30–08463; License No. 29–15035–01; EA 88–97

Bridgeton Hospital; Order Imposing Civil Monetary Penalties

I

Bridgeton Hospital, Bridgeton, New Jersey 08302 (the "licensee") is the holder of License No. 29–15035–01 (the "license") issued by the Nuclear

Regulatory Commission (the "Commission" or "NRC") which authorizes the medical use of byproduct material by the licensee. The license was issued on March 29, 1972, was most recently renewed on February 18, 1988, and is due to expire on March 31, 1993.

II

An NRC safety inspection of the licensee's activities under the license was conducted on March 25 and 28, 1988. During the inspection, the NRC staff determined that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty was served upon the licensee by letter dated May 13, 1988. The Notice states the nature of the violations, the provisions of the Nuclear Regulatory Commission's requirements that the licensee had violated, and the civil penalty amount of each of the violations. Two responses, both dated June 7, 1988, to the Notice of Violation and Proposed Imposition of Civil Penalty, were received from the licensee.

III

Upon consideration of the answers received, the statements of facts, explanations, and arguments for remission or mitigation of the proposed civil penalty contained therein, and as set forth in the Appendix to this Order, the Deputy Executive Director for Regional Operations has determined that the penalty proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalty should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282, Pub. L. 96–295), and 10 CFR 2.205, it is hereby ordered that:

The licensee pay a civil penalty in the amount of One Thousand Two Hundred and Fifty Dollars ($1,250) within thirty days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

V

The licensee may, within thirty days of the date of this order, request a hearing. A request for a hearing shall be clearly marked as a "Request for Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region I.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within thirty days of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, this Order should be sustained.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 29th day of July 1988.

James M. Taylor,

Deputy Executive Director for Regional Operations.

Appendix—Evaluation and Conclusion

On May 13, 1988, a Notice of Violation and Proposed Imposition of Civil Penalty was issued for violations of a license issued to Bridgeton Hospital. The licensee responded to the Notice by two letters, dated June 7, 1988, and admits the violations, but requested a complete waiver of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's responses are as follows:

I. Restatement of Violations

A. 10 CFR 71.5(a) requires that each licensee who delivers any licensed material to a carrier for transport to comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170–189.

49 CFR 172.403 and 49 CFR 172.200, respectively require, that (1) unless excepted from labelling by §§ 173.421 through 173.425, each package of radioactive material shall be labelled with a Radioactive White-I, Radioactive Yellow-II, or Radioactive Yellow-III label as appropriate; and (2) the material offered for transport shall be described on the shipping paper.

Contrary to the above, from January 1986 to March 25, 1988, packages containing approximately 225 millicuries of molybdenum-99 in used molybdenum-99/technetium-99m generators were shipped on a weekly basis to the manufacturer (E.I. Dupont—NEN Products), and these packages, which were not excepted from labelling in accordance with §§ 173.421–173.425 of 49 CFR:

1. Did not have affixed an appropirate label indicating the radiation level at the surface of the package and transport index in accordance with 49 CFR 172.403; and

2. Were incorrectly described on the shipping paper as "Empty".

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the regulations of Part 20, and are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on March 25, 1988, and for an indeterminate period prior to that date, a survey was not made to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material contained in waste. Specifically, during that time, such material located in the Nuclear Medicine Department was surveyed at the end of each day, but the waste material was routinely not picked up until the following day. As a result, the waste materials added subsequent to the survey but prior to the pickup were not surveyed to assure that licensed material was disposed of in a manner authorized by 10 CFR 20.301.

C. 10 CFR 35.51(c) requires that each survey instrument be checked for proper operations with a dedicated check source each day of use.

Contrary to the above, on March 25, 1988, technologists in the Nuclear Medicine Department did not properly check their Ludlum Model 14C and Victoreen survey instruments for proper operation prior to use in that the checks were made to ensure that the instrument needle moved, but did not ensure that the needle indicated the appropriate check reading. Further, the checks of the Ludlum instrument were performed with the wrong source.

D. 10 CFR 35.204(b) requires that the molybdenum-99 concentration in each eluate or extract be measured by a licensee who uses molybdenum-99/technetium-99m generator for preparing a technetium-99m radiopharmaceutical.

Contrary to the above, from February 1985 to March 25, 1988, the molybdenum-99 concentration in each eluate from the molybdenum-99/technetium-99m generator was not properly measured in that the dose calibrator was set incorrectly during the assay. Specifically, the dose calibrator should have been set for "030" and the

results multiplied by 3.5, as specified by the manufacturer; however, the instrument was being operated at a setting of "180" with no correction factor applied.

E. 10 CFR 19.12 requires, in part, that all individuals working in any part of a restricted area by instructed in the purposes and functions of protective devices employed, and be instructed in the applicable provisions of the Commissions regulations and license conditions.

Contrary to the above, as of March 25, 1988, two individuals working in the Nuclear Medicine Department (a restricted area) were not instructed in the proper use of the dose calibrator, a protective device, for making molybdenum breakthrough tests, were not instructed in the proper technique for performing operational checks on survey instruments, a protective device, and were not instructed in the Commission's regulations pertaining to the preparation of packages for shipment.

These violations are categorized in the aggregate as a Severity Level III problem. (Supplement IV, V and VI)

Civil Penalty—$1,250—assessed equally among the violations.

II. Summary of License Response

The licensee, in its responses, admits the occurrence of the violations. However, the licensee requests that the NRC waive the $1,250 civil penalty in light of their immediate response to the violations, their aggressive and ongoing plan to remain in full compliance with applicable regulations, and their past enforcement history.

III. NRC Evaluation of Licensee Response

The NRC recognizes that the licensee's enforcement history prior to the inspection was good, and on that basis, the civil penalty amount of $2,500 was mitigated by 50%. However, full mitigation based on enforcement history was unwarranted in light of the duration of the violations, which indicated a significant lack of management control and oversight since the prior inspection. Furthermore, the licensee's response to the violations and their plans to remain in full compliance, although acceptable, were not considered unusually prompt and extensive. Although the corrective actions for individual violations were taken immediately, action to correct the underlying cause of the violations, in particular, the lack of management's attention to and oversight of the radiation safety program was not in place at the time of the enforcement conference. In addition, management issues described in the licensee's response to the Notice of Violation and Proposed Imposition of Civil Penalty are not so extensive to warrant mitigation as they appear to be those actions that one would reasonably expect to assure management oversight.

IV. NRC Conclusion

The licensee did not provide a sufficient basis for further mitigation of the amount of the civil penalty. Therefore, the NRC concludes that a civil penalty of $1,250 should be imposed.

[FR Doc. 88-18387 Filed 8-12-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-182

Renewal of Facility Operating License No. R-87; Purdue University

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 9 to Facility Operating License No. R-87 for Purdue University (the licensee), which renews the license for operation of the training and research reactor located on the campus in West Lafayette, Indiana.

The facility is a non-power reactor that has been operating at a power level not in excess of one kilowatt (thermal). The renewed Operating License No. R-87 will expire twenty years from its date of issuance.

The amended license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I. Those findings are set forth in the license amendment. Opportunity for hearing was afforded in the notice of the proposed issuance of this renewal in the **Federal Register** on August 26, 1986 at 51 FR 30454. No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

Continued operation of the reactor will not require a alteration of buildings or structures, will not lead to changes in effluents released from the facility to the environment, will not increase the probability or consequences of accidents, and will not involve any unresolved issues concerning alternative uses of available resources. Based on the foregoing and on the Environmental Assessment, the Commission concludes that renewal of the license will not result in any significant environmental impacts.

The Commission has prepared a Safety Evaluation Report (NUREG-1283) for the renewal of Facility Operating License No. R-87 and has, based on that report, concluded that the facilty can continue to be operated by the licensee without endangering the health and safety of the public.

The Commission also prepared an Environmental Assessment which was published in the **Federal Register** on August 5, 1988 (53 FR 29534), for the renewal of Facility Operating License No. R-87 and has concluded that this 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 June 30, 1986, as supplemented; (2) Amendment No. 9 to Operating License R-87; (3) the related Safety Evaluation Report (NUREG-1283) and (4) the Environmental Assessment dated July 29, 1988. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Copies of NUREG-1283 may be purchased by calling (202) 275-2060 or (202) 275-2171 or write the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, D.C. 20013-7982.

Dated at Rockville, Maryland, this 8th day of August 1988.

For the Nuclear Regulatory Commission.

Charles L. Miller,

Acting Director, Standardization and Non-Power Reactor Project Directorate, Division of Reactor Projects—III, IV, V and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 88-18386 Filed 8-12-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 30-09472; License No. 15-15618-01; EA 87-125]

Veterans Administration Medical Center; Order Imposing Civil Monetary Penalty

I

Veterans Administration Medical Center, Wichita, Kansas (licensee) is the holder of Materials License No. 15-15618-01 issued by the Nuclear Regulatory Commission on August 14, 1973, and last amended on July 10, 1987. The license authorizes the licensee to possess and use radiopharmaceuticals as set forth in 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 31.11, and to possess and use phosphorus-32, calcium-45,

tritium, and carbon-14 in accordance with the conditions of the license.

II

A routine inspection of the licensee's activities on June 8, 1987, disclosed that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty was served upon the licensee by letter dated April 13, 1988. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violations. The licensee reponded to the Notice of Violation and Proposed Imposition of Civil Penalty in two letters, both dated June 3, 1988. In its response, the licensee admitted each violation and requested full mitigation of the civil monetary penalty.

III

After consideration of the licensee's response and the statements of fact, explanation, and request for mitigation contained therein, the Deputy Executive Director for Regional Operations has determined as set forth in the Appendix to this Order that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalty should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, it is hereby ordered that:

The licensee pay a civil penalty in the amount of Two Thousand Five Hundred Dollars ($2.500) within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

The licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regualtory Commission, Region IV.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee request a hearing as provided above, the issues to be considered at such hearing shall be whether, on the basis of the violations, this Order should be sustained.

Dated at Rockville, Maryland, this 2nd day of August 1988.

For the Nuclear Regulatory Commission.

James M. Taylor,

Deputy Executive Director for Regional Operations.

Appendix—Evaluations and Conclusions

On April 13, 1988, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for the violations identified during an NRC inspection. Veterans Administration Medical Center responded to the Notice on June 3, 1988. The licensee admitted the violations, described corrective steps taken to ensure compliance now and in the future, and requested that the civil penalty be mitigated to zero. The following includes a restatement of the violations, a summary of the licensee's response and the NRC's evaluation and conclusion regarding the licensee's request.

I. Restatement of Violations

A. License Condition 11 of byproduct material license 15–15618–01, as amended on June 18, 1986, authorized three specified physicians to use or supervise the use of licensed materials.

Contrary to the above, between December 1986 and June 8, 1987, one unauthorized physician used licensed material without being supervised by any of the designated individuals. This physician was later determined by the NRC to have no clinical experience with diagnostic imaging radiopharmaceuticals authorized by 10 CFR 35.200 and therefore was not technically qualified to use these licensed materials.

B. License Condition 15 of the byproduct material license 15–15618–01 requires, in part, that the licensee conduct its program in accordance with the statements, representation, and procedures contained in the licensee's application and letters dated December 16, 1983, August 6, 1984, and June 3, 1986.

1. Item 5 of the license application, as amended on August 6, 1984, designated certain specified individuals to be the Radiation Safety Officer (RSO) and an Alternate Radiation Safety Officer.

Contrary to the above, between December 1986 and June 8, 1987, the designated RSO and Alternate RSO were no longer present at the facility and replacements to provide oversight responsibilities had not been approved.

2. Item 10 of the license application requires the dose calibrator be calibrated in accordance with NRC Regulatory Guide 10.8. Regulatory Guide 10.8 requires for the dose calibrator daily constancy tests, quarterly linearity tests, and annual instrument accuracy tests.

Contrary to the above, the Licensees records indicated that between July 26, 1984 and June 8, 1987, constancy tests were performed weekly rather than daily, linearity tests had not been performed on a quarterly frequency, and annual accuracy tests had not been performed.

3. Item 12 of the license application requires that ancillary personnel whose duties may require them to work in the vicinity of radioactive materials be trained on a quarterly basis.

Contrary to the above, as of June 8, 1987, the required training of housekeeping and maintenance personnel had not been accomplished.

4. Item 17 of the license application requires area radiation surveys to be performed in accordance with NRC Regulatory Guide 10.8. Appendix I of NRC Regulatory Guide 10.8 requires that radiation surveys of elution, preparation and injection areas shall be done daily. Furthermore, laboratory and other radioactive material usage and storage areas shall have weekly contamination surveys performed.

Contrary to the above, as of June 8, 1987, neither daily radiation surveys nor weekly contamination surveys were being performed.

Collectively the above violations have been categorized as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty—$2,500 assessed equally among the violations.

II. Summary of Licensee's Response/ Request for Mitigation

The licensee argued: (1) That prior to this inspection only one violation had been cited, failure to conduct quarterly meetings of the Medical Isotope Committee in 1984, and therefore, they have a good past compliance record, (2) that the licensee took prompt corrective actions and full compliance was achieved quickly, (3) that there is no evidence that any of the violations have caused any injury to any patient, user, or other employee at the Medical

Center, (4) that dose calibrator testing, surveys, and training were performed even though they were not performed at the required frequencies for full compliance and there was never a willful disregard of the regulations, (5) that the fine would come from congressional appropriation designated for patient care, and (6) that the use of licensed material by an unauthorized user would not have occurred if the NRC had acted promptly on a license amendment request that was mailed to NRC on December 29, 1986, and received by NRC on January 20, 1987.

III. NRC Evaluation of Licensee's Request for Mitigation

In regard to the unauthorized and unauthorized/unqualified users, had the Radiation Safety Committee (Medical Isotopes Committee) adequately performed its duties to review the training and experience of Dr. Gay to determine that his qualifications were sufficient to perform his duties safely in accordance with the NRC regulations and conditions of the license, and to ensure that the license was amended prior to change in personnel as specified in the license, the violation may have been precluded. Additionally, the licensee did not obtain the services of a visiting physician authorized by Condition 12, Amendment 12, of License No. 15–15618–01 to supervise the use of licensed material by Drs. Gay and Huycke during the time period allowed by this license condition, which would have precluded the violation. It is true that the application for approval of Drs. Huycke and Gay was received by NRC on January 20, 1987. It should be understood, however, that the application indicated no sense of urgency and, therefore, was assigned no special priority. It also is true that the licensee's letter of March 6, 1987, requesting that the application be expedited. However, the licensee had not yet informed NRC that there were no authorized physicians at the hospital. On April 24, 1987, NRC wrote to the licensee regarding deficiencies in the application. On May 12, 1987, the licensee requested and received an extension to the 30-day response time specified in the deficiency letter. The licensee's response to the deficiency letter was not received until July 1, 1987, further indicating no urgency on the licensee's part.

Meanwhile, NRC did not learn until its June 8, 1987, inspection that the licensee had no physicians authorized to use licensed material. This problem still being unresolved, on June 24, 1987, NRC issued a Confirmation of Action Letter confirming discontinuance of nuclear medicine activities pending appropriate license amendment. On June 26, 1987, the licensee requested and was granted an emergency amendment adding Dr. Huycke as an authorized user. The licensee clearly was delinquent in not notifying NRC of the lack of authorized users, in not making it clear in its license amendment request that this was the case, and in not precluding the violation by employing a visiting physician to supervise the use of materials until the physicians were authorized by the NRC.

The staff acknowledges that licensee has had a good compliance record. This was considered in arriving at the proposed monetary civil penalty amount. However, any credit that might have been given for this factor was balanced by the duration of the violations, the multiple examples of the violations and the fact that the licensee knew that none of its physicians were authorized users of licensed materials.

The NRC finds that the corrective actions taken to bring the licensee's radiation safety program back into compliance are essentially those as submitted to the NRC in its renewal application enclosed in licensee's letter dated December 16, 1983. The corrective actions were neither unusually prompt nor extensive enough to warrant mitigation of the civil penalty.

The staff acknowledges that there is no evidence of injury to patients, users, or employees as a result of these violations. However, actual injury as a result of violations of the NRC's regulations is not necessary under the Enforcement Policy to warrant a civil penalty. The violations in the aggregate indicated a breakdown of management oversight and control which created a potential for safety problems, thus increasing their safety significance.

The NRC recognizes that some surveys, training, and testing of the dose calibrator were performed, but not at required frequencies. The licensee has established these required frequencies in procedures submitted in its letter dated December 16, 1983, and approved by the NRC on June 4, 1984. Testing of the dose calibrator daily for constancy, quarterly for linearity, and annually for accuracy is necessary to asure that the dose delivered to the patient does not differ from the prescribed dose by more than 10 percent.

Daily radiation level surveys and weekly wipe test surveys in the injection, preparation, and storage area are necessary to assure that no contamination or radiation levels exist to which individuals would be unnecessarily exposed. Refresher training is necessary for all personnel to re-emphasize procedures to protect their health and safety. The licensee chose to provide this training quarterly and unilaterally chose to decrease the frequency without approval from the NRC.

It is not enough for a licensee to do some testing, surveying, and training; it is necessary to perform these procedures at some established frequency to assure that health and safety of the public is protected. The licensee established the frequencies at which it would perform these procedures. Failure to perform the procedures at the required frequency is an indication of management's lack of oversight of its program.

The NRC recognizes that the licensee is a federal agency. However, this does not exempt the licensee from enforcement actions such as civil penalties that apply to all NRC licensee. Congress in enacting Section 234 of the Atomic Energy Act did not elect to execute federal agencies from the NRC's enforcement authority. Civil penalties are intended to emphasize the need for a licensee to make lasting improvement in its radiation safety program. Moreover, the amount of the civil penalty in this case is relatively small and should not significantly impact on patient care.

IV. NRC Conclusion

The NRC staff concludes that the licensee's request for full mitigation of the proposed civil penalty is not supported by the licensee's arguments made in its June 3, 1988, response. Consequently, the proposed civil penalty in the amount of $2,500 should be imposed.

[FR Doc. 88–18388 Filed 8–12–88; 8:45 am]
BILLING CODE 7590–01–M

[Docket No. 50–482; License No. NPF–42; EA 87–213]

Wolf Creek Nuclear Operating Corp., Wolf Creek Generating Station; Order Imposing Civil Montetary Penalty

I

Wolf Creek Nuclear Operating Corporation (licensee) is the holder of Operating License No. NPF–42 (license) issued by the Nuclear Regulatory Commission (NRC/Commission) on June 4, 1985. The license authorizes the licensee to operate the Wolf Creek Generating Station in accordance with the conditions specified therein.

II

Three safety inspections of the licensee's activities were conducted during the period from October 1 through November 18, 1987. The results

of these inspections indicated that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty was served upon the licensee by letter dated March 17, 1988. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violations. The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalty by letter dated April 14, 1988. In the licensee's response, the violations were admitted, but the licensee considered escalation of the base civil penalty to be inappropriate.

III

After consideration of the licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the Deputy Executive Director for Regional Operations has determined, as set forth in the Appendix to this Order, that an inadequate basis was provided for mitigation of the proposed penalty and that the penalty proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalty should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, it is hereby ordered that:

The licensee pay a civil penalty in the amount of One Hundred Thousand Dollars ($100,000) within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

V

The licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Assistant General Counsel for Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, and the NRC resident inspector at Wolf Creek Generating Station.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of the violations set forth in the Notice of Violation and Proposed Imposition of Civil Penalty referrenced in Section II above, this Order should be sustained.

Dated at Rockville, Maryland, this 28th day of July 1988.

For the Nuclear Regulatory Commission.

James M. Taylor,

Deputy Executive Director for Regional Operations.

Appendix—Evaluations and Conclusions

On March 17, 1988, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued to Wolf Creek Nuclear Operating Corporation (WCNOC), the licensee. On April 14, 1988, the licensee responded to the Notice. In its response, the licensee did not deny any of the violations, which were classified in the aggregate as a Severity Level III problem, but did request a reduction in the amount of the civil penalty. The NRC's evaluation and conclusions regarding the licensee's response are as follows:

I. Restatement of Violation

A. Failure To Follow Procedures

10 CFR Part 50, Appendix B, Criterion V, requires, in part, that activities affecting quality be prescribed by documented instructions, procedures, or drawings. The activities shall be accomplished in accordance with these instructions, procedures, or drawings.

1. Procedure MPE E 009Q–01, Revision 0, "13.8KV and 4.16KV Switchgear Inspection and Testing" establishes the requirements for accomplishing maintenance work in the NB02 switchgear when terminals in the NB02 switchgear are energized.

Step 6.1 of Procedure MPE E 009Q–01, Revision 0 states, "Check the electrical drawings and identify any area(s) which will have high voltage potential present even when the bus is grounded. List the areas on the Attachment "A" sign-off sheet."

Step 6.3.9.5 of Procedure MPE E–009Q–01, Revision 0 states, "Clean the insulator and high voltage connection in each tube. Check the insulators for cracks and the rosettes for damaged fingers."

Step 6.4.3. of Procedure MPE E–009Q–01, Revision 0 states "Using the high voltage gloves and tester, check the stationary disconnects for high voltage potential. If no potential is found, check that the high voltage connections are dischared."

Contrary to the above, on October 14, 1987, Procedure MPE E 009Q–01 was not followed in that: (1) Cubicle NB0209 feeder from Cubicle XNB02 was not identified as an area that had a high voltage potential present and therefore was not listed in Attachment "A" sign-off sheet as required by Step 6.1 of Procedure MPE Q 009Q–01, Revision 0; (2) Step 6.3.9.5 of the Procedure MPE E 009Q–01, Revision 0, had been signed off for cleaning the insulators and checking the insulators for cracks and the rosettes for damaged fingers as completed; however, had the insulator been actually cleaned, the person performing this step would have encountered it energized and would have been unable to perform the required cleaning, and (3) the electrician failed to check the stationary disconnects for high voltage potential to ensure that the high voltage connections were discharged as required by Step 6.4.3. of Procedure MPE E 009Q–01, Revision 0.

2. Procedure 10–3, Revision 2, "Sluicing Media from Duratek EVR System" describes the methods to sluice resin from the Durateck System to a disposal container.

Contrary to the above, on October 10, 1987, two contract workers failed to follow the methods described in Procedure 10–3, Revision 2, when they physically "opened" a clogged pipe resulting in the contamination of the individuals themselves and the surrounding area.

3. Procedure ADM 03–101, Revision 9, "Radiation Work Permit Program," requires that a radiation work permit (RWP) be issued for all entries into the radiological controlled area (RCA). For work activities to be performed in the RCA, Radiation Work Permit (RWP) 870017 required that a continuous air sample be drawn during the work.

Contrary to the above, on October 10, 1987, a continuous air sample was not drawn as required by Procedure ADM 03–101, Revision 9 while work activities were being performed in the RCA, so that any potential airborne contamination that may have existed in the area would not have been detected.

4. Procedure ADM 03–202, Revision 4, "Radiological Control and Unconditional Release of Tools and Equipment," in Step 4.1.1 states, "All items prior to leaving the RCA, will be surveyed for loose contamination and for fixed contamination * * *" and "will be verified to have no * * * contamination."

Contrary to the above, the licensee failed to comply with Procedure ADM 03–202, Revision 4, on November 9, 1987, in that it released radioactive material to the Coffey County Landfill that was neither surveyed for loose and fixed contamination, nor was the material verified to have no contamination.

5. Procedure ADM 01–057, Revision 12, "Work Request" establishes the use of the Work Request to document and control work activities involving Safety Related items.

a. Work Request (WR) 05013–86 required the documentation of the hydrostatic test manifold relief valve setting for the hydrostatic test of Spool Piece EF05–S050.

Contrary to the above, as of November 13, 1987, the hydrostatic test manifold relief valve setting for the hydrostatic test of Spool Piece EF05–S050 (pursuant to WR 05013–86) had not been documented.

b. WR 02827–87, Step 5.0, required the quality control verification of the installation of an air dam bag downstream of Valve EF V–058 on pipe 080–UBC–24.

Contrary to the above, as of November 2, 1987, the quality control verification of the installation of an air dam bag downstream of Valve EF V–058 on pipe 080–UBC–24 (pursuant to WR 02827–87) had not been performed.

6. 10 CFR Part 50, Appendix B, Criterion IX, requires, in part, that measures be established to assure that special processes, including welding, be controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards specifications, criteria, and other special requirements.

a. Procedure ADM 08–302, Revision 4, "Wolf Creek Generating Station Control of Welding Filler Material," Step 6.2.4, requires that each welder have in his possession only that type and classification of weld filler material authorized on the Field Welding Material Requisition.

Contrary to the above, twice on November 5 and once on November 6, 1987, welders were issued and used material different from what was authorized on the Field Welding Material Requisition.

b. Quality Control Procedure QCI 12.1–601, Revision 2, "Inspection of ASME/ANSI Welds," requires that the quality control inspector verify that the weld filler material is as specified.

Contrary to the above, on November 5, 1987, a quality control inspector mistakenly verified the wrong material as being the correct material, thereby resulting in the use of improper weld filler metal in three instances for Field Welding Material Requisitions 9443, 9446, and 9448.

c. Procedure ADM 08–302, Revision 4, Step 6.2.1, requires that shielded metal arc welds be performed by welders who are qualified to perform shielded metal arc welds.

Contrary to the above, on November 12, 1987, during the performance of Plant Modification Request PMR–2116, a welder performed a shielded metal arc weld thta he was not qualified to perform.

B. Failure To Have Appropriate Procedures

10 CFR Part 50, Appendix B, Criterion V, requires, in part, that activities affecting quality be prescribed by documented instruction procedures, or drawings of a type appropriate to the circumstances.

1. Procedure GEN 00–007, Revision 8, "RCS Draindown," used to purge hydrogen form the Reactor Coolant System (RCS) and pressurizer, in Step 4.3.4, states, in part, "Commence raising pressurizer level towards 100 percent on BB LI–462, pressurizer level cold calibration, carefully observing reactor coolant system pressure."

Contrary to the above, on October 14, 1987, the licensee experienced an inadvertent ignition of hydrogen in the pressurizer because Procedure GEN 00–007, Revision 8 was not appropriate to ensure that all the hydrogen was purged out of the pressurizer. The upper taps for the level instrumentation are approximately 3 feet below the top of the pressurizer. Therefore, even though the instruments (BB LI–462) indicated 100 percent as required by the procedure, the pressurizer still had a vapor space with enough hydrogen present to support a burn.

2. Procedure ADM 13–101, Revision 4, "Control of Ignition Sources," requires verification that the pressurizer be purged of flammable material.

Contrary to the above, on October 14, 1987, the licensee experienced an inadvertent ignition of hydrogen in the pressurizer because Procedure ADM 13–101, Revision 4 was not appropriate in that it failed to require that a sample be taken to confirm that the pressurizer had been purged of flammable material.

3. Procedure SYS NG–331, Revision 5, "Deenergization of 480 Volt (Class 1E) Bus(es)" provides instructions necessary to deenergize the 480 Volt (Class 1E) load centers and/or transformers.

Contrary to the above, on October 15, 1987, when the 4.16KV Bus NB02 was taken out of service for routine maintenance, the normal power supplied to the 125 V DC Buses NK01 and NK04 was deenergized and the loads were then transferred and placed upon Battery Banks NK12 and NK14, respectively. While Procedure SYS N6–331 provided instructions to deenergize the 480 Volt (Class 1F) load centers, the procedure was inadequate in that no instructions existed to guide personnel in calculating the length of time the batteries could carry the electrical loads and in determining the battery attributes which should have been periodically checked.

4. Procedure STS IC–725B, Revision 1, "7300 Process and N.I. Response Time Test (2/4 Logic) Protection Set II," establishes the requirements for testing of response times of the Analog Channels that generate certain Reactor Trip and Engineered Safeguard Feature functions. Licensee Technical Specification (TS) 3.9.2 requires, in part, "As a minimum, two source range neutron flux monitors shall be operable * * *" and "With one of the above required monitors inoperable or not operating, immediately suspend all operations involving core alterations* * *."

Contrary to the above, on November 7, 1987, while making core alterations, the licensee performed Procedure STC IC–725B. Procedure STS IC–725B specified that both source ranges be deenergized; however, the TS required that both source range neutron flux monitors were to be operable. Thus, the procedure was not adequate to ensure TS requirements were satisfied during all modes of plant operation.

Collectively, these violations have been categorized in the aggregate as a Severity Level III problem (Supplement I).

Cumulative Civil Penalty—$100,000 (assessed equally between the violations).

II. Summary of Licensee Response

The licensee, in its response, does not deny any of the violations. However, the licensee does request a reduction in the civil penalty amount and states that escalation of the base civil penalty is considered inappropriate based on the following reasons.

A. WCNOC believes the NRC statement relative to the lack of

corrective actions prior to October 21, 1987, is not supported by the record in that a self-initiated work stoppage was imposed and several actions were immediately initiated. Therefore, it is inappropriate to increase the base civil penalty amount.

B. WCNOC believes that it was inappropriate to use the number of violations as a reason for both the escalation of the severity level classification and as justification for increasing the amount of the base civil penalty.

C. WCNOC believes that it is important to note that the incidents all occurred while the plant was in a cold shutdown status and none of the incidents posed a threat to the health and safety of the public. In addition, essentially all of the problems were self-identified and the corrective actions taken by WCNOC were self-initiated and reported.

WCNOC requests that the NRC reduce the proposed civil penalty to the base amount of $50,000.

III. NRC Evaluation of Licensee Response

The NRC staff has carefully reviewed the licensee's response and has concluded that the licensee has not provided any information that was not previously considered in determining the amount of the proposed civil penalty. With respect to the corrective actions taken by WCNOC prior to October 21, 1987, the NRC does not consider the self-initiated work stoppage and associated actions sufficient to satisfy all of the elements expected in a good corrective action program. The immediate actions taken by the licensee were viewed to be that expected of a licensee in response to significant outage problems. However, the NRC was concerned that management's oversight of the evaluation of the root cause of problems had not been investigated fully and therefore on balance neither escalation nor mitigation was deemed appropriate for corrective actions.

The licensee, in its response, implies that these various procedural violations were individually characterized at a lower severity level, aggregated into a Severity Level III problem, and then the number of violations used to increase the civil penalty amount. These violations were evaluated in the aggregate and found to represent a significant weakness in the licensee's management controls and oversight of safety-related activities. In accordance with the Enforcement Policy, they were characterized as one Severity Level III problem. Contrary to the licensee's assertion, multiple examples may appropriately be considered in both aggregating violations for purposes of determining the severity level of a problem and in determining whether a civil penalty should be increased. This is especially true in this case where aggregation of the violations to a Severity Level III problem would have been appropriate based on far fewer examples than set forth in the Notice. In addition, there were multiple examples of significant procedural deficiencies in areas including electrical equipment operations and maintenance, radiation safety/health physics, disposal of contaminated materials, and control of welding processes, several of which might, in themselves, be argued to be Severity Level III violations. Increasing the base civil penalty was warranted based on the added significance of the management issue with the numerous examples of the failure to adhere to or have appropriate procedures.

Although the NRC recognizes that these violations occurred during the refueling outage, the violations represented significant weaknesses in the licensee's procedures for administrative and management controls and were cause for significant regulatory concern. The nature and extent of the enforcement action proposed was intended to reflect the seriousness of the violations involved.

The licensee also asserts in its response that essentially all of the problems were self-identified. The NRC staff notes that these violations were the results of events which occurred during the 1987 outage and that in many of these events (i.e., maintenance of electrical switchgear, while being inadvertently energized, contamination of contract technicians, hydrogen burn in the pressurizer, and lake water entry into the steam generators) there was minimal involvement of the licensee in identifying the violations. The NRC staff considers the ease of discovery among other factors when evaluating this factor. These were not cases identified as a result of the licensee's initiatives. Therefore, the NRC staff considers it inappropriate to mitigate the base civil penalty on the basis of identification of such clear and easily discovered violations.

IV. NRC Conclusion

An adequate basis for mitigation of the proposed civil penalty has not been provided. Therefore, the NRC concludes that a $100,000 civil penalty should be imposed.

[FR Doc. 88-18389 Filed 8-12-88; 8:45 am]
BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Information Collection for OMB Review

AGENCY: Office of Personnel Management.

ACTION: Notice of information collection from the public submitted to OMB for clearance.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), this notice announces a proposed extension of four forms that collect information from the public. Executive Order 10450 requires that investigations be conducted on all persons entering the Federal service. OFI Form 41 is a voucher form sent to former employers and/or supervisors for employment data and supervisory information. The OFI Form 42 is a voucher form sent to references for personal information. The OFI Form 43 is a voucher sent to educational institutions for student record information, and the OFI 44 is a voucher sent to local law enforcement agencies in conducting OPM investigations as prescribed in section 3(a) of Executive Order 10450. These checks are a part of the investigation conducted for determining suitability for Federal employment/security clearances. Each form takes approximately 5 minutes to complete. When fully implemented there will be 1,898,400 forms completed annually for a total public burden of 158,200 hours. For copies of this proposal call C. Ronald Trueworthy, Agency Clearance Office, on (202) 632-0261.

DATE: Comments on this proposal should be received on or before August 25, 1988.

ADDRESSES: Send or deliver comments to:

C. Ronald Trueworthy, Agency Clearance Officer, U.S. Office of Personnel Management, 1900 E Street, NW., Rm. 6410, Washington, DC 20415

and

Joseph Lackey, Information Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Rm. 3235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: C. Ronald Trueworthy (202) 632-0261.

Office of Personnel Management.

Constance Horner,

Director.

FR Doc. 88-18324 Filed 8-12-88; 8:45 am]

BILLING CODE 6325-01-M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 34-25984; File No. SR-MCC-88-8]

Self-Regulatory Organizations; Filing and Immediate Effectiveness of Proposed Rule Change by Midwest Clearing Corp. Relating to a Revised Fee Schedule

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on August 1, 1988, the Midwest Clearing Corporation ("MCC") filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement on the Terms of Substance of the Proposed Rule Change

In an effort to recover its costs, MCC finds it necessary to increase the following fees: (1) The fee for shipping insured packages of securities (*i.e.*, insured deliveries) to its participants, from $6.40 to $9.40 per package; and (2) the fee for delivering securities to transfer agents for re-registration or other purposes, by $1.00 per delivery.

II. Self-Regulatory Organization's Statement on the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement on the Purpose of, and Statutory Basis for, the Proposed Rule Change

The MCC Revised Fee Schedule, effective July 1, 1988, more accurately reflects the cost of providing securities and Participant Package shipments for MCC Participants.

The Revised Fee Schedule is consistent with section 17A of the Securities Exchange Act of 1934 in that it provides for the equitable allocation of reasonable dues, fees and other charges among MCC's Participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Midwest Clearing Corporation does not believe that any burdens will be placed on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other that those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-referenced self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by September 6, 1988.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

Dated: August 9, 1988.

[FR Doc. 88-18357 Filed 8-12-88; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. 34-25985; File No. SR-MSTC-88-4]

Self-Regulatory Organizations; Filing and Immediate Effectiveness of Proposed Rule Change by Midwest Securities Trust Co. Relating to a Revised Fee Schedule

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on August 1, 1988, the Midwest Securities Trust Company ("MSTC") filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement on the Terms of Substance of the Proposed Rule Change

In an effort to recover its costs, MSTC finds it necessary to increase the following fees: (1) The fee for shipping insured packages of securities (*i.e.*, insured deliveries) to its participants, from $6.40 to $9.40 per package; and (2) the fee for delivering securities to transfer agents for re-registration or other purposes, by $1.00 per delivery.

II. Self-Regulatory Organization's Statement on the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement on the Purpose of, and Statutory Basis for, the Proposed Rule Change

The MSTC Revised Fee Sechedule, effective July 1, 1988, more accurately reflects the cost of providing securities and Participant Package shipments for MSTC participants.

The Revised Fee Schedule is consistent with section 17A of the Securities Exchange Act of 1934 in that it provides for the equitable allocation of reasonable dues, fees and other charges among MSTC's Participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Midwest Securities Trust Company does not believe that any burdens will be placed on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments were either solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b–4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-referenced self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by September 6, 1988.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

Dated: August 9, 1988.

[FR Doc. 88–18356 Filed 8–12–88; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 34–25983; File No. SR–NASD–88–33]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval to Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to NASDAQ Companies Providing the NASD with Notice of Material News Releases

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 27, 1988, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed amendments to Part II of Schedule D to the NASD By-Laws would require NASDAQ issuers to provide notice to the NASD of material news releases prior to the release of such information to the press and to respond to information requests by the NASD. The proposed amendment to the "Notification to NASD of News Releases," also contained in Part II of Schedule D, would recommend that issuers notify the NASD of such material information at least ten minutes prior to its release to the press. In Release No. 34–25792, dated June 9, 1988, the Commission approved substantially similar amendments for a period of 60 days (proposed rule change SR–NASD–88–16). Those amendments required issuers to notify the NASD "at least simultaneously" with the release of news releases to the press. In Release No. 34–25874, dated July 1, 1988 (53 FR 25716, July 8, 1988), the Commission requested comment on permanent approval of the amendments (proposed rule change SR–NASD–88–24). In view of the Commission's grant of accelerated approval to the present proposed rule change, the NASD, by letter dated August 5, 1988, has withdrawn SR–NASD–88–24.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule change would require that NASDAQ companies provide notice to NASD Market Surveillance prior to the release of such information to the news media. The current provisions of Schedule D to the NASD By-Laws require the public disclosure of material information but only recommend that notification to the NASD take place simultaneously with such release. It is the belief of the NASD Board of Governors that in view of recent market events and of proposals by the NASD to mandate the use of the NASD's Small Order Execution System for transactions in NASDAQ National Market System securities, it will be of critical importance for the NASD to be notified in a timely fashion of material news. This will be necessary in order to make appropriate determinations with respect to trading halts.

In addition, the proposed rule change would delete the current requirement in section 5(b)(2) of Part II to Schedule D that information released after 5:00 p.m. Eastern Time be reported by 9:00 a.m. of the following trading day and add a footnote to the Notification Provision indicating that notification can be provided directly to the NASD Market Surveillance Department, a 24-hour telephone number, and clarifying that oral notification must be confirmed promptly in writing. These proposed rule changes reflect the fact that NASD Market Surveillance now has the

capacity to receive information 24 hours a day.

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(11) of the Act which mandates that the rules of the Association include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange, and that such rules shall be designed to produce fair and informative quotations, to prevent fictitious and misleading quotations, and to promote orderly procedures for collecting, distributing, and publishing quotations. The NASD believes that requiring issuers to provide the NASD with material information prior to its release to the public will substantially assist the NASD in carrying out its obligations under this provision of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed amendments impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests the Commission to find good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of the filing. As noted in Part I above, the Commission approved the proposed rule change in substantially similar form on June 9, 1988 for a period of 60 days. On July 8, 1988, the Commission published for comment the proposed rule change requesting permanent approval of the amendments approved on June 9. No comments were received by the Commission. Subsequent to the filing of that proposed rule change, the NASD's Board of Governors approved a further amendment that would require NASDAQ issuers to notify the NASD of news releases "prior to," rather that "at least simultaneously with," the release of such news to the press. Because the Commission received no comments on the prior published proposed rule change, and in view of the imminent expiration of the temporary approval granted on June 9, the NASD requests accelerated approval of the present proposed rule change. Such accelerated approval would allow the NASD to put the language of the current proposed rule change into effect immediately, rather than waiting for the normal comment period to expire.

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 section 15A 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. The Commission does not anticipate that it will receive any significant negative comment on the proposed rule change in its present form in view of the fact that no comments were received on the previously published language. In addition, accelerated approval of the proposed rule change will aid the NASD in facilitating the recent changes to its Small Order Execution System. By requiring issuers to notify the NASD of material news releases prior to notification of the press, the NASD will be able to communicate the news to market makers immediately. Furthermore, in the event that a trading halt would be an appropriate response to the news, such notice will given the NASD an opportunity to make such a judgment and order a trading halt before the news becomes public. This should assist the NASD in its duty to maintain fair and orderly markets.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–88–33 and should be submitted by September 6, 1988.

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, 17 CFR 200.30–3(a)(12).

Jonathan G. Katz,

Secretary.

Dated: August 8, 1988.

[FR Doc. 88–18358 Filed 8–12–88; 8:45 am]

BILLING CODE 810–01–M

[Rel. No. IC–16517; 812–6926]

ML Venture Partners II, L.P., et al.; Application

August 8, 1988.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "1940 Act").

Applicants: ML Venture Partners II, L.P. ("MLVP II" or "Partnership"), Merrill Lynch Venture Capital Inc. ("Venture Capital"), Merrill Lynch KECALP L.P. 1986 ("KECALP 1986"), Merrill Lynch KECALP L.P. 1987 ("KECALP 1987"), KECALP Inc., Merrill Lynch Interfunding Inc. ("MLIF"), Merrill Lynch Capital Appreciation Partnership No. VIII, L.P. ("ML Capital VIII"), ML Offshore LBO Partnership No. VIII ("ML Offshore VIII"), ML Employees LBO Partnership No. I, L.P. ("ML Employees I") and Merrill Lynch & Co., Inc. ("ML & Co.") (collectively, "Applicants").

Relevant 1940 Act Sections: Exemption requested under sections 17(b) and 57(c) from the provisions of sections 17(a) and 57(a)(1), and pursuant to sections 57(i) and 17(d) and Rule 17d–1 thereunder, approving certain transactions.

Summary of Application: Applicants seek an order permitting the acquisition of certain securities (i) deemed "joint transactions" under the 1940 Act or (ii) from "affiliated persons," as defined in the 1940 Act.

Filing Dates: The application was filed on November 27, 1987, and amended on July 22, 1988.

Hearing or Notification of Hearing: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any requests must be received by the SEC by 5:30 p.m., on August 31, 1988. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit or, for

lawyers, by certificate. Request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20459. MLVP II and Venture Capital, 717 Fifth Avenue, New York, New York 10022; KECALP 1986, KECALP 1987, KECALP Inc., ML Capital VIII, ML Offshore VIII and ML Employees I, World Financial Center, North Tower, 27th Floor, New York, New York 10281; MLIF, World Financial Center, North Tower, 18th Floor, New York, New York 10281; and ML & Co., World Financial Center, North Tower, 32nd Floor, New York, New York 10281.

FOR FURTHER INFORMATION CONTACT: Staff Attorney Regina Hamilton (202) 272–2856, or Branch Chief Karen L. Skidmore (202) 272–3023 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier: (800) 231–3282 (in Maryland (301) 258–4300).

Applicants' Representations

1. The Partnership, a limited partnership organized under the laws of Delaware, is a business development company under the 1940 Act. The investment objective of the Partnership is to seek long-term capital appreciation by making venture capital investments. The Partnership has five general partners, four of whom are individuals (the "Individual General Partners"). In accordance with section 56(a) of the 1940 Act, a majority of the Individual General Partners are persons who are not "interested persons" of the Partnership within the meaning of section 2(a)(19) of the Act (the "Independent General Partners").

2. The managing general partner of the Partnership, MLVPII Co., L.P. (the "Managing General Partner"), a New York limited partnership, is responsible for its venture capital investments. The general partner of the Managing General Partner is Venture Capital, a Delaware corporation, which is also the management company for the Partnership. Venture Capital is an indirect subsidiary of ML & Co., holding company, which, through its subsidiaries, provides investment, financing, insurance, real estate and related services. MLIF, a Delaware corporation and indirect wholly-owned subsidiary of ML & Co., specializes in leveraged buyouts, bridge loans and other short-term financings.

3. KECALP 1986 and KECALP 1987 (the "KECALP Partnerships"), limited partnerships organized under the laws of Delaware, are employees' securities companies as defined in section 2(a)(13) of the 1940 Act, and registered as non-diversified, closed-end management companies. Each of KECALP Partnerships operates in accordance with the terms of an exemptive order issued pursuant to section 6(b) of the Act in Investment Company Act Release No. 12363 (April 8, 1982) (the "KECALP Exemptive Order"). The general partner for each of the KECALP Partnerships is KECALP Inc., a Delaware corporation and indirect wholly-owned subsidiary of ML & Co. KECALP Inc. is responsible for managing and making investment decisions for the KECALP Partnerships. All investments by KECALP 1986 and KECALP 1987 are approved by the Board of Directors of KECALP Inc.

4. ML Capital VIII, a Delaware limited partnership, and ML Offshore VIII, a Cayman Islands limited partnership, were formed in connection with the acquisition of Borg-Warner Corporation. They engage solely in the business of owning shares of Borg-Warner Holding Corporation. Merrill Lynch LBO Partners No. II, L.P., a Delaware limited partnership, is the general partner of ML Capital VIII and ML Offshore VIII.

5. ML Employees I, a Delaware limited partnership, specializes in making equity and equity related investments in leveraged buyouts of established companies or divisions thereof. Merrill Lynch Employees LBO Managers, Inc., a Delaware corporation and indirect wholly-owned subsidiary of ML & Co, is the general partner of ML Employees I.

6. Merrill Lynch Capital Partners, Inc. ("MLCP"), a Delaware corporation and wholly-owned subsidiary of ML & Co., controls the general partner of ML Capital VIII, ML Offshore VIII and ML Employees I. MLCP initiates and structures leveraged or management buyouts and manages a fund of equity capital committed by institutional investors for investment in the equity portion of leveraged buyout transactions.

7. Borg-Warner Corporation ("Borg-Warner"), a Delaware corporation, is engaged in the chemical and plastics, automotive, protective services and information services industries. During 1987, MLCP structured a leveraged buyout of Borg-Warner, such that Borg-Warner's equity securities are owned by Borg-Warner Holdings Corporation ("Borg-Warner Holdings"). Borg-Warner Holdings is a newly formed Delaware corporation which was organized solely for the purpose of effecting the leveraged buyout of Borg-Warner Corporation. Borg-Warner Holdings' equity securities are owned by certain members of Borg-Warner's managment, ML & Co., ML Capital VIII, ML Offshore VIII, ML Employees I, MLIF, Venture Capital and KECALP Inc.

8. Because ML & Co. and its affiliates purchased 10.2 million shares of Borg-Warner Holdings Common Stock at $10.00 per share on the effective date of the merger, July 30, 1987, the investments by the Partnership and the KECALP Partnerships could not be made concurrently with the other ML & Co. affiliated entities without the relief requested. Accordingly, Venture Capital agreed to purchase and hold 500,000 shares of Borg-Warner Holdings Common Stock, and to sell such shares to the Partnership at the price determined as described below following the granting of the relief requested. Similarly, KECALP Inc. agreed to purchase and hold 40,000 and 200,000 shares of Borg-Warner Holdings Common Stock, and to sell such shares to KECALP 1986 and KECALP 1987, respectively, at the price determined as described below following the granting of the relief requested. The 500,000, 40,000 and 200,000 shares of Borg-Warner Holdings Common Stock represent 2.5%, 0.2% and 1% of the shares presently outstanding. No dividends have been declared on the Borg-Warner Holdings Common Stock. The Partnership and the KECALP Partnerships incurred no obligation to purchase such shares prior to approval of such investments by the Independent General Partners of the Partnership or the Board of Directors of KECALP Inc., as applicable.

9. The purchase price to be paid by the Partnership and the KECALP Partnerships to Venture Capital and KECALP Inc. will be the lower of (i) the value of the investments (as determined by the Independent General Partners of the Partnership and the Board of Directors of KECALP Inc.) on the dates the Partnership and the KECALP Partnerships acquire the Common Stock, or (ii) the cost to Venture Capital and KECALP Inc., respectively, of purchasing and holding the respective investments. With respect to clause (ii), such cost shall be the original purchase price of $10.00 per share paid by Venture Capital and KECALP Inc. for the Borg-Warner Holdings Common Stock on July 30, 1987, plus carrying costs related to such investments as separately determined for the Partnership and the KECALP Partnerships. The KECALP Partnerships and the Partnership will not pay any carrying costs in respect of the period

prior to the later of (i) the date of acquisition of the Borg-Warner Holdings Common Stock by KECALP Inc. and Venture Capital, respectively, or (ii) the date the Board of Directors of KECALP Inc. approved and the Independent General Partners of the Partnership authorized the proposed investments. For purposes of these transactions, carrying costs consist of interest charges computed at the lower of (i) the prime commercial lending rate charged by Citibank, N.A. during the period for which carrying costs are being paid or (ii) the effective cost of borrowings by ML & Co. during such period. The effective cost of borrowings by ML & Co. is its actual "Average Cost of Funds," which it calculates on a monthly basis by dividing its consolidated financing expenses by the total amount of borrowings during the period.

10. Supermarkets General Corporation ("Supermarkets General"), a Delaware corporation, is a diversified retailer primarily engaged in the operation of large supermarket-drug stores, located principally in the Middle Atlantic and New England states. During 1987, MLCP structured a leveraged buyout of Supermarkets General, such that Supermarket General's equity securities are owned by Supermarket General Holdings Corporation ("SG Holdings"), a newly formed Delaware corporation organizaed solely for the purpose of effecting the acquisition of Supermarkets General. SG Holding's equity securities are owned by certain members of Supermarket General's Management, MLIF, certain partnerships affiliated with ML & Co., Manufacturers Hanover Venture Capital Corporation and The Equitable Life Assurance Society of the United States and certain of its affiliates (the "Equitable Investors").

11. Because affiliates of ML & Co. purchased 550,000 shares of SG Holdings Common Stock at $100.00 per share on the effective date of the merger, October 5, 1987, the investment by KECALP 1987 could not be made concurrently with MLIF without the relief requested herein. Acordingly, MLIF agreed to purchase and sell up to 12,118 shares of its SG Holdings Common Stock to KECALP 1987 at the price determined as described below following the granting of the relief requested. The 12,118 shares of SG Holdings Common Stock represent 1.8% of such shares presently outstanding. KECALP 1987 incurred no obligation to purchase such shares prior to the approval of such investment by the Board of Directors of KECALP Inc. No dividends have been declared on the SG Holdings Common Stock.

12. The purchase price to be paid by KECALP 1987 to MLIF for the SG Holdings Common Stock will be the lower of (i) the value of the investment (as determined by the Board of Directors of KECALP Inc.) on the date KECALP 1987 acquires the SG Holdings Common Stock or (ii) the cost to MLIF of purchasing and holding the investment. With respect to clause (ii), such cost shall be the original purchase of $100.00 per share paid by MLIF for the SG Holdings Common Stock on October 5, 1987, plus carrying costs related to such investment. KECALP 1987 will not pay carrying costs in respect of the period prior to the later of (i) the date of acquisition of the SG Holdings Common Stock by MLIF, or (ii) the date the Board of Directors of KECALP Inc. approved the proposed investment. For purposes of these transactions, carrying costs consist of interest charges computed at the lower of (i) the prime commercial lending rate charged by Citibank, N.A. during the priod for which carrying costs are being paid or (ii) the effective cost of borrowings by ML & Co. during such period. The effective cost of borrowings by ML & Co. is its actual "Average Cost of Funds," which it calculates on a monthly basis by dividing its consolidated financing expenses by the total amount of borrowings during the period.

13. Applicants seek relief: (a) Under Sections 17(b) and 57(c) of the 1940 Act to permit the sale of (i) 500,000 shares of Borg-Warner Holdings Common Stock by Venture Capital to the Partnership; (ii) 200,000 shares of Borg-Warner Holdings Common Stock by KECALP Inc. to KECALP 1987, (iii) 40,000 shares of Borg-Warner Holdings Common Stock by KECALP Inc. to KECALP 1986; and (iv) of up to 12,118 shares of SG Holdings Common Stock by MLIF to KECALP 1987 on the terms described in the application; and (b) under sections 57(i) and 17(d) of the 1940 Act and Rule 17d–1 thereunder approving the investment by the Partnership and the KECALP Partnerships in securities of Borg-Warner Holdings and by KECALP 1987 in securities of SG Holdings on the terms described in the application.

Applicants' Legal Conclusions

1. Relief under sections 17(b) and 57(c) of the Act is justified by both the terms of the transactions and the fact that the proposed investments are not otherwise available to the Partnership and the KECALP Partnerships. With respect to the terms of the transactions, KECALP Inc. (on behalf of the KECALP Partnerships) and the Managing General Partner (on behalf of the Partnership) have reviewed the proposed investments in detail. The members of the Board of Directors of KECALP Inc. and the Managing General Partnership of the Partnership are sophisticated and experienced in valuing securities and evaluating financial transactions generally. The members of the Board of Directors of KECALP Inc. and the Managing General Partner of the Partnership considered all information deemed relevant, including the nature of the investments, the nature of the investments by ML & Co. and affiliates of ML & Co. and the fairness of the purchase prices proposed to be paid by the Partnership and the KECALP Partnerships. The Managing General Partner and KECALP Inc. determined that the proposed investments by the Partnership and the KECALP Partnerships will not directly or indirectly benefit ML & Co. or the entities affiliated with ML & Co. Moreover, at a meeting of the Board of Directors of KECALP Inc. held on July 24, 1987, the investment in Borg-Warner Holdings by each of the KECALP Partnerships was approved after consideration of each of the factors set forth in section 17(b) of the 1940 Act. At a meeting of the Independent General Partners of the Partnership held on July 28, 1987, the Partnership's investment in Borg-Warner Holdings was approved after consideration of each of the factors set forth in section 57(c) of the 1940 Act. At a meeting of the Board of Directors of KECALP Inc. on June 17, 1987, the investment in SG Holdings by KECALP 1987 was approved after consideration of each of the factors listed in section 17(b) of the 1940 Act.

2. In evaluating the terms of the transactions, the Board of Directors of KECALP Inc. and the Partnership's Independent General Partners considered the fact that the proposed purchase prices to be paid by the Partnership and the KECALP Partnerships will include carrying costs incurred by an affiliated person (*i.e.*, Venture Capital, KECALP Inc. and MLIF) if the value of each investment at the time of acquisition by the Partnership and the KECALP Partnerships is more than the sum of the purchase price plus the affiliate's carrying costs. In approving purchase prices which may include carrying costs, the Board of Directors of KECALP Inc. recognized that it receives no compensation for serving as general partner of the KECALP Partnerships and that ML & Co. has incurred considerable expenses in organizing the KECALP Partnerships. The KECALP Partnerships

and the Partnership believe that it is entirely appropriate to reimburse affiliates for carrying costs in a situation in which an affiliate purchased an investment as, in effect, their nominee and the KECALP Partnerships and the Partnership would have purchased such investments directly if it had not been deemed necessary to obtain the relief requested in the application. In light of these factors, the Managing General Partner of the Partnership and the Board of Directors of KECALP Inc. believe it is wholly appropriate for the purchase price paid for portfolio investments to reflect carrying costs provided the value of the investment at the time of acquisition exceeds the amount of the purchase price plus carrying costs. Applicants submit that to deny reimbursement for carrying costs would result in a further and unwarranted loss to Venture Capital, KECALP Inc. or MLIF and provide a disincentive to act on behalf of the Partnership and the KECALP Partnerships in future transactions of this type.

3. Issuance of the order requested is appropriate and necessary because the described investments are not otherwise available for purchase by the Partnership or the KECALP Partnerships. The Managing General Partner of the Partnership and the Board of Directors of KECALP Inc. have approved such investments after review of a considerable number of possible investments for the Partnership and the KECALP Partnerships. The Partnership and the KECALP Partnerships submit that their investment program will be prejudiced if they are not permitted to make the investments referred to in the application. The Board of Directors of KECALP Inc. believes that the proposed investments are consistent with the rationale underlying the establishment of each of the KECALP Partnerships as an "employees' securities company." Similarly the proposed transactions are consistent with the purposes of the Partnership and the KECALP Partnerships and their respective stated policies.

4. With respect to the relief requested pursuant to sections 57(i) and 17(d) of the Act and Rule 17d–1 thereunder, the Managing General Partner of the Partnership and the Board of Directors of KECALP Inc. reviewed the proposed investments, and determined that such investments were consistent with the Partnership's and the KECALP Partnerships' investment objectives of seeking long-term capital appreciation, and that the investments would not disadvantage the Partnership or either of the KECALP Partnerships in making such investments, maintaining their investment positions or disposing of such positions. The Independent General Partners of the Partnership also made such determinations with respect to the purchase of Borg-Warner Holdings Common Stock.

5. In reaching such determinations, the Managing General Partner, the Independent General Partners and the Board of Directors of KECALP Inc. considered several factors, including the difference in the amount proposed to be invested by the Partnership, each of the KECALP Partnerships, ML & Co. and the other entities affiliated with ML & Co. It was recognized that the terms of purchase by such participants would be the same in terms of the price paid per share of stock. Applicants submit that the transactions would be consistent with the provisions, policies and purposes of the Act.

6. Both the KECALP Exemptive Order and the prospectus of each of the KECALP Partnerships indicated that affiliates of ML & Co. would be involved in identifying and investing in many of KECALP's protfolio investments. The prospectus of the Partnership indicated that the Partnership may be co-investor in protfolio companies with affiliates of management. The Partnership and the KECALP Partnerships thus submit that the relief requested is consistent with the purposes of the Partnership and the KECALP Partnerships, their stated policies and the disclosure made to prospective investors.

Applicants' Condition

The investments in Borg-Warner Holdings and SG Holdings will be acquired by the Partnership and the KECALP Partnerships in the manner and on the terms described in the application.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 88–18359 Filed 8–12–88; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Region IV Advisory Council Meeting

The U.S. Small Business Administration Region IV Advisory Council, located in the geographical area of Louisville, Kentucky, will hold a public meeting at 10:00 a.m. to 3:00 p.m., Wednesday, September 14, 1988 at the Louisville District Office, 600 Federal Place, Room 188, Louisville, Kentucky, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information; write or call William Federhofer, District Director, U.S. Small Business Administration, P.O. Box 3527, Louisville, KY 40201 (502) 582–5971.

Jean M. Nowak,

Director, Office of Advisory Councils.

July 28, 1988

[FR Doc. 88–18400 Filed 8–12–88; 8:45 am]

BILLING CODE 8025–01–M

Region IV Advisory Council Meeting

The U.S. Small Business Administration Region VII Advisory Council, located in the geographical area of St. Louis, will hold a public meeting at 8:30 a.m. on Thursday, September 22, 1988, at Peat Marwick Main & Co., 1010 Market Street, St. Louis, Missouri, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information; write or call Robert L. Andrews, District Director, U.S. Small Business Administration, 815 Olive St., Room 242, St. Louis, Missouri, 63101—(314) 539–6600.

Jean M. Nowak,

Director, Office of Advisory Councils.

August 9, 1988

[FR Doc. 88–18403 Filed 8–12–88; 8:45 am]

BILLING CODE 8025–01–M

Region IV Advisory Council Meeting

The U.S. Small Business Administration Region VI Advisory Council, located in the geographical area of Lower Rio Grande Valley of Texas, will hold a public meeting at 1:30 p.m. on Thursday, September 15, 1988, at the Board Room of Pan American University Edinburg, Texas, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Miguel A. Cavazos, Jr., District Director, U.S. Small Business Administration, 222 E. Van Buren, Suite 500, Harlingen, Texas—(512) 427–8625.

Jean M. Nowak,

Director, Office of Advisory Councils.

July 28, 1988.

[FR Doc. 88–18401 Filed 8–12–88; 8:45 am]

BILLING CODE 8025–01–M

Region IV Advisory Council Meeting

The U.S. Small Business Administration Region IV Advisory Council, located in the geographical area of Columbia, South Carolina, will hold a public meeting at 9:00 a.m. on Tuesday, September 27, 1988, at the Radisson Hotel, 937 Assembly Street, Columbia, South Carolina, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call John C. Patrick, Jr., District Director, U.S. Small Business Administration, P.O. Box 2786, Columbia, South Carolina—803/765–5339.

Jean M. Nowak,

Director, Office of Advisory Councils.

August 9, 1988.

[FR Doc. 88–18402 Filed 8–12–88; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF STATE

[Public Notice CM–8/1207]

The U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT), National Committee; Meeting

The Department of State announces that the National Committee of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT) will meet on September 8, 1988 in room 1205, and for two days October 19 (Room 1205) and October 20, 1988 (Room 1912), Department of State, 2201 C Street, NW., Washington, DC. The meetings will begin each day at 9:30 a.m.

The National Committee assists in the resolution of administrative/procedural problems pertaining to U. S. CCITT activities; provides advice on matters of policy and positions in the preparation for CCITT Plenary Assemblies and meetings of the International Study Groups; provides advice and recommendations in regard to the work of the U.S. CCITT Study Groups; and recommends the disposition of proposed U. S. contributions to the international CCITT which are submitted to the Committee for consideration.

The purpose of these meetings is to:

1. Continue preparatory activities for IXth CCITT Plenary Assembly, Melbourne, Australia, November 14–25, 1988 and in particular receive reports of the ad-Hoc groups assigned to review U. S. positions on the proposed texts of study questions for the next Plenary Period (1989–92) as well as candidates for leadership positions. The membership may be requested to convene separate meetings to resolve issues concerning Study Group questions, or strategy for supporting candidates.

2. Receive reports on preparatory activities for World Administrative Telegraph and Telephone Conference (WATTC), Melbourne, Australia, November 28–December 9, 1988.

3. Continuing preparatory activities for the ITU Plenipotentiary Conference, 23 May–29 June, 1989, Nice, France.

The October 19 and 20 meetings will be the final preparatory meetings prior to the convening of the IXth CCITT Plenary Assembly. All accredited members of the U.S. Delegation will be required to attend this meeting.

Members of the general public may attend the meeting and join in the discussion, subject to the instructions of the Chairman. Admittance of public members will be limited to the seating available. In that regard, entrance to the Department of State building is controlled and entry will be facilitated if arrangements are made in advance of the meeting. Prior to the meeting, persons who plan to attend should so advise the office of Mr. Earl Barbely, State Department, Washington, DC; telephone (202) 653–6102 or (202) 647–5832. All attendees must use the C Street entrance to the building.

Date: July 29, 1988.

Earl S. Barbely,

Director, Office of Telecommunications and Information Standards, Chairman, U.S. CCITT National Committee.

[FR Doc. 88–18333 Filed 8–12–88; 8:45 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended August 5, 1988

The following applications for certificates of public convenience and necessity and foreign air carrier permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et. seq.*). The due date for answers, conforming application, or motion to modify scope are set forth below for each application. Following the answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket No. 45741

Date Filed: August 2, 1988.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 30, 1988.

Description: Application of Air Espana, S.A. t/a Air Europa, pursuant to section 402 of the Act and Subpart Q of the Regulations, requests a foreign air carrier permit to engage in charter foreign air transportation of persons, property and mail between any point or points in Spain and any point or points in the United States.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 88–18366 Filed 8–12–88; 8:45 am]

BILLING CODE 4910–62–M

Federal Aviation Administration

Informal Airspace Meetings; Alabama and Georgia

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of informal airspace meetings.

SUMMARY: This notice announces informal airspace meetings to discuss the following: 1. Establishment of an Airport Radar Service Area (ARSA) at Montgomery, AL; and 2. Establishment of an ARSA at Macon, GA.

DATES: The informal airspace meetings will be held on October 13, 1988, for the Montogomery, AL, ARSA and October 18, 1988, for the Macon, GA, ARSA.

ADDRESSES: The informal airspace meeting locations are as follows:.

Montgomery, AL, ARSA

Date: October 13, 1988

Time: 7:00 p.m.

Location: State Highway Department, 1409 Coliseum Boulevard, Montgomery, AL

Macon, GA, ARSA

Date: October 18, 1988

Time: 7:30 p.m.

Location: Fire Rescue Building, Lewis B. Wilson Airport, Macon, GA

FOR FURTHER INFORMATION CONTACT: Joe Gill, Airspace Brach (ATO–240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–9252.

Issued in Washington, DC, on August 9, 1988.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 88-18373 Filed 8-12-88; 8:45 am]

BILLING CODE 4910-13-M

Informal Airspace Meetings; Tennessee

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of informal airspace meetings.

SUMMARY: This notice announces informal airspace meetings to discuss the establishment of a Terminal Control Area (TCA) at Memphis, TN.

DATE: The informal airspace meetings will be held on October 4, 1988.

ADDRESSES: The informal airspace meeting locations is as follows:.

Memphis: TN, TCA

Date: October 4, 1988
Time: 7:00 p.m.
Location: Memphis Air Route Traffic Control Center, Conference Room, 3929 Democrat Road, Memphis, TN

FOR FURTHER INFORMATION CONTACT: Joe Gill, Airspace Branch (ATO-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9252.

Issued in Washington, DC, on August 9, 1988.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 88-18383 Filed 8-12-88; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: August 9, 1988.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bueau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 15th and Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: New
Form Number: IRS Form 8801
Type of Review: New collection
Title: Credit for Prior Year Minimum Tax
Description: Form 8801 is used by individuals, estates, trusts, and corporations to compute the minimum tax credit, if any, available from a tax year beginning after 1986 to be used in the current year to be carried forward for use in a future year.
Respondents: Individual or households, Businesses or other forprofit, Small businesses or organizations
Estimated Number of Respondents: 100,000
Estimated Burden Hours Per Response: 30 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 50,000 hours

OMB Number: 1545-0168
Form Number: IRS Form 4361
Type of Review: Extension
Title: Application for Exemption from Self-Employment Tax for Use by Ministers, Members of Religious Orders and Christian Science Practitioners
Description: Form 4361 is used by ministers, members of religious orders, or Christian Science Practitioners to file for an exemption from self-employment on certain earnings and to certify that they have informed the church or order that they are opposed to the acceptance of certain public insurance benefits.
Respondents: Individuals or households
Estimated Number of Respondents: 10,270
Estimated Burden Hours Per Response: 31 minutes
Frequency of Response: One time only
Estimated Total Reporting Burden: 5,242 hours

OMB Number: 1545-0191
Form Number: IRS Form 4952
Type of Review: Revision
Title: Investment Interest Expense Deduction
Description: Form 4952 is used by taxpayers who paid or accrued interest or money borrowed to purchase or carry investment property. The form is used to compute the allowable deduction for interest on investment indeptedness and the information obtained is necessary to verify the amount actually deducted.
Respondents: Individuals or households, Businesses or other forprofit, Small businesses or organizations
Estimated Number of Respondents: 800,000
Estimated Burden Hours Per Response: 42 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 562,133

OMB Number: 1545-0203
Form Number: IRS Form 5329
Type of Review: Revision
Title: Return for Individual Retirement Arrangement and Qualified Retirement Plans Taxes
Description: This form is used to compute and collect taxes related to distributions from individual retirement arrangements (IRAs) and other qualified plans. These taxes are excess contributions to an IRA, premature distributions from and IRA, and other qualified retirement plans excess accumulations in an IRA and excess distributions from qualified retirement plans. The data is used to help verify that the correct amount of tax has been paid.
Respondents: Individuals or households
Estimated Number of Respondents: 250,000
Estimated Burden Hours Per Response: 28 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 116,971

OMB Number: 1545-0976
Form Number: IRS Form 990-W
Tye of Review: Revision
Title: Estimated Tax on Unrelated Business Taxable Income for Tax-Exempt Trust
Description: Form 990-W is used by tax-exempt trust to figure estimated unrelated business income tax liability and the amount of each installment payment. Form 990-W is a worksheet only. It is not required to be filed.
Respondents: Businesses or other for-profit, Non-profit institutions
Estimated Number of Respondents: 13,265
Estimated Burden Hours Per Response: 39 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 8,633

OMB Number: 1545-1024
Form Numbers: IRS Form 8656
Type of Review: Revision
Title: Alternative Minimum Tax—Fiduciaries
Description: This form was developed to assist fiduciaries in computing the alternative minimum tax under new Code sections 55 through 59. The

minimum tax is determined by recomputing the distributable net income of the fiduciary on a minimum tax basis. The distributable net alternative minimum taxable income is then allocated to the beneficiaries.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 1,200,000
Estimated Burden Hours Per Response: 1 hour and 42 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 2,047,492 hours
Clearance Officer: Garrick Shear (202) 535–4297, Internal Revenue Service, Room 5571, 1111 Constitition Avenue, NW., Washington, DC 20224
OMB Reviewer: Milo Sunderhaul (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 88–18352 Filed 8–12–88; 8:45 am]

BILLING CODE 4810–25–M

Public Information Collection Requirements Submitted to OMB for Review

Date: August 8, 1988.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 15th and Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0047
Form Number: CF 5523
Type of Review: Extension
Title: Invoice Details for Footwear
Description: The information is needed to provide Customs personnel with the necessary details on imported footwear not normally provided on commercial invoices for the purposes of proper classification.
Respondents: Business or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 137,500
Estimated Burden Hours Per Response: 2 hours and 2 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 561,454 hours

OMB Number: 1515–0109
Form Number: None
Type of Review: Extension
Title: Proof of Use for Rates of Duty Dependent on Actual Use
Description: The declaration is needed to ensure Customs control over merchandise which is duty free. The declaration shows proof of use and must be submitted within 3 years of the date of entry or withdrawal for consumption.
Respondents: Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 700
Estimated Burden Hours Per Response: 20 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 4,025 hours
Clearance Officer: B. J. Simpson (202) 566–7529, U.S. Customs Service, Room 6426, 1301 Constitution Avenue, NW., Washington, DC 20229
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 88–18353 Filed 8–12–88; 8:45 am]

BILLING CODE 4810–25–M

Public Information Collection Requirements Submitted to OMB for Review

Date: August 5, 1988.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Office listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 15th and Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0092
Form Number: 1041 and related Schedules D, J, and K–1
Type of Review: Revision
Title: U.S. Fiduciary Income Tax Return; Capital Gains and Losses; Trust Allocation of an Accumulation Distribution; Beneficiary's Share of Income, Deductions, Credits, etc.
Description: Internal Revenue Code section 6012 requires that an annual income tax return be filed for estates and trusts. Data used to determine that the estates, trusts, and beneficiaries filed the proper returns and paid the correct tax.
Respondents: Individuals or households, Businesses or other for-profit
Estimated Number of Respondents: 2,250,000
Estimated Burden Hours Per Response: Form 1041: 2 hours and 2 minutes Schedule D: 1 hour and 13 minutes Schedule J: 4 hours and 24 minutes Schedule K–1: 24 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 6,635,560 hours

OMB Number: 1545–0099
Form Number: 1065 and Schedules D and K–1
Type of Review: Revision
Title: U.S. Partnership Return of Income, Capital Gains and Losses, Partner's Share of Income, Credits, Deductions, etc.
Description: Internal Revenue Code section 6031 requires partnerships to file returns that show income items, allowable deductions, partners' names, addresses, and distribution shares, and other information. This information is used to verify correct reporting of partnership items and for general statistics.
Respondents: Individuals or households, Farms, Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 1,900,026
Estimated Burden Hours Per Response: Form 1065: 5 hours and 27 minutes Schedule D: 56 minutes Schedule K–1: 55 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 20,453,280 hours

OMB Number: 1545–0228
Form Number: 6252
Type of Review: Revision
Title: Computation of Installment Sale Income
Description: Information is needed to figure and report an installment sale for a casual or incidental sale of personal property, and sale of real property by someone not in the business of selling real estate. Data is used to determine whether the installment sale has been properly reported and the correct amount of profit included in income on the taxpayer's return.

Respondents: Individuals or households, Farms, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations
Estimated Number of Respondents: 782,848
Estimated Burden Hours Per Response: 1 hour and 32 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 1,196,609 hours
Clearance Officer: Garrick Shear (202) 535-4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 88-18354 Filed 8-12-88; 8:45 am]
BILLING CODE 4810-25-M

Senior Executive Service; Performance Review Board

AGENCY: Treasury Department.
ACTION: Notice of members of Performance Review Board (PRB).

SUMMARY: This notice announces the appointment of members of the composite PRB for the U.S. Savings Bonds Division, the Bureau of the Public Debt, the Bureau of Engraving and Printing, the United States Mint, and the Financial Management Service.

FOR FURTHER INFORMATION CONTACT: Michael D. Serlin, Assistant Commissioner, Field Operations, Financial Management Service, 401 14th Street, SW., Washington, DC; Telephone (202) 287-0311.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4313(c)(4) and the Civil Service Reform Act of 1978, the members of the Senior Executive Service Performance Review Board for the U.S. Savings Bonds Division, the Bureau of the Public Debt, the Bureau of Engraving and Printing, the United States Mint, and the Financial Management Service are listed below. This Board reviews the performance of career senior executives below the level of bureau head and principal deputy in the five bureaus. At least three voting members constitute a quorum.

Bureau	Primary	Alternate
SB	Jerrold B. Speers, Executive Director	Lorn Harvey, Deputy Executive Director for Savings Bond Division.
PD	Kenneth W. Rath, Assistant Commissioner (Administration)	Eleanor J. Holsopple, Assistant Commissioner (Securities and Accounting Services).
E&P	L. Paul Blackmer, Jr., Assistant Director (Administration)	Carl D'Alessandro, Acting Assistant Director (Operations).
Mint	Eugene H. Essner, Deputy Director	Michael F. Hill, Associate Director for Policy and Management
FMS	Michael D. Serlin, Assistant Commissioner, Field Operations	Bland Brockenborough, Assistant Commissioner, Headquarters Operations.

This notice does not meet the Department's criteria for significant regulation.

Michael D. Serlin,
Assistant Commissioner, Field Operations, Financial Management Service PRB Chairman, 1988.
[FR Doc. 88-18384 Filed 8-12-88; 8:45 am]
BILLING CODE 4810-25-M

Internal Revenue Service

Art Advisory Panel; Closed Meeting

AGENCY: Internal Revenue Service, Treasury.
ACTION: Notice of closed meeting of Art Advisory Panel.

SUMMARY: Closed meeting of the Art Advisory Panel will be held in Washington, DC.

DATES: The meeting will be held September 15 and 16, 1988.

FOR FURTHER INFORMATION CONTACT: Karen Carolan, CC:AP:V, 1111 Constitution Avenue NW., Room 2575, Washington, DC 20224, Telephone No. (202) 566-9259 (not a toll free number).

Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1982), that a closed meeting of the Art Advisory Panel will be held on September 15 and 16 in Room 2004 beginning at 9:30 a.m., Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC 20224.

The agenda will consist of the review and evaluation of the acceptability of fair market value appraisals of works of art involved in Federal income, estate, or gift tax returns. This will involve the discussion of material in individual tax returns made confidential by the provisions of section 6103 of Title 26 of the United States Code.

A determination as required by section 10(d) of the Federal Advisory Committee Act has been made that this meeting is concerned with matters listed in section 552(c) (3), (4), (6), and (7) of Title 5 of the United States Code, and that the meeting will not be open to the public.

The Commissioner of Internal Revenue has determined that this document is not a major rule as defined in Executive Order 12291 and that a regulatory impact analysis therefore is not required. Neither does this document constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. Chapter 6).

Lawrence B. Gibbs,
Commissioner.
[FR Doc. 88-18381 Filed 8-12-88; 8:45 am]
BILLING CODE 4830-01-M

UNITED STATES INFORMATION AGENCY

Grants Program for Private, Non-Profit Organizations in Support of International Educational and Cultural Activities

The Office of Private Sector Programs of the United States Information Agency (USIA) announces a program of limited grant support for non-profit U.S. institutions and organizations in the private sector which as described below promotes the long-term foreign policy objective of the United States by promoting mutual understanding between its people and the people of other countries. The primary purpose of the program is to enhance the achievement of the United States' international public diplomacy goals and objectives by stimulating and encouraging increased private sector commitment, activity, and resources.

Projects must include an international people-to-people component, have an educational or cultural focus, and demonstrate a substantial contribution to long-term communication and understanding between the United States and other countries. Subjects must be consistent with USIA themes, priorities, and USIS post requirements.

The Office of Private Sector Programs works with U.S. not-for-profit organizations on cooperative international group projects which introduce American and foreign participants to one another's traditions, arts, social and political structures, and international interests. The Office will accord priority status to worldwide projects involving leaders or potential leaders in their fields such as parliamentarians, jurists, journalists, development officials, public policy experts, artistic practitioners. Proposals are welcome involving any area of the world, with special attention given to otherwise excellent projects involving regions and countries—such as Africa, the Near East and South and Southeast Asia—which have participated less frequently in exchanges. Each private sector activity must meet the highest professional standards, be non-partisan, and address substantive areas of mutual interest. Priority consideration is given to projects that involve United States Information Agency posts in the development of the program and the selection of the participants.

USIA grant assistance constitutes only a portion of total project funding. Proposals should list other anticipated sources of support—both financial and in-kind. Actual programs range from one to six weeks; the duration of the entire grant period does not normally exceed one year. Most funding assistance is limited to participant travel and per diem requirements with modest contributions to cover administrative costs. Grants are not ordinarily given to support performing arts tours, plastic arts exhibitions, reserch projects or professional training, youths or youth-related activities, or to fund publications. Student exchanges or projects which are scholarly or academic in purpose should be directed to USIA's Office of Academic Programs.

The Office of Private Sector Programs is now considering projects whose activities will begin after December 1, 1988, since final proposals must be received at least four months in advance of the activity date and will be accepted only when the final submission is in accord with Project Proposal Information Requirements (OMB #3118-0175). Inquiries are welcome prior to submission of applications.

For further information, organizations should contact Dr. Raymond H. Harvey, Office of Private Sector Programs, Bureau of Educational and Cultural Affairs, United States Information Agency, 301 4th Street, SW., Washington, DC 20547, or call (202) 485-7348.

Dated: August 10, 1988.

Robert Francis Smith,

Director, Office of Private Sector Programs.

[FR Doc. 88-18378 Filed 8-12-88; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 157
Monday, August 15, 1988

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).

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

August 10, 1988.

TIME AND DATE: 10:00 a.m., Wednesday, August 17, 1988.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following:

1. *Rushton Mining Company*, Docket No. PENN 85–253–R, etc. (Issues include whether the Secretary of Labor should be assessed attorney's fees and costs pursuant to Fed. R. Civ. P. 11)

Any person attending this meeting who requires special accessiblity features and/or auxiliary aids, such as sign language interpreters must inform the Commission in advance of those needs. Subject to 20 CFR § 2706.150(a)(3) and § 2706.160(d).

TIME AND DATE: Immediately following oral argument.

STATUS: Closed [Pursuant to 5 U.S.C. § 552b(c)(10)].

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the above listed case.

It was determined by a unanimous vote of Commissioners that this portion of the meeting be closed.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629 / (202) 566–2673 for TDD Relay.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 88–18439 Filed 8–11–88; 1:49 pm]

BILLING CODE 6735-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Notice forwarded to Federal Register on August 5, 1988.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 12:00 noon, Monday, August 15, 1988.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting:

Report of the operations review of the Office of the Secretary.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3024.

Date: August 11, 1988.

William W. Wiles,

Secretary of the Board.

FR Doc. 88–18463 Filed 8–11–88; 1:50 pm]

BILLING CODE 6210-01-M

PAROLE COMMISSION

DATE AND TIME: Friday August 19, 1988, 11:30 a.m., eastern daylight time.

PLACE: 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

STATUS: Open—Meeting to be conducted by conference telephone call.

MATTERS TO BE CONSIDERED: The following matter has been placed on the agenda for the open Parole Commission meeting:

Whether the Commission should extend its special parole procedures for YCA inmates in the *Watts* v. *Hadden* class action for all youth offenders sentenced under 18 U.S.C. § 5010(b) or (c).

AGENCY CONTACT: Rockne Chickinell, Office of General Counsel, United States Parole Commission (301) 492–5959.

Date: August 11, 1988.

Patrick J. Glynn,

General Counsel, U.S. Parole Commission.

[FR Doc. 88–18438 Filed 8–11–88; 1:48 pm]

BILLING CODE 4410-1-M

Corrections

Federal Register
Vol. 53, No. 157
Monday, August 15, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ADMINISTRATIVE COMMITTEE OF THE FEDERAL REGISTER

1 CFR Parts 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 20, 21, and 22

Updates and Changes to Publication Procedures; Proposed Rule

Correction

In proposed rule document 88-17820 beginning on page 29990 in the issue of Tuesday, August 9, 1988, make the following corrections:

1. On page 29990, in the second column, in the first complete paragraph, in the fifth line, "or" should read "of".

2. On page 29991, in the first column, in the second complete paragraph, in the third line insert a period between "17.2" and "Section".

3. On the same page, in the second column, in the third line from the bottom "received" should read "revived". Also in the last line, "5 U.S.C. et seq." should read "5 U.S.C. 551 et seq.".

4. On page 29993, in the first column, in the last paragraph, in the third line "on" should read "of".

§ 8.3 [Corrected]

5.On page 29995, in the first column, in the second line of item 3 "regulations" should read "regulation".

§ 8.10 [Corrected]

6. On the same page, in the second column, in § 8.10(b), in the sixth line "details that" should read "details the".

§ 11.5 [Corrected]

7. On page 29996, in the first column, in § 11.5, in the first line of the section heading, "Paper" should read "Papers".

§ 19.1 [Corrected]

8. On page 29999, in the second column, in § 19.1, footnote 2 at the bottom of the second column should be transferred to the end of paragraph 2.

BILLING CODE 1505-01-D

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 385

[DoD Directive 5111.1]

Under Secretary of Defense for Policy

Correction

In rule document 88-17553 beginning on page 29329 in the issue of Thursday, August 4, 1988, make the following correction:

On page 29329, in the first column, the subject heading was incorrect and should read as set forth above.

BILLING CODE 1505-01-D

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 387

[DoD Directive 5132.2]

Assistant Secretary of Defense (International Security Affairs)

Correction

In rule document 88-17552 beginning on page 29330 in the issue of Thursday, August 4, 1988, make the following correction:

On page 29330, in the second column, the subject heading was incorrect and should read as set forth above.

BILLING CODE 1505-01-D

FEDERAL TRADE COMMISSION

16 CFR Part 600

Fair Credit Reporting Act; Statements of General Policy or Interpretation; Proposed Official Commentary

Correction

In proposed rule document 88-17655 beginning on page 29696 in the issue of Monday, August 8, 1988, make the following correction:

On page 29696, in the first column, in the heading, the CFR line should appear as set forth above.

BILLING CODE 1505-01-D

federal register

Monday
August 15, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310, 346, and 369

Anorectal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 346, and 369

[Docket No. 80N-0050]

Anorectal Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) anorectal drug products for the relief of symptoms associated with hemorrhoids and other anorectal disorders are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 13, 1988. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. New data by August 15, 1989. Comments on the new data by October 15, 1989. Written comments on the agency's economic impact determination by December 13, 1988.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 27, 1980 (45 FR 35576), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC anorectal drug products, together with the recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products (Hemorrhoidal Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by August 25, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by September 24, 1980.

In a notice published in the **Federal Register** of September 26, 1980 (45 FR 63876), the agency advised that it had reopened the administrative record for OTC anorectal drug products to allow for consideration of recommendations on camphor-containing drug products that had been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) after the date the administrative record previously had officially closed. The agency concluded that the Miscellaneous External Panel's recommendations should be available to the agency in developing a proposed regulation on anorectal drug products in the form of a tentative final monograph. (See comment 21 below.)

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking, nine drug manufacturers, one drug manufacturers' association, six health professionals, and one consumer submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on May 27, 1980 (45 FR 35576), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish Part 346 (21 CFR Part 346), FDA states for the first time its position on the establishment of a monograph for OTC anorectal drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC anorectal drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC anorectal drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summaries of the comments and FDA's responses to them.

In the **Federal Register** of February 8, 1983, the agency published a tentative final monograph for OTC external analgesic drug products which included a labeling claim "for external anal itching" for hydrocortisone-containing products. After reviewing and evaluating that tentative final monograph and in response to a comment submitted to the anorectal rulemaking, the agency has decided to retain the above labeling claim and hydrocortisone in the external analgesic rulemaking rather than include them in the anorectal rulemaking. In this way, the various conditions for which hydrocortisone is effective will be listed in one monograph. In a future issue of the **Federal Register**, the agency will amend the tentative final monograph for OTC external analgesic drug products to include a requirement that hydrocortisone-containing products labeled for "anal itching" also be labeled with appropriate general warnings and directions consistent with other OTC anorectal drug products. (See comment 25 below.)

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required)

at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC anorectal drug products (published in the Federal Register of May 27, 1980; 45 FR 35576), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the Federal Register and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the Federal Register. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the Federal Register of April 26, 1973 (38 FR 10307) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Anorectal Drug Products

1. Two comments expressed their continuing position that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comments referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the Federal Register of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).

2. Several comments pointed out that a number of the Panel's recommendations do not represent the unanimous opinion of the Panel members because the Panel was divided four to three on many issues. Some of the comments argued that the minority view often demonstrated a greater clinical understanding than the majority view. The comments urged FDA, when evaluating the Panel's recommendations, to consider the minority view and the fact that there was not a clear consensus of the Panel.

Other comments contended that the Panel did not apply the same standards in classifying the various active ingredients, arguing that pramoxine was placed in Category I on the basis of old and questionable data, while live yeast cell derivative was placed in Category III despite objective data that were endorsed by experts. The comments requested that the agency carefully review all of the Panel's recommendations to determine if the Panel took an equitable approach in its evaluation of all ingredients contained in hemorrhoidal drug products.

In evaluating the Panel's recommendations, the agency has considered the comments' criticisms, reviewed the data submitted to the Panel, considered the minority's views, reviewed the current scientific literature, and evaluated new data submitted since the Panel's report was published. The agency's proposals in this tentative final monograph are based on consideration of all of these factors. (See comments 14 and 23 below for specific discussions of pramoxine and live yeast cell derivative.)

3. One comment requested that the agency include all available transcripts of the Panel's meetings in the administrative record.

The agency does not ordinarily include transcripts of panel meetings in the administrative record. The reasons for this are stated in the preamble to the "Proposal to Designate the Contents and the Time of Closing of the

Administrative Record," published in the **Federal Register** of June 4, 1974 (39 FR 19878). (The final rule was published in the **Federal Register** of November 8, 1974 (39 FR 39556).) Any comments relating to transcripts of panel meetings should state the reasons that would warrant the agency's consideration of the transcripts or particular portions of the transcripts, notwithstanding the reasons given by the agency for not ordinarily considering them. The comment did not state any reasons; therefore, the agency is not including the transcripts of the Panel's meetings in the administrative record.

4. Murray Berdick, Ph. D., commented that his name was omitted from the list of individuals who appeared before the Panel (45 FR 35577). He stated that his presentation is included in the transcript of the Panel's April 29, 1977 meeting and is cited as reference 12 at 45 FR 35627. He also indicated that his name was incorrectly spelled at 45 FR 35635, column 2, reference 6.

The agency regrets that Dr. Berdick's name was omitted from the list of persons who appeared before the Panel and was incorrectly spelled in the cited reference at 45 FR 35635.

5. One comment stated that the Thornton and Minor Clinic and Hospital and the McCleary Hospital of Kansas City, Missouri, were not mentioned in the Panel's overview of the history of anorectal diseases and their treatment (45 FR 35581). The comment added that the Clinic specializes in the research and treatment of anorectal disorders and included an account of its history.

The agency appreciates the comment's pointing out these omissions from the Panel's report. However, the historical discussion of anorectal diseases and their treatment was included as background in the Panel's report and was not intended to be all-inclusive.

6. One comment pointed out that the correct citation at 45 FR 35627 for data submitted in support of the barrier effect of protectants should have been Reference 9, OTC Volume 120052, not Reference 6, which is "Remington's Practice of Pharmacy." Another comment stated that a protocol for a product containing dibucaine apparently was erroneously attributed to Ciba-Geigy in the administrative record and that this firm did not submit this protocol.

The agency acknowledges that Reference 6 at 45 FR 35627 should have been identified as OTC Volume 120052. The protocol erroneously attributed to Ciba-Geigy should have been attributed to Myer Laboratories.

7. One comment argued that publication of a call-for-data notice in the **Federal Register** amounted to inadequate notice to manufacturers of hemorrhoidal drug products and discriminated against the smaller manufacturer or packager who, with only a small support staff, may not have the resources to employ an individual to read the **Federal Register** every day. The comment stated that its marketed hemorrhoidal preparation containing ephedrine alkaloid and 8-hydroxyquinoline was not submitted to the Panel for review because of this lack of notice. Consequently, these ingredients were not reviewed by the Panel and would become Category II in a final rule. The comment objected to such a Category II classification for these ingredients, adding that the rectal preparation in which they are combined has been used successfully for over 20 years.

In addition to the call-for-data notice (38 FR 10307), the agency regularly published notices in the **Federal Register** announcing the dates of the Panel's meetings and the part of each meeting that was open to the public. The minutes of each meeting were made publicly available, and the industry liaisons, who served on the Hemorrhoidal Panel as nonvoting members, were nominated by The Proprietary Association, the national trade association of OTC drug manufacturers. In addition, the OTC drug review has been highly publicized, and the Panel's review of anorectal drug products covered a period of over 4 years.

For these reasons, the agency believes that adequate opportunity was provided for all parties to present their positions to the Panel. Ample opportunities have existed and continue to exist for all interested persons to express their opinions before publication of the final rule. For example, interested persons could have submitted comments and data during the comment period following publication of the Panel's report and may do so again following publication of the tentative final monograph. (See § 330.10(a) (6) and (7).)

The comment did not submit any data to support the safety and effectiveness of ephedrine alkaloid or 8-hydroxyquinoline used in anorectal drug products. Therefore, the agency has no basis for classifying these ingredients in this tentative final monograph. As stated above, additional data may be submitted for 12 months following publication of this tentative final monograph.

8. One comment contended that the Panel failed to evaluate or discuss two clinical studies submitted to show that its proposed product (an aerosol medicated anal wipe foam) was significantly effective for relief of pain and itching in persons with anorectal disease (Refs. 1 and 2). Referring to the statement at 45 FR 35590 that "the need to produce a foam for delivering the active ingredient is not clear to the Panel," the comment contended that the Panel failed to perceive that all foams are not "shaving lather-type" foams. The comment stated that its anhydrous foam is a "quick-breaking" type of foam and serves only as a delivery vehicle. As the foam is applied to the toilet tissue it breaks and leaves a local anesthetic suspension, while the emollients and other ingredients are left in solution for skin application.

Although not referred to in the Panel's general statement on foams, the data submitted by the comment were reviewed by the Panel and referred to in the discussion of testing guidelines at 43 FR 35595. The Panel also discussed the use of foam products for delivering an active ingredient externally in the anal canal and in the lower rectum below the dentate line (43 FR 35589 and 35590). Because the agency is not proposing the Panel's requirement for final formulation testing in this tentative final monograph, Category I anorectal ingredients can be formulated in any dosage form for external use, including foams, provided the product meets each condition of the final monograph. (See comment 55 below.)

However, the proposed product to which the comment referred would have anesthetic, counterirritant, emollient, and/or antipruritic properties (Ref. 1). The Panel concluded that it is not rational to combine a local anesthetic and a counterirritant and placed such combinations in Category II.

The agency concurs. Thus, the comment's proposed product would be considered a Category II combination. (See comment 34 below.)

References

(1) OTC Volume 120035.
(2) OTC Volume 120037.

B. Comments on Local Anesthetics

9. One comment supported the opinion of the Panel minority that local anesthetics in anorectal drug products should be Category I for intrarectal use instead of Category III, as recommended by the Panel majority. The comment cited the minority's reasoning that, even without double-blind studies, the effectiveness of local anesthetic-containing anorectal drug products that are used intrarectally is supported by marketing records of repeat sales, use

experience, and Panel members' clinical experience with patients who claimed relief of discomfort after intrarectal use of these products.

The agency has thoroughly considered the issue of intrarectal (internal) use of local anesthetics and finds that, at present, there is insufficient evidence of general recognition of the safety and effectiveness of this use of local anesthetics. The lack of general recognition is demonstrated by the fact that the Panel was not unanimous in its recommendations.

The Panel majority pointed out that there are no known sensory pain fibers above the dentate line (45 FR 35607). Hence, the majority concluded that there is insufficient evidence to prove that local anesthetics used intrarectally are effective. In addition, the Panel majority felt that local anesthetics can easily diffuse through mucous membranes and, when applied intrarectally can be absorbed directly into the systemic, central, and portal blood circulations almost as rapidly, under certain conditions, as intravenous administration. Thus, these drugs raise potential safety questions and could cause severe reactions in certain individuals.

After reviewing the available scientific evidence, the Panel concluded that certain local anesthetics, i.e., benzocaine, benzyl alcohol, dyclonine, and pramoxine, could be used safely intrarectally but that data were still needed to establish effectiveness. (See 45 FR 35613 to 35619.)

The Panel minority believed that the majority based its conclusion on the fact that there are no anatomically identifiable sensory nerve endings or nerve fibers in the rectal mucosa or submucosa. However, the minority argued that there are known and identifiable nerve fibers and plexuses between the muscular layers that are associated with peristaltic muscular contraction of the rectum. The minority concluded that these nerve fibers, which are known to innervate the smooth musculature of the rectum, have synapses with cells in the myenteric and submucosal plexuses. In addition, the fibers have or are in adjacent association with sensory conducting nerve fibers, which transmit impulses to the central nervous system.

The minority argued that, although electrical stimulation or application of a mustard suspension to the rectal mucosa has not been shown to evoke a pain response in healthy mucosa, pain perception may result when blood vessels supplied with sensory pain fibers become diseased with hemorrhoids. However, evidence based on well-controlled clinical studies is lacking to support this argument. In addition, both the majority and minority of the Panel discussed the fact that some sensation of pressure can be produced in the rectum by distention due to feces or gas (45 FR 35607 to 35608). The agency is not aware of evidence that the source or sources of this sensation are also capable of transmitting the sensations of pain or itching.

Finally, in support of intrarectal use of local anesthetics, both the comment and the Panel minority cited marketing records of repeat sales of products containing local anesthetics for intrarectal use. They also cited use experience, particularly that of Panel members' patients who claimed relief of anorectal discomfort after use of these products. The agency recognizes that proof of effectiveness may not always consist of controlled clinical investigations. In fact, the OTC drug review regulations in 21 CFR 330.10(a)(4)(ii) provide that investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. However, after carefully reviewing all the available literature, the agency agrees with the Panel majority (45 FR 35607) that the intrarectal effectiveness of all local anesthetics remains unsubstantiated and requires further study. (See also comment 11 below.) However, the agency emphasizes that this decision does not affect the external use of these ingredients. OTC anorectal anesthetics are being included in the tentative final monograph with appropriate labeling for external use only.

The agency invites public comment and submission of data on the safety and effectiveness of OTC anorectal anesthetic drugs for intrarectal use. Pending receipt and review of such data and information, the agency proposes that the intrarectal use of OTC anorectal anesthetic ingredients be considered a Category III condition except for those ingredients or conditions that are proposed as Category II.

10. One comment stated that the Panel's recommended monograph refers to dibucaine base and dibucaine hydrochloride, but that only dibucaine base is presently available in formulations intended for anorectal use.

In addition to the data submitted on dibucaine base, the Panel chose to review the hydrochloride salt, noting that the base is slightly water soluble and moderately lipid soluble, whereas the hydrochloride salt is soluble in water and in organic solvents (45 FR 35614). The Panel considered dibucaine base and dibucaine hydrochloride as pharmacologically equivalent, and the agency concurs. Dibucaine base and dibucaine hydrochloride were classified by the Panel as Category III for external and intrarectal use (45 FR 35614) and therefore were not included in the Panel's recommended monograph. However, as discussed in comment 12 below, the agency is proposing Category I status in this tentative final monograph for dibucaine base and dibucaine hydrochloride for external use. Intrarectal use of these ingredients is Category III. (See comment 9 above and comment 11 below.)

11. One comment submitted summaries of six studies (Ref. 1) and requested that dibucaine be classified Category I as a local anesthetic for intrarectal use. Noting that these same summaries had been submitted to the Panel (Ref. 2), the comment stated that the Panel apparently found the results presented in these summaries to be insufficient to demonstrate the effectiveness of dibucaine for intrarectal use. The comment added that, although the data generated by these studies do not demonstrate statistical significance in all parameters, it believes that dibucaine has been shown in the clinical practice setting to be effective in the relief of hemorrhoidal symptoms. The comment pointed out that the studies had been reviewed by other authorities who found that the studies, as a whole, demonstrate the effectiveness of dibucaine used intrarectally (Refs. 3 and 4). The comment subsequently submitted additional effectiveness data (Ref. 5).

In addition, the comment disputed the Panel's conclusion that dibucaine had not been shown to be safe for intrarectal use because of possible systemic toxicity when administered intrarectally. Contending that further safety data are not needed, the comment stated that studies in which dogs and monkeys were administered high doses of dibucaine intrarectally did not show serum levels as high as those of dibucaine administered intravenously. The comment added that lipid vehicles retard the rate and extent of absorption of local anesthetics, that marketing history and submitted studies attest to dibucaine's safety when used intrarectally, and that further testing of humans using high doses of dibucaine would be unethical.

The agency has evaluated the summaries submitted by the comment (Ref. 2) and the additional effectiveness data (Ref. 5). The same summaries were submitted to the Panel on April 27, 1977

(Ref. 2). Other data and information on these studies including the opinions of the other authorities mentioned by the comment had also been submitted to the Panel on June 22, 1973 (Ref. 4) and on July 29, 1974 (Ref. 3). The Panel reviewed all of these data, plus other data, and concluded that the effectiveness of local anesthetics, including dibucaine, for intrarectal use is unproven (45 FR 35616). The agency concurs with that determination.

The additional effectiveness data involved a randomized, double-blind comparison in 143 patients of an ointment containing dibucaine base and the ointment base minus dibucaine for relief of pain, burning, and/or itching associated with internal, external, or mixed hemorrhoids (Ref. 5). (The summary of this study had been reviewed by the Panel (Ref. 2).) Only 127 cases were suitable for analysis; 65 patients received the ointment containing dibucaine base while 62 patients received the ointment base without dibucaine. Despite several problems in evaluation, including heterogeneous disease processes of external hemorrhoids, internal hemorrhoids, and mixed hemorrhoids, and variable patient medication compliance, and despite probable contribution from the ointment vehicle base, the ointment containing dibucaine base was shown in this study to be superior to the ointment base in seven of the measurements for which there was significance at the 5-percent level or greater; this leaves two measurements where the ointment base was judged superior at the same level of significance.

Only 15 patients who received the ointment containing dibucaine base and 14 patients who received the vehicle alone had internal hemorrhoids. The rest of the patients had either external hemorrhoids or mixed hemorrhoids (50 patients who received the ointment containing dibucaine base and 48 patients who received the vehicle control).

In about 75 percent of the cases there were external complaints (external to the dentate line) and in about 25 percent of the cases complaints were judged to be as a result of internal hemorrhoids. However, the data are analyzed only for the entire group, with no analysis exclusively for those patients with internal hemorrhoids. Further, the agency believes such an analysis would not be meaningful because it would involve 29 patients derived from 9 investigators or about 3 cases per investigator.

There are insufficient data to establish that the ointment containing dibucaine base is effective for the relief of pain, burning, discomfort, and itching associated with internal hemorrhoids. The safety of internal application also has to be established for dibucaine base. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 6).

References

(1) Comment No. C00008, Docket No. 80N-0050, Dockets Management Branch.
(2) OTC Volume 120064.
(3) OTC Volume 120023.
(4) OTC Volume 120010.
(5) Comment No. SUP002, Docket No. 80N-0050, Dockets Management Branch.
(6) Letter from W. E. Gilbertson, FDA, to R. Gauch, Ciba-Geigy Corp., coded LET011, Dockets Management Branch.

12. Disputing the Panel's statement at 45 FR 35616 that "there are no studies using dibucaine in the perianal area," one comment cited data on a controlled study that had been submitted to the Panel. The study involved approximately 45 patients with external hemorrhoids and 65 patients with both internal and external hemorrhoids (Ref. 1). The comment argued that the Panel placed pramoxine in Category I for external use based on data from two uncontrolled studies and placed benzocaine in Category I for external use based on one unblinded, nonrandomized study that used only 13 patients. The comment stated that the Panel either used different standards in determining the effectiveness of dibucaine than it used for pramoxine and benzocaine or discounted or ignored the "superior" data submitted for dibucaine.

Contending that proof of dibucaine's effectiveness as a local anesthetic need not relate solely to its use in the perianal area, the comment pointed out that the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) classified dibucaine in Category I for external use for "the temporary relief of pain and itching due to * * * minor cuts, abrasions * * *, and minor skin irritations." The comment added that the Hemorrhoidal Panel stated that dibucaine is probably effective on abraded skin of the perianal area, and that the Topical Analgesic Panel found dibucaine to be effective on abraded skin generally. The comment further contended that abraded skin is abraded skin regardless of its location and that there is no justification for categorizing dibucaine as anything less than Category I for use on perianal skin. The comment urged the agency to consider the fact that many patients over the years have obtained relief using dibucaine and that, for all of the above reasons, a Category I classification of dibucaine as a local anesthetic for external use in anorectal disease is warranted.

Although the comment requested Category I status specifically for dibucaine, the agency notes that the Panel considered dibucaine (base) and dibucaine hydrochloride to be pharmacologically equivalent (see comment 10 above); therefore, this discussion on external use applies to both ingredients. (The intrarectal use of local anesthetics is discussed in comment 9 above.)

The Panel reviewed the data referred to by the comment and applied the same standards in reaching its conclusions on benzocaine, dibucaine, dibucaine hydrochloride, and pramoxine hydrochloride (45 FR 35609 to 35610 and 35614 to 35617), namely that the effectiveness of an OTC anorectal active ingredient should be demonstrated in the vehicle in which it would be marketed and that the final formulation should be tested in the anorectal area. The Panel concluded that adequate data were submitted to permit classification of benzocaine and pramoxine hydrochloride in specific vehicles in Category I for external use. However, although the data submitted to the Panel contained studies using final formulations of dibucaine, the Panel concluded that because of the lack of studies on perianal skin the data were not sufficient to establish the effectiveness of dibucaine for external use for relieving anorectal conditions (45 FR 35616).

In the tentative final monograph for OTC external analgesic drug products, published in the **Federal Register** of February 8, 1983 (48 FR 5852), the agency tentatively adopted the recommendations of the Topical Analgesic Panel and proposed that dibucaine and dibucaine hydrochloride in concentrations of 0.25 to 1 percent be generally recognized as safe and effective for external use. Having reviewed both Panels' recommendations, the agency believes that the data on dibucaine and dibucaine hydrochloride show that these ingredients when applied to the skin of the perianal area and anal canal are as safe and effective as when used on the skin of other areas of the body. Therefore, in this tentative final monograph the agency is proposing dibucaine and dibucaine hydrochloride as Category I for external use.

The agency notes that the Hemorrhoidal Panel's recommended

dosage range for dibucaine and dibucaine hydrochloride was 2.5 milligrams (mg) to 20 mg per dosage unit. The minimum effective dose of 2.5 mg per dosage unit was based on the amount of dibucaine in a marketed suppository for intrarectal use, for which data were submitted to the Panel. The maximum safe dose of 20 mg per dosage unit was based on the amount of the ingredient contained in a 2-gram (g) dose of a 1-percent ointment for external and intrarectal use, for which data were also submitted to the Panel. The agency notes that the 2.5-mg suppository dosage form is no longer marketed and is unaware of any other currently marketed product that contains 2.5 mg dibucaine per dosage unit. The 1-percent ointment is still marketed. Therefore, the agency is proposing that the dosage of dibucaine and dibucaine hydrochloride for external use be expressed in a concentration range of 0.25 to 1 percent for use up to 3 or 4 times daily, which is consistent with the tentative final monograph for OTC external analgesic drug products (48 FR 5852). In addition, because the agency did not propose any limitation on the maximum safe daily dose of this ingredient for topical use in the external analgesic tentative final monograph, and because the Panel's recommended limitation on the maximum daily dose of dibucaine was based on the potential safety concerns resulting from intrarectal application, the agency is not proposing the 80-mg maximum daily dose limitation recommended by the Hemorrhoidal Panel for dibucaine and dibucaine hydrochloride.

Reference

(1) OTC Volume 120064, pp. 6, 7, 10, 19–21, 31–33, and 50–57.

13. One comment supported the Panel's interim decision, made at its 7th and 16th meetings, to place diperodon (0.5 to 1 percent) in Category I for external use. The comment contended that the Panel's decision during its 28th meeting to place diperodon in Category III was based largely on double-blind studies showing that diperodon was only slighty more effective than placebo. The comment disputed the Panel's final recommendation to place diperodon in Category II for external use and cited a study to support the effectiveness of diperodon (Ref. 1). The comment also cited the **Federal Register** of June 18, 1971, in which the comment stated that FDA published the findings of the National Academy of Sciences-National Research Council's (NAS–NRC) Drug Efficacy Study Group that diperodon was possibly effective for the temporary relief of anorectal pain and itching, as well as for anesthetic and mild antiseptic action. The comment stated that safety is not at issue and contended that the difference in scientific opinion as to diperodon's effectiveness should not result in its placement in Category II.

During the course of the Panel's deliberations the classification of diperodon was tentative; however, with the publication of its recommendations in the **Federal Register**, the Panel's final classification of diperodon was as follows: Category II for external use and Category III for intrarectal use. Only the external use of diperodon is discussed in this response. The intrarectal use of local anesthetic ingredients is discussed elsewhere in this document. (See comment 9 above.)

After reviewing the data submitted to the Panel and the references cited by the comment, the agency concludes that diperodon can be reclassified from Category II to Category III for external anorectal use but that the data remain inadequate to reclassify it into Category I.

The published study (Ref. 1) and the June 18, 1971 **Federal Register** notice describing the NAS–NRC report, which were referenced by the comment, and an unpublished study in humans (Ref. 2) were evaluated and cited by the Panel in its discussion of the effectiveness of diperodon for external use (45 FR 35612). The Panel concluded that diperodon was not effective for OTC external anorectal use because the predominant results of the studies show no statistical difference between diperodon and placebo.

With respect to the published study (Ref. 1), although the investigators concluded that diperodon was effective as a topical anesthetic in this dermal abrasion study in the guinea pig, there is a lack of evidence that diperodon produces clinically significant topical anesthetic action in humans.

In the unpublished study, 43 patients were randomized to receive an ointment containing diperodon or placebo in double-blind fashion on the day following anorectal surgery (Ref. 2). The patients evaluated the degree of pain (none, mild, moderate, severe) on the morning of the first post-operative day just prior to application of the test product (baseline) and again at 10, 20, 40, and 60 minutes following ointment application. The agency has analyzed the pain score data and concludes that the response at 40 and 60 minutes favored the diperodon-containing ointment, although differences did not achieve statistical significance at the conventional 0.05 level.

Results of four other controlled studies of the ointment containing diperodon that were submitted to the Panel (Ref. 3) failed to confirm the positive results of the above unpublished study (Ref. 2). Two of these studies were similar in design to the unpublished study discussed above and involved more patients; however, all of these studies failed to show a significant drug effect. Without independent replication of the findings in the unpublished study (Ref. 2), it is difficult to draw definitive conclusions concerning the effectiveness of diperodon as a topical anesthetic.

Although the evidence of the effectiveness of diperodon as a local anesthetic is conflicting, some of the data are suggestive of effectiveness. Therefore, the agency is upgrading diperodon as a local anesthetic for external anorectal use from Category II to Category III. Additional data are needed before the effectiveness of diperodon for external anorectal use can be established. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 4).

References

(1) Campbell, A.H. et al., "In Vivo Evaluation of Local Anesthetics Applied Topically," *Journal of Pharmaceutical Sciences*, 57:2045–2048, 1968.

(2) Lieberman, W., Protocol 039–WL–001, OTC Volume 120075.

(3) OTC Volume 120075.

(4) Letter from W.E. Gilbertson, FDA, to J.P. Tierney, Counsel for Thornton-Minor McCleary Ointment Co., coded LET009, Docket No. 80N–0050, Dockets Management Branch.

14. One comment requested that the Panel's recommendations in § 346.10(b) for a cream or jelly formulation for pramoxine hydrochloride be expanded to include ointments and aqueous vehicles. The comment stated that the rate-limiting step in drug absorption in the anorectal area is the rate of release of the dissolved drug from the melted base. With a salt such as pramoxine hydrochloride, the rate of release would be increased by using a lipid base because the salt would be released rapidly from lipid to water and be available for treating the affected area. This comment also stated that if the intrarectal use of local anesthetics is classified in Category III, the suppository dosage form of pramoxine hydrochloride should also be included in Category III.

Two comments requested that the monograph include an aerosol foam dosage form of pramoxine hydrochloride. Noting that the Panel

stated that the need for a foam anorectal dosage form was unclear, one of the comments argued that the agency established the need and rationale for this dosage form by approving as safe and effective two prescription anorectal drug products containing a steroid in an aerosol foam. The comment submitted data to show that the mucoadhesive properties of the aerosol foam product, discussed by the Panel at 45 FR 35590, provide a rapid and complete coverage of the rectal mucosa compared with the slow and incomplete coverage provided by a conventional suppository (Ref. 1).

The submissions on pramoxine hydrochloride presented to the Panel included information on various dosage forms (45 FR 35590, 35610, and 35611); however, only one submission for jelly and cream dosage forms contained complete information as to the content of the final formulation, i.e., inactive ingredients (Ref. 2). Because the Panel concluded that the final formulation of anorectal products must be tested for safety and effectiveness (45 FR 35588) and because the only data submitted which identified the complete final formulation were for a cream and a jelly (Ref. 2), it placed only those dosage forms and the specific ingredients contained in the marketed formulations in its recommended monograph. Nevertheless, after reviewing the submitted data for all dosage forms, including those which did not specifically identify the inactive ingredients in the final formulations, the Panel stated that no toxic effects were noted in the clinical use of pramoxine hydrochloride as an aerosol foam, in suppositories, and in other vehicles including ointments and solutions (45 FR 35610 and Ref. 3).

Regarding the use of an aerosol foam, the Panel stated that the need to produce a foam for delivering the active ingredient was not clear (45 FR 35590) and that a properly designed ointment applicator should serve the same purpose as a foam delivery system. However, the Panel also stated that it did not intend to restrict ingenuity in product design as long as the product accomplishes the claimed effect and met the same final formulation requirements of safety and effectiveness as any other dosage form. The agency is aware that topical aerosol foam products containing pramoxine hydrochloride 1 percent labeled for anorectal use have been marketed OTC for a number of years (Refs. 4 and 5). Accordingly, based on the safety of this ingredient for external anorectal use and the knowledge that an aerosol foam is an effective delivery system for external anorectal use, the agency finds a topical aerosol foam dosage form of pramoxine hydrochloride acceptable for OTC use. Likewise, based on the history of many anorectal drug products being marketed in ointment dosage forms and the data submitted to the Panel (Ref. 2), the agency believes that an ointment vehicle would be acceptable for pramoxine hydrochloride when used externally.

Suppositories containing pramoxine hydrochloride, however, would not be acceptable dosage forms at this time because of insufficient data to establish the effectiveness of local anesthetics when used intrarectally. (See comment 9 above.) There is a lack of experience with formulations of this drug and similar anorectal drugs in aqueous vehicles. The Panel stated that an aqueous solution of pramoxine hydrochloride is not useful in anorectal products because the ingredient will not remain at the site of action (45 FR 35611).

As discussed in comment 55 below, specific dosage forms or specific formulations for anorectal active ingredients are not identified in this tentative final monograph. Thus, in formulating anorectal drug products containing pramoxine hydrochloride, manufacturers should assure that the vehicle is safe and suitable for anorectal use and that the active ingredient will be properly released from the formulation.

References

(1) Comment No. C00015, Docket No. 80N–0050, Dockets Management Branch.
(2) OTC Volume 120084.
(3) OTC Volume 120015.
(4) OTC Volume 120039.
(5) OTC Volume 120050.

C. Comments on Vasoconstrictors

15. One comment questioned whether the Panel's Category I recommendation for ephedrine sulfate and phenylephrine hydrochloride "in aqueous solution" for external and intrarectal use could be interpreted to mean that the ingredients could be dissolved in the aqueous phase of either an oil-in-water or water-in-oil emulsion vehicle.

The data reviewed by the Panel primarily focused on aqueous solutions of ephedrine sulfate and phenylephrine hydrochloride (45 FR 35622 and 35624). Because of the Panel's concerns about the need for final formulation testing to support safety and effectiveness, the agency believes that the Panel felt that these ingredients had only been determined to be effective when present in an aqueous solution. The agency is not proposing the Panel's recommendation for final formulation testing, and therefore specific vehicles (e.g., oil-in-water or water-in-oil emulsions) for anorectal active ingredients are not being identified in this tentative final monograph. (See comment 55 below.) Thus, in formulating anorectal drug products containing ephedrine sulfate or phenylephrine hydrochloride, manufacturers should assure that the vehicle is appropriate for anorectal use and that the active ingredient will be properly released from the formulation. Manufacturers should be aware that the newness of a dosage, or method * * * of administration or application, or other condition of use * * * may affect the "newness" of a drug. (See 21 CFR 310.3(h)(5).)

16. One comment maintained that statements made by the Panel concerning formulations containing ephedrine sulfate are contradictory. The comment noted that the Panel stated at 45 FR 35587 that water-soluble, oil-insoluble salts, such as ephedrine sulfate, are preferred for rapid absorption from a fat-type base, such as cocoa butter, but that the Panel stated at 45 FR 35622 that ephedrine sulfate is Category I only in an aqueous solution.

In discussing the effectiveness of ephedrine sulfate, the Panel stated that incorporation of ephedrine sulfate in an ointment appears reasonable to provide better surface contact and greater effectiveness. However, the Panel noted that neither a literature survey nor a review of the submitted data provided effectiveness studies on the formulation of ephedrine sulfate in an ointment (45 FR 35623). The Panel recommended that ephedrine sulfate be formulated only in an aqueous solution, as this formulation was the only one containing ephedrine sulfate of which the Panel was aware (45 FR 35622). However, because the agency is not proposing the Panel's recommendation for final formulation testing, specific vehicles for anorectal active ingredients, including ephedrine sulfate, are not identified in this tentative final monograph. Thus, anorectal active ingredients may be formulated in any safe and suitable vehicle. (See comment 55 below.)

D. Comments on Protectants

17. One comment requested that hydrogenated vegetable oils and waxes be included as Category I anorectal protectants. Another comment requested that semisynthetic bases, such as those derived from coconut oil or mixtures of triglycerides of fatty acids, be recognized as Category I anorectal protectants.

The Panel did not review these substances because no data on them were submitted. The comments did not submit any data to support their requests, nor is the agency aware of any data on these substances when used as anorectal protectant active ingredients. The agency therefore lacks sufficient data for Category I status for these substances at this time.

18. One comment stated that the Panel did not discuss palm kernel oil as a protectant and suppository base, nor did it evaluate two submissions that it received on this ingredient (Refs. 1 and 2). The comment added that the Panel failed to use its expertise to evaluate and designate palm kernel oil as a "protectant vehicle" when the only use of this ingredient that it mentioned was as an inactive ingredient (45 FR 35580). The comment stated that palm kernel oil is combined with other nonirritating oils, such as coconut oil, for use as an ointment base or a suppository base and has been used as a "protectant vehicle" in a therapeutic formulation for the treatment of psoriasis and eczema. The comment referred to published studies on the safety of hydrogenated palm kernel oil as a suppository base and on the rate of release of pharmacologically active ingredients from palm kernel oil ointment bases. The comment stated that the wide use of this protectant ingredient, in addition to the data, attests to its safety for human use topically and internally. The comment provided a bibliographical listing of 17 references to support its statements and copies of 9 of these references (Ref. 3).

The agency has reviewed the submissions cited by the comment and the nine references provided and concludes that the data are inadequate to support the classification of palm kernel oil as a Category I protectant for anorectal use. However, it should be noted that this nonmonograph classification and the Panel's classification of palm kernel oil is an inactive ingredient do not prevent its use in an ointment or suppository base.

One of the submissions referred to by the comment was a letter to the Panel describing a marketed suppository containing a combination of two suppository bases in approximately equal amounts (Ref. 1). The letter also stated that the bases were synthetic triglycerides derived from coconut or palm kernel oil and requested that the Panel include coconut oil and palm kernel oil in its list of pharmaceutical necessities (inactive ingredients). Accordingly, the Panel added these ingredients to its list of pharmaceutical necessities as "coconut oil (palm kernel oil)" (45 FR 35580). The letter did not mention the use of coconut oil or palm kernel oil as protectants.

Subsequently, on May 14, 1975, another submission was made to the Panel by the same manufacturer on its ointment and suppository products (Ref. 2). The submission lists the ingredients of an anorectal ointment and suppository, including the suppository bases described in the letter above. The submission did not make a specific request that these ingredients be considered as protectants nor was any information provided in the submission on the safety and effectiveness of coconut oil or palm kernel oil as protectants.

As mentioned above, the comment provided copies of 9 of the 17 references that it cited. The other 8 references appear to have been published in foreign languages, and the agency has been able to obtain a complete translation for only one of these references (Ref. 4). The data contained in the available references provide general information as to the fatty acid content of the oil, manufacturing processes, chemical and physical properties, and use of the oil in soaps (Refs. 5 through 12).Golucki (Ref. 4) studied the liberation rate of citric acid and salicylic acid from palm kernel oil ointments. These references relate to safety, but do not support the effectiveness of palm kernel oil as a protectant. Interested persons may submit additional data to establish the effectiveness of palm kernel oil as a protectant during the comment period following the publication of this tentative final monograph. Any data received will be evaluated and addressed in the final rule.

The agency's detailed comments and evaluation of the submissions and the references cited by the comment are on file in the Dockets Management Branch (Ref. 13).

References

(1) Letter submitted by Bristol-Myers Products, dated June 17, 1974, to T. DeCillis, FDA, in OTC Volume 12APA3, Docket No. 80N–0050, Dockets Management Branch.

(2) OTC Volume 120031.

(3) Comment No. C00014 and Report No. RPT, Docket No. 80N–0050, Dockets Management Branch.

(4) Golucki, Z. "The Relationship Between the Concentration of a Pharmacologically Active Substance and the Rate of Its Liberation From Ointment Base," *Dissertationes Pharmaceuticae et Pharmacologicae*, 23:83–87, 1971.

(5) Myddleton, W.W., "Cosmetic Materials. Their Origin, Characteristics, Uses and Dermatological Action," Vol. II, "The Principles and Practice of Modern Cosmetics," Chemical Publishing Co., Inc., New York, p. 315, 1963.

(6) Balsam, M.S., and E. Sagarin, "Cosmetics. Science and Technology," 2d Ed., Wiley-Interscience, New York, p. 8, 1972.

(7) Dreger, E. E., and J. Ross, United States Patent No. 2,462,831 (abstract), assigned to Colgate-Palmolive-Peet Co., March 1, 1949.

(8) Wade, A., editor, "Martindale. The Extra Pharmacopoeia," 27th Ed., The Pharmaceutical Press, London, pp. 1049–1050, 1977.

(9) "British Pharmacopoeia—1973," 10th Ed., Medicines Commission, London, pp. 339–340, 1973.

(10) Allen, A., G.H. Padley, and G.R. Whalley, "The Fatty Acid Composition of Some Soapmaking Fats and Oils, Part 2. Coconut and Palm Kernel Oils," *Soap, Perfume, Cosmetics*, 42:372, 374, 376, 378, and 380, 1969.

(11) Cornelius, J.A., "Palm Oil and Palm Kernel Oil," *Progress in the Chemistry of Fats and Other Lipids*, 15:5–27, 1977.

(12) Szczepanska, H., H. Grynberg, and Z. Elsner, "Some Interdependence of Physicochemical and Pharmaceutical Properties of Fats," *Fette-Seifen-Anstrichmittel*, 22:68–71, 1970.

(13) Letter from W.E. Gilbertson, FDA, to W.B. Elvers, Bristol Myers Products, coded LET007, Docket No. 80N–0050, Dockets Management Branch.

19. One comment requested that the advance notice of proposed rulemaking be amended to include cocoa butter substitutes derived from natural food grade coconut and/or palm kernel oils as Category I protectants. Stating that cocoa butter substitutes are currently marketed in OTC anorectal drug products and are more readily available and less costly than cocoa butter, the comment submitted excerpts from pharmaceutical compendia in support of this statement (Refs. 1, 2, and 3). The comment added that cocoa butter substitutes, sometimes referred to in labeling as bland hydrogenated vegetable oil base ("Adeps Solidus"), are contained in suppository products submitted to the Hemorrhoidal Panel, but did not specify any submitted products as containing these ingredients. The comment subsequently submitted copies of an unpublished clinical study (Ref. 4), a published clinical study (Ref. 5), and results of a Draize eye test (Ref. 6).

The agency considered the comment's request as a petition to reopen the administrative record and included the new data and information on cocoa butter substitutes. Subsequently, the agency evaluated these data and information and determined that they relate only to safety and do not address effectiveness. In addition, the composition of cocoa butter substitutes was not defined, nor was a use concentration established. Lacking

specific data to show composition and use concentration of cocoa butter substitutes, the agency cannot evaluate the safety and effectiveness of these ingredients and thus cannot consider them as Category I anorectal protectants.

The compendial references provide general information that describes cocoa butter substitutes as suppository bases (Refs. 1 and 2) or describes physical characteristics of these ingredients, such as melting points, compatibility, etc. (Ref. 3). While these data relate to the safety of cocoa butter substitutes, they do not address the effectiveness of these ingredients as anorectal protectants or adequately define their composition or the optimum concentration for anorectal protectant use. The unpublished clinical study states that 100 cases were studied, but does not mention the ingredient content of the suppositories that were used (Ref. 4). The published study discusses the use of "Adeps solidus" and "oleum cacao" as "suppository compositions" in young dogs and reports no inflammatory reactions (Ref. 5). The results of the Draize eye test showed that a formulation described as "WITEPSOL S58017" can be safely used as a medium for vaginal application of medications, but did not disclose the ingredient content of this formulation. The data are inadequate to establish general recognition of the safety and effectiveness of these ingredients as anorectal protectants.

The agency's detailed comments and evaluations of the above data are on file in the Dockets Management Branch (Ref. 7). In response to the agency's comments, the firm submitted two additional studies on WITEPSOL (Refs. 8 and 9) and a protocol to evaluate cocoa butter substitutes as anorectal protectants (Ref. 10). One study (Ref. 8) compared WITEPSOL to several substances to determine skin irritancy while the other study (Ref. 9) discussed the use of WITEPSOL as a suppository vehicle for the delivery of preanesthetic medication in young children. These data are also inadequate to support the effectiveness of WITEPSOL as an anorectal protectant. The agency's detailed comments and evaluations of these data (Ref. 11) and of the protocol (Ref. 12) are also on file in the Dockets Management Branch. In response to the agency's comments, the firm has submitted additional information (Refs. 13 through 16). This information is currently being evaluated and will be addressed in the final rule.

As noted in comment 18 above, the Panel classified palm kernel oil as an inactive ingredient, but this classification does not prevent use of palm kernel oil as an anorectal suppository base because this is not considered an active ingredient use. Similarly, a cocoa butter substitute derived from food grade coconut oil could be used as a suppository base without being classified as a Category I anorectal active ingredient.

References

(1) "United States Pharmacopeia XX—National Formulary XV," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1029, 1980.

(2) Wade, A., editor, "The Extra Pharmacopeia," 27th Ed., Council of the Pharmaceutical Society of Great Britain, London, p. 1047, 1977.

(3) "European Pharmacopoeia," Vol. III, The Council of Europe, Sainte-Ruffine, France, pp. 139–140, 1975.

(4) Neumann, H., "Clinical Test of the Suppository Composition Imhausen H.," English translation of an unpublished study, included in CP (Citizen Petition), Docket No. 80N–0050, Dockets Management Branch.

(5) Neuwald, F., and J. Meyer-Lohman, "Comparative Test of Compatibility of Adeps Solidus and Oleum Cacao," (English translation), *Arzneimittelforschung*, 8:620–622, 1958.

(6) "A Report Prepared for Dynamit Nobel, A. G., Draize Eye Test," Consultox Laboratories LTD, London, 1970.

(7) Letter from W. E. Gilbertson, FDA, to B. Pagliocca, Kay-Fries, Inc., coded LET008, Docket No. 80N–0050, Dockets Management Branch.

(8) Motoyoshi, K., et al., "Comparative Studies on the Irritancy of Oils and Synthetic Perfumes to the Skin of Rabbit, Guinea Pig, Rat, Miniature Swine and Man," *Cosmetics & Toiletries*, 94:41–48, 1979.

(9) Shochat, S. J., J. Lewin-Epstein, and E. Superstine, "Preanesthetic Suppository for Ambulatory Children: Importance of the Base," *Anesthesia and Analgesia; Current Researches*, 48:427–436, 1969.

(10) Reply Comment coded RC002, Docket No. 80N–0050, Dockets Management Branch.

(11) Letter from W. E. Gilbertson, FDA, to V. Piermattie, Kay-Fries, Inc., coded LET012, Docket No. 80N–0050, Dockets Management Branch.

(12) Letter from W. E. Gilbertson, FDA, to B. Pagliocca, Kay-Fries, Inc., coded LET013, Docket No. 80N–0050, Dockets Management Branch.

(13) Letters from B. Pagliocca, Kay-Fries, Inc., to FDA, coded LET014, LET015, and LET016, Docket No. 80N–0050, Dockets Management Branch.

(14) Letter from J. (Whelan) Nikitakis, CTFA, to Dr. Hulsmann, Dynamit Nobel Aktiengesellschaft, coded LET017, Docket No. 80N–0050, Dockets Management Branch.

(15) Letter from B. Pagliocca, Kay-Fries, Inc., to Dr. Hulsmann, Dynamit Nobel Aktiengesellschaft, coded LET018, Docket No. 80N–0050, Dockets Management Branch.

(16) Letter from Dr. Hulsmann and Mr. Heers, Dynamit Nobel Aktiengesellschaft, to J. Whelan, CTFA, coded LET019, Docket No. 80N–0050, Dockets Management Branch.

20. One comment recommended that the concentration of shark liver oil be lowered to 2 to 10 percent in combination with other protectants instead of the Panel's recommended concentration of at least 50 percent per 2-g dosage unit. The comment argued that the lower concentration would allow the combination of shark liver oil with other protectants so that the total amount of protectants in the product would be at least 50 percent (the Panel's required concentration for making protectant claims), and the amount of vitamin A provided by daily use of the product would not exceed the Panel's recommended daily limit for anorectal use of 10,000 International Units (IU) of vitamin A. The comment referred to a presentation to the Panel showing that a particular marketed product, if labeled according to the Panel's recommended dosage schedule of up to six applications per 24 hours, would provide 150,000 to 210,000 IU of vitamin A, or 15 to 21 times the Panel's recommended maximum daily allowance of 10,000 IU (Ref. 1). The comment stated that, based on the transcript of the Panel's last meeting, the Panel intended that the percentage of shark liver oil should be reduced appropriately so that it could be formulated in combination with other protectants, providing a total protectant combination of at least 50 percent without exceeding 10,000 IU of vitamin A in daily use (Ref. 2).

The Panel noted that in the past, shark liver oil was required to contain not less than 16,500 IU of vitamin A and 40 IU of vitamin D per g of oil, but there is no current standard, and the concentration of vitamin A and vitamin D in shark liver oil may vary (45 FR 35634). According to the transcript of the Panel's last meeting, each g of the shark liver oil used in the product described above contains 25,000 to 35,000 IU of vitamin A (Ref. 2). The Panel also noted at this meeting that 16,500 IU of vitamin A is about the lowest concentration that might be expected to occur in each g of shark liver oil. In either case, one application of a product containing the Panel's recommended shark liver oil concentration of at least 50 percent per 2-g dosage unit would exceed the Panel's maximum daily allowance of 10,000 IU of Vitamin A. Therefore, the agency concurs that shark liver oil should be used in a concentration of less than 50 percent in anorectal drug products.

The Panel concluded that a reasonable maximum allowable concentration for safe OTC topical use is 10,000 IU of Vitamin A and 400 IU of Vitamin D per 24 hours (45 FR 35634).

Because of this safety limitation, the agency is not proposing a dosage as with other protectants, i.e., a contribution of at least 12.5 percent by weight. Instead, the agency is proposing in this tentative final monograph that when shark liver oil is used in anorectal drug products, each product is to be formulated and labeled for use up to six times daily so that the total amount of the product to be applied over a 24-hour period contains 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of vitamin D (now named cholecalciferol). (One U.S.P. unit is equivalent to 1 international unit.) Thus, a single application could contain one-sixth of the 10,000-U.S.P. units maximum daily allowance of vitamin A (1,666⅔ U.S.P. units) and one-sixth of the 400-U.S.P. units maximum daily allowance of cholecalciferol (66⅔ U.S.P. units).

Based on the above safety discussion, the agency is proposing in this tentative final monograph that shark liver oil for protectant use be formulated only in combination with other protectants. This use is consistent with the marketing history of shark liver oil in OTC anorectal drug products and allows a reasonable latitude in the formulation of such products to permit a total protectant content of at least 50 percent without exposing the user to excessive amounts of vitamin A.

Likewise, the agency is proposing the same conditions for cod liver oil for protectant use. Therefore, the Panel's recommended dosage for cod liver oil has been revised to be consistent with the dosage being proposed for shark liver oil, as discussed above.

As discussed in comment 30 below, calamine and zinc oxide, which are limited to concentrations of less than 50 percent, may be used only in combination with other protectants (not to exceed four) in order to assure that the protectant content of the final formulation is at least 50 percent.

References

(1) Transcript of the 29th Meeting of the Advisory Review Panel on OTC Hemorrhoidal Drug Products, January 22–24, 1978, p. 53.

(2) Ibid., pp. 143–148.

E. Comment on Counterirritants

21. One comment, submitted in response to the reopening of the anorectal administrative record to include the Miscellaneous External Panel's statement on camphor-containing drug products (45 FR 63876), objected to that Panel's recommendation that camphor be limited to 360 mg per package, preferably in a child-proof container. The comment maintained that this would be a burdensome restriction for all OTC drug products containing low concentrations of camphor and is not justified in view of these products' long history of safe household use. Another comment stated that the risk exceeds the benefit in many drug uses of camphor and that consumers should no longer be exposed to these uses.

These comments were also submitted to the rulemaking for external analgesic drug products, and the agency adddressed the general issue of the safety of camphor in the tentative final monograph on OTC external analgesic drug products. (See the **Federal Register** of February 8, 1983; 48 FR 5854–5855.) The Hemorrhoidal Panel found camphor not safe and not effective for use in OTC anorectal drug products (45 FR 35642) and placed it in Category II. The agency is retaining the Category II classification in this proposed rule.

F. Comment on Astringents

22. One comment asked whether zinc sulfate can be assumed to be classified in the same category (astringent) as zinc oxide because both are zinc salts and display similar properties.

Zinc sulfate cannot be classified as an astringent at this time because no data have been submitted to show its safety and effectiveness for this use.

G. Comment on Wound-Healing Agents

23. Several comments agreed with the Panel's minority report that supports the OTC use of live yeast cell derivative as a wound-healing agent. The comments stated that adequate data had been provided to the Panel to support the safety and effectiveness of live yeast cell derivative as a wound-healing agent. One comment added that a number of world-renowned wound-healing experts from the United States and Europe met with the Panel in January 1977 and concluded that evidence from the available studies of live yeast cell derivative as a wound-healing agent can be used to support the use of live yeast cell derivative in the anorectal area, and that live yeast cell derivative is an appropriate ingredient in an OTC anorectal drug product. Another comment argued that the claims placed in Category III by the Panel (45 FR 35657) for wound-healing agents are valid Category I claims which should be included in the tentative final monograph. Referring to the Panel's Category III labeling for wound-healing agents, one comment stated that personal experiences in testing a product containing a Category III wound-healing agent had demonstrated that the product accelerated repair and that "with injury comes swelling, with repair, inevitably comes 'shrinkage'."

The agency concurs with the majority of the Panel that the submitted studies on rabbits and white rats, excised human tissue, human fibroblasts, experimental abrasions to human skin, and paired skin grafts of burn wounds suggest a positive influence of live yeast cell derivative on wound healing and that live yeast cell derivative has the characteristics of a wound-healing agent, i.e., increased oxygen uptake, hydroxyproline formation which is associated with collagen biosynthesis, tissue growth, and epithelization. Regarding safety, the Panel noted that no studies of the safety of live yeast cell derivative have been specifically carried out, although no toxicity has been noted when the compound was used in experimental animals and no reports of clinical toxicity have been made or noted in the various clinical studies of the commercial product containing live yeast cell derivative (45 FR 35651). The Panel therefore assumed that the compound is safe for limited use (1 week or less).

Although the agency agrees with the Panel that live yeast cell derivative is safe for use as a wound-healing agent for limited use (1 week or less), there remains a lack of sufficient data on its effectiveness. Data to support the effects of live yeast cell derivative on wound healing of the type proposed for OTC use in human subjects are currently not included in this rulemaking. Since the time the comment period closed following publication of the advance notice of proposed rulemaking, new information, including clinical studies, has been submitted to the rulemaking for OTC skin protectant drug products and will be addressed in that rulemaking. These new data are now under review. With publication of this proposed rule for OTC anorectal drug products, the new information will also be included as part of the administrative record in this rulemaking and will be addressed in the final rule. Therefore, at this time, live yeast cell derivative remains in Category III for effectiveness for use as an OTC wound-healing agent in the anorectal area.

The agency's detailed comments and evaluation of the data currently in the administrative record are on file in the Dockets Management Branch (Ref. 1).

Because the data are insufficient to reclassify wound healing ingredients in Category I, the agency finds that there is insufficient basis at this time to reclassify the labeling claims for these ingredients in Category I, as the comment argued. Should any Category

III wound-healing ingredients be upgraded to Category I, the agency will upgrade the Category III claims recommended by the Panel or develop appropriate label claims based on the data available at that time.

Peference

(1) Letter from W.E. Gilbertson, FDA, to S.F. Barshay, Whitehall Laboratories, coded LET 010, Docket No. 80N-0050, Dockets Management Branch.

H. Comment on Antiseptics.

24. One comment disagreed with the Panel's conclusion that antiseptics should not be included in OTC anorectal drug products because no data had been submitted showing that antiseptics in these products are more effective than soap and water. The comment asserted also that data had not been submitted showing that antiseptics may be harmful when used in these products and pointed out that resorcinol and 8-hydroxyquinoline have both been used safely for many years as antiseptics in its OTC anorectal drug products. The comment maintained that anorectal drug products are often used when soap and water for cleansing the anorectal area are not available and that including antiseptics in these products may help prevent infection or itching.

The Panel concluded that the inclusion of antiseptics in OTC anorectal drug products "is useful in concept," but "that proof of any significant clinical benefit of claimed antiseptic ingredients must be demonstrated in clinical trials" (45 FR 35659). The Panel believed that, because of the large numbers of microorganisms present in feces, there is little likelihood that effective antisepsis could be obtained in the anorectal area with antiseptics any more than with soap and water. The Panel was also concerned about possible toxicity from the absorption of ingredients such as resorcinol through mucous membranes (45 FR 35661) and therefore classified resorcinol in Category III for external use and Category II for intrarectal use. As discussed in comment 7 above, the ingredient 8-hydroxyquinoline was not submitted to the Panel for review. The comment did not submit any data to support the use of these ingredients in particular, or the use of antiseptics in general, in anorectal drug products. Therefore, the agency has no basis for including these ingredients in the tentative final monograph.

I. Comment on Hydrocortisone

25. One comment pointed out that the Panel did not consider the status of hydrocortisone for use in OTC anorectal drug products and requested that this use be clarified because another Panel's recommended labeling for OTC external analgesic drug products containing hydrocortisone included a claim "for itchy genital and anal areas." (See 44 FR 69865.)

Although the Hemorrhoidal Panel did not review and classify hydrocortisone for use as an anorectal active ingredient, in the tentative final monograph for OTC external analgesic drug products (48 FR 5852) the agency proposed the use of hydrocortisone and hydrocortisone acetate in concentrations of 0.25 to 0.5 percent for various types of itching including "anal itching." The agency's proposed indication is similar to the various phrases regarding relief of itching that the Hemorrhoidal Panel recommended as portions of the indications for OTC anorectal drug products. Because a claim for hydrocortisone and hydrocortisone acetate for the temporary relief of anal itching is already included in the OTC external analgesic tentative final monograph, the agency sees no reason to repeat that claim in this tentative final monograph. Further, the agency believes that, whenever possible, various related conditions for which an ingredient is considered generally recognized as safe and effective for OTC use should be listed in a single appropriate monograph, which, in this case, is the monograph for OTC external analgesic drug products.

The agency does, however, note that the Hemorrhoidal Panel recommended specific warnings and directions for products labeled to relieve itching in the anal area. These include specific warnings to consult a physician promptly in case of bleeding and to cleanse the anorectal area, when practical, before applying the product. The agency is adopting these warnings and directions in this tentative final monograph. The agency believes that any hydrocortisone-containing (or any other) drug product labeled for the relief of anal itching should bear appropriate warnings and directions information. Therefore, in a future issue of the **Federal Register**, the agency will amend the tentative final monograph for OTC external analgesic drug products so that products containing ingredients subject to that monograph that bear claims for the relief of "anal itching" also bear the appropriate warnings and directions contained in § 346.50 (c)(2), (3), and (4) and (d)(1) of this tentative final monograph for anorectal drug products.

J. Comment on Inactive Ingredients

26. One comment stated that bismuth subgallate, classified by the Panel as a protectant when present in a product in at least 50 percent of a 2-g dosage unit, should also be classified as an inactive ingredient (or pharmaceutical necessity) when included in an anorectal drug product in small quantities. The comment stated that a marketed suppository contains a small quantity of bismuth subgallate as a stiffening agent and that no protectant labeling claim is made for this product.

Bismuth subgallate was classified by the Panel as a Category III protectant active ingredient for external and intrarectal use in a concentration of 17.5 to 166 mg per dosage unit, not to exceed 1 g per 24 hours (45 FR 35639). The Category III classification of bismuth subgallate would not preclude its use as a pharmaceutical necessity so long as the labeling of the product does not refer to bismuth subgallate as an active ingredient or associate it with any protectant activity. The agency concurs with the comment that bismuth subgallate could be an inactive ingredient when used as a stiffening agent in a suppository dosage form.

K. Comments on Dosage

27. One comment expressed concern that the Panel implied that a 2-g dosage unit is the size of choice for delivery to the anorectal area. The comment emphasized that, although studies may have shown that an average of 2 g of a product is used, a 2-g dosage unit should not be mandated as the standard.

The Panel stated at 45 FR 35591 that "a 2-gram dosage unit is reasonable, but this does not imply that other dosage sizes are not acceptable". The Panel also cited an official compendium as stating that the average adult suppository weighs 2 g (Ref. 1) and added that in studies reviewed by the Panel, patients used an average of 2 g of ointment per application (Ref. 2). The Panel recognized that exceptions to dosage unit size do occur, and its recommended monograph did not specify that dosage units be limited to 2 g. The agency agrees with the Panel and is not proposing a standard dosage unit in this tentative final monogaph.

References

(1) "The United States Pharmacopeia," 19th Revision, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 704, 1975.

(2) OTC Volume 120022.

28. One comment contended that there is no basis in the Panel's report, or in any of the references cited, for limiting the dosage of petrolatum in

§ 346.56(d)(11), which reads: "* * * not to exceed six applications per 24 hours or after each bowel movement." Arguing that the proposed dosage limitation is misleading because petrolatum poses a very low risk to health from overuse, the comment requested that the dosage for petrolatum be "use as needed."

The agency agrees with the comment that there is no basis in the Panel's report, or on record, for limiting the dosage of petrolatum and that the ingredient is safe when applied liberally as needed. Petrolatum is relatively inert and is not absorbed through intact or broken skin or mucous membranes. Its safety has been established by decades of use as a base for anorectal and other medications and as a skin protectant. The agency believes that the directions for use for petrolatum in this tentative final monograph should be the same as those in the skin protectant tentative final monograph (published in the Federal Register of February 15, 1983; 48 FR 6820) and therefore is proposing that § 346.56(d)(6) of this tentative final monograph read: "Apply liberally as often as necessary."

29. One comment disagreed with the Panel's recommended dosage in § 346.14(k) of "50 percent or greater per dosage unit" to justify a protectant claim for petrolatum. The comment stated that the Panel incorrectly interpreted the studies cited on transepidermal water loss (45 FR 35627) and that protection can be obtained at a much lower film thickness than calculated by the Panel. The comment cited an oral presentation made to the Panel in which it was explained that only by specifying a dose could a concentration figure have meaning (Ref. 1). The comment provided an example to show that protection can be obtained from as little as a 25-percent concentration in a dosage unit.

The agency has reviewed the Panel's discussion of protectants (45 FR 35627), the Panel's discussion of petrolatum (45 FR 35634), and the presentation made by Dr. M. Berdick (Ref. 1). The agency concludes that the Panel's recommendation for a 50-percent or greater concentration of protectants per 2 g dosage unit provides a reasonable basis for establishing the minimum quantity of a protectant that is necessary to provide relief. The Panel also discussed the possibility that testing might establish that a protectant could achieve the same effect at a lower concentration (45 FR 35628). However, the comment did not submit any clinical data to support a 25-percent concentration. Therefore, the agency proposes to adopt the Panel's recommendation of a 50-percent or greater concentration for most anorectal protectants, including petrolatum. (See comments 20 above and 30 below.)

Reference

(1) Summary Minutes of the 27th Meeting of the Advisory Review Panel on OTC Hemorrhoidal Drug Products, April 29 and 30, 1977, OTC Volume 12APA2.

30. Several comments noted that there appeared to be an inconsistency in the Panel's recommended monograph between the concentration of protectants when used as single ingredients and when used in combination. The comment believed that the Panel intended "that to justify a claim for protectant effect a combination of two but not more than four protectants must be present for a combined concentration of at least 50 percent." The comments requested that recommended §§ 346.14 and 346.22 be clarified and made consistent with the Panel's intent that the combined concentration of protectants be at least 50 percent.

The Panel concluded that to justify a claim for protectant effect, either of the following criteria must be met: (1) At least one protectant must be present to provide at least 50 percent by weight (1 g of a 2-g dosage unit); or (2) a combination of two but not more than four protectants must be present to provide at least 50 percent by weight (1 g of a 2-g dosage unit). (See 45 FR 35627.) The Panel believed that a minimum of 50 percent by weight (1 g of a 2-g dosage unit) would still permit the addition of other active ingredients as well as any inactive ingredients that may be necessary to formulate a pharmaceutically acceptable preparation (45 FR 35628).

The Panel determined that for certain protectant ingredients limited to concentrations of less than 50 percent the data submitted to the Panel indicated that these ingredients are usually present in combination with other protectant ingredients (45 FR 35592). Therefore, the agency concludes that the intent of the Panel was that these ingredients, because of their physical characteristics, cannot be used as single ingredients but may be used only in combination with other protectants in order to meet the Panel's recommended minimum protectant content per dosage unit, i.e., 50 percent concentration by weight (1 g of a 2-g dosage unit). Accordingly, the agency is clarifying the Panel's recommendation and is proposing in § 346.14(b) of this tentative final monograph that calamine, cod liver oil, shark liver oil, and zinc oxide be used only in combination with other protectants.

The Panel believed that limiting combinations of protectants to two but not more than four protectants would provide reasonable latitude in the formulation of anorectal products because only four products submitted to the Panel had four or more protectant ingredients. However, because the Panel did not establish a concentration range for all protectant ingredients, the agency believes it is reasonable to propose that certain protectant ingredients (aluminum hydroxide gel, cocoa butter, glycerin (20 to 45 percent aqueous solution), kaolin, lanolin, mineral oil, petrolatum, starch, and white petrolatum) be limited to a minimum concentration that contributes at least 12.5 percent by weight of the final dosage unit (0.25 g of a 2-g dosage unit). This will enable the formulation of combinations of up to 4 protectants without permitting inactive levels of ingredients to be included and will meet the Panel's recommended minimum combined protectant concentration of 50 percent per dosage unit.

Consistent with this determination, the agency is proposing that the minimum allowable amount of calamine or zinc oxide in a combination also be 12.5 percent by weight. In addition, because the dosage for calamine is calculated on its zinc oxide content and because both calamine and zinc oxide are classified as Category I anorectal astringents as well as anorectal protectants, the agency concludes that the combined weight of zinc oxide in any anorectal combination product should not exceed the maximum safe concentration of zinc oxide recommended by the Panel, i.e., 25 percent by weight per dosage unit. Cod liver oil and shark liver oil should be present in a combination drug product in accord with the dosage discussed in comment 20 above.

Accordingly, recommended § 346.22 (redesignated as § 346.22(a) in this tentative final monograph) is revised to read as follows: "Any two, three, or four protectants identified in § 346.14 may be combined, provided that the combined percentage by weight of all protectants in the combination is at least 50 percent of the final product (1 gram of a 2-gram dosage unit). Any protectant ingredient included in the combination must be present at a level that contributes at least 12.5 percent by weight (0.25 gram of a 2-gram dosage unit). If an ingredient in § 346.14(b) is included in the combination, it must not exceed the concentration limit specified in § 346.14(b)." In addition, new § 346.22(o) has been added to this tentative final monograph as follows: "Any product

containing calamine for use as a protectant and/or as an astringent and/or containing zinc oxide for use as a protectant and/or as an astringent may not have a total weight of zinc oxide exceeding 25 percent by weight per dosage unit."

L. Comments on Combinations.

31. Several comments objected to the Panel's recommended requirement that a combination of Category I anorectal active ingredients be shown safe and effective in final formulation testing. The comments particularly objected to the Panel's recommendation that final formulation testing for effectiveness of a combination "should demonstrate in clinical trials that there is a statistically significant difference in effectiveness of the combination for relief of a symptom as compared to the combination without each of the active ingredients, excluding protectants" (45 FR 35594). The comments argued that such testing of combinations is unprecedented and arbitrary and is neither called for in the agency's combination policy as set forth in § 330.10(a)(4)(iv), nor consistent with the FDA general guidelines for OTC combination drug products (Ref. 1).

The comments asserted that the combination policy for anorectal active ingredients could be made meaningful by deleting final formulation testing and basing decisions regarding safety and effectiveness of combinations on the evaluation of their active ingredients. The comments noted that the Panel placed in Category III a number of combinations of Category I ingredients from different therapeutic categories and that these combinations would have been considered Category I were it not for the requirement of final formulation testing. (See 45 FR 35593, part II, paragraphs K.10.a. (1), (2), and (3).) The comments requested that these combinations be placed in Category I.

As discussed in comment 55 below, the agency is not requiring final formulation testing of either single-ingredient or combination anorectal drug products. As a result, the agency is not requiring clinical trials to demonstrate a statistically significant difference in effectiveness between the combination in final formulation and the combination without each active ingredient.

The regulations at § 330.10(a)(4)(iv) state that an OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population. In addition, paragraph (1) of the agency's general guidelines (Ref. 1), which were not available at the time of the Panel's deliberations, provides for the combination of Category I active ingredients from different therapeutic categories to treat different symptoms concurrently if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC combination policy in § 330.10(a)(4)(iv) in all other respects. Therefore, the agency is proposing that the combinations of Category I ingredients from up to three different therapeutic categories (except protectants) that the Panel placed in Category III pending final formulation testing be reclassified in Category I consistent with § 330.10(a)(4)(iv) and the agency's supplementary guidelines for OTC combination drug products (Ref. 1).

The combination of up to four protectants identified in § 346.22 of the Panel's recommended monograph is redesignated § 346.22(a) in this tentative final monograph. As discussed above, the agency is proposing that the following combinations be included in the designated paragraphs of § 346.24 of this tentative final monograph:

(b) Any single anorectal ingredient identified in § 346.10, § 346.12, § 346.16, § 346.18, or § 346.20 may be combined with up to four protectants in accordance with paragraph (a) of this section.

(c) Any single local anesthetic identified in § 346.10 may be combined with any single vasoconstrictor identified in § 346.12.

(d) Any single local anesthetic identified in § 346.10 may be combined with any single astringent identified in § 346.18.

(e) Any single local anesthetic identified in § 346.10 may be combined with any single keratolytic identified in § 346.20.

(f) Any single vasoconstrictor identified in § 346.12 may be combined with any single astringent identified in § 346.18.

(g) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single astringent identified in § 346.18.

(h) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single keratolytic identified in § 346.20.

(i) Any single astringent identified in § 346.18 may be combined with any single keratolytic identified in § 346.20.

(j) Any single local anesthetic identified in § 346.10 may be combined with any single vasoconstrictor identified in § 346.12 and with any single astringent identified in § 346.18.

(k) Any single local anesthetic identified in § 346.10 may be combined with any single astringent identified in § 346.18 and with any single keratolytic identified in § 346.20.

(l) Any single vasoconstrictor identified in § 346.12 may be combined with any single analgesic, anesthetic, and antipruritic identified in § 346.16 and with any single astringent identified in § 346.18.

(m) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single astringent identified in § 346.18 and with any single keratolytic identified in § 346.20.

(n) Any combination of ingredients listed in paragraphs (c) through (m) of this section may be combined with up to four protectants in accordance with paragraph (a) of this section.

The redesignation of the term "counterirritant" to "analgesic, anesthetic, and antipruritic" is discussed in Part II.B.6 below—*Summary of the Agency's Changes in the Panel's Recommendations.* The Panel's classification of combinations of more than three Category I ingredients from different pharmacologic groups, except protectants, is discussed in comment 32 below.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

32. Two comments objected to the Panel's recommendation to limit the number of ingredients included in hemorrhoidal preparations. The comments stated that limiting ingredients to only three pharmacological groups is unscientific, uncorroborated, and arbitrary. One comment maintained that limiting hemorrhoidal preparations to four or fewer nonprotectant active ingredients would tend to make them "fungible" and would discourage ingenuity in the development of combination products. The comment argued that these recommendations contradict FDA guidelines for combination drug products in § 330.10(a)(4)(iv). The comments recommended that a fixed limit not be arbitrarily placed upon the

number of active ingredients in a combination of hemorrhoidal ingredients when there is evidence that the combination is rational, safe, and effective with a suitable target population. One comment stated, as an example, that a product containing a vasoconstrictor to shrink hemorrhoids, a local anesthetic to deaden pain, a protectant to soothe the irritated area, a counterirritant to cool the irritated area until the local anesthetic can take effect, and an antiseptic to help prevent infection and help relieve itching would be beneficial to many hemorrhoid sufferers.

The agency agrees with the comments that a fixed limit need not be placed upon the number of active ingredients in a combination product if it can be shown to be a rational, safe, and effective combination with a suitable target population. This position is consistent with FDA policy for OTC combination drug products in § 330.10(a)(4)(iv) and with the guidelines for combinations (Ref. 1). However, the agency believes that the interest of consumers is best served if the desired therapeutic effect is achieved safely and effectively by the smallest number of active ingredients.

The Panel placed certain two-ingredient and three-ingredient combination products in Category III pending final formulation testing (45 FR 35593). Because the agency is not adopting the Panel's requirements for final formulation testing, the agency is proposing that these combinations be Category I in this tentative final monograph. (See comment 31 above.) The agency will consider any other combinations for Category I, regardless of the number of ingredients and the formulation, provided adequate data are presented in accordance with the combination policy and the guidelines mentioned above. The specific combination of five ingredients cited by one comment has not been included in this tentative final monograph because the comment submitted no data for the agency to evaluate.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

33. One comment suggested revising the Panel's language in Part II. paragraph K.8.d.—Criteria for Category I combination products for external and/or intrarectal use, which reads as follows: "Products that do not claim protectant activity and contain one Category I active ingredient from each pharmacologic group in the combinations identified below are classified as Category I combination products, provided that (1) the active ingredients and their labeling are generally recognized as safe and effective, (2) such ingredients are present in amounts within the effective dosage range, and (3) the final formulation has been shown to be safe and effective."

The comment suggested revising the first part of this paragraph to read "Combinations of Category I active ingredients each from a different pharmacologic group identified below, combined with or without one or more protectants, are classified as Category I combination products * * * *" In addition, the comment recommended that paragraph K.10.a.(1), which reads "Combinations containing any single Category I active ingredient and one or more protectants," be moved to paragraph K.8.d., and a new paragraph K.8.e. be added to read as follows: "Any single Category I active ingredient and one or more protectants."

The combinations referred to in paragraphs K.8.d. and K.10.a. of the Panel's report are the same combinations of Category I ingredients from different therapeutic categories that the agency is proposing as Category I in § 346.22 (b) through (n) of this tentative final monograph. Therefore, the comment's suggested revisions of the Panel's report are not necessary. (See comment 31 above.)

34. One comment objected to the Panel's conclusion that the combination of a local anesthetic and a counterirritant in a hemorrhoidal drug product is irrational (45 FR 35593). The comment argued that, although the Panel acknowledged that the onset of action of the local anesthetic may be briefly preceded by the action of the counterirritant, it ignored the importance of "fast, cooling relief, even if superseded by another ingredient's soothing effect later." The comment stated that a counterirritant and a local anesthetic should be combined in a hemorrhoidal product if the inclusion of both ingredients results in any extra relief and satisfaction for the user. The comment stated that it was not aware of any adverse reactions to menthol when used as a counterirritant in the strength used in its rectal ointments.

The Panel concluded that the simultaneous use of a counterirritant (such as menthol) and a local anesthetic is irrational. The mechanism of action of a counterirritant is dependent upon an intact nerve function, but nerve function is specifically blocked by an effective local anesthetic. The action of a counterirritant that may briefly precede the action of a local anesthetic is not sufficient justification for the combination.

The agency concurs with the Panel and notes that the Topical Analgesic Panel in its report on external analgesic drug products also classified the combination of a local anesthetic and a counterirritant in Category II. The Topical Analgesic Panel concluded that it is irrational to combine pharmacologic groups that act in opposition to each other and that such a combination may be unsafe (44 FR 69790). No comments objecting to that Panel's conclusions were submitted during the comment period following the publication of the Panel's report. In the tentative final monograph on OTC external analgesic drug products (48 FR 5852), the agency reaffirmed that Panel's Category II classification for this combination.

The Hemorrhoidal Panel concluded that menthol is safe and effective for external use as a counterirritant (45 FR 35641). The Panel also concluded that menthol is safe but not effective for intrarectal use (45 FR 35643); the agency concurs.

The deciding factor for the Category II classification of the combination of a local anesthetic and a counterirritant was not the safety of menthol as a counterirritant, but rather the lack of medical rationale for combining these two pharmacologic groups.

35. One comment recommended that the tentative final monograph for anorectal drug products include the combination of live yeast cell derivative and protectants, including shark liver oil.

The Panel classified live yeast cell derivative in Category III as a wound-healing agent in anorectal drug products and recommended that if a Category III ingredient is present in a combination product containing no Category II ingredient, the combination is classified as Category III (45 FR 35593 and 35594). On the basis of the Panel's combination policy, the combination of live yeast cell derivative and any Category I protectant, such as shark liver oil, is a Category III combination. The Panel's recommendation is consistent with the agency's policy for combination drug products in § 330.10(a)(4)(iv) and the combination guidelines (Ref. 1). Live yeast cell derivative remains in Category III in this tentative final monograph; therefore the agency considers the combination of live yeast cell derivative and any Category I protectant to be a Category III combination product at this time. (See comment 23 above.)

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

M. Comments on Labeling of Anorectal Drug Products

36. Two comments stated that existing statutory provisions (15 U.S.C. 1453(a), 21 CFR 201.61, and sections 508 and 502(e) of the Federal Food, Drug, and Cosmetic Act) do not show a congressional intent to authorize FDA to legislate the exact wording of OTC drug claims to the exclusion of other equally accurate and truthful claims for these products, and that section 502(c) of the act demonstrates a congressional intent to the contrary. The comments maintained that there are truthful phrases, other than those recommended by the Panel, that would be in keeping with the conclusions of the Panel.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions in § 330.1(c)(2).

37. Several comments objected to the Panel's recommendation that all inactive ingredients be listed in the labeling of OTC anorectal drug products. The comments argued that a list of inactive ingredients in the labeling would be meaningless, confusing, and misleading to most consumers. The comments noted that the act does not require that inactive ingredients of drug products be included in labeling and argued that listing these ingredients would obscure information that is more meaningful to consumers.

Two of the comments also cited the warning recommended by the Panel in § 346.50(c)(5) for anorectal drug products containing perfume as an example of labeling related to inactive ingredients that should not be required. This warning states, "If redness, burning, itching, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician." One comment stated that the warning would be confusing to consumers because the symptoms identified in the warning are the same as those that the product is intended to treat and that such symptoms obviously will already be present. Two of the comments pointed out that neither cosmetic products nor soaps are required to contain a warning statement to indicate their perfume content.

The agency agrees that the Federal Food, Drug, and Cosmetic Act does not require the identification of all inactive ingredients in the labeling of OTC drug products. Section 502(e) (21 U.S.C. 352(e)) does require disclosure of active ingredients and of certain ingredients, whether included as active or inactive components in a product. Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be useful information for some consumers. Consumers with known allergies or intolerances to certain ingredients would then be able to identify substances that they may wish to avoid.

The Proprietary Association, the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of volume of all OTC drug products sold in the United States, has established guidelines (Ref. 1) for its member companies to list voluntarily inactive ingredients in the labeling of OTC drug products. Under another voluntary program begun in 1974, the member companies of The Proprietary Association have been including the quantities of active ingredients on OTC drug labels. The agency is not at this time proposing to require the listing of inactive ingredients in OTC drug product labeling. However, the agency commends these voluntary efforts and urges all other OTC drug manufacturers to similarly label their products.

If a safety problem has been demonstrated for an inactive ingredient, the agency will take appropriate action. (See 21 CFR 201.20.) Because perfumes are considered to be inactive ingredients and because the Panel did not establish that a safety problem exists for specific perfumes, the agency is not proposing the Panel's recommended warning in this tentative final monograph.

Reference

(1) "Guidelines for Disclosure of Inactive Ingredients in OTC Medicines," The Proprietary Association, Washington, DC, July 12, 1984, copy included in OTC Volume 12ATFM.

38. Four comments objected to the Panel's recommendation that the term "anorectal" be used in the statement of identity (§ 346.50(a)) and urged the agency to use instead the more familiar term "hemorrhoidal." To support this position, two comments submitted the results of a survey of 144 consumers aged 18 and older to determine what percentage of consumers understand the word "anorectal." According to one comment, the survey results indicated that 70 percent of the consumers did not understand the term "anorectal." The comments further argued that using the term "hemorrhoidal" would eliminate confusion and aid consumers in purchasing a product to help treat specific symptomology. One comment stated that the term "hemorrhoid" has come to mean more than clinically defined hemorrhoids and that consumers understand this term as encompassing various kinds of anorectal discomforts and disorders. Another comment disliked the popular use of the terms "piles" and "hemorrhoids" and commended the Panel for educating the public by properly defining terms used to describe anorectal disorders.

The agency could not evaluate the merits of the survey because only the results were submitted, and no details were included. However, the agency agrees with the comments in principle that the term "hemorrhoidal" is more familiar and understandable to consumers than the term "anorectal." The agency further believes it is important to educate the consumer as to the proper use of these products. The Panel recommended that anorectal products be labeled for the relief of symptoms associated with hemorrhoids, piles, and other anorectal disorders and stated that consumers must be able to understand the information presented in labeling in order to use these products safely and effectively. Therefore, the agency is proposing that the term "hemorrhoidal" may appear alone or in

parentheses next to the term "anorectal" in the statement of identity for all OTC anorectal drug products in § 346.50(a). In addition, the dosage form, e.g., cream, lotion, or ointment, may be included in the statement of identity.

39. One comment pointed out that several statements of identity could be required for petrolatum because the review of this multipurpose ingredient by several OTC advisory review panels has resulted in multiple labeling requirements. The comment noted that statements of identity of "skin protectant" and "anorectal agent" or "anorectal product" have already been recommended and that additional statements of identity are yet to come in other monographs. The comment recognized the need for a statement of identity in the labeling of every OTC drug product, but argued that the agency should allow a single statement of identity for a multipurpose ingredient such as petrolatum. The comment contended that a statement such as "topical protectant and lubricant" would adequately cover every OTC drug use of petrolatum and would also satisfy the requirements of § 201.61(b) (21 CFR 201.61(b)).

Petrolatum has been placed in Category I by advisory review panels for the following OTC uses: Ophthalmic emollient, anorectal agent, and skin protectant. Ophthalmic drug products containing petrolatum are sterile to avoid the risk of contamination and usually are marketed with indications for ophthalmic use only, but other OTC drug products containing petrolatum could be labeled for both anorectal and skin protectant use. The comment's recommended statement of identity, "topical protectant and lubricant," does not make clear that such a product could be used anorectally and therefore does not fully satisfy the requirements of § 201.61(b). Concerning the comment's suggestion to use "lubricant" in a statement of identity for petrolatum, the agency stated in the tentative final monograph for OTC skin protectant drug products that the term "lubrication" is a cosmetic claim. (See the **Federal Register** of February 15, 1983; 48 FR 6828.) Likewise, the agency believes that "lubricant" is inappropriate in a statement of identity for OTC anorectal drug products.

To make it clear to consumers that the product could be used both as an anorectal agent and as a skin protectant, its labeling should contain the statement of identity, indications, warnings, and directions for use from both rulemakings. As an alternative, manufacturers may choose to label the product for only one of its intended uses.

In this tentative final monograph, the agency is proposing that the statement of identity for petrolatum be "anorectal (hemorrhoidal)," "hemorrhoidal," "anorectal (hemorrhoidal) (insert dosage form, e. g., cream, lotion, or ointment)," or "hemorrhoidal (insert dosage form, e.g., cream, lotion, or ointment)." (See comment 38 above.) A combined statement of identity recognizing the uses established in both monographs, e.g., "anorectal (hemorrhoidal)/skin protectant," would not be burdensome and would meet the requirements of § 201.61(b).

40. One comment suggested that, to eliminate duplication of words or phrases, § 346.50(b) be revised to permit combining the many indications recommended by the Panel, provided that the combined statement is clear and understandable with no change in meaning or emphasis.

The agency agrees with the comment and, consistent with the format and style used in other recently published tentative final monographs, proposes to revise the general indication for all anorectal drug products in § 346.50(b) as follows: ("For the temporary relief of," "Gives temporary relief of," or "Helps relieve the") (as an option, select neither, one, or both of the following: "local" or "anorectal") [select one or more of the following: "discomfort," "itching," or "itching and discomfort," followed by: "associated with" (select one or more of the following: "hemorrhoids," "anorectal disorders," "inflamed hemorrhoidal tissues," "hemorrhoidal tissues," "anorectal inflammation," or "piles (hemorrhoids).")] (See part II. paragraph B.9. below.)

In addition the agency has also revised the indications statements recommended by the Panel for specific therapeutic groups for clarity and to eliminate duplicative words and phases as appropriate.

41. One comment questioned why the Panel did not include the claim "shrinks hemorrhoids" for anorectal drug products containing zinc oxide and other astringents. The comment cited the following statement from a medical reference (Ref. 1): "This 'astringent' (drawing together) action is characterized by visible contraction of the tissue, blanching and wrinkling of mucous membranes * * *. The principal astringents are: metallic salts * * *." The comment stated that zinc salts, particularly zinc oxide, are considered typical and effective astringents, and requested that the labeling claim "shrinks hemorrhoids" be allowed for anorectal preparations containing such astringents.

The Panel did not specifically address the claim "shrinks hemorrhoids" in relation to anorectal astringents. However, in its general discussion of astringents, the Panel concluded that an effect of astringents is a "decrease in cell volume (implying a reduction in swelling)," but that this effect is not sufficient to warrant a labeling claim for the reduction of swelling (45 FR 35645 and 35649).

In its discussion of Category II labeling for vasoconstrictors, the Panel stated that the applicability of claims such as "shrinks hemorrhoids" for certain combinations of ingredients rested primarily on a definition of the word "shrink" (45 FR 35626). Although the Panel generally agreed that the word "shrink" refers to a reduction in size, there were differing opinions on whether this signifies a temporary phenomenon or implies a permanent change. The Panel stated that consumers would probably consider that a permanent change is to be expected. However, data submitted to the Panel indicated that vasoconstrictors produce a temporary reduction in swelling, and rebound swelling may occur in the long run. Thus, the Panel found that an anorectal vasoconstrictor can "temporarily reduce swelling" or "temporarily shrinks" and that these words sufficiently conveyed the usefulness of vasoconstrictors in the short-term treatment of anorectal symptoms (45 FR 35626). The agency concurs. (See the indications for vasoconstrictors in § 346.50(b)(2)(ii) of the tentative final monograph.)

The comment did not submit any data to show that astringents effectively shrink hemorrhoids even temporarily. Therefore, the agency has no basis for including the requested claim for anorectal astringents in this tentative final monograph.

Reference

(1) Sollman, T., "Local Irritants, Corrosives and Astringents," in "A Manual of Pharmacology," W.B. Saunders Co., Philadelphia, p. 139, 1957.

42. Three comments objected to the Panel's recommendation in § 346.50(c) that warning statements be placed in a "box border" and printed in black ink or the most prominent color of the label. The comments argued that a "box border" is not only inappropriate but also counterproductive because indiscriminately highlighting multiple minor warnings, such as those recommended by the Panel, would increase the probability that serious

hazards will be ignored in other situations. Two of the comments argued that there are no warnings regarding the use of anorectal preparations that justify a "box border" requirement. The comments stated that FDA specifies only two uses for "box borders": To convey important information to physicians regarding indications for drugs found to be less than effective in the Drug Efficacy Study (21 CFR 201.200), and to warn against serious or even life-threatening toxic effects of prescription drugs (21 CFR 201.316).

The agency agrees with the comments that a "box border" should be reserved for special information that should be highlighted to prevent potential serious hazards. This requirement is not justified for any of the OTC anorectal drug product warnings, and in fact there have been only two instances so far in the OTC drug review in which the agency believed a "box border" was justified. The first instance was in the tentative final monograph for OTC emetic drug products, published in the **Federal Register** of September 5, 1978 (43 FR 39544), in which the agency proposed that the warning "Call a physician, Poison Control Center, or emergency room for advice before using, and call immediately if vomiting does not occur within 20 minutes after a second dose has been given" be printed in red and conspicuously boxed. The second instance was in the **Federal Register** of May 1, 1986 (51 FR 16258) in which the agency published a final rule that amended the exclusivity policy and established new labeling requirements for OTC drug products. The final rule provides manufacturers three alternatives for the labeling of OTC drug products. One of those alternatives provides that the label and labeling contain in a prominent and conspicuous location indications for use that have been established under a final OTC drug monograph. At the option of the manufacturer, this labeling may be designated "APPROVED USES," or be given a similar permitted designation, each time it appears in the labeling. If the "APPROVED USES" or a similar designation is used, the labeling involved shall appear within a boxed area. Other applicable labeling, e.g., warnings and directions, may be included in the boxed area, in which case the boxed area shall be designated "APPROVED INFORMATION" rather than "APPROVED USES."

As the comment noted, the Panel also recommended that warnings on anorectal drug products be printed in a special type, size, or color or be illustrated to aid consumers. The agency does not believe that these recommendations are necessary to ensure proper labeling of these products and is not including them in this tentative final monograph.

43. Two comments requested deletion of the pregnancy warning recommended by the Panel in § 346.50(c)(7)(i) for all intrarectal products except protectants. The warning states, "The safety of this product has not been established for use by pregnant women or by nursing mothers." The comments stated that the Panel had no evidence to show any risk to pregnant or nursing women from the use of intrarectal products. One comment contended that the Panel was "merely expressing its belief that it is a good policy for pregnant or nursing women to take no more drugs than are essential." The comment stated that warnings based on a speculative hypothesis would only serve to dilute the importance of other warnings and that if the Panel's warning were heeded, pregnant women would be deprived of the use of products that could relieve some of the major discomforts of pregnancy.

A final rule requiring a warning concerning the use of OTC drugs by pregnant or nursing women was published in the **Federal Register** of December 3, 1982 (47 FR 54750). This warning (21 CFR 201.63) is specific to OTC drugs that are intended for systemic absorption and therefore is not required for OTC anorectal drug products that are intended for local effect.

44. Three comments objected to the Panel's recommended 7-day use limitation in § 346.50(c)(1), "If symptoms do not improve, do not use this product for more than 7 days and consult a physician." Two of the comments contended that this limitation is arbitrary and unsupported by documentation. The third comment contended that minor anorectal conditions normally are amenable to a 2-week treatment period before a doctor should be consulted.

The purpose of a limitation-of-use statement on a product is to inform the consumer of the period of time that is reasonable to allow for symptoms to begin to show improvement or to clear. The Panel concluded that symptoms of minor anorectal disorders that can be self-treated should be significantly relieved, if not completely cleared, in 7 days. The Panel was concerned that the continued self-treatment of the symptoms associated with hemorrhoids and other anorectal conditions may mask more serious medical problems, such as anal fissures, fistulae, abscesses, anal warts, or fecal impactions. The Panel believed that if symptoms do not respond to self-treatment in 7 days, the condition could be a serious one, requiring professional diagnosis and treatment.

The comments did not submit any data to show that more than 7 days may be required to obtain benefits from OTC anorectal drug products. Therefore, the agency proposes that the 7-day limitation be retained, but is revising this warning to advise consumers that a doctor should also be consulted if the condition worsens. The revised warning is proposed as follows: "If condition worsens or does not improve within 7 days, consult a doctor."

45. Two comments suggested revising the Panel's recommended warning statement in § 346.50(c)(7)(ii) that is specific to intrarectal products to be used with special applicators, such as pile pipes or other mechanical devices. The warning states, "Do not use this product if the introduction into the rectum causes additional pain. Consult a physician promptly." One of the comments contended that less trauma would result by applying the product intrarectally with the fingers and suggested that the warning state, "If use of (device) is painful, apply with fingers." The other comment noted that no comparable warning was proposed for suppositories, which usually cause some initial discomfort upon insertion, and suggested that the warning be deleted or altered to reflect common use conditions for products used with applicators.

The Panel stated that special applicators, such as pile pipes, are used to allow the introduction of a preparation above the anal sphincter so that it may remain in contact with the rectal mucosa where attempted insertion of an ointment by the finger is not apt to be successful (45 FR 35589). However, the Panel was concerned that there is some danger that the rectal mucosa can be perforated if a special applicator, such as a pile pipe, is not inserted into the rectum correctly. Accordingly, the Panel believed that the warning it recommended was necessary to alert consumers that there should not be any additional pain (caused by further injury) with the use of a pile pipe. The warning was not intended, as suggested by the comment, to alert consumers about any discomfort that may occur from the insertion of a pile pipe or a suppository. The agency agrees with the Panel that the warning is beneficial but is revising it for clarity as follows: "Do not use this product with an applicator if the introduction of the

applicator into the rectum causes additional pain. Consult a doctor promptly."

46. One comment stated that the Panel did not adequately define the terms "internal" and "external" for the purpose of describing "locus and necessary sites of treatment of anal/rectal irritation." The comment contended that many of the Panel's statements "imply that the entire anal canal is a portion of the anal/rectal 'interior,' " but that this "interior" area is not a proper location for application of certain hemorrhoidal ingredients. The comment objected to the Panel's recommended warnings in § 346.52(c)(2) for hemorrhoidal products containing local anesthetics for external use only, "*Caution:* This product is for external use only. Do not apply inside the rectum in any way," and in § 346.50(c)(6) for products for external use only, "Do not put this product into the rectum by using fingers or any mechanical device or applicator."

The comment argued that these warnings can be construed by the general public as prohibiting insertion of certain hemorrhoidal drug preparations into the anal canal, but that this apparently was not the Panel's intended meaning. The comment added that if these warnings go uncorrected, misinterpretation by the general public "will result in a great deal of unalleviated consumer 'hemorrhoidal' discomfort." The comment stated that pain stemming from irritation in the anal canal below the mucocutaneous junction can be effectively treated only by "internal" application (insertion through the anal canal and into the rectum) of a hemorrhoidal drug preparation. The comment described certain suppositories and ointments that liquefy when inserted and then work their way down, through, and over the cutaneous area below the mucocutaneous junction. The comment contended that the Panel's conclusions concerning the use of an anesthetic in a hemorrhoidal drug product do not make allowance for the internal use of suppositories and ointments for the treatment of skin in the anal canal below the mucocutaneous junction. The comment urged that the Panel's definitions of "external" and "internal" and its recommended labeling be clarified to promote correct consumer use of these products.

The Panel used the term "external," but not the word "internal," preferring "intrarectal" instead. The Panel consistently referred to the skin of the perianal area and the skin of the anal canal up to the mucocutaneous junction as external, and to the mucous membranes above the mucocutaneous junction, i.e., in the rectum, as intrarectal. It is apparent that, in the Panel's view, the point of distinction between "external" and "internal" use was the mucocutaneous junction. The agency believes that the Panel's definition of external use and intrarectal use are appropriate. Therefore, the agency is proposing those definitions in this tentative final monograph.

The comment is correct in stating that the Panel did not recommend labeling for the intrarectal application of suppositories and ointments containing a local anesthetic to relieve pain stemming from irritation outside the rectum (i.e., in the anal canal below the mucocutaneous junction and perianal area). Although the comment contends that such an intrarectal application would be effective because of liquefaction of the product and subsequent seepage through the anal canal, the Panel considered seepage only within the context of an incontinent anal sphincter and not within the context that an incontinent anal sphincter would provide a means to relieve external symptoms on the skin of the perianal area and the anal canal. Rather, the Panel considered intrarectal application only for local effect inside the rectum. The comment provided no data to alter the Panel's recommendations, and the agency believes that the intrarectal application of a suppository or ointment is not an appropriate means to alleviate external symptoms through liquefaction and seepage. Further, the agency disagrees with the comment's argument that the Panel's recommended warnings will result in a great deal of unalleviated consumer "hemorrhoidal discomfort." Most of the ingredients included in the tentative final monograph, but not local anesthetics, may be used intrarectally to alleviate discomfort. The Panel's recommended warnings would only apply to the small number of OTC anorectal drug products to be used externally only. Accordingly, the general warning for any anorectal ingredient intended for external use, as recommended by the Panel in § 346.50(c)(6), is being included in this tentative final monograph, but has been redesignated as § 346.50(c)(4). However, the warning recommended by the Panel in § 346.52(c)(2) for products containing local anesthetics for external use is not being proposed in this tentative final monograph because it is repetitive of the warning proposed § 346.50(c)(4).

47. One comment disagreed with the warning recommended by the Panel in § 346.54(c), "Do not use this product if you have heart disease, high blood pressure, hyperthyroidism, diabetes, difficulty in urination, or are taking tranquilizers or nerve pills." The comment stated that this warning would virtually eliminate the use of OTC anorectal drug products containing vasoconstrictor active ingredients by a large number of persons over 35 years of age who self-treat hemorrhoidal disorders. The comment recommended substituting a cautionary statement in place of the phrase "do not use."

The agency has reviewed the Panel's general discussion of vasoconstrictors (45 FR 35620) and the warning recommended in § 346.54(c) and has compared this warning with the warnings proposed for vasoconstrictor active ingredients in the final monograph for OTC bronchodilator drug products, published in the **Federal Register** of October 2, 1986 (51 FR 35326), and in the tentative final monograph for OTC nasal decongestant drug products, published in the **Federal Register** of January 15, 1985 (50 FR 2220). The Panel stated that a concomitant effect occurs on receptors in the heart and lungs when vasoconstrictors are applied to receptors in the anorectal area (45 FR 35620). Because of these potentially serious side effects and because useful effects are achieved with minimum quantities of vasoconstrictors, the Panel recommended that the safe OTC anorectal dosages of vasoconstrictors be equivalent to safe intravenous dosages. The Panel stated that when vasoconstrictors are used in these doses for local effect, undesirable systemic effects can be avoided (45 FR 35621).

However, the Panel recommended the warning in § 346.54(c) to alert consumers to undesirable side effects that can occur if systemic absorption occurs from either external or intrarectal application. These side effects can include elevated blood pressure, cardiac arrhythmia or irregular heart rate, central nervous system disturbance or nervousness, tremor, sleeplessness, and aggravation of symptoms of hyperthyroidism. Prolonged use of excessive dosage can also lead to anxiety or paranoia (45 FR 35621).

The agency concludes that vasoconstrictors used in the anorectal area, if absorbed, could cause the same undesirable systemic effects as vasoconstrictors used as bronchodilators and nasal decongestants, but that significant absorption is unlikely to occur when vasoconstrictors are used externally on intact skin for a short time. However, because the skin of the anorectal area is

usually abraded, and swollen hemorrhoids may be present, there is an increased potential for systemic absorption of vasoconstrictors used externally.

Therefore, the agency agrees with the Panel that a warning for anorectal vasoconstrictors is appropriate for both external and intrarectal use; however, the agency is proposing an expanded warning in this tentative final monograph to be consistent with the warnings required for these drugs when used as bronchodilators and nasal decongestants. The revised warning reads as follows for externally applied anorectal vasoconstrictors: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor." In addition, the phrase "* * * or are taking tranquilizers or nerve pills" recommended by the Panel in § 346.54(c) is changed to the following standard drug interaction precaution that appears in the bronchodilator final monograph for drug products containing ephedrine and epinephrine and in the nasal decongestant tentative final monograph for drug products containing phenylephrine hydrochloride for oral use: "Do not use this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor."

Because of the seriousness of the side effects that may occur if vasoconstrictors are systemically absorbed, cautionary language, as suggested by the comment, would not be adequate to alert consumers. However, the agency has added to the warnings the qualifying phrases "unless directed by a doctor," "consult your doctor," and "without first consulting your doctor" to make it clear that consumers to whom the warnings are directed may not need to completely forgo the use of these products, but may be able to use them under the advice or supervision of a doctor. Based on the bronchodilator final monograph, the agency is proposing the following additional warning for anorectal drug products containing ephedrine: "Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor."

48. One comment stated that the warnings recommended for all anorectal drug products in § 346.50(c) (1), (2), and (3) should not apply to petrolatum. Concerning the warning in § 346.50(c)(1), "If symptoms do not improve, do not use this product for more than seven days and consult a physician," the comment argued that the use of this ingredient for more than 7 days would not be hazardous per se because petrolatum is remarkably safe and does not cause any allergic reaction or skin irritation.

The comment stated that the warning in § 346.50(c)(2), "Do not exceed the recommended daily dosage except under the advice and supervision of a physician," would clutter the label without benefit to the consumer because petrolatum can be applied liberally to the affected anorectal area without hazard to the patient.

Concerning the warning in § 346.50(c)(3), "If itching persists for more than 7 days, consult a physician," the comment argued that 7 days is an arbitrary limitation because the dividing line between acute and chronic conditions has not been shown to be 7 days. The comment added that including the warnings in § 346.50(c) (1) and (3) would be redundant. The comment stated that the following warning is appropriate for petrolatum: "If symptoms continue to occur or increase, consult physician."

The warning recommended by the Panel in § 346.50(c)(1) is a general warning for all anorectal drug products and is intended to inform the consumer of the period of time that is reasonable to allow for symptoms of anorectal disorders to begin to show improvement or to clear. As discussed in comment 44 above, the agency is proposing that § 346.50(c)(1) be revised in this tentative final monograph to read as follows: "If condition worsens or does not improve within 7 days, consult a doctor." The agency concludes that this warning should be required for all anorectal drugs, including petrolatum, in order to provide the consumer with appropriate limitation-of-use information for OTC anorectal drug products. The warning suggested by the comment did not include this information.

The warning in § 346.50(c)(2) is also a general warning for all anorectal drug products. In the tentative final monograph for OTC skin protectant drug products, published in the **Federal Register** of February 15, 1983 (48 FR 6820), the agency proposed that the directions for use for petrolatum state, "Apply liberally as often as necessary." Because a warning such as in § 346.50(c)(2) is not required for petrolatum in the skin protectant tentative final monograph, the agency is proposing that petrolatum be exempt from this warning in this tentative final monograph.

The general warning recommended by the Panel in § 346.50(c)(3) for all anorectal drug products specifically addresses the condition of itching. As revised, the warning in § 346.50(c)(1), which addresses all conditions, makes the warning in § 346.50(c)(3) repetitive and unnecessary and it is not included in this tentative final monograph.

49. One comment stated that the directions for anorectal drug products recommended by the Panel in § 346.50(d) should not be listed separately for external and intrarectal use. The comment contended that the directions would be understood without putting them under separate headings, and that repeating each set of directions "for all products" is redundant and contributes to label clutter.

The agency agrees with the comment. As the Panel noted, many anorectal products may be used externally as well as intrarectally. The agency acknowledges this fact and has developed directions for use in this tentative final monograph that take into account the dual use of many of these products. However, there is certain additional directions information that applies to intrarectal use only, e.g., use of a special applicator to apply the product into the rectum. In those cases, the agency believes that a special heading indicating that these directions apply to intrarectal use is appropriate.

50. Four comments opposed, and one comment favored, the following directions recommended by the Panel in § 346.50(d)(2) for all anorectal drug products: "When practical wash the anorectal area with mild soap and warm water and rinse off all soap before application of this product." The comments contended that the statement is impractical and inappropriate and that it is not always convenient or even possible for the consumer to wash the anorectal area, especially after each bowel movement or when away from home. The comments argued that the Panel did not present evidence that washing is safe and effective and that washing might not serve a useful purpose, but instead might aggravate painful burning and itching disorders. Two comments further stated that cleansing pads are a more comfortable alternative if soap and water irritate sensitive or broken skin. The comment in favor of these directions commended the Panel for emphasizing good anal hygiene when treating anorectal disorders.

The Panel was concerned about the importance of anal hygiene and stated that washing the anorectal area daily and after each bowel movement with

soap and water and then carefully removing the soap greatly aids in the relief of anorectal symptoms and may prevent recurrence of perianal itching (45 FR 35584). The Panel also emphasized that, to avoid further irritation, the skin of the perianal area should be patted or blotted rather than rubbed dry.

The agency agrees with the comments' suggestion that cleansing pads are a suitable alternative to washing with soap and water, but recognizes that cleansing pads may not always be available. Accordingly, the directions proposed in this tentative final monograph, which appear in § 346.50(d)(1), have been revised for clarity. In addition, the directions have also been revised because the agency is not including the Panel's recommended warning in § 346.50(c)(7)(iii) for certain products for intrarectal use, "Do not use this product in children under 12 years of age except under the advice and supervision of a physician." Rather, the directions in § 346.50(d)(i) of this tentative final monograph have been revised to state clearly that a doctor should be consulted before using any anorectal drug product in children under 12 years of age to be more consistent with the Panel's general discussion on pediatric dosages in which the Panel stated that most anorectal disorders in children are brought to a physician for evaluation and treatment (45 FR 35579). In light of the revised directions, the agency believes that the warning recommended by the Panel is repetitious and unnecessary. The revised directions are as follows: "*Adults:* "When practical, cleanse the affected area" (select one or both of the following: "with mild soap and warm water and rinse thoroughly" or "by patting or blotting with an appropriate cleansing pad"). "Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product." [Other appropriate directions may be inserted here.] "Children under 12 years of age: consult a doctor."

51. One comment urged deletion of the phrase "or as directed by a physician" from the directions for petrolatum recommended by the Panel in § 346.56(d). The comment contended that the phrase is unnecessary and irrelevant for petrolatum because petrolatum is not usually prescribed by physicians, and therefore its use is rarely directed or supervised by a physician. The comment further contended that in the unusual case when a physician does direct the use of petrolatum, the physician's directions to the patient would take precedence over the label directions without the need for a statement to that effect on the label.

The agency agrees with the comment that the phrase "or as directed by a physician" is unnecessary in the directions for petrolatum. In addition, the agency believes that this phrase is unnecessary for any OTC anorectal drug product and is not including it in this tentative final monograph. Deleting this phrase makes the directions for all anorectal drug products consistent with the directions for other OTC topically applied ingredients contained in other tentative final monographs, i.e., skin protectants and external analgesics. (See comment 28 above.)

52. One comment objected to several of the Panel's Category II labeling recommendations as being excessive and unnecessary. The comment disagreed with the Panel's conclusion at 45 FR 35602 that the labeling claims "simple anorectal irritation," "anorectal disorders," and "simple inflammatory rectal conditions" are too general and contended that these terms are intended to encourage OTC hemorrhoidal drug use only in cases in which medical supervision is unnecessary. The comment added that labeling a hemorrhoidal product for a "simple anorectal condition" may be the best method of encouraging consumers to obtain medical advice if the condition persists or becomes a "complicated" anorectal condition.

The agency agrees with the Panel that labeling claims such as "simple anorectal irritation," "anorectal disorders," and "simple inflammatory rectal conditions" are too general or unclear if used alone (45 FR 35602). Further, the agency finds that such labeling claims, when used alone, could imply that OTC anorectal drug products treat diseases or conditions rather than relieve symptoms and, therefore, should remain in Category II. However, when these terms or similar terms are used with additional language describing the relief of associated symptoms, e.g., itching, discomfort, etc., the resulting labeling claims clearly describe that OTC anorectal drugs are primarily for the relief of symptoms and not the treatment of disease. Therefore, the agency is not proposing that the terms recommended by the comment be used alone as labeling for anorectal drug products. However, these terms or similar terms when used with additional language are included in the labeling proposed in § 346.50(b). (See comment 40 above.)

53. One comment objected to the Panel's criticism of labeling claims that may cause the consumer to believe that certain hemorrhoidal drug products are superior to other available products for any of a number of reasons (45 FR 35602) and what the comment described as the Panel's impression that one hemorrhoidal drug product is as good as another.

The Panel gave the following examples of labeling that may cause the consumer to believe that certain products are superior to other available products: "Contains no narcotic, anesthetic, or habit forming ingredients," "nonnarcotic," "without the use of narcotics," or "contains no stinging, smarting astringents" (45 FR 35602). The Panel stated that these claims clearly imply a stronger or more effective product, greater safety, and that other products are narcotics, anesthetics, or astringents and are harmful without any evidence that this is so. The agency has reviewed currently marketed products and finds no known marketed OTC anorectal drug products that contain narcotics. Therefore, the agency believes it would be inappropriate for manufacturers to state in the labeling of these products that the product "contains no narcotic." However, because anesthetics are present in some OTC anorectal products, manufacturers could state in their labeling, if they wish, that the product "contains no anesthetic." The agency is not aware of any data that show that astringents incorporated into an ointment or suppository base cause stinging and smarting in the anorectal area and, thus, believes that the statement "contains no stinging, smarting astringents" would be inappropriate for anorectal drug products.

N. Comments on Testing Guidelines.

54. A number of comments disagreed with parts of the Panel's testing guideline requirements, e.g., that the pharmacologic action of ingredients must always be demonstrated in the anorectal area, that clinical relief of symptoms must be correlated with pharmacologic activity, and that testing must be accomplished within 7 days. The comments also criticized the criteria for selection of patients with anorectal disease, the use of a product's vehicle as the control, double-blind studies, and the dose and frequency limitations. Two comments suggested that the Panel's testing requirements for anorectal drug products at 45 FR 35594 are more rigorous than for other drug entities, while another comment stated that the proposed requirements would limit manufacturers and independent testing organizations to inappropriate and

impossible testing methods. Several comments supported the Panel's minority opinion that extrapolation of data from tests performed in other areas of the body to the anorectal area is allowable (45 FR 35608 and 35652).

The agency has not addressed specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part II. paragraph A.2. below—*Testing of Category II and Category III conditions.*)

55. A number of comments objected to the Panel's recommendation of final formulation testing (bioavailability) for moving Category III anorectal drug products to Category I. There were no comments supporting the Panel's views. Some comments stated that adopting this requirement as part of the final rule would violate the Panel's charter, which was to review data on OTC ingredients and combinations, to make recommendations on their safety and efficacy, and to avoid a product-by-product review. Several comments cited 21 CFR 320.22(b)(2) as providing for a waiver of in vivo bioavailability requirements for topically applied preparations intended for local therapeutic effect. The comments also stated that none of the anorectal ingredients reviewed by the Panel has been cited as having bioavailability problems.

Two of the comments contended that consideration of the bioavailability of anorectal drug products is irrelevant, and that the Panel had not supported the final formulation testing recommendation with any documentation. One comment from a biopharmaceutics expert who had written a letter in 1975 (Ref. 1) that was reviewed and quoted by the Panel to support its conclusion to require final formulation testing for anorectal drug products (45 FR 35586 to 35588) contended that the Panel misconstrued the content of the letter. The comment stated that final formulation testing is not necessary for safety because there would be no significant risk to the user even if any of the Category I and III anorectal active ingredients were 100 percent bioavailable systemically. Another comment agreed with the Panel's minority report regarding final formulation testing (45 FR 35608, 35609, and 35652) and stated that "final formulation testing would be wasteful, a threat to * * * viability as a hemorrhoidal drug marketer, and, ultimately, a financial detriment to consumers."

FDA does not agree with the comment concerning the 1975 letter cited in the Panel's report. After reviewing the Panel's discussion of its reasons for recommending final formulation testing (45 FR 35586 to 35588), it is evident that the Panel did not quote from the letter discussed in the summary above, nor does it appear that the letter was cited for the proposition mentioned in the comment.

Although the Panel stated that final formulation testing of all ingredients and combinations could not be avoided in its testing guidelines for placing Category III ingredients and labeling in Category I (45 FR 35594 to 35598), the Panel also stated, and the agency concurs, that the use of a questionnaire, photography, and physician evaluation would be adequate to demonstrate statistically significant symptomatic improvement and would be acceptable for proof of effectiveness for claims of symptomatic relief of burning, pain, itch, swelling (as in hemorrhoids and/or hemorrhoidal tissue) and discomfort due to these symptoms.

While it is not clear whether the Panel intended testing of all products, including formulations containing Category I ingredients, FDA agrees with the comments that final formulation testing should not be required for anorectal drug products because the products are topically applied and because, to date, there has been no demonstrated bioavailability problem with any of the products at issue. The in vivo waiver provision of § 320.22(b)(2) for topically applied products reflects the fact that certain topically applied products, that are applied directly to the site of drug action, are less prone to bioavailability problems than are some other drugs and, accordingly, their bioavailability may, in some instances, be determined by means other than in vivo product testing. With regard to the products subject to this monograph, FDA will not require in vivo bioavailability testing, but will address product bioavailability in the context of the monograph requirements of (1) appropriate vehicles and other inactive ingredients and (2) compliance with appropriate good manufacturing practices.

Accordingly, the agency will not require final formulation testing of anorectal drug products covered by a final monograph. Category I anorectal active ingredients may be formulated in appropriate vehicles without additional testing, provided the product is manufactured according to the regulations for the Current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR Part 211). Manufacturers should be aware that the newness of a dosage, or method * * * of administration or application, or other condition of use * * * may affect the "newness" of a drug. (See 21 CFR 310.(h)(5).)

Reference

(1) Letter to J. K. Jones from S. Riegelman, March 13, 1975, OTC Volume 120051.

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions.

1. Summary of ingredient categories.

The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and has made the following changes in the categorization of anorectal active ingredients recommended by the Panel.

Because final formulation testing is not being proposed in this tentative final monograph, benzyl alcohol, dibucaine, dibucaine hydrochloride, dyclonine hydrochloride, epinephrine, lidocaine, tetracaine, and tetracaine hydrochloride have been reclassified from Category III to Category I for external use. (See comment 55 above.) However, these ingredients remain in Category III for intrarectal use because of insufficient data to establish safety and/or effectiveness for this use. Diperodon has been reclassified from Category II to Category III for external use while remaining in Category III for intrarectal use. (See comment 13 above.)

For the convenience of the reader, the following tables are included as a summary of the categorization of anorectal active ingredients by the Panel and the proposed classification by the agency:

Anorectal active ingredients	Panel	Agency [(e) = external use; (i) = intrarectal use]
Local anesthetics		
Benzocaine	I(e),III(i)	I(e),III(i)
Benzyl alcohol	III(e,i)	I(e),III(i)
Dibucaine	III(e,i)	I(e),III(i)
Dibucaine hydrochloride	III(e,i)	I(e),III(i)
Diperodon	II(e),III(i)	III(e,i)
Dyclonine hydrochloride	III(e,i)	I(e),III(i)
Lidocaine	III(e,i)	I(e),III(i)
Phenacaine hydrochloride	II(e,i)	II(e,i)
Pramoxine hydrochloride	I(e),III(i)	I(e),III(i)
Tetracaine	III(e,i)	I(e),III(i)
Tetracaine hydrochloride	III(e,i)	I(e),III(i)
Vasoconstrictors		
Ephedrine sulfate	I(e,i)	I(e,i)
Epinephrine	III(e,i)	I(e),III(i)
Epinephrine hydrochloride	I(e),II(i)	I(e),II(i)
Epinephrine undecylenate	III(e),II(i)	III(e),II(i)
Phenylephrine hydrochloride	I(e,i)	I(e,i)
Protectants		
Aluminum hydroxide gel	I(e,i)	I(e,i)
Bismuth oxide	III(e,i)	III(e,i)
Bismuth subcarbonate	III(e,i)	III(e,i)
Bismuth subgallate	III(e,i)	III(e,i)
Bismuth subnitrate	II(e,i)	II(e,i)
Calamine [1]	I(e,i)	I(e,i)
Cocoa butter	I(e,i)	I(e,i)
Cod liver oil [1]	I(e,i)	I(e,i)
Glycerin [2]	I(e)	I(e)
Kaolin	I(e,i)	I(e,i)
Lanolin	I(e,i)	I(e,i)
Lanolin alcohols [3]	I(e,i)	III(e,i)
Mineral oil	I(e,i)	I(e,i)
Petrolatum	Not reviewed	I(e,i)
Shark liver oil [1]	I(e,i)	I(e,i)
Topical starch [4]	I(e,i)	I(e,i)
White petrolatum	I(e,i)	I(e,i)
Zinc oxide [1]	I(e,i)	I(e,i)
Counterirritants		
Camphor (greater than 3 to 11 percent)	II(e,i)	II(e,i)
Hydrastis	II(e,i)	II(e,i)
Juniper tar (1 to 5 percent)	III(e,i)	N/A [5]
Menthol (1.25 to 16 percent)	II(e,i)	II(e,i)
Turpentine oil (rectified) (6 to 50 percent)	II(e,i)	II(e,i)
Astringents		
Calamine	I(e,i)	I(e,i)
Tannic acid	II(e,i)	II(e,i)
Hamamelis water, NF XI [2, 6]	I(e)	I(e)
Zinc oxide	I(e,i)	I(e,i)
Wound-healing agents		
Cholecalciferol [7]	III(e,i)	III(e,i)
Cod liver oil	III(e,i)	III(e,i)
Live yeast cell derivative	III(e,i)	III(e,i)
Peruvian balsam	III(e,i)	III(e,i)
Shark liver oil	III(e,i)	III(e,i)
Vitamin A	III(e,i)	III(e,i)
Antiseptics		
Boric acid	II(e,i)	II(e,i)
Boroglycerin	II(e,i)	II(e,i)
Hydrastis	II(e,i)	II(e,i)
Phenol	II(e,i)	II(e,i)
Resorcinol	III(e),II(i)	III(e),II(i)
Sodium salicylic acid phenolate	II(e,i)	II(e,i)
Keratolytics		
Alcloxa [2]	I(e)	I(e)
Resorcinol	I(e),II(i)	I(e),II(i)
Precipitated sulfur	III(e),II(i)	III(e),II(i)
Sublimed sulfur	III(e),II(i)	III(e),II(i)
Anticholinergics		
Atropine	II(e,i)	II(e,i)
Belladonna extract	II(e,i)	II(e,i)
Analgesics, anesthetics, and antipruritics		
Camphor (0.1 to 3 percent)	N/A	I(e)
Juniper tar (1 to 5 percent)	N/A	I(e)
Menthol (0.1 to 1 percent)	N/A	I(e)
Miscellaneous		
Collinsonia extract	II(e,i)	II(e,i)
E.coli vaccines	II(e,i)	II(e,i)
Hydrocortisone	N/A	Ext. Anal.[8]
Hydrocortisone acetate	N/A	Ext. Anal.[8]

Anorectal active ingredients	Panel	Agency [(e) = external use; (i) = intrarectal use]
Lappa extract	II(e,i)	II(e,i)
Leptandra extract	II(e,i)	II(e,i)
Mullein	II(e,i)	II(e,i)

[1] For use only in combination and not as single ingredients. (See comment 30 above.)
[2] Not categorized for intrarectal use.
[3] "Wool alcohols" was the name designated by the Panel for this ingredient. "Lanolin alcohols" is the official title of this ingredient in the "United States Pharmacopeia XXI—National Formulary XVI."
[4] "Starch" was the name designated by the Panel for this ingredient. "Topical starch" is the official title of this ingredient in the "United States Pharmacopeia XXI—National Formulary XVI."
[5] Juniper tar was redesigned an "analgesic, anesthetic, and antipruritic" ingredient. (See Part II.B.6 below—*Summary of the Agency's Changes in the Panel's Recommendations.*)
[6] "Witch hazel water" was the name designated by the Panel for this ingredient. "Hamamelis Water" was last recognized as the official title of this ingredient in National Formulary XI, and the agency has determined that this is the appropriate name for this ingredient.
[7] "Vitamin D" was the name designated by the Panel for this ingredient. "Cholecalciferol" is the official title of this ingredient in the "United States Pharmacopeia XXI—National Formulary XVI."
[8] Hydrocortisone and hydrocortisone acetate were not reviewed by the Panel. These ingredients are being addressed in the rulemaking for OTC external analgesic drug products. (See comment 25 above.)

2. Testing of Category II and Category III conditions.

The Panel recommended testing guidelines for anorectal drug products (45 FR 35594 to 35598). The agency's position regarding these testing guidelines and regarding final formulation testing is discussed in comments 54 and 55 above. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any anorectal ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency is proposing dibucaine and dibucaine hydrochloride as Category I anorectal local anesthetics for external use in a concentration range of 0.25 to 1 percent for use up to 3 or 4 times daily. (See comment 12 above.)

The agency is also proposing the following anorectal ingredients as Category I for external use. (See part II. paragraph A. 1. above—*Summary of ingredient categories.*) The concentrations in this tentative final monograph are the equivalent of the dosages recommended by the Panel for a 2-g or a 2-mL dosage unit.

(a) Benzyl alcohol 1 to 4 percent.

(b) Dyclonine hydrochloride 0.5 to 1 percent.

(c) Lidocaine 2 to 5 percent.

(d) Tetracaine and tetracaine hydrochloride 0.5 to 1 percent.

(e) Epinephrine 0.005 to 0.01 percent.

2. In its recommended monograph, the Panel stated the amounts of the vasoconstrictor active ingredients identified in § 346.12 in terms of a given weight per 2-g or 2-mL dosage unit. The agency proposes that the ingredients be expressed in terms of percentage concentration to be consistent with the manner of stating other ingredients in this tentative final monograph. Accordingly, the vasoconstrictor active ingredients in § 346.12 of this tentative final monograph are expressed as follows:

(a) Ephedrine sulfate 0.1 to 1.25 percent.

(b) Epinephrine 0.005 to 0.01 percent.

(c) Epinephrine hydrochloride 0.005 to 0.01 percent

(d) Phenylephrine hydrochloride 0.25 percent.

The agency is aware that in the Panel's report (45 FR 35625) the statement is made that "a 0.5 mg dose of phenylephrine hydrochloride in a 2 mL dosage unit is equal to the amount of phenylephrine used safely and effectively in producing nasal decongestion, as discussed in the September 9, 1976 document at page 38399." The statement is incorrect and should have read "a 5-mg dose." Such a dose represents a concentration of 0.25 percent phenylephrine.

3. The agency is reclassifing lanolin alcohols from Category I to Category III as protectants in OTC anorectal drug products. Lanolin alcohols were not contained in any products submitted to the Panel for review, and the agency has no information on currently marketed anorectal drug products that contain these ingredients or on their appropriate concentration for anorectal protectant use. Such information is needed before lanolin alcohols can be considered generally recognized as safe and effective as anorectal protectants, and the agency invites public comment and the submission of data.

4. The agency is not requiring the final formulation testing of combination drug products recommended by the Panel. Accordingly, combinations of Category I ingredients from up to three different therapeutic categories that were placed in Category III by the Panel are reclassified in Category I. (See comment 31 above.)

5. The agency is proposing in § 346.14(b) in this tentative final monograph that calamine, cod liver oil, shark liver oil, and zinc oxide not be used alone but only in combination with other protectants to provide at least 50 percent by weight of the final product. Section 346.22 of the Panel's recommended monograph has been redesignated as § 346.22(a) and has been expanded to clarify that any two, three, or four protectants identified in § 346.14 may be combined, provided that any ingredient identified in § 346.14 is included at a level that contributes at least 12.5 percent by weight (e.g., 0.25 g of a 2-g dosage unit) and provided that if any ingredient identified in § 346.14(b) is present in the combination, it must not exceed the concentration limit specified in § 346.14(b). In addition, the combined percentage by weight of all protectants in the combination must be at least 50 percent of the final product (e.g., 1-g of a 2-g dosage unit). New § 346.22(o) provides that the amount of zinc oxide in a combination may not exceed 25 percent by weight per dosage unit. (See

comment 30 above.) In addition, on its own initiative, the agency is expanding the list of protectant active ingredients in § 346.14 to include petrolatum as well as white petrolatum. Although the use of white petrolatum in lieu of petrolatum results in a more aesthetically pleasing anorectal ointment, the use of white petrolatum is not medically necessary.

6. The agency is redesignating several ingredients that the Panel classified as "counterirritants" to be "analgesic, anesthetic, and antipruritic" ingredients in this rulemaking. The Panel classified the ingredients camphor (1.6 to 7 percent), hydrastis (no concentration given), juniper tar (1 to 5 percent), menthol (0.25 to 1 percent), and turpentine oil (no concentration given) as counterirritants (45 FR 35640 to 35645). The Topical Analgesic Panel also reviewed and classified camphor (0.1 to 3 percent), juniper tar (1 to 5 percent), and menthol (0.1 to 1 percent) as analgesic, anesthetic, and antipruritic active ingredients (44 FR 69865) and camphor (3 to 11 percent), menthol (1.25 to 16 percent), and turpentine oil (6 to 50 percent) as counterirritant ingredients (44 FR 69864 to 69865). The agency agreed with that Panel's classifications in the tentative final monograph for OTC external analgesic drug products (48 FR 5852; February 8, 1983), and further clarified that menthol at a concentration of 0.1 to 1 percent was an analgesic, anesthetic, or antipruritic and at a concentration of 1.25 to 16 percent was a counterirritant. (See comment 6 at 48 FR 5855.)

The Anorectal Panel classified menthol at a concentration of 0.25 to 1 percent in aqueous solution as a counterirritant for the temporary relief of itching in the anorectal area.

Based on the agency's findings in the tentative final monograph for OTC external analgesic drug products and to promote consistency between the rulemakings for anorectal and external analgesic drug products, the agency is proposing to redesignate menthol below 1 percent as an analgesic, anesthetic, and antipruritic ingredient rather than as a counterirritant in the anorectal rulemaking and to revise its Category I concentration from 0.25 to 1 percent to 0.1 to 1 percent. Likewise, camphor 0.1 to 3 percent and juniper tar 1 to 5 percent will be redesignated as analgesic, anesthetic, and antipruritic ingredients in the anorectal rulemaking. The Anorectal Panel did not classify these ingredients for these uses. However, because these ingredients are indicated for pain and itching of minor skin irritations when labeled as an external analgesic and for itching and discomfort when labeled for anorectal/hemorrhoidal use, the agency has determined that menthol, camphor, and juniper tar at the above concentrations should be listed as Category I analgesic, anesthetic, and antipruritic ingredients in the anorectal tentative final monograph.

Camphor exceeding 3 percent to 11 percent, menthol 1.25 to 16 percent, and turpentine oil 6 to 50 percent are designated as counterirritants in the anorectal rulemaking. Because the Anorectal Panel classified camphor and turpentine oil in Category II as counterirritants for anorectal use, they are not being included in this tentative final monograph. Likewise, the Panel did not propose Category I status for menthol above 1 percent as a counterirritant; therefore, it also is not being included in this tentative final monograph as a counterirritant. This approach is consistent with the labeling of counterirritants in the external analgesic tentative final monograph because those products are used to relieve aches and pains of muscles and joints associated with backaches, arthritis, etc., and not to relieve itching and discomfort of minor skin irritations. Hydrastis also remains in Category II as a counterirritant in OTC anorectal drug products.

The agency is adding the definitions of "analgesic, anesthetic" and "antipruritic" to this tentative final monograph to be consistent with those definitions as proposed in the tentative final monograph for OTC external analgesic drug products. (See the **Federal Register** of February 8, 1983; 48 FR 5852.) In addition, the agency is not including the definition of counterirritant in this tentative final monograph.

7. The agency is redesignating Subpart D as Subpart C and is placing the labeling sections of the tentative final monograph in Subpart C. To improve clarity and to eliminate duplicative words and phrases, the agency has shortened and simplified the general indications and the indications recommended by the Panel for different therapeutic categories. (See comment 40 above.) In some cases, the agency has eliminated indications from the different therapeutic categories when the same or very similar indications were already part of the general indications.

8. The agency is proposing that the term "hemorrhoidal" be allowed to appear alone or in parentheses next to the term "anorectal" as the statement of identity for all OTC anorectal drug products. (See comment 38 above.)

9. The agency is proposing in § 346.50(b) that certain labeling statements may be combined in the labeling of anorectal combination drug products. The agency is proposing in § 346.54 that indications, warnings, and directions applicable to each active ingredient of the combination product may be combined, respectively, to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

10. Cosmetic-related terms, such as "bland," "soothing," "lubrication," "lubricates," "* * * soften and lubricate dry * * *" are not included in the labeling for protectants in § 346.50(b)(iii) of this tentative final monograph. The agency's policy on such labeling was stated in the tentative final monograph for OTC skin protectant drug products. (See 48 FR 6827, comment 22.)

11. In § 346.52(c)(1), § 346.56(c)(2), § 346.58(c), and § 346.62(c)(1)(i), the Panel recommended the use of the signal word "Caution" in labeling for which the heading "Warnings" was also recommended. The agency notes that historically there has not been a consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in § 369.20 and § 369.21 (21 CFR 369.20 and 369.21), which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances, either of these signal words is used to convey the same or similar precautionary information.

FDA has considered which of these signal words would be most likely to attract consumers' attention to that information describing conditions under which the drug product should not be used or its use should be discontinued. The agency concludes that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems.

12. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulation will give manufacturers the option of using either the word "physician" or the

word "doctor." This tentative final monograph includes that option.

13. The Panel's recommendations concerning a "box border" and various graphic effects for highlighting warnings on anorectal drug products are not included in § 346.50(c). (See comment 42 above.)

14. The agency is revising the general warning in § 346.50(c)(1) to read as follows: "If condition worsens or does not improve within 7 days, consult a doctor."

The agency is not including the general warning recommended by the Panel in § 346.50(c)(3), "If itching persists for more than 7 days, consult a physician," because the revised warning in proposed § 346.50(c)(1) addresses all conditions, not just itching. (See comment 48 above.)

The agency is proposing in § 346.56(c)(3) that petrolatum be exempt from the warning in § 346.50(c)(2), "Do not exceed the recommended daily dosage unless directed by a doctor."

15. The agency is revising the warning recommended by the Panel in § 346.50(c)(7)(ii) for clarity, to read as follows: "Do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly." (See comment 45 above.)

16. The agency is not including the Panel's recommended warning in § 346.52(c)(2) for products containing local anesthetics for external use because it would be repetitive of the general warning proposed in § 346.50(c)(4). (See comment 46 above.)

17. The agency is proposing that anorectal vasoconstrictors bear the same warnings for anorectal use as for bronchodilator and nasal decongestant use. These warnings include the following: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor"; and the drug interaction precaution "Do not use this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor." The agency is proposing the following additional warning for ephedrine sulfate: "Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor." (See comment 47 above.)

18. The Panel's recommended warning and directions for use for lanolin (wool) alcohols (§ 346.56 (c)(2) and (d)(12)) are not included in this tentative monograph because lanolin alcohols are being reclassified from Category I to Category III as anorectal protectants. (See part II. paragraph B.3. above.)

19. The agency is not accepting the Panel's recommendation to have complete and separate directions for products labeled for both external and intrarectal use. Rather, the agency has developed directions for use that take into account the dual use of these products. (See comment 49 above.)

20. The Panel's recommended directions in § 346.50(d)(2) (redesignated as § 346.50(d)(1)) has been revised for clarity as follows: "*Adults*: "When practical, cleanse the affected area" (select one or both of the following: "with mild soap and warm water and rinse thoroughly" or "by patting or blotting with an appropriate cleansing pad"). "Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product." [Other appropriate directions may be inserted here.] "Children under 12 years of age: consult a doctor." (See comment 50 above.)

21. The agency is not proposing the phrase "or as directed by a physician" in the directions for any anorectal product in this tentative final monograph. The directions for use of petrolatum have been revised to be consistent with the directions in the skin protectant tentative final monograph, so that proposed § 346.56(d)(6) reads "Apply liberally as often as necessary." (See comments 28 and 51 above.)

22. A claim for hydrocortisone and hydrocortisone acetate for the temporary relief of anal itching is already included in the tentative final monograph for OTC external analgesic drug products. In a future issue of the **Federal Register**, the agency will amend that tentative final monograph so that external analgesic drug products containing hydrocortisone or hydrocortisone acetate and bearing claims for the relief of "anal itching" would also bear the appropriate warnings and directions for anorectal drug products. (See comment 25 above.)

The agency is proposing to remove the existing labeling requirements of § 310.201(a)(23)(v)(b) (21 CFR 310.201(a)(23)(v)(*b*)) relating to dyclonine hydrochloride at the time that a final monograph for OTC anorectal drug products becomes effective. In addition, the agency is proposing to revise § 369.20 to remove the reference to rectal preparations from the entry for "BELLADONNA PREPARATIONS * * *" and to remove the entry for "RECTAL PREPARATIONS FOR EXTERNAL USE" because these entries will be superseded by a final monograph for OTC anorectal drug products.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC anorectal drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC anorectal drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC anorectal drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC anorectal drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on anorectal drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has carefully considered the potential environmental effects of that action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not

required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Interested persons may, on or before December 13, 1988 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 13, 1988. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before August 15, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before October 15, 1989. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on October 15, 1989. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR

21 CFR Part 310

Administrative practice and procedure, Drugs, New drugs, Prescription exemption, Reporting and recordkeeping requirements.

21 CFR Part 346

Anorectal drug products, Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Over-the-counter drugs, Warning and caution statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR Part 310 is revised to read as follows:

Authority: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055 as amended (21 U.S.C. 352, 353, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

§ 310.201 [Amended]

2. Section 310.201 *Exemption for certain drugs limited by new-drug applications to prescription sale* is amended by removing paragraph (a)(23)(v)(*b*) and reserving it.

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. Part 346 is added to read as follows:

Subpart A—General Provisions.

Sec.
346.1 Scope.
346.3 Definitions.

Subpart B—Active Ingredients

346.10 Local anesthetic active ingredients.
346.12 Vasoconstrictor active ingredients.
346.14 Protectant active ingredients.
346.16 Analgesic, anesthetic, and antipruritic active ingredients.
346.18 Astringent active ingredients.
346.20 Keratolytic active ingredients.
346.22 Permitted combinations of anorectal active ingredients.

Subpart C—Labeling

346.50 Labeling of anorectal drug products.
346.52 Labeling of permitted combinations of anorectal active ingredients.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

Subpart A—General Provisions

§ 346.1 Scope.

(a) An over-the-counter anorectal drug product in a form suitable for external (topical) or intrarectal (rectal) administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 346.3 Definitions.

As used in this part:

(a) *Analgesic, anesthetic drug.* A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors.

(b) *Anorectal drug.* A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

(c) *Antipruritic drug.* A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors.

(d) *Astringent drug.* A drug that is applied to the skin or mucous membranes for a local and limited protein coagulant effect.

(e) *External use.* Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal.

(f) *Intrarectal use.* Topical application of an anorectal drug product to the mucous membrane of the rectum.

(g) *Keratolytic drug.* A drug that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis.

(h) *Local anesthetic drug.* A drug that produces local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations.

(i) *Protectant drug.* A drug that provides a physical barrier, forming a protective coating over skin or mucous membranes.

(j) *Vasoconstrictor drug.* A drug that causes temporary constriction of blood vessels.

Subpart B—Active Ingredients

§ 346.10 Local anesthetic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentrations established for each ingredient:

(a) Benzocaine 5 to 20 percent.

(b) Benzyl alcohol 1 to 4 percent.

(c) Dibucaine 0.25 to 1 percent.

(d) Dibucaine hydrochloride 0.25 to 1 percent.

(e) Dyclonine hydrochloride 0.5 to 1 percent.

(f) Lidocaine 2 to 5 percent.

(g) Pramoxine hydrochloride 1 percent.

(h) Tetracaine 0.5 to 1 percent.

(i) Tetracaine hydrochloride 0.5 to 1 percent.

§ 346.12 Vasoconstrictor active ingredients.

The active ingredient of the product consists of any of the following when used within the concentrations established for each ingredient:

(a) Ephedrine sulfate 0.1 to 1.25 percent.

(b) Epinephrine 0.005 to 0.01 percent.

(c) Epinephrine hydrochloride 0.005 to 0.01 percent.

(d) Phenylephrine hydrochloride 0.25 percent.

§ 346.14 Protectant active ingredients.

(a) The following active ingredients may be used as the sole protectant active ingredient in a product if the ingredient as identified constitutes 50 percent or more by weight of the final product. In addition, the following active ingredients may be used in combinations in accordance with § 346.22 (a), (b), or (n).

(1) Aluminum hydroxide gel.

(2) Cocoa butter.

(3) Glycerin in a 20- to 45-percent (weight/weight) aqueous solution.

(4) Kaolin.

(5) Lanolin.

(6) Mineral oil.

(7) Petrolatum.

(8) Topical starch.

(9) White petrolatum.

(b) The following active ingredients may not be used as a sole protectant ingredient but may be used in combination with one, two, or three other protectant active ingredients in accordance with § 346.22 (a), (b), (n), and (o) and with the following limitations:

(1) Calamine not to exceed 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).

(2) Cod liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

(3) Shark liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

(4) Zinc oxide not to exceed 25 percent by weight per dosage unit.

§ 346.16 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentrations established for each ingredient:

(a) Camphor 0.1 to 3 percent.

(b) Juniper tar 1 to 5 percent.

(c) Menthol 0.1 to 1 percent.

§ 346.18 Astringent active ingredients.

The active ingredient of the product consists of any of the following when used within the concentrations established for each ingredient:

(a) Calamine, within a concentration of 5 to 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).

(b) Hamamelis water, NF XI, 10 to 50 percent.

(c) Zinc oxide, within a concentration of 5 to 25 percent by weight per dosage unit.

§ 346.20 Keratolytic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentrations established for each ingredient:

(a) Alcloxa 0.2 to 2 percent.

(b) Resorcinol 1 to 3 percent.

§ 346.22 Permitted combinations of anorectal active ingredients.

(a) Any two, three, or four protectants identified in § 346.14 may be combined, provided that the combined percentage by weight of all protectants in the combination is at least 50 percent of the final product (e.g., 1 gram of a 2-gram dosage unit). Any protectant ingredient included in the combination must be present at a level that contributes at least 12.5 percent by weight (e.g., 0.25 gram of a 2-gram dosage unit), except cod liver oil and shark liver oil. If an ingredient in § 346.14(b) is included in the combination, it must not exceed the concentration limit specified in § 346.14(b).

(b) Any single anorectal ingredient identified in § 346.10, § 346.12, § 346.16, § 346.18, or § 346.20 may be combined with up to four protectants in accordance with paragraph (a) of this section.

(c) Any single local anesthetic identified in § 346.10 may be combined with any single vasoconstrictor identified in § 346.12.

(d) Any single local anesthetic identified in § 346.10 may be combined with any single astringent identified in § 346.18.

(e) Any single local anesthetic identified in § 346.10 may be combined with any single keratolytic identified in § 346.20.

(f) Any single vasoconstrictor identified in § 346.12 may be combined with any single astringent identified in § 346.18.

(g) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single astringent identified in § 346.18.

(h) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single keratolytic identified in § 346.20.

(i) Any single astringent identified in § 346.18 may be combined with any single keratolytic identified in § 346.20.

(j) Any single local anesthetic identified in § 346.10 may be combined with any single vasoconstrictor identified in § 346.12 and with any single astringent identified in § 346.18.

(k) Any single local anesthetic identified in § 346.10 may be combined with any single astringent identified in § 346.18 and with any single keratolytic identified in § 346.20.

(l) Any single vasoconstrictor identified in § 346.12 may be combined with any single analgesic, anesthetic, and antipruritic identified in § 346.16 and with any single astringent identified in § 346.18.

(m) Any single analgesic, anesthetic, and antipruritic identified in § 346.16 may be combined with any single astringent identified in § 346.18 and with any single keratolytic identified in § 346.20.

(n) Any combination of ingredients listed in paragraphs (c) through (m) of this section may be combined with up to four protectants in accordance with paragraph (a) of this section.

(o) Any product containing calamine for use as a protectant and/or as an astringent and/or containing zinc oxide for use as a protectant and/or as an astringent may not have a total weight of zinc oxide exceeding 25 percent by weight per dosage unit.

Subpart C—Labeling

§ 346.50 Labeling of anorectal drug products.

The labeling of the product contains the following information for anorectal

ingredients identified in §§ 346.10, 346.12, 346.14, 346.16, 346.18, and 346.20, and for combinations of anorectal ingredients identified in § 346.22. Unless otherwise specified, the labeling in this subpart is applicable to anorectal drug products for both external and intrarectal use.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as "anorectal (hemorrhoidal)," "hemorrhoidal," "hemorrhoidal (anorectal) (insert dosage form, e.g., cream, lotion, or ointment)."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) ("For the temporary relief of," "Gives temporary relief of," or "Helps relieve the") [As an option, select one or both of the following: "local" or "anorectal") [select one or more of the following: "discomfort," "itching," or "itching and discomfort," followed by: "in the perianal area" or "associated with" (select one or more of the following: "hemorrhoids," "anorectal disorders," "inflamed hemorrhoidal tissues," "anorectal inflammation," "hemorrhoidal tissues," or "piles (hemorrhoids)."]]

(2) *Additional indications.* Indications applicable to each active ingredient of the product may be combined to eliminate duplicative words or phrases so that the resulting indication is clear and understandable. In addition to the indication identified in paragraph (b)(1) of this section, the labeling of the product intended for external or intrarectal use may also contain the following indications, as appropriate.

(i) *For products for external use only containing any ingredient identified in § 346.10.* "For the temporary relief of" (select one or more of the following: "pain," "soreness," or "burning").

(ii) *For products containing epinephrine or epinephrine hydrochloride identified in § 346.12 (b) and (c) for external use only, and for products containing ephedrine sulfate or phenylephrine hydrochloride identified in § 346.12 (a) and (d).*

(A) "Temporarily reduces the swelling associated with" (select one of the following: "irritated hemorrhoidal tissue and other anorectal disorders" or "irritation in hemorrhoids and other anorectal disorders").

(B) "Temporarily shrinks hemorrhoidal tissue."

(iii) *For products for external use only containing glycerin identified in § 346.14(a)(3) and for products for external and/or intrarectal use containing any protectant identified in § 346.14(a) (2), (5) through (9), and (b) (1) through (4).*

(A) "Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues."

(B) "Temporarily protects irritated areas."

(C) "Temporarily relieves burning."

(D) "Provides temporary relief from skin irritations."

(E) "Temporarily provides a coating for relief of anorectal discomforts."

(F) "Temporarily protects the inflamed, irritated anorectal surface" (select one of the following: "to help make bowel movements less painful" or "from irritation and abrasion during bowel movement").

(G) "Temporarily protects inflamed perianal skin."

(H) "Temporarily relieves the symptoms of perianal skin irritation."

(iv) *For products containing aluminum hydroxide gel identified in § 346.14(a)(1) and for products containing kaolin identified in § 346.14(a)(4).* "For the temporary relief of itching associated with moist anorectal conditions."

(v) *For products for external use only containing any analgesic, anesthetic, and antipruritic identified in § 346.16.*

(A) "For the temporary relief of" (select one or both of the following: "pain" or "burning").

(B) "Can help distract from pain."

(C) "May provide a cooling sensation."

(vi) *For products for external use only containing hamamelis water identified in § 346.18(b), and for products for external use and/or intrarectal use containing calamine or zinc oxide identified in 346.18 (a) and (c).*

(A) "Aids in protecting irritated anorectal areas."

(B) "Temporary relief of" (select one or both of the following' "irritation" or "burning").

(vii) *For products for external use only containing any ingredient identified in § 346.20.* The indication in paragraph (b)(1) of this section applies.

(c) *Warnings.* Warnings applicable to each active ingredient of the product may be combined to eliminate duplicative words or phrases so that the resulting warning is clear and understandable. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "If condition worsens or does not improve within 7 days, consult a doctor."

(2) "Do not exceed the recommended daily dosage unless directed by a doctor."

(3) "In case of bleeding, consult a doctor promptly."

(4) *For products for external use only.* "Do not put this product into the rectum by using fingers or any mechanical device or applicator."

(5) *For products for intrarectal use to be used with a special applicator such as a pile pipe or other mechanical device.* "Do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly."

(6) *For products for external use only containing any local anesthetic identified in 346.10, menthol identified in § 346.16(c), or resorcinol identified in § 346.20(b).* "Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor."

(7) *For products containing any vasoconstrictor identified in § 346.12.*

(i) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(ii) *"Drug interaction precaution.* Do not use this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor."

(iii) For products containing ephedrine sulfate identified in § 346.12(a). "Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor."

(8) *For products containing aluminum hydroxide gel identified in § 346.14(a)(1) and for products containing kaolin identified in § 346.14(a)(4).* "Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area."

(9) *For products for external use only containing resorcinol identified in § 346.20(b).* "Do not use on open wounds near the anus."

(d) *Directions.* Directions applicable to each active ingredient of the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. The labeling of the product contains the following information under the heading "Directions":

(1) *"Adults:* When practical, cleanse the affected area" (select one or both of the following: "with mild soap and warm water and rinse thoroughly" or "by patting or blotting with an appropriate cleansing pad"). "Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product." [Other appropriate directions in this section may be inserted here.] "Children under 12 years of age: consult a doctor."

(2) *For products for external use only.* "Apply externally to the affected area" [insert appropriate time interval of administration as identified in paragraphs (d)(6), (7), (8), or (9) of this section).

(3) *For products for external use that are pads containing anorectal ingredients.* "Gently apply to the affected area by patting and then discard."

(4) *For products for intrarectal use that are wrapped suppositories.* "Remove wrapper before inserting into the rectum."

(5) *For products for intrarectal use that are to be used with a special applicator such as a pile pipe or other mechanical device.* "FOR INTRARECTAL USE: Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum."

(6) *For products for external use only containing any of the local anesthetics identified in § 346.10; analgesics, anesthetics, and antipruritics identified in § 346.16; or alcloxa or resorcinol identified in § 346.20.* Apply to the affected area up to 6 times daily.

(i) *For products for external use only containing dibucaine or dibucaine hydrochloride identified in § 346.10 (c) and (d).* Apply to the affected area up to 3 or 4 times daily.

(ii) *For products for external use only containing pramoxine hydrochloride identified in § 346.10(g).* Apply to the affected area up to 5 times daily.

(7) *For products containing vasoconstrictors identified in § 346.12.* Apply to the affected area up to 4 times daily.

(8) *For products for external use only containing glycerin identified in § 346.14(a)(3) or hamamelis water identified in § 346.18(b), and for products for external and/or intrarectal use containing any protectant identified in § 346.14(a) (1), (2), (4), (5), (6), and (8), and (b) (1), (2), (3), and (4), or any astringent identified in § 346.18 (a) and (c).* Apply to the affected area up to 6 times daily or after each bowel movement.

(9) *For products containing petrolatum or white petrolatum identified in § 346.14(a) (7) and (9).* Apply liberally to the affected area as often as necessary.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

§ 346.52 Labeling of permitted combinations of anorectal active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this subpart.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of this subpart.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of this subpart.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of this subpart. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

4. The authority citation for 21 CFR Part 369 continues to read as follows:

Authority: Secs. 502, 503, 506, 507, 701, 52 Stat. 1050–1052 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 352, 353, 356, 357, 371); 21 CFR 5.10 and 5.11.

§ 369.20 [Amended]

5. In Subpart B, § 369.20 *Drugs; recommended warning and caution statements* is amended by removing the statement, "See also Rectal Preparations for additional warnings," from the entry for "BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE, HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE)); HYOSCYAMUS, STRAMONIUM, THEIR DERIVATIVES, AND RELATED DRUG PREPARATIONS."

§ 369.20 [Amended]

6. In Subpart B, § 369.20 *Drugs; recommended warning and caution statements* is amended by removing the entry "RECTAL PREPARATIONS FOR EXTERNAL USE."

Dated: May 2, 1988

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88–18200 Filed 8–12–88; 8:45 am]

BILLING CODE 4160-01-M

federal register

Monday
August 15, 1988

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 357

Cholecystokinetic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 87N-0181]

Cholecystokinetic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) cholecystokinetic drug products to include the ingredient hydrogenated soybean oil. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATE: Written comments or objections by October 14, 1988.

ADDRESS: Written comments or objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 1983 (48 FR 27004), FDA issued a final monograph for OTC cholecystokinetic drug products (21 CFR Part 357, Subpart C). The only active ingredient included in the monograph was a 50-percent aqueous emulsion of corn oil.

On March 16, 1984, FDA received a citizen petition (Docket No. 79N-0368/CP) requesting that the final monograph for OTC cholecystokinetic drug products be amended to include a powder dosage form containing hydrogenated soybean oil and lecithin. The citizen petition was supplemented by data contained in letters dated January 14, 1985, November 14, 1985, June 1, 1987, and January 13, 1988. These letters are on file in Docket No. 79N-0368 as LET004, LET006, LET009, and LET011, respectively.

After reviewing the citizen petition and the supplemental data, the agency concludes that there is sufficient evidence to generally recognize hydrogenated soybean oil as safe and effective and not misbranded for use as an OTC cholecystokinetic drug product. The citizen petition contained the results of a study designed to compare the effectiveness of two contrast agents at two different dosage levels both without and with a fatty meal (consisting of 12.4 grams (g) of hydrogenated soybean oil) prior to ingestion of the contrast agent. Although specific data on gallbladder contraction were not provided, the study results did indicate that of the subjects who received the hydrogenated soybean oil product, 40 percent (134 visualizations recorded in a total of 330 examinations) had the cystic duct visualized upon radiographic examination. The agency concludes that the submitted data are adequate to demonstrate the effectiveness of hydrogenated soybean oil in producing gallbladder contraction.

Information provided in the supplemental data indicates that the role of lecithin in the product is as an inactive ingredient. The information also indicates that lecithin and the other inactive ingredients would not contribute significantly to the cholecystokinetic effect of the product. Additionally, FDA was informed by the petitioner that the hydrogenated soybean oil contained in the product was food-grade, partially-hydrolyzed soybean oil with a melting point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows (Ref. 1):

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	.1
Arachidic acid	.5
Behenic acid	.2

Hydrogenation of vegetable oils is a chemical reaction consisting of addition of hydrogen at double bonds of unsaturated acyl groups. This process results in a decreased susceptibility of oils to oxidative deterioration (Ref. 2). Corn oil and hydrogenated soybean oil have a similar high content of long chain triglycerides of fatty acids, e.g., oleic acid, linoleic acid, palmitic acid, and stearic acid (Refs. 2, 3, and 4). Although it has long been generally known that gallbladder contraction occurs in response to a fatty meal (Refs. 5, 6, and 7), recent data suggest that the ingestion of long-chain triglycerides of fatty acids initiates gallbladder contraction. Two studies, in which the effect of medium-chain triglycerides and long-chain triglycerides of fatty acids on gallbladder contraction were compared, demonstrated that patients responded with normal and vigorous gallbladder contraction after ingesting a meal of long-chain triglycerides of fatty acids whereas no significant response was observed after ingestion of medium-chain triglycerides of fatty acids (Refs. 8 and 9). Because the long-chain triglyceride content of corn oil and soybean oil as described above is similar, the effect on gallbladder contraction is also similar.

Accordingly, the agency is proposing to amend the final monograph on OTC cholecystokinetic drug products to include hydrogenated soybean oil as described above as an active ingredient. The agency proposes that the statement of identity and indications for products containing this ingredient follow § 357.250 (a) and (b) of the cholecystokinetic final monograph. The agency is also proposing that the directions section of the monograph (21 CFR 357.250(d)(3)) be modified to include the following: Oral dosage is 12.4 grams hydrogenated soybean oil in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

The agency is aware that the hydrogenated soybean oil product covered by the petition is currently being marketed as a prescription drug. Although the agency is proposing in this notice to switch hydrogenated soybean oil to OTC use from its present status as a prescription drug, OTC marketing may not begin at this time. In the **Federal Register** of June 3, 1983 (48 FR 24925), FDA explained the enforcement policy for drugs that were originally on prescription status but which were being proposed for OTC marketing under the OTC drug review. As noted there, 21 CFR 330.13 permits OTC marketing of a drug previously limited to prescription use prior to publication of a final monograph provided that certain conditions are met. To qualify for such status, the drug must, at a minimum, have been considered by an OTC drug advisory review panel and either been recommended for OTC marketing by the panel or subsequently determined by FDA to be suitable for OTC marketing. Hydrogenated soybean oil was not considered by a panel and, therefore, does not qualify for early OTC marketing under the terms of the enforcement policy set out in § 330.13. FDA believes that public comments submitted in response to the proposed switch in status should be evaluated before a final agency decision on OTC status is made and before OTC marketing begins. Accordingly, until such comments are reviewed,

hydrogenated soybean oil will remain a prescription drug.

References

(1) Letter from Richard A. Sosin, Summit Medical Products, Inc., to Dr. William E. Gilbertson, January 13, 1988, coded LET011, Docket No. 79N–0368, Dockets Management Branch.

(2) DeMan, J.M., "Principles of Food Chemistry," AVI Publishing Company, Inc., Westport, CT, pp. 35–85, 1976.

(3) Windholz, M., editor, "The Merck Index," 10th Ed., Merck and Co., Rahway, NJ, p. 361 and 1249, 1983.

(4) Tyler, V.E., L.R. Brady, and J.E. Robbers, "Pharmacognosy," 8th Ed., Lea and Febiger, Philadelphia, 1981.

(5) Wiener, I., et al., "Release of Cholecystokinin in Man. Correlation of Blood Levels With Gallbladder Contraction," *Annals of Surgery*, 194:321–325, 1981.

(6) Bobba, V.R., et al., "Gallbladder Dynamics Induced by a Fatty Meal in Normal Subjects and Patients With Gallstones; Concise Communication," *Journal of Nuclear Medicine*, 25:21–24, 1984.

(7) Upp, J.R., Jr., et al., "Correlation of Cholecystokinin Receptors With Gallbladder Contractility in Patients With Gallstones," *Annals of Surgery*, 205:641–648, 1987.

(8) Ladas, S.D., et al., "Comparison of the Effects of Medium and Long Chain Triglyceride Containing Liquid Meals on Gallbladder and Small Intestinal Function in Normal Man," *Gut*, 25:405–411, 1984.

(9) Isaacs, P.E.T., et al., "Comparison of Effects of Ingested Medium- and Long-Chain Triglyceride on Gallbladder Volume and Release of Cholecystokinin and Other Gut Peptides," *Digestive Diseases and Sciences*, 32:481–486, 1987.

The agency advises that any final rule resulting from this proposed rule will be effective 12 months after its date of publication in the **Federal Register**. On or after that date, any OTC drug product that is not in compliance may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC cholecystokinetic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC cholecystokinetic drug products is not expected to pose such an effect on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC cholecystokinetic drug products. Comments regarding the impact of this rulemaking on OTC cholecystokinetic drug products should be accompanied by appropriate documentation.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Interested persons may, on or before October 14, 1988, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 357

Cholecystokinetic drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 357 as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 357 is revised to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 357.210 is revised to read as follows:

§ 357.210 Cholecystokinetic active ingredients.

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

(a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrolyzed with a melting point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	.1
Arachidic acid	.5
Behenic acid	.2

3. In § 357.250, paragraphs (d) (2) and (3) are revised to read as follows:

§ 357.250 Labeling of cholecystokinetic drug products.

* * * * *

(d) * * *

(2) *For products containing 50-percent aqueous emulsion of corn oil.*

(i) "Shake well before using."

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) *For products containing hydrogenated soybean oil.* Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

* * * * *

4. Section 357.280 is revised to read as follows:

§ 357.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § 357.210: *Indication.* "For visualization of biliary ducts during cholecystography."

Dated: June 6, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-18201 Filed 8-12-88; 8:45 am]

BILLING CODE 4160-01-M

Federal Register

Monday
August 15, 1988

Part IV

Department of Education

34 CFR Parts 706, 707 and 708

Regional Educational Laboratories and Research and Development Centers Programs; Final Regulations

DEPARTMENT OF EDUCATION

34 CFR Parts 706, 707, and 708

Regional Educational Laboratories and Research and Development Centers Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the Regional Educational Laboratories and Research and Development Centers Programs. These amendments are needed to implement certain provisions of the General Education Provisions Act (GEPA), as amended by Title XIV of the Higher Education Amendments of 1986, and to improve the operation of the programs.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Dr. Lawrence Bussey, Jr., Office of Research, Office of Educational Research and Improvement, U.S. Department of Education, 555 New Jersey Avenue, NW., Suite 610, Washington, DC, 20208-1633. Telephone number: (202) 357-6249.

SUPPLEMENTARY INFORMATION: On March 22, 1988, the Secretary published in the **Federal Register** (52 FR 9408) a Notice of Proposed Rulemaking for the Regional Educational Laboratories and Research and Development Centers Programs.

The Regional Educational Laboratories Program makes financial assistance available to regional educational laboratories established by public agencies or private nonprofit institutions. Each laboratory, under the sole guidance of a regionally representative governing board, serves the education needs of a specific geographic region of the Nation. The Research and Development Centers Program provides financial assistance, to conduct educational research and development, to institutions of higher education, institutions of higher education in consort with public agencies or nonprofit organizations, and interstate agencies established by compact that operate subsidiary bodies to conduct postsecondary educational research and development.

Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, three organizations submitted comments on the proposed regulations. The Secretary has made a technical change in these regulations to clarify the intent under the selection criteria for planning awards and has added a research priority under the list of funding priorities. An analysis of the comments and of the changes in the regulations is published as an appendix to these final regulations. Substantive issues are discussed under the section of the regulations to which they pertain. Technical and other changes—and suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects

34 CFR Part 706

Colleges and universities, Education, Educational research, Grants programs—education, Local educational agencies, Nonprofit organizations, Reporting and recordkeeping requirements, State educational agencies.

34 CFR Part 707

Colleges and universities, Education, Educational research, Grants programs—education, Local educational agencies, Nonprofit organizations, Reporting and recordkeeping requirements, State educational agencies.

34 CFR Part 708

Colleges and universities, Education, Educational research, Grants programs—education, Local educational agencies, Nonprofit organizations, Reporting and recordkeeping requirements, State educational agencies.

Dated: July 25, 1988.

William J. Bennett,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.117: Regional Educational Laboratories and Research and Development Centers Programs)

The Secretary amends Title 34 of the Code of Federal Regulations by revising Parts 706, 707 and 708 to read as follows:

PART 706—REGIONAL EDUCATIONAL LABORATORIES AND RESEARCH AND DEVELOPMENT CENTERS PROGRAMS: GENERAL PROVISIONS

Subpart A—General

Sec.

706.1 What are the Regional Educational Laboratories and Research and Development Centers Programs?
706.2 Who is eligible for an award?
706.3 What priorities may the Secretary establish?
706.4 What regulations apply?
706.5 What definitions apply?

Subpart B—How Does One Apply for an Award?

706.10 What assurances must an applicant make?
706.11 What information is needed for a multi-year project for institutional operations?

Subpart C—How Does the Secretary Make an Award?

706.20 How does the Secretary evaluate an application?
706.21 What additional procedures may the Secretary use to determine which applications will be selected for funding?
706.22 What additional factors may the Secretary consider in selecting an application for a planning award?
706.23 What additional factors may the Secretary use to select an application for an institutional operations award?

Authority: 20 U.S.C. 1221e, unless otherwise noted.

Subpart A—General

§ 706.1 What are the Regional Educational Laboratories and Research and Development Centers Programs?

Under the Regional Laboratories and Research and Development Centers Programs, the Secretary provides support for planning, institutional operations, and special activities of regional educational laboratories and research and development centers.

(Authority: 20 U.S.C. 1221e)

§ 706.2 Who is eligible for an award?

(a) The following parties are eligible to apply for awards for the planning of a laboratory or center:

(1) Public or private organizations, institutions or agencies.

(2) Individuals.

(b) The following parties are eligible to apply for awards for institutional operations:

(1) For regional educational laboratories, public agencies or private nonprofit organizations.

(2) For research and development centers, institutions of higher education, institutions of higher education in consort with public agencies or private nonprofit organizations or interstate agencies established by compact that operate subsidiary bodies established to conduct postsecondary educational research and development.

(c) In any fiscal year, the Secretary may make grants for special activities to regional educational laboratories or research and development centers that receive institutional operations awards in the same fiscal year.

(Authority: 20 U.S.C. 1221e)

§ 706.3 What priorities may the Secretary establish?

(a) The Secretary may select funding priorities from a list of biennial research priorities published in the Federal Register for public comment pursuant to section 405(b)(4) of the Act, and published in final form in the Federal Register. These biennial research priorities may include one or more priorities from paragraph (b) of this section.

(b) The Secretary may also select one or more funding priorities by choosing from the following list of individual priorities or a combination of these priorities:

(1) Learning.

(2) Teaching.

(3) Technology in education.

(4) Instructional processes and materials, including textbooks and computer software for instruction.

(5) Education and staff development for teachers, administrators and other education staff.

(6) Organization and management of schools, including effective education leadership.

(7) Evaluation and indicator measures, including testing, measurement, and standards of performance.

(8) Governance of education, including school board policies and practices.

(9) Educational finance and productivity.

(10) Education and the law.

(11) Dissemination and knowledge utilization in education.

(12) Improvement in education, including State and local reform initiatives.

(13) Student achievement, including students' motivation to learn, their failure to learn, and their failure to attend school and graduate.

(14) Home, family, cultural, and community influences on education, including parental choice and involvement in schooling.

(15) Education, work, and careers.

(16) Equity and excellence, including the effects of ability grouping.

(17) Guidance and counseling.

(18) International education.

(19) English literacy, including reading, writing, and language skills.

(20) Mathematics.

(21) Science.

(22) Foreign languages.

(23) Early childhood education.

(24) History and social sciences, including economics, geography, political science, sociology, anthropology, and psychology.

(25) Physical and health education.

(26) Humanities, including music, art, literature and dance.

(27) Citizenship and character education.

(28) Elementary education.

(29) Secondary education.

(30) Early adolescent education.

(31) Adolescent education.

(32) Postsecondary education.

(33) Adult and continuing education.

(34) Teachers.

(35) School professionals and personnel.

(36) Public and private educational institutions.

(37) School discipline and crime in the schools.

(38) Education of special populations, including the educationally disadvantaged or students-at-risk, those with limited English proficiency, the handicapped, immigrants, and the academically gifted and talented.

(39) Implementation and effects of educational policies.

(Authority: 20 U.S.C. 1221e)

§ 706.4 What regulations apply?

(a) *Grants.* The following regulations apply to grants under this program:

(1) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants), Part 75 (Direct Grant Programs), Part 77 (Definitions That Apply to Department Regulations), Part 78 (Education Appeal Board), and Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(2) The regulations in this Part 706 and in 34 CFR Parts 707 and 708.

(b) *Contracts.* (1) The following regulations apply to contracts under this program:

(i) The Federal Acquisition Regulation (FAR) in 48 CFR Chapter 1.

(ii) The Education Department Acquisition Regulation (EDAR) in 48 CFR Chapter 34.

(2) Requirements substantially similar to the following sections of the regulations in this Part 706 and 34 CFR Parts 707 and 708 will be incorporated into the solicitation for a laboratory or center contract, to the extent that these sections are consistent with applicable regulations in the FAR and EDAR:

(i) *Part 706.* Sections 706.1, 706.5, 706.10, 706.11, 706.22 and 706.23.

(ii) *Part 707.* Sections 707.1, 707.2, 707.10, 707.11, 707.12, and 707.20.

(iii) *Part 708.* Sections 708.1, 708.10, 708.11, 708.12, and 708.20.

(Authority: 20 U.S.C. 1221e)

§ 706.5 What definitions apply?

(a) *Definitions in EDGAR.* The following terms used in these regulations are defined in 34 CFR 77.1:

Applicant
Application
Award
Department
EDGAR
Grant
Nonprofit
Private
Public
Secretary
State

(b) *Other definitions.* The following definitions also apply to this part:

"Act" means the General Education Provisions Act, as amended.

"Center" means an educational research and development center authorized under section 405(d)(4)(A)(ii) of the Act.

"Contract" means a procurement contract entered into by the Federal government to purchase, rent, lease or otherwise obtain supplies or services from nonfederal sources.

"Educational research" means basic and applied research, development, planning, surveys, assessments, evaluations, investigations, experiments, and demonstrations in the field of education and related fields.

"Institution of higher education" means an institution of higher education as defined in section 1201 of the Higher Education Act of 1965, as amended.

"Institutional operations" means the activities of a laboratory or center conducted under a long-term plan approved by the Secretary.

"Laboratory" means a regional educational laboratory authorized under section 405(d)(4)(A)(i) of the Act.

"Mission" means the priority or priorities for a center established by the Department in accordance with § 706.3.

"Planning" means activities related to preparing an application for institutional operations of a laboratory or center.

"Special activities" means activities carried out by a Regional Educational Laboratory or a Research and Development Center in addition to those included in its institutional operations award.

(Authority: 20 U.S.C. 1141; 1221e)

Subpart B—How Does One Apply for an Award?

§ 706.10 What assurances must an applicant make?

In its application for an award for institutional operations, an applicant shall make assurances that the laboratory or center involved will—

(a) Be responsible for the conduct of the research and development activities in its approved application;

(b) Prepare a long-range plan relating to the conduct of those research and development activities;

(c) Ensure that information developed as a result of those research and development activities, including new educational methods, practices, techniques, and products, are appropriately disseminated;

(d) Provide technical assistance to appropriate educational agencies and institutions; and

(e) To the extent practicable, provide training for individuals, emphasizing training opportunities for women and members of minority groups, in the use of new educational methods, practices, techniques and products developed in connection with those activities.

(Authority: 20 U.S.C. 1221e)

§ 706.11 What information is needed for a multi-year project for institutional operations?

In addition to the information required in 34 CFR 75.117, an application for a multi-year project for institutional operations must contain a mission statement for the proposed center as a whole or a proposed long range plan for the proposed laboratory. The mission statement or proposed long range plan must describe goals and objectives for each year of the proposed project and discuss how they relate to the specific activities described in the application.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850–0602)

Subpart C—How Does the Secretary Make an Award?

§ 706.20 How does the Secretary evaluate an application?

(a) For each competition the Secretary uses the applicable selection criteria in 34 CFR 707.10, 707.11, 707.12, 708.10, 708.11 or 708.12 to evaluate applications for new awards under this program.

(b) The maximum score for all the criteria in each section is 100 points, including any reserved points to be distributed in accordance with paragraph (d) of this section.

(c) Subject to paragraph (d) of this section, the maximum possible score for each criterion is indicated in parentheses.

(d) For any competition for center awards, the Secretary assigns 10 additional points to one or more of the criteria described in the applicable section (34 CFR 708.10, 708.11, or 708.12).

(Authority: 20 U.S.C. 1221e)

§ 706.21 What additional procedures may the Secretary use to determine which applications will be selected for funding?

In addition to the review procedures in 34 CFR 75.217, the Secretary may use the following procedures to determine which applications will be selected for funding:

(a) After review of applications and preparation of a rank order of the applications in accordance with 34 CFR 75.217 (b) and (c) and § 706.20, the Secretary may select applications for further consideration on the basis of the rank order and the factors in 34 CFR 75.217(d). The Secretary informs each applicant whether its application has been chosen for further consideration.

(b) (1) Each applicant chosen for further consideration shall submit any additional information requested by the Secretary.

(2) In requesting additional information of applicants chosen for further consideration, the Secretary—

(i) Provides applicants with a reasonable opportunity to revise and resubmit their applications; and

(ii) Does not provide information to any applicant about the contents of other applications chosen for further consideration, or otherwise provide any information that could give an applicant a competitive advantage over other applicants.

(c) The Secretary may conduct site visits to all or some of the applicants to obtain further information on the activities described in an application and an applicant's capability to perform those activities.

(Authority: 20 U.S.C. 1221e)

§ 706.22 What additional factors may the Secretary consider in selecting an application for a planning award?

In addition to the selection criteria in 34 CFR 707.10 or 708.10 and the additional information in accordance with § 706.21, the Secretary considers the following in making awards for planning of a laboratory or center:

(a) The relationship between the technical merit of the proposed educational research and development program and its cost in comparison to other proposed programs.

(b) The extent to which funding an application would contribute to a collection of laboratory and center activities that are both diverse and balanced.

(Authority: 20 U.S.C. 1221e)

§ 706.23 What additional factors does the Secretary use to select an application for an institutional operations award?

In addition to the criteria in 34 CFR 707.11 and 708.11 and the additional information obtained in accordance with § 706.21, the Secretary considers the following in making awards for institutional operations of a laboratory or center:

(a) The extent to which funding an application would contribute to a collection of laboratory and center activities that are both diverse and balanced; and

(b) The relationship between the technical merit of the proposed program and its cost in comparison to other proposed programs.

(Authority: 20 U.S.C. 1221e)

PART 707—REGIONAL EDUCATIONAL LABORATORIES

Subpart A—General

Sec.

707.1 What regulations apply?
707.2 What geographic regions do the laboratories serve?

Subpart B—How Does the Secretary Make an Award?

707.10 What are the selection criteria for laboratory awards for planning?
707.11 What are the selection criteria for laboratory awards for institutional operations?
707.12 What are the selection criteria for laboratory awards for special activities?

Subpart C—What Conditions Must Be Met by a Grantee?

707.20 What requirements must be met by a grantee?

Authority: 20 U.S.C. 1221e, unless otherwise noted.

Subpart A—General

§ 707.1 What regulations apply?

The regulations in this part and the regulations cited in 34 CFR 706.5 apply to awards for regional educational laboratories.

(Authority: 20 U.S.C. 1221e)

§ 707.2 What geographic regions do the laboratories serve?

(a) A laboratory established under this program serves one of the following geographic regions:

(1) Connecticut, Maine, Massachusetts, New Hampshire, New York, Puerto Rico, Rhode Island, Vermont, Virgin Islands.

(2) Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania.

(3) Kentucky, Tennessee, Virginia, West Virginia.

(4) Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina.

(5) Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, Wisconsin.

(6) Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

(7) Colorado, Kansas, Missouri, Nebraska, North Dakota, South Dakota, Wyoming.

(8) Arizona, California, Nevada, Utah.

(9) Alaska, Idaho, Montana, Oregon, Washington.

(10) American Samoa, Guam, Hawaii, Palau (to the extent authorized by Pub. L. 99–658 and until the effective date of the Compact of Free Association with the Government of Palau), and to the extent approved by the Secretary, the Marshall Islands and the Federated States of Micronesia (in accordance with section 226 of the compact of Free Association as set forth in section 201 of Pub. L. 99–239), and Palau (after the effective date of the compact of Free Association with the Government of Palau), in accordance with section 222 of that Compact as set forth in section 201 of Pub. L. 99–658.

(b) For each competition for a laboratory award, the Secretary announces which one or more of the geographic regions designated in § 707.2(a) will be served.

(c) In the event that funding of a particular laboratory serving a region under this program is discontinued, the Secretary may provide additional funds to another laboratory for continuation of laboratory services to States in that region.

(Authority: 20 U.S.C. 1221e)

Subpart B—How Does the Secretary Make an Award?

§ 707.10 What are the selection criteria for laboratory awards for planning?

The Secretary uses the following criteria to evaluate applications for laboratory awards for planning:

(a) *Understanding of the educational settings and issues in the region* (25 points). The Secretary reviews each application to determine the extent to which the applicant—

(1) Understands the educational settings and issues in the region;

(2) Demonstrates knowledge of the strengths and needs of the educational systems—public and private, elementary, secondary, and postsecondary—in the region;

(3) Understands significant trends expected to influence education in the region over the next five years;

(4) Demonstrates knowledge of the capabilities of existing organizations that provide research, dissemination, training, and assistance to educational agencies in the region and how a laboratory can complement their work; and

(5) Understands the barriers and challenges facing a laboratory in the region and ways of overcoming them.

(b) *Organizational ability to conduct planning and design tasks* (20 points). The Secretary reviews each application to determine the organizational ability of the applicant to conduct the required planning and design tasks, including—

(1) The extent to which the applicant has successful experience in planning or conducting multi-State activities related to educational research and development; and

(2) Whether the existing relationships in the region give the applicant access to important groups of clients in the region and contribute to cooperative planning activities.

(c) *Plan of operation* (20 points). The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) The quality of the design of the project;

(2) The extent to which the management plan ensures proper and efficient administration of the project;

(3) The degree to which the objectives of the project relate to the purpose of the program; and

(4) The adequacy of the applicant's plans to use its resources and personnel to achieve each objective.

(d) *Quality of key personnel* (20 points).

(1) The Secretary reviews each application to determine the qualifications of the key personnel the applicant plans to use in the project, including—

(i) The qualifications of the project director;

(ii) The qualifications of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (d)(1) (i) and (ii) of this section will commit to the project; and

(iv) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping conditions.

(2) To determine personnel qualifications under paragraphs (d)(1) (i) and (ii) of this section, the Secretary considers—

(i) Experience and training, in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the quality of the project.

(e) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support the project; and

(2) Costs are reasonable in relation to the objectives and activities of the project.

(f) *Evaluation plan* (5 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(1) Are appropriate for the project; and

(2) To the extent possible, are objective and produce data that are quantifiable.

(g) *Adequacy of resources* (5 points). The Secretary reviews each application to determine the adequacy of the resources to be devoted to the project, including facilities, equipment and supplies.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850–0602)

§ 707.11 What are the selection criteria for laboratory awards for institutional operations?

The Secretary uses the following criteria to evaluate applications for laboratory awards for institutional operations:

(a) *Understanding of and responsiveness to regional needs* (10 points). The Secretary reviews each application to determine the applicant's understanding of and responsiveness to the needs of the region, including—

(1) The degree to which the applicant demonstrates an understanding of current and projected educational conditions and needs in the region;

(2) The extent to which the applicant proposes adequate mechanisms and procedures for assessing the educational research and development needs and capabilities of the region and for determining laboratory priorities; and

(3) The quality of the applicant's analysis of strategic options and a plan for responding to regional needs.

(b) *Strength of relationships with the region* (15 points). The Secretary reviews each application to determine the strength of the applicant's relationship with the region to be served, including—

(1) The extent to which the proposed governing board's membership reflects regional interests and constituencies;

(i) The quality of the applicant's plans for a governing board designed to take an active role in setting policy and determining the regional agenda of the laboratory;

(ii) The extent to which the applicant's plans for a governance structure provide the organizational autonomy necessary for neutrality, balance, and equity in the selection of clients and the delivery of services;

(2) The quality, extent, and feasibility of proposed collaborative relationships with appropriate organizations, such as—

(i) Public education agencies at State, intermediate, and local levels;

(ii) Educational research and development agencies;

(iii) Organizations providing assistance in the use of research outcomes;

(iv) Clearinghouses, including those compromising the Education Resources Information Clearinghouse system;

(v) Professional associations;

(vi) Institutions of higher education;

(vii) Community-based organizations;

(viii) Business and industry; and

(ix) National Diffusion Network: State and Private School Facilitators; and

(3) Evidence of successful work in the past with organizations listed in paragraph (b)(2) of this section.

(c) *Institutional capability* (15 points). The Secretary reviews each application to determine the qualifications of the applicant to sustain a long-term, high-quality, and coherent program of research and services, including—

(1) The extent to which adequate organizational mechanisms and procedures exist for managing work internally and in collaboration with other institutions;

(2) The degree to which there are adequate procedures for quality control and self-evaluation; and

(3) The degree to which there are adequate plans for effecting improvement in organizational performance and staff development during the project period.

(d) *Plan of operation* (25 points). The Secretary reviews each application to determine the quality of the plan of operation for the project; including—

(1) Quality in the design of the project;

(2) The degree to which the management plan ensures proper and efficient administration of the project;

(3) The degree to which the objectives of the project relate to the mission of the laboratory;

(4) The adequacy of the applicant's plans to use its resources and personnel to achieve each objective;

(5) The quality of the applicant's plan to provide equitable services to students and teachers in elementary and secondary public and private schools;

(6) The extent to which proposed activities relate logically to statements of regional needs and priorities;

(7) The degree of coherence of work within and among program activities;

(8) The extent to which the proposed activities complement related efforts inside and outside the region;

(9) The extent of the anticipated contribution of the work to educational improvement; and

(10) The appropriateness of provisions for sequencing and pacing work activities.

(e) *Quality of key personnel* (20 points).

(1) The Secretary reviews each application to determine the qualifications of the key personnel the applicant plans to use in the project, including—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (e)(1) (i) and (ii) of this section will commit to the project; and

(iv) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping condition.

(2) To determine personnel qualifications under paragraphs (e)(1) (i) and (ii) of this section, the Secretary considers—

(i) Experience and training, in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the project.

(f) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the adequacy of the budget and cost effectiveness, including the extent to which—

(1) The budget for the project is adequate to support the project activities; and

(2) Costs are reasonable in relation to the objectives of the project.

(g) *Evaluation plan* (5 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the adequacy of—

(1) A peer review process for evaluating laboratory products, research instruments, and self-evaluation designs;

(2) The participation of the governing board in setting requirements and examining results of laboratory self-evaluation of activities and outcomes;

(3) The methods which document the laboratory's progress in relation to its objectives; and

(4) The methods which document the impact of the laboratory's program on the needs of those served in the designated region.

(h) *Adequacy of resources* (5 points). The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850-0602)

§ 707.12 What are the selection criteria for laboratory awards for special activities?

The Secretary uses the following criteria to evaluate applications for laboratory awards for special projects:

(a) *Strength of relationships with appropriate organizations and agencies in the region* (15 points). The Secretary reviews each application to determine the quality, extent and feasibility of proposed collaborative relationships of the laboratory with organizations listed in § 707.11(b)(2) to the focus and purpose of the special activity.

(b) *Institutional capability* (15 points). The Secretary reviews each application to determine the adequacy of the laboratory's organizational capacity for implementing the special activity.

(c) *Plan of operation* (30 points). The Secretary reviews each application to determine the quality of the plan for implementing the special activity.

(d) *Quality of key personnel* (25 points). The Secretary reviews each application to determine the

qualifications of the key personnel, including experience and training related to the objectives of the activity.

(e) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the adequacy and cost effectiveness of the budget for the special activity.

(f) *Evaluation plan* (5 points). The Secretary reviews each application to determine the quality of the evaluation plan to document accomplishment of the activity's objectives.

(g) *Adequacy of resources* (5 points). The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the activity, including facilities, equipment, and supplies.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850-0602)

Subpart C—What Conditions Must Be Met by a Grantee?

§ 707.20 What requirements must be met by a grantee?

An applicant receiving a laboratory award for institutional operations shall meet the following post-award requirements:

(a) Establish a governing board that—

(1) Is the sole entity that—

(i) Guides and directs the laboratory in satisfying the terms and conditions of the award; and

(ii) Determines the regional agenda of the laboratory, consistent with the priority research and development needs established by the Secretary; and

(2) Reflects a balanced representation of the States in the region, as well as the interests and concerns of regional constituencies.

(b) Facilitate communication among educational agencies and individuals in the region.

(c) Identify concerns and priorities through regionally representative governing and advisory structures and activities that help regional clients define their needs.

(d) Conduct applied research, development, and related activities to address regional needs.

(e) Promote the use in the region of research and development results from all sources inside and outside the region, including the laboratory.

(f) Collaborate with centers, other laboratories, the Education Resources Information Clearinghouses, and the National Diffusion Network: State and Private School Facilitators.

(g) Establish a peer review process for evaluating laboratory products, research instruments, and self-evaluation designs.

(Authority: 20 U.S.C. 1221e)

PART 708—RESEARCH AND DEVELOPMENT CENTERS

Subpart A—General

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708.1 What regulations apply?

Subpart B—How Does the Secretary Make an Award?

708.10 What are the selection criteria for awards for center planning?
708.11 What are the selection criteria for center awards for institutional operations?
708.12 What are the selection criteria for center awards for special activities?

Subparts C-D [Reserved]

Subpart E—What Conditions Must Be Met by a Grantee?

708.20 What requirements must be met by a grantee?
708.21 What additional factors does the Secretary consider in making continuation awards?

Authority: 20 U.S.C. 1221e, unless otherwise noted.

Subpart A—General

§ 708.1 What regulations apply?

The regulations in this part and the regulations cited in 34 CFR 706.4 apply to awards for research and development centers.

(Authority: 20 U.S.C. 1221e)

Subpart B—How Does the Secretary Make an Award?

§ 708.10 What are the selection criteria for awards for center planning?

The Secretary uses the following criteria to evaluate applications for awards for center planning:

(a) *Mission and strategy* (40 points). The Secretary reviews each application to determine the extent to which the applicant understands the state of knowledge and practice with respect to the problem area and priorities of the center for which the applicant is applying, including the extent to which the applicant shows—

(1) An understanding of the mission of the proposed center;

(2) Knowledge of relevant research and theory;

(3) Knowledge of relevant problems in educational practice;

(4) Familiarity with relevant strategies of research, development, and dissemination; and

(5) Familiarity with strategies for relating to other organizations in educational research, development, and practice.

(b) *Potential to influence practice or policy* (20 points). The Secretary reviews each application to determine if the planning process will address strategies for influencing educational practice or policy, including—

(1) The extent to which the project will address practitioners' or policymaker's needs as identified; and

(2) The extent to which the planning process will result in a design that will yield knowledge that can be used in an educational or policymaking setting.

(c) *Plan of operation (10 points).* The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) The quality in the design of the project;

(2) The effectiveness of the management plan; and

(3) The degree to which the research needs of both public and private elementary and secondary schools or institutions of higher education will be addressed.

(d) *Quality of key personnel* (20 points).

(1) The Secretary reviews each application to determine the qualifications of the key personnel the applicant plans to use on the project, including—

(i) The qualifications of the project director;

(ii) The qualifications of each of the center's key personnel to be involved in the center's planning;

(iii) The time that each person referred to in paragraphs (d)(1) (i) and (ii) of this section will commit to the project; and

(iv) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping condition.

(2) To determine personnel qualifications, under paragraphs (d)(1) (i) and (ii) of this section the Secretary considers—

(i) Experience and training, in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the quality of the project.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850-0602)

§ 708.11 What are the selection criteria for center awards for institutional operations?

The Secretary uses the following criteria to evaluate applications for center awards for institutional operations:

(a) *Mission and strategy* (15 points). The Secretary reviews each application to determine the extent to which the

applicant understands the state of knowledge and practice related to the priorities established by the Secretary for the center's mission, including—

(1) The extent of the applicant's understanding of the mission of the proposed center;

(2) How the activities of the proposed center will contribute to the advancement of relevant theory and practice;

(3) The quality of plans to establish effective working relations with other organizations in educational research, development, and practice;

(4) The quality of the plans to address the problems of special populations and of both public and private institutions in terms of the mission of the proposed center; and

(5) The quality of long-range plans for developing an appropriate, coherent, and effective program of educational research, development, and dissemination.

(b) *Institutional capability* (15 points). The Secretary reviews each application to determine the capabilities of the host institution to sustain a long-term, high-quality, and coherent program of research, development, and dissemination, in the mission area, including the extent to which the application shows evidence of—

(1) An appropriate organizational structure and commitment to provide the services of appropriate faculty or staff members from the applicant's organization;

(2) An appropriate mixture of scholarly and practitioner backgrounds in the project staff of the applicant;

(3) Past successes of the applicant in collaborating with individuals and organizations to conduct educational research and development;

(4) Structure and governance arrangements likely to provide appropriate direction, quality control, and cost effective management; and

(5) Availability of appropriate resources for the effective implementation of research and development activities.

(c) *Plan of operation* (15 points). The Secretary reviews each application to determine the quality of the plan of operation for the proposed center, including—

(1) The degree to which the plan for center management ensures proper and efficient administration of the project;

(2) The effectiveness of proposed strategies for providing national leadership within the center's mission;

(3) The extent to which the applicant proposes strategies for disseminating center products, including the identification of intended audiences and reasonable timelines for dissemination; and

(4) The adequacy of the applicant's plans to use its resources and personnel to achieve each objective.

(d) *Technical soundness* (20 points). The Secretary reviews each application to determine the technical soundness of the proposed research, including—

(1) The extent to which the applicant demonstrates a thorough knowledge of current research and development concepts, theories, and outcomes and relates these to the proposed activities and the mission of the center;

(2) The adequacy of the research design and methodologies to address the research questions posed; and

(3) Evidence that, where appropriate, the perspectives of a variety of disciplines are used.

(e) *Quality of key personnel* (15 points).

(1) The Secretary reviews each application to determine the qualifications of the key personnel the applicant plans to use on the project, including—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project; and

(iii) The applicant's policy, as part of its nondiscriminatory employment practices, to ensure that its personnel are selected without regard to race, color, national origin, gender, age, or handicapping condition.

(2) To determine personnel qualifications under paragraphs (e)(1) (i) and (ii) of this section the Secretary considers—

(i) Experience and training in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the project.

(f) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the extent to which the project has an adequate budget and is cost effective, including the extent to which—

(1) The budget for the project is adequate to support the project activities;

(2) The equipment and supplies that the applicant plans to use are adequate; and

(3) Costs are reasonable in relation to the objectives and activities of the project.

(g) *Evaluation plan* (5 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the adequacy of—

(1) The peer review process for evaluating research instruments and products;

(2) The plan for advisory board evaluation of center research activities and resources;

(3) The methods which will be used to document the center's progress in relation to its objectives; and

(4) The methods which will be used to document the impact of the center's program on its target audiences.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850–0602)

§ 708.12 What are the selection criteria for center awards for special activities?

The Secretary uses the following criteria to evaluate applications for awards for special activities:

(a) *Mission and strategy* (15 points). The Secretary reviews each application to determine the extent to which the special activity contributes to the current mission of the center, including the extent to which—

(1) The program of work will contribute to the advancement of relevant theory and practice;

(2) The plans to establish working relations, as appropriate, with other organizations in educational research, development, and practice will be effective;

(3) The proposed activities will advance the center's mission; and

(4) The proposed activities incorporate plans to address the problems of special populations and of both public and private elementary and secondary schools and institutions of higher education in terms of the mission of the proposed center.

(b) *Capacity of center* (10 points). The Secretary reviews each application to determine whether the institution has the appropriate organization and fiscal resources to complete the special activity, including—

(1) Strong evidence of an effective organizational structure and a commitment to provide the services of appropriate faculty or staff members from the applicant's organization;

(2) Inclusion of an appropriate mixture of scholarly and practitioner backgrounds in the project staff of the applicant;

(3) Structure and governance arrangements likely to provide appropriate direction, quality control, and cost effective management; and

(4) Adequate allotment of resources and facilities.

(c) *Plan of operation* (20 points). The Secretary reviews each application to determine the adequacy of the plan of

operation for the activities and how they complement the center's current plans, including—

(1) The extent to which an effective plan of project management ensures proper and efficient administration of the activities:

(2) The extent to which the applicant plans to use its resources and personnel to achieve each objective; and

(3) The degree to which the research needs of both public and private elementary and secondary schools and institutions of higher education are addressed by the proposed research, if appropriate.

(d) *Technical soundness* (25 points). The Secretary reviews each application to determine the technical soundness of the proposed activities, including—

(1) The extent to which the application demonstrates a thorough knowledge of current research and development concepts, theories, and outcomes and relates this knowledge to the proposed activity and the mission of the center;

(2) The adequacy, as appropriate, of the research design and methodologies to address the research questions posed; and

(3) The extent to which, where appropriate, the perspectives of a variety of disciplines are used.

(e) *Quality of key personnel* (15 points). The Secretary reviews each application to determine the qualifications of the key personnel assigned to the special activities project, including the adequacy of—

(1) The qualifications of the project director;

(2) The qualifications of each of the other key personnel to be used in the project; and

(3) The applicant's policy, as part of its nondiscriminatory employment practices will ensure that its personnel are selected without regard to race, color, national origin, gender, age, or handicapping condition.

(4) To determine personnel qualifications under paragraphs (e) (1) and (2) of this section, the Secretary considers—

(i) Experiences and training in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the project.

(f) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the appropriateness of the budget in relation to the proposed activities, including the extent to which—

(1) The budget for the project is adequate to support the project activities;

(2) The facilities' equipment and supplies that the applicant plans to use are adequate; and

(3) Costs are reasonable in relation to the objectives and activities of the project.

(Authority: 20 U.S.C. 1221e)

(Approved by the Office of Management and Budget under control number 1850–0602)

Subparts C–D [Reserved]

Subpart E—What Conditions Must Be Met by a Grantee?

§ 708.20 What requirements must be met by a grantee?

A grantee receiving an award for institutional operations shall—

(a) Provide national research leadership with respect to the mission of its center;

(b) Establish and maintain a nationally representative advisory panel; and

(c) Collaborate with laboratories, other centers, appropriate Education Resources Information Clearinghouses, and National Diffusion Network: State and Private School Facilitators.

(Authority: 20 U.S.C. 1221e)

§ 708.21 What additional factors does the Secretary consider in making continuation awards?

In making continuation awards under 34 CFR 75.253, the Secretary considers, among other factors, whether—

(a) All products and reports that were due during the budget period that is about to end have been received by the Department;

(b) The project's activities have been carried out in a manner consistent with the previously approved application;

(c) The products and reports are of adequate technical quality; and

(d) The project plans for the subsequent budget period are likely to advance the mission of the center, including the extent to which—

(1) The potential of any new or redirected research project or other center activity within the scope of the project plan will advance the mission of the center;

(2) The center's plan of operation for managing these activities is adequate;

(3) Any new research projects or other activities are technically sound;

(4) The center's personnel are qualified to accomplish the proposed activities; and

(5) The budget is appropriate in relation to the scope of the proposed activities.

(Authority: 20 U.S.C. 1221e)

Editorial Note.—The following appendix will not appear in the Code of Federal Regulations.

Appendix—Analysis of Comments and Responses

The following is an analysis of comments and changes in the regulations since publication of the NPRM. Substantive issues are discussed under the section of the notice to which they pertain. Technical and other minor changes are not addressed.

General

Comment: One commenter asked whether these regulations will govern the competition of the regional educational laboratories in fiscal year 1990.

Discussion: Unless these regulations are amended, they will govern subsequent competitions, including the fiscal year 1990 competition. At this time, the Secretary does not anticipate amending these regulations prior to the fiscal year 1990 competition.

Change: None.

Part 706—Regional Educational Laboratories and Research and Development Centers Programs: General Provisions

What are the Regional Educational Laboratories and Research and Development Centers Programs? (Section 706.1)

Comment: Three commenters suggested changes to the provisions on special activities awards. The commenters were concerned that special activities awards would be used to fund small grant competitions, create unnecessary competitions among laboratories or centers, and reduce the amount of funding available for institutional operations awards.

Discussion: The Secretary has proposed special activities awards to allow needed flexibility to provide supplemental funding to existing laboratories or centers to carry out additional research and related activities that are consistent with the mission of a center or the long range plan of a regional laboratory approved by the Secretary. Special activities awards provide the Secretary with flexibility in supporting additional research and related activities not addressed by currently funded centers or laboratories. Special activities awards may be supported from funds set aside for laboratories and centers pursuant to section 405(g)(1) (A) and (B) of the General Education Provisions Act, as amended (GEPA). Funds for special activities may reduce the amount of

funding available for institutional operations awards. However, the Secretary intends only to use a minimum amount of funds to support special activities awards.

Change: None.

Who is eligible for an award? (Section 706.2)

Comment: Two commenters questioned the proposed changes to the eligibility provisions for regional educational laboratories. One commenter suggested that the proposed changes were beyond the scope of the authorizing statute because they included public agencies as eligible applicants for a laboratory award.

Discussion: The Secretary has not changed the eligible parties for this program. Section 405(d)(4) of GEPA specifically provides that the Secretary supports regional educational laboratories established by public agencies or private nonprofit organizations. Under these regulations, these entities are eligible to apply for an institutional operations award. The revised language makes clear that an eligible party may apply for a laboratory institutional operations award without first establishing a laboratory.

Change: None.

What priorities may the Secretary establish? (Section 706.3)

Comment: One commenter recommended two additional priorities: the implementation and effects of educational policies, and the relationship between education and the economy.

Discussion: The regulations include a priority that addresses the commenter's concern about the relationship between education and the economy: Education, work and careers. However, the Secretary agrees with the commenter's recommendation to add a priority concerning the implementation and effects of educational policy.

Change: The list of research priorities has been amended to add a priority on the implementation and effects of educational policies.

What regulations apply? (Section 706.4)

Comment: Two commenters expressed concern that technical changes proposed concerning the applicability of the regulations to contracts suggested the Department's intent to support only grants.

Discussion: The technical changes do not affect the Department's authority to award contracts. The Secretary may make awards under contracts, as well as grants. These changes have been made to be consistent with the Department's policy that contracts not be governed by program regulations. While these regulations no longer govern contracts, requirements substantially similar to pertinent provisions of the program regulations will be incorporated into any solicitation for a laboratory or center contract, to the extent that the requirements are consistent with applicable contract regulations.

Change: None.

What definitions apply? (Section 706.5)

Comment: One commenter objected to the change in the definition for "mission" to mean the priority or priorities for the laboratory or center established by the Secretary. The commenter felt that under this definition the Secretary rather than the regionally representative governing board would establish the laboratory's regional agenda. Another commenter asked why the definition of "educational research" had been changed to eliminate dissemination, policy studies and technical assistance, and whether the elimination of these terms meant that regional educational laboratories were no longer authorized to carry out these activities.

Discussion: The Secretary did not intend to limit the role of the regionally representative governing board to set the regional agenda of the laboratory.

The definition of educational research has been changed to be consistent with the definition in section 405(a)(3)(C) of GEPA. Regional laboratories are authorized under § 707.20(d) to carry out research, development and related activities.

Change: The definition of "mission" has been changed to clarify that the Secretary does not determine the agenda of a laboratory.

Part 707—Regional Educational Laboratories

What geographic regions do the laboratories serve? (Section 707.2)

Comment: One commenter asked for clarification about how services would be provided to the Pacific Trust Territories. The commenter also requested clarification of the role of the regional educational laboratories in providing services to the Pacific Trust Territories.

Discussion: Until the effective date of its Compact of Free Association, the current Pacific Trust Territory, Palau, will continue to receive technical assistance. After the effective date of its Compact of Free Association, Palau will be situated similarly to the Marshall Islands and the Federated States of Micronesia. These entities may receive technical assistance from a laboratory, to the extent approved by the Secretary. Assistance would be provided pursuant to the Compacts of Free Association with these entities, and the role of the laboratory in providing this assistance would be determined by the Department and the regional governing board of the laboratory.

Change: A technical change has been made to clarify that after the effective date of its Compact of Free Association, Palau may continue to receive technical assistance, to the extent approved by the Secretary.

What are the selection criteria for laboratory awards for planning? (Section 707.10(d)—Plan of operation and Section 707.10(e)—Quality of key personnel)

What are the selection criteria for laboratory awards for institutional operations? (Section 707.11(d)—Plan of operation and Section 707.11(e)—Quality of key personnel)

Comment: One commenter objected to the removal of provisions in the selection criteria for laboratory planning and institutional operation awards related to an applicant's commitment to ensure that "traditionally underrepresented groups" are served and employed by the project. The commenter believes that the removal of these provisions may be interpreted as an abandonment of the principle that an important goal of the Regional Educational Laboratories Program to provide equality of educational opportunity for poor and minority children.

Discussion: The removal of the provisions in the selection criteria concerning traditionally underrepresented groups does not mean that the Secretary intends to support laboratories which ignore the needs of underrepresented groups. The selection criteria in §§ 707.10(a) and 707.11(a) concerning the extent to which the applicant understands and is responsive to the needs of the region to be served, would include the needs of underrepresented groups. In addition, these regulations require applicants to provide assurances that they will provide training for individuals, emphasizing training opportunities for women and members of minority groups. The Secretary has replaced the language in the selection criteria concerning the employment of underrepresented groups with selection criteria addressing the extent to which the applicant uses nondiscriminatory

employment practices. The Secretary believes that these changes are consistent with efforts to provide equal access for special populations to participate in the projects and with ensuring nondiscriminatory employment practices.

Changes: None.

What are the selection criteria for laboratory awards for institutional operations? (Section 707.11(g)—Evaluation plan)

Comment: One commenter requested clarification of the term "evaluation." The commenter also asked whether the provision concerning the adequacy of an applicant's "peer review process" means external review and if it does, how the peer review will affect the prerogatives of a laboratory governing board to make adjustments in laboratory programs. The commenter asked whether the provision addressing methods of documenting the laboratory's impact on the needs of "those served" in the region referred to direct or indirect audiences.

Discussion: The evaluation plan is a description of how the applicant would assess the degree to which the objectives of the application are being achieved and how the applicant would use the results of the self evaluation. The laboratory's governing board is expected to participate in the evaluation process and the examination of the results of the self evaluation. Peer review refers to the process that the applicant proposes to use to judge the adequacy of laboratory products, research instruments, and self evaluation designs. Peer reviewers are generally investigators or scholars external to an organization in the same or comparable fields or disciplines.

The term "those served" refers to those audiences proposed in the laboratory's plans as the recipients of service. Those served may include audiences that participate directly in the laboratory's activities, such as classroom teachers participating in an inservice training program, or those students who receive laboratory services indirectly as a result of the training received by their teachers.

Change: None.

Part 708—Research and Development Centers

What are the selection criteria for awards for center planning? (Section 708.10(b)—Potential to influence practice)

Comment: One commenter suggested expanding this criterion to include potential to influence policy. The commenter recommended that proposed research should address critical issues of relevance to policy as well as practice.

Discussion: The Secretary agrees with the recommendation of the commenter because the purpose of planning awards is to support center activities that have the potential to influence both policy and practice.

Change: The criterion has been expanded to include the potential to influence policymaking.

What are the selection criteria for center awards for institutional operations? (Section 708.11(d)—Technical soundness)

Comment: One commenter recommended incorporating technical soundness as a subcriterion under the selection criteria for mission and strategy and plan of operation (§ 708.11 (a) and (c)). The commenter suggests that technical soundness is a relevant and significant factor that should apply to the proposed mission and plan of operation.

Discussion: The criterion, technical soundness, is intended to be a separate criterion used to judge whether appropriate and adequate methodologies are employed in the research of the center. The mission and strategies criterion addresses an applicant's understanding of a center's mission but does not address the actual means by which the research and related activities of the proposed project may be carried out. The criterion for the plan of operation is intended to assess the adequacy of the overall management plan for the center and the institutional roles and responsibilities. These criteria are independent factors to be considered in judging the overall merit of an application for a center award.

Change: None.

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Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 23

Small Airplane Airworthiness Review Program, Amendment No. 1; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. 25147; Amdt. No. 23-36]

Small Airplane Airworthiness Review Program, Amendment No. 1

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment to Part 23 of the Federal Aviation Regulations upgrades the standards for cabin safety and occupant protection during emergency landing conditions for airplanes type certificated to the airworthiness standards of Part 23. This action is based on the results of research testing, service experience, and a number of issues discussed at the Small Airplane Airworthiness Review Conference, held October 22–26, 1984. This amendment is intended to increase small airplane occupant protection during emergency landing conditions.

EFFECTIVE DATE: September 14, 1988.

FOR FURTHER INFORMATION CONTACT: Ronald K. Rathgeber, Aerospace Engineer, Standards Office (ACE-110), Aircraft Certification Division, Central Region, Federal Aviation Administration, Room 1656, 601 East 12th Street, Kansas City, Missouri 64106; telephone (816) 374-5688.

SUPPLEMENTARY INFORMATION:

Regulatory History

This amendment is based on Notice of Proposed Rulemaking, Notice No. 86-19, published in the **Federal Register** on December 12, 1986 (51 FR 44878). All comments received in response to Notice No. 86-19 were considered in adopting this amendment.

Background

The FAA announced its Small Airplane Airworthiness Review Program in Notice No. CE-83-1 in the **Federal Register** on January 31, 1983 (48 FR 4290), and invited all interested persons to submit proposals for consideration. The review program goal is to provide an opportunity for the public to participate in improving, updating, and developing the airworthiness standards applicable to small airplanes, as set forth in Part 23. When applicable, the review program is extended to the new commuter category requirements because the commuter category incorporated existing small airplane requirements as set forth in Amendment No. 23-34 (52 FR 1806; January 15, 1987) of Part 23.

In Notice No. CE-83-1A, published in the **Federal Register** on June 9, 1983 (48 FR 26623), the FAA extended the period for submission of proposals, invited by Notice No. CE-83-1, to May 3, 1984.

Prior to the FAA's announcement of the Part 23 Review Program, the General Aviation Safety Panel (GASP), representing a broad constituency from the general aviation community, was formed at the request of the FAA for the purpose of recommending regulatory and nonregulatory means by which the FAA could improve general aviation safety. As a result of numerous GASP technical working sessions, the panel submitted proposals for enhanced cabin safety and occupant protection in small airplanes. These proposals were supported by data from FAA and National Aeronautics and Space Administration (NASA) Research programs. The GASP proposals were included in the approximately 560 proposals received in response to Notice Nos. CE-83-1 and CE-83-1A.

Following receipt of the proposals, the FAA published Notice No. CE-84-1 on July 25, 1984 (49 FR 30053), containing the availability of agenda, compilation of proposals, and announcement of the Small Airplane Airworthiness Review Program Conference. The conference was held on October 22-26, 1984, in St. Louis, Missouri. A copy of the transcript of all discussions held during the conference is filed in FAA Regulatory Docket No. 23494.

After reviewing the proposals and public comments received at the conference, the FAAs first related rulemaking action concentrated on updating safety standards related to cabin safety and improved crashworthiness. On December 12, 1986, the FAA published Notice No. 86-19, titled "Small Airplane Airworthiness Review Program Notice No. 1" in the **Federal Register** (51 FR 44878). Notice No. 86-19 proposed changes to §§ 23.561, 23.783, 23.785, 23.787, and 23.807, and included a new § 23.562, which proposed dynamic testing and evaluation requirements for the seat/restraint systems of small airplanes.

At the time Notice No. 86-19 was developed, the FAA was also considering the adoption of an additional category of airplane within Part 23. On November 15, 1983, the FAA published Notice No. 83-17 in the **Federal Register** (48 FR 52010), which proposed certification procedures, airworthiness and noise standards, and operating rules for a commuter category airplane. Notice No. 83-17 proposed to include additional airworthiness standards for airplanes with a maximum seating capacity, excluding pilot seats, of 19 or less and a maximum certificated takeoff weight of 19,000 pounds or less. Final action for the adoption of standards for the commuter category airplane was not complete when Notice No. 86-19 was published and, as a result, the commuter category airplane was not specifically addressed in the proposals made in Notice No. 86-19. With the exception of dynamic testing of seats and shoulder harness requirements, the proposals in Notice No. 86-19 were formulated to be compatible with the requirements in the proposed commuter category. The background information of Notice No. 86-19 noted the pending rulemaking activity of Notice No. 83-17 and the FAA plans for considering additional requirements for the commuter category airplane. The FAA has initiated a rulemaking project to address dynamic testing of seats and occupant protection for commuter category airplanes.

Part of the outcome of Notice No. 83-17 was adoption of Amendment No. 23-34, published in the **Federal Register** on January 15, 1987 (52 FR 1806). That rulemaking action, in part, added the airworthiness standards for commuter category airplanes to Part 23, and added new requirements to certain sections of Part 23 which were proposed to be changed by Notice No. 86-19. Therefore, the final rulemaking action resulting from Notice No. 86-19 has been prepared with consideration for both public comments to Notice No. 86-19 and the changes to Part 23 resulting from Amendment No. 23-34.

Discussion of Comments

General

Interested persons were invited to participate in the development of this final rule by submitting written data, views, or arguments to the regulatory docket on or before June 12, 1987. In response to Notice No. 86-19, the FAA received nine sets of comments. Substantive changes and changes of an editorial nature have been made to the proposed rules based on both relevant comments received and further review by the FAA. One commenter supports these rules and refers to this set of regulatory changes as a significant safety consideration. Another commenter is concerned that, if these proposed rules are not incorporated, extended periods of research will follow before any improved seat standards are incorporated. The FAA recognizes the significance of this project and has prepared this final action as a result of the issues in the notice. A number of editorial changes have been made to

this final rule for compatibility with the text of recently adopted Amendment No. 23–34. The proposals, comments, and substantive changes are discussed below.

Discussion of Comments to Specific Sections of Part 23

The following comments and discussions are keyed to like-numbered proposals in Notice No. 86–19:

Proposal 1–1. This proposal contains the authority citation for Part 23.

Proposal 1–2. This proposal would reorganize § 23.561, make reference to a new § 23.562, add strength requirements for the retention of items of mass in normal, utility, and acrobatic category airplanes, and state turnover requirements in objective terms which include the variables to be considered in determining the likelihood of a turnover during emergency landing conditions. This proposal was made as a result of proposals 218, 219, 220, 221, 222, and 518 presented at the Small Airplane Airworthiness Review Conference.

One commenter states the need to provide emergency landing static load factors for commuter category airplanes. Amendment No. 23–34 adopted certification requirements for the commuter category airplane in Part 23, which include emergency landing static load factors for commuter category airplanes.

One commenter proposes replacing the term "minor crash landing" in proposed § 23.561(b) with the term "emergency landing conditions" to add consistency. The same commenter suggests replacing the words "escape serious injury" with the words "designed to protect each occupant". The FAA agrees, and the wording proposed by the commenter is used in § 23.561(b). Also, as a result of the previous comment, emergency landing static load factors for all categories of Part 23 airplanes are set forth in § 23.561(b) of this final rule.

One commenter proposes that the ultimate static load factors of proposed § 23.561(d) be changed so that the upward load factor is 4.5g, the sideward load factor is 4.5g, and a rearward load factor of 1.5g is added, and suggests these load factors apply to all Part 23 airplanes. The commenter offers no technical basis for support of these load factors. Since the commenter's proposals go beyond the scope of the notice and are unsupported, they are not incorporated in this final rule.

Several comments address proposed § 23.561(b)(3), which stated restraint requirements for items of mass in the cabin. Some of these comments also address the specific load factors for items of mass shown in proposed § 23.561(d). One commenter recommends that the load factors referenced by proposed § 23.561(b)(3) be changed to match those proposed for transport airplanes in Notice No. 86–11, which was published in the **Federal Register** on July 17, 1986 (51 FR 25982). The development of the proposed static load requirements for items of mass, as proposed in § 23.561(b)(3), was a part of the development of the seat/restraint system dynamic tests proposal of the GASP. Although the GASP originally recommended that items of mass be dynamically tested, the FAA and the GASP subsequently concluded that, for evaluating the retention of items of mass in the cabin, a static test, to the proposed ultimate static load factors, achieves the intent of the original dynamic test conditions at a significant decrease in certification cost to the applicant and achieves the increase in cabin safety intended by the GASP recommendations.

Another commenter agrees with the 4.5g sideward load factor for items of mass, but disagrees with the proposed 18g forward load factor. The commenter states that experience indicates that the existing 9g forward load requirement has resulted in adequate static strength. The FAA does not consider the 9g load factor sufficient for the level of cabin safety proposed in Notice No. 86–19. Actual crash demonstration tests conducted in a joint FAA/NASA project provided data which showed that impact loads during simulated survivable crashes could exceed 9g in the longitudinal axis. NASA Technical Paper 2083, dated November 1982, titled, "Correlation and Assessment of Structural Airplane Crash Data With Flight Parameters at Impact" is one of several reports which evaluate the results of the FAA/NASA small airplane crash test project. As proposed by the GASP, the purpose of the proposed static load factors is to ensure that the attachments of items of mass in the cabin are adequately restrained considering the enhanced cabin safety provided by other sections of this final rule, including the new requirements in § 23.562 for dynamic tests of seat/restraint systems. This commenter proposes changing § 23.561(b)(3) to require that equipment and other large mass items be positioned so that, if they break loose, they are unlikely to cause injury to the occupants, penetrate fuel lines, or block exits after an emergency landing. The FAA disagrees. For many small airplane designs, the concept of locating all items of significant mass, particularly cargo, at a location in the cabin which will ensure no occupant injury or fuel system penetration during impact is impractical. The higher load factors for items of mass are necessary in this final rule to ensure that the attachment strength for mass items in the cabin is adequate with the set/restraint system dynamic load conditions of § 23.562(b). The higher static load factors are expected to prevent injuries which could result from mass items coming loose during an emergency landing ground impact.

One commenter suggests that a rearward load factor of 1.5g be added to the proposed ultimate static load factors to ensure that items, such as rear-facing compartments, do not fail due to rebound loads resulting in the contents falling on occupants below the compartment. The FAA understands the commenter's concern and will evaluate the need for such requirements for future rulemaking action. Since the suggestion goes beyond the scope of the notice, it has not been adopted in this final rule.

One commenter concludes that the addition of the table of static load factors for items of mass will lead to inconsistencies when another section of Part 23 refers to the emergency landing conditions of § 23.561. In consideration of this comment and the rule changes made with Amendment No. 23–34, several editorial changes have been made to § 23.561. The emergency landing ultimate static load factors, which apply in general to all categories of Part 23 airplanes, have been put in § 23.561(b)(2). The reference to § 23.562 in proposed § 23.561(b) is removed.

Several comments were received regarding the proposed § 23.561(c) which stated requirements for occupant protection from turnover. One commenter asks for clarification of this proposal and concludes that the intent of this requirement is to evaluate the turnover case as a static rather than a dynamic condition. The FAA agrees with this interpretation, and it is not the intent of the FAA for turnover protection to be evaluated as a dynamic condition such as the seat/restraint system dynamic tests requirements of § 23.562. This commenter also concludes that, using the proposed criteria for establishing the likelihood of a turnover in proposed § 23.561(c), almost all tricycle landing gear airplanes will show a likelihood to turn over. The commenter neither provides any technical data to support this concern, nor proposes any alternate criteria. As noted in the explanation to this proposed rule in the notice, although airplanes configured with tricycle landing gear are inherently resistant to turnover during normal

operations, FAA accident/incident data showed that tricycle gear small airplanes have turned over during emergency landing conditions (including incidents of undershoot, overshoot, loss of directional control, etc.). These data revealed that the frequency of turnover of high-wing, tricycle gear airplanes is higher than for low-wing, tricycle gear airplanes; however, the data showed that low-wing tricycle gear small airplanes also turn over during emergency landing conditions with sufficient frequency that the likelihood of turnover should be investigated for these airplanes also. Some recent designs of low-wing tricycle gear small airplanes feature a sliding transparent canopy which provides very little occupant protection in a turnover. The proposed conditions for evaluating turnover are compatible with the level of safety provided by the other requirements of § 23.561, and the FAA considers the requirements of proposed § 23.561(c) to be rational criteria for evaluating the likelihood of turnover during emergency landing conditions.

One commenter suggests that the wording of proposed § 23.561(c) (1) and (2) be changed to require turnover evaluation in the most adverse combination of all-up-weight and center-of-gravity position. The FAA disagrees since all-up-weight is not a defined term used in Part 23. The forward center-of-gravity position is usually the most critical for turnover evaluation. Another commenter suggests that proposed § 23.561(c)(6) be designated as § 23.561(d) and that proposed § 23.561(d) be designated § 23.561(e). The FAA agrees that, while paragraphs (1) through (5) of proposed § 23.561(c) provide criteria for determining the likelihood of a turnover, paragraph (6) defines requirements for the loads to be applied to the inverted airplane after a turnover, for evaluating the occupant protection provided by the airframe. In response to this comment and other editorial changes made to § 23.561, proposed § 23.561(c) is designated § 23.561(d) and reformatted for clarity in this final rule and present § 23.561(c) is retained.

Proposal 1–3. Proposed § 23.562, Emergency landing dynamic conditions, would add dynamic test requirements to be applied to seat/restraint systems used in normal, utility, and acrobatic category airplanes, and contain specific test parameter values and pass/fail criteria. For the purpose of these requirements, the seat/restraint system includes the seat and its immediate attachments to seat rails or the airframe, the safety belt and shoulder harness, and any fittings or assemblies used to attach them to the seat or airframe. The proposal was the result of a GASP submittal to the Small Airplane Airworthiness Review Conference (proposal 518), was based on state-of-the-art technology, and was supported by the consensus of the general aviation community represented at the conference.

The specific dynamic test conditions in § 23.562 are supported by several research studies including: (1) A series of full-scale crash impact "drop tests" conducted by the National Aeronautics and Space Administration (NASA), (2) accident evaluation information from the National Transportation Safety Board (NTSB), (3) dynamic tests conducted by the FAA Civil Aeromedical Institute (CAMI), and (4) generally accepted human impact injury criteria developed by the military and other sources.

Several technical issues discussed at the conference with regard to this proposal were addressed in Notice No. 86–19. With regard to the variations in impact deceleration amplitude and duration between the first row of seats and the seats behind the first row, it was noted in the notice that crash test data indicated that these parameters vary with the seat location in small airplanes due to load attenuation by the airframe structure. Since the initial impact velocity is a constant at any point in the airframe, the test velocities proposed in the notice do not vary depending on seat location. This ensures that all seats will be evaluated for the same level of kinetic energy. Full scale impact tests at NASA have provided data to validate these concepts. Tests of full-scale hardware, using anthropomorphic test dummies (ATD's) create the most accurate simulation of actual emergency landing conditions. The ATD weight of 170 pounds is considered a nominal weight for the occupants of small airplanes. Higher weights were not proposed because a nominal weight results in the most acceptable evaluation of the energy absorbing and load limiting capabilities of the seat/restraint system. The 50th percentile male ATD, defined in National Highway Traffic Safety Administration Regulation, 49 CFR Part 572, Subpart B, was cited because the specifications for this ATD were readily available to the public. Military and automotive testing, which used the Part 572 ATD, provided a data base for evaluating the results of dynamic testing using this dummy.

The test conditions of proposed § 23.562(b)(1) required a 60-degree pitched orientation of the seat relative to the velocity vector and were intended to create a predominantly vertical decelaration input to assess the occupant spinal protection provided by the seat/restraint system. This test condition has a longitudinal component of deceleration to simulate a more realistic impact environment where the restraint system is loaded by the initial impact.

The test conditions of proposed § 23.562(b)(2) required a 10-degree yaw of the seat relative to the velocity vector, and were intended to create a predominantly longitudinal deceleration input to assess the occupant restraining capability of the seat/restraint system. The 10-degree yaw was intended to provide a test condition which would ensure that the seat/restraint system would provide the capability to restrain the occupant during impact conditions with a side load component. Floor warpage requirements were included in the proposal to assess the ability of the seat/restraint system to function and maintain structural integrity after floor deformation has occurred.

A number of comments were received concerning the overall concept of dynamic testing of seat/restraint systems. Three commenters state their support of the basic concepts of this program, and one of these commenters states concern that if the requirements proposed in the notice are not incorporated, an extended period of additional research will follow before any improved seat standards are incorporated. The dynamic seat test requirements proposed in Notice No. 86–19 and incorporated in this final rule are supported by extensive research and testing done in support of the FAA Crash Dynamics Program and the GASP proposal.

One commenter suggests changing the term "upper torso restraint system" used in proposed § 23.562(b)(2) and proposed § 23.562(c)(6) to the words "shoulder harness". As a result of this comment, the FAA reviewed the terms used throughout the proposed rules of Notice No. 86–19. In this amendment, terms related to occupant seats or belt restraints, are used to improve clarity and standardization. These terms include the *Shoulder Harness*, also known as the upper torso restraint, which refers to that portion of the torso restraint system which includes one or more straps that pass over the shoulders and restrains the upper torso of the occupant and the *Torso Restraint System*, which refers to that system used for providing torso restraint which includes the safety belt, the shoulder

harness if provided, and the associated hardware used to attach the system to the seat or airframe structure. Therefore, the change proposed by this commenter is not adopted.

One commenter considers the design criteria of proposed § 23.562 to be arbitrary since each crash situation is different. The FAA disagrees. The occupant protection in this section are based on extensive research data. These criteria were intended to provide conservative, but reasonable, standards for the occupant protection provided by seat/restraint systems developed for use in small airplanes. This commenter proposes the use of a simplified dynamic test which would not require the use of an ATD and other associated test equipment. The test procedure proposed by the commenter would require instrumenting the seat to ensure that the test pulse meets the requirements and would require performance criteria based on seat deformation without failure. The FAA does not agree with the simplified approach because it does not provide for the evaluation of all the occupant injury protection features required in proposed § 23.562(c). The FAA knows of no simple dynamic test procedure which will provide human-like load distributions on the seat/restraint system without using an ATD. Since the comment does not provide for occupant injury protection evaluation and does not provide technical data to show that the simplified procedure would provide an equivalent level of safety to that proposed in Notice No. 86-19, the simplified procedure is not adopted.

One commenter suggests that a static test be required, in lieu of the proposed dynamic tests, which would require that first a minimum static load be reached before allowing any deformation of the seat, followed by an ultimate load test for which a determined amount of yielding must be evident. This commenter suggests that minimum load factors in the longitudinal axis be 8g prior to any permanent deformation and 12g for failure or excessive deformation which would impede rapid evacuation. The FAA does not agree because this procedure would not provide data for evaluating the occupant motion or loading criteria which would be required by the proposed rule. Experience has shown that static deformation requirements may conflict with the seat/restraint system performance under dynamic conditions. The FAA agrees with the concept of developing seat assemblies which will limit occupant loads by yielding at one predefined load while maintaining structural integrity up to another higher load; however, available static test methods alone cannot provide the data necessary to evaluate the occupant protection provisions of these seat/restraint systems.

One commenter suggests that improved safety would be achieved by requiring upper torso restraints in all airplanes produced after a certain date. Requirements to this effect were added to Part 23 with Amendment No. 23-32. Part 23 now requires that each normal, utility, or acrobatic category airplane manufactured after December 12, 1986, must protect each occupant from serious head injury by a safety belt and shoulder harness for forward- and aft-facing seats, and a restraint means for other seat orientations that provides an equivalent level of occupant protection.

One commenter suggests that measurements be made during dynamic testing to ensure that the attachment loads are no greater than those for a 9g acceleration, since a 9g forward load factor is the current structural requirement. The FAA agrees that evaluating the reaction loads at the floor attachments during the dynamic seat test can provide useful data for structural design; however, the airframe support structure was not included in the dynamic tests of the seat/restraint system. This comment goes beyond the scope of the notice. It is unrealistic to apply loads, measured on a rigid test fixture during dynamic tests, as static loads to less rigid airframe structure. During an emergency landing impact, the airplane floor structure will typically yield under severe local loads, and this will tend to alter the attachment loads at the seat/restraint system interface to the airframe structure. Incorporating procedures to include airframe structure in the dynamic tests of proposed § 23.562 would greatly increase the complexity and costs of these tests. Airframe structure supporting the seat/restraint system must meet the static strength requirements of § 23.561 and other sections of Part 23. Therefore, this final rule does not require measurement of attachment loads, although such measurements may provide useful design information.

One commenter is concerned that the proposed rule would restrict, if not eliminate, refurbishing older airplanes with new seats or shoulder harnesses. The FAA disagrees. These requirements are intended to apply to airplanes which will include this amendment to Part 23 as part of their type certification basis. For modifications of previously certificated airplanes, the applicant is required to comply with the original type certification basis for the airplane; however, the FAA considers it in the best interest of the modifier to demonstrate the highest level of occupant protection possible. The dynamic test procedures in § 23.562 provide a method for demonstrating that new seat/restraint system designs offer a significant increase in occupant protection.

One commenter suggests that the proposed dynamic test requirements should not apply to seats installed in single-engine airplanes weighing less than 3,000 pounds. The commenter argues that, for this size airplane, the impact energy is low, in some designs the seats are integrated to the airframe, and dynamic seat tests are too expensive. The FAA has no unique category or certification rules for airplanes of less than 3,000 pounds. Although these smaller airplanes typically have emergency landings at lower velocities than heavier airplanes with higher stall speeds, the airframe structure of these smaller airplanes provides less energy attenuation capabilities. Since the FAA cannot quantify the trade-offs of airplane velocity to airframe size with regard to impact severity, one set of tests was proposed for all normal, utility, and acrobatic category airplanes. Therefore, only one set of criteria is adopted in this final rule.

Several comments address specific technical aspects of the proposed § 23.562. One commenter supports the test parameters of both the vertical and longitudinal tests as proposed and agrees that these proposed requirements will result in a substantial improvement in the dynamic strength capabilities of small airplane seats. This commenter also supports the performance criteria which limit the impact loads for the occupant's head and lumbar spine.

One commenter suggests that floor misalignment in the roll axis be added to the floor warpage requirements of proposed § 23.562(b)(2) and that these floor warpage provisions be added to the requirements of § 23.562(b)(1). The FAA agrees with adding floor deformation preload in the roll axis to the longitudinal test conditions prescribed in proposed § 23.562(b)(2). This paragraph provides for a test of the occupant retention strength of the seat/restraint system. Floor deformation preloading is an important aspect of this test, and floor warp in both the pitch and roll axes is possible during an emergency landing. The FAA disagrees with adding floor deformation preload requirements to the test conditions of proposed § 23.562(b)(1). This paragraph

provides for test parameters intended to evaluate the energy absorbing capability of the seat under repeatable conditions to demonstrate a minimum level of occupant protection. Floor warp preloads will add complexities to this test which may adversely affect the evaluation of the energy absorbing capability of the seat/restraint system. To add clarity and ensure that floor warpage is understood to be a preload condition, to be set prior to conducting the dynamic test, the floor deformation requirements in proposed § 23.562(b)(2) are removed, and the expanded requirements are set forth in § 23.562(b)(3) of this final rule.

One commenter questions the rationale for lesser test loads for the rear seats, and suggests that all occupants should be equally protected to 26g. This issue was discussed at the Small Airplane Airworthiness Review Conference and was addressed in Notice No. 86–19. Full-scale impact tests of small airplanes, conducted as part of a joint FAA/NASA project, resulted in data which indicate that impact deceleration levels reduce the farther aft an occupant is sitting in a small airplane. This is a result of local structural yielding of the airframe. Consequently, the closer the occupant is to the initial impact point, the higher the deceleration rate, even though the velocity change is the same for all occupants. This is the result of additional airframe yielding between the front and aft seats. These full scale impact test data also showed that the period of the impact pulse was, in general, greater for aft-seat occupants than for front-seat occupants as a result of the effects of structural yielding during the impact. For seats aft of the front row, the proposed dynamic test criteria would require test parameters which have lower peak deceleration rates and longer impact times than the front seats. These test conditions are justified by the FAA/NASA full scale drop test data. Since the commenter offers no technical data to support the position that the same impact parameters should be applied to all seats, the criteria for the test paramaters are adopted as proposed in the notice.

One commenter suggests that these new regulations should consider the loads imposed on a seat by the occupant seated behind the system being evaluated, or these rules should provide appropriate limitations for seat pitch (spacing). The FAA disagrees with this concept for small airplane seat evaluations for several reasons. Part 23 currently requires that normal, utility, and acrobatic category airplanes, manufactured after December 12, 1986, must be equipped with a safety belt and shoulder harness. These restraint systems are intended to limit occupant motion during impact. The limited occupant motion will reduce the severity of any contact the occupant will have with the adjacent seat or structure. The addition of multiple row dynamic testing would significantly increase the cost and complexity of these tests. Multiple row testing goes beyond the scope of Notice No. 86–19.

Two commenters suggest that the requirements in § 23.562(b) should allow the use of a properly validated analysis. Proposed § 23.562(d) would allow the applicant to use an alternate means of compliance to this rule, provided that the alternate method results in a level of safety as great as, or greater than, that established by the rule. Proposed § 23.562(d) has been retained in this final rule except the words "paragraph (c) of" have been removed for clarity. Therefore, the FAA considers the intent of the comments to be achieved by § 23.562(d).

One commenter is concerned that the specific ATD defined by 49 CFR Part 572, Subpart B, will not always be available. The specified ATD has been the standard used by the automotive industry for many years. Because the results of dynamic tests can be significantly affected by the specific ATD used, the FAA considers it necessary to specify a standard ATD for showing compliance to the requirements of § 23.562. However, several other ATD designs have been manufactured, and the FAA is monitoring the development of new ATD designs. If an applicant desires to use a different ATD configuration for showing compliance with § 23.562, the applicant must show that use of the substitute ATD will not significantly affect the test results and obtain FAA approval to use an alternate ATD design prior to conducting certification tests.

One commenter is not sure if the term "level landing attitude" used in proposed paragraphs (1) and (2) of § 23.562(b) is intended to have the same meaning as used in § 23.479(a). The intent is substantially the same as the meaning of "level landing attitude" in § 23.479(a); however, this does imply the need to do dynamic tests of the airframe structure. The intent is to apply these tests to the seat, restraint system, and immediate attachments. Therefore, in this final rule, the seat orientation is described relative to the test impact vector, and the term "level landing attitude" is removed.

Several editorial comments were received. One commenter suggests the rule require the test dummy to be seated in the normal upright position. This commenter also suggests that units of time and acceleration be added to the equation in proposed § 23.562(c)(5). These comments are incorporated in this final rule for clarity. One commenter suggests that the words "seats or" be added between the words "the" and "seating devices" in the last sentence of proposed § 23.562(b)(2). In consideration of this comment and for more consistency with other rules regarding the occupant seating systems, the words "seat, or other seating device" in proposed paragraphs (1) and (2) of § 23.562 are replaced with the words "seat/restraint system" in this final rule. In addition, the term "seat/restraint system" is used throughout this final rule to refer to any system used to provide the primary means to support a seated occupant and restrain the occupant during emergency landing conditions. One commenter suggests replacing the phrase "if the shape of the input pulse deviates significantly from a symmetric triangle" in proposed § 23.562(b)(3), with the phrase "in order to approximate a symmetric triangle." The commenter considers the words "deviates significantly" to be too nebulous to define the outer limits of compliance. The specific criteria of the impact pulse condition is based on the concept that in the ideal case, the shape of this pulse would approach that of a symmetric triangle, which was supported by NASA analysis of the full-scale small airplane crash test data; however, most impact test facilities will have difficulty producing a symmetric triangular pulse. Although the FAA considers the symmetric triangular pulse to be the optimum, the objective of the required dynamic tests can be met by impact pulses producible in many available test facilities, provided the impact pulse has the necessary test velocity, and reaches the necessary minimum deceleration level within a specified time limit. Therefore, this final rule does not specify a triangular pulse. The proposed paragraph (3) of § 23.562(b) is omitted and, as previously noted, is replaced by a new paragraph (3) which contains clarified floor warpage requirements.

Several commenters express concern about the costs of conducting dynamic tests on seat/restraint systems. One commenter bases cost estimates on the assumption that airframes would have to be provided and that test rigs would have to be developed and built. The FAA disagrees. In most cases, only the

attachment devices for the seat and restraint system need be provided and test facilities are available to conduct the tests at a reasonable fee. Dynamic testing of seats presently costs from $2,000 to $5,000 and these costs are expected to decrease as a result of increased testing of seat/restraint systems to be used in Part 23 and Part 25 airplanes. This commenter further suggests that the FAA conduct the dynamic testing of seat/restraint systems. The FAA disagrees. Conducting the tests and showing compliance by the FAA would be contrary to U.S. certification processes whereby any FAA tests are only to validate previous tests conducted by the applicant. The FAA concludes that this testing should be left to private industry and that there are adequate test facilities available in the United States.

Three commenters from outside of the United States are concerned about the lack of dynamic test facilities in their countries and the costs involved in building such facilities. The FAA concludes that more facilities will become available as a result of foreign nations requiring dynamic testing for transport category airplane seats and the concern about crashworthiness in automobiles. In addition, foreign manufacturers can make use of U.S. facilities.

Proposal 1–4. This proposal would add several new requirements for external doors to § 23.783 and was the result of proposals 281 and 282 of the Small Airplane Airworthiness Review Conference. Proposed § 23.783(c) would add requirements for a locking means for external passenger doors. This paragraph would require that: (1) Each external passenger door provide a means to lock and safeguard against inadvertent opening in flight; (2) these doors be openable from the inside and outside when the internal locking mechanism is in the locked position; (3) the opening means be simple, easily located, and operated in darkness; and (4) each of these doors meet particular marking requirements. Proposed § 23.783(d) would require that each external passenger door be free of jamming as a result of fuselage deformation during a minor crash or emergency landing. Proposed § 23.783(e) would add several requirements applicable to external doors forward of any engine or propeller and to all doors of the pressure vessel of a pressurized airplane. Proposed § 23.783(e)(1) would require that these doors be provided with a means to be locked and safeguarded against inadvertent opening or mechanical failure. Proposed § 23.783(e)(2) would require provisions for direct visual inspections of the locking mechanisms of each external door for which the initial opening movement is not inward. The proposed paragraph would also require that these provisions be discernible in operating lighting conditions by a crewmember using a flashlight or equivalent. Proposed § 23.783(e)(3) would provide requirements for a visual warning to signal if any external door is not fully closed and locked.

A concern was expressed at the Small Airplane Airworthiness Review Conference that conference proposal 281, relative to jamming of doors, addressed each external door in contrast to the current requirements which address passenger doors only. As noted in Notice No. 86–19, the FAA concluded that only external passenger doors need be addressed since there is no need to require that cargo or similar doors of normal, utility, or acrobatic category airplanes be free of jamming as a result of fuselage deformation in an emergency landing. The FAA has further examined this concern and has concluded that the word "passenger" must be expanded to "passenger or crew" for clarification.

The requirement of proposed § 23.783(c) that each external passenger door must be openable from either the inside or the outside when the internal locks are in the locked position was proposed as a result of recorded accidents in which fatalities have occurred because persons attempting to rescue the airplane occupants were unable to open the door.

The requirements of proposed § 23.783(e), addressing minimum standards for ensuring the integrity of external doors in pressurized airplanes, are similar to requirements which have already been adopted as special conditions for the type certification of Part 23 airplanes. Proposed § 23.783(e) also applies to doors forward of any engine or propeller to ensure that external doors forward of any engine do not inadvertently open in flight and thereby allow the compartment contents to be ingested into an engine or propeller.

One commenter suggests that proposed § 23.783(c) should not be required on airplanes with maximum certificated weight of less than 3,000 pounds. This commenter contends that the wording used in proposed paragraph (c) "clearly shows that it is applicable for commuters or light twins." This commenter also contends that, for single-engine airplanes with a maximum certificated weight of less than 3,000 pounds, the doors can be adequately protected from inadvertent opening by providing: (1) A convenient location for the handle that allows monitoring and direct action by the pilot, (2) a convenient motion of the handle such as an opening motion in which the handle moves down in front of the arm rest, or (3) design precautions against mechanical failure. The FAA does not consider unique rules for airplanes with maximum certificated weights of less than 3,000 pounds to be justified by the technical issues. The methods proposed by the commenter to protect against inadvertent door opening may be applied to the door design as part of the compliance to the rules in proposed § 23.783(c). At present, Part 23 does not make a distinction on cabin safety issues based on maximum certificated weight.

One commenter suggests that the requirements of proposed § 23.783(d) are undefinable as to degree of compliance and the method of compliance. The FAA disagrees. Similar requirements already exist for transport and commuter category airplanes. Advisory Circular No. 25.783–1 contains guidance material for complying with a substantively equivalent requirement for transport airplanes. According to the information in this advisory circular, this Part 25 rule may be complied with by designs which provide sufficient clearance between the door and the surrounding fuselage support structure to accommodate likely distortions. Also, the possibility of distortion in the door cutout can be minimized by designing the door cutout frame with more strength than that of the surrounding structure. Equivalent means of compliance may be used for complying with these Part 23 requirements.

Several comments are editorial in nature. One of the commenters suggests changing the term "minor crash" to "emergency landing" in proposed § 23.783(d). This final rule does refer to the emergency landing condition for consistency with other sections of Part 23. One commenter suggests adding the words "inside and outside" between the words "marked" and "so" in § 23.783(c). Similar words are used in the rules for commuter category airplanes. These words have been added to this final rule for consistency with the new commuter category requirements. Several commenters suggest changes to the proposal in Notice No. 86–19 to provide compatibility with the rules applicable to commuter airplanes which were added to Part 23 with Amendment No. 23–34. The FAA has compared the proposed § 23.783 with the same section

in Part 23 after Amendment No. 23–34 and has reformatted § 23.783 in this final rule action to include the commuter category rule requirements and the applicable sections from this proposal. Section 23.783(c) in this final rule includes those requirements which are common to normal, utility, acrobatic, and commuter category airplanes. Since the external marking requirements of proposed § 23.807(c) are moved to a new § 23.811 in this final rule, § 23.783(c)(4) references § 23.811 in this final rule.

Since § 23.807(d) of Amendment No. 23–34, which was issued after Notice No. 86–19, included requirements for doors as well as emergency exits, the requirements added by Amendment No. 23–34 are integrated with the proposed requirements adopted in this final rule. The requirements that auxiliary locking devices used to secure the airplane must be designed to be overridden by the normal internal opening means were included in proposed § 23.807(b) for emergency exits. Since the passenger and crew doors generally serve as the primary means of emergency exit in Part 23 airplanes, the requirements for overriding the external locking devices are also stated for external doors in § 23.783(b) of this final rule.

To provide background information about this final rule format of § 23.783, the following table lists a cross reference of the requirements in this final rule, the proposed rule (Notice No. 86–19), and the final rule published at 52 FR 1806, Jan. 15, 1987 (Amendment No. 23–34):

Cross Reference for Section 23.783

Final Rule	Notice	Amend. 23–34
§23.783(c)(1)	§23.783(c)	§23.783(c)(1)
§23.783(c)(2)	§23.783(c)	§23.783(c)(1)
§23.783(c)(3)	§23.783(c)	§23.783(c)(1)
§23.783(c)(4)	§23.783(c)	§23.807(d)(3)
§23.783(c)(5)	§23.783(d)	§23.783(c)(2)
§23.783(c)(6)	§23.807(b)	§23.807(d)(1)
§23.783(d)(1)	N/A	§23.783(c)(1)
§23.783(d)(2)	N/A	§23.783(c)(1)
§23.783(d)(3)	N/A	§23.783(c)(1)
§23.783(e)(1)	§23.783(e)(1)	§23.783(c)(1)
§23.783(e)(2)	§23.783(e)(2)	§23.783(c)(3)
§23.783(e)(3)	§23.783(e)(3)	§23.783(c)(3)

Proposal 1–5. The FAA proposed a substantial revision of the requirements for seats, berths, litters, safety belts, and shoulder harnesses in § 23.785. The new requirements proposed in the notice were based on proposals 283, 284, 285, 285a, 286, 287, and 518 submitted at the Small Airplane Airworthiness Review Conference. These proposals were based, in large measure, on FAA, NASA, and NTSB research studies and impact analyses.

Proposed § 23.785(a) cited requirements for protecting seated occupants from injurious objects when the occupant is subjected to the emergency landing dynamic conditions of proposed § 23.562. Proposed § 23.785(b) would add reference to the head injury protection specified in proposed § 23.562(c)(5). Proposed § 23.785(c) would require a combined shoulder harness and safety belt restraint system with a single point release. Proposed § 23.785(d) was a redesignation of the rules stated in § 23.785(c) in effect at the time of the notice. Proposed § 23.785(e) was redesignation of the rules stated in § 23.785(d) in effect at the time of the notice. Proposed § 23.785(f) would require that the seat/restraint system withstand the loads imposed by a 215-pound occupant when subjected to the design load conditions in the approved flight/ground operating envelope of the airplane. The 215-pound occupant size relates to a 95 percentile male. The heavier occupant is recommended so that the strength of the seat/restraint system will be adequate for the loads expected in normal operations. This requirement was considered necessary because of concern that evaluating a seat/restraint system for only the emergency landing conditions would not require that it function properly during normal operations. Proposed § 23.785(g) would provide a specific definition of what comprises a "seating device system," and this section was included so that all necessary components are included in a system being evaluated to the emergency landing dynamic test requirements of § 23.562. Proposed § 23.785(h) would state that crushing or separation of certain parts of the seat would be allowed to show compliance with § 23.562. Proposed § 23.785(i) would add requirements for seat stops to prevent the seat from sliding off the track. Proposed § 23.785(j) would contain the requirements for protecting occupants in a berth or litter that is installed parallel to the airplane longitudinal axis.

One commenter suggests replacing the term "shoulder harness" in proposed § 23.785(b) by the term "seat belt and shoulder harness," and two other commenters suggest removing the reference to § 23.561 for this section. After reviewing proposed § 23.785(b) the FAA concludes that these requirements are redundant with other requirements of §§ 23.785 and 23.562 of this final rule; therefore, proposed § 23.785(b) is not adopted.

One commenter suggests changes to proposed § 23.785(c) so that seat orientations other than forward-facing or aft-facing seats are addressed. Proposed § 23.785(c), for clarity in this final rule, is separated into four paragraphs—paragraphs (b), (d), (e), and (g). The new paragraph (b) references requirements of § 23.562 for normal, utility, and acrobatic category airplane seat/restraint systems and includes the existing requirements for § 23.785(g)(1) relative to seat orientations other than side-facing and aft-facing seats. As no other comments were received relative to proposed § 23.785(c), the requirements proposed for a single-point release, the need for a crewmember to perform all functions necessary to flight operations with the restraint system fastened, and the means to secure the safety belt and shoulder harness when not in use, are in paragraphs (d), (e), and (g) of this final rule, respectively.

One commenter questions why § 23.785(g) of Amendment No. 23–34 was removed, and if the intent was to replace that section with proposed § 23.785(c). Notice No. 86–19 was issued prior to the incorporation of the provisions of Amendment No. 23–34 into Part 23. Because § 23.785 was changed by Amendment No. 23–34 after Notice No. 86–19 was released for public comment, this final rule action combines the requirements of both. For clarity and conciseness, § 23.785 is reformatted in this final rule. This final rule does not specify emergency landing dynamic conditions for commuter category airplanes since this issue is beyond the scope of Notice No. 86–19, and this issue will be addressed in future rulemaking actions.

No comments were received in response to proposed § 23.785(f). It is designated as § 23.785(a) and adopted as proposed.

The requirements relative to emergency landing conditions in § 23.785(a) and the requirements in § 23.785(g)(2) remain applicable to the commuter category airplanes. In this final rule, these requirements have been combined into § 23.785(c).

No comments were received relative to § 23.785(j). The FAA now considers the last sentence of proposed § 23.785(j) to be a policy statement, and it is not included in this final rule. For the purpose of the requirements in § 23.785, the FAA considers a litter to be a device for carrying a person, primarily in a prone position, into an airplane. As the FAA is not aware of any differences between the various categories of Part 23 airplanes, the proposed rule is therefore adopted as § 23.785(m), to be applicable to all categories of Part 23 airplanes.

To provide background information about this final rule format of § 23.785, the following table lists a cross reference of the requirements in this final rule, the proposed rule Notice No. 86–19), and the final rule published at 52 FR 1806, Jan. 15, 1987 Amendment No. 23–34):

Cross Reference for Section 23.785.

Final Rule	Notice No. 86-19	Amendment 23-34
§ 23.785(a)	§ 23.785(f)	§ 23.785(a)
§ 23.785(b)	§ 23.785(c)	§ 23.785(g)(1)
§ 23.785(c)	N/A	§ 23.785(a) and (g)(2)
§ 23.785(d)	§ 23.785(c)	N/A
§ 23.785(e)	§ 23.785(c)	§ 23.785(h)
§ 23.785(f)	§ 23.785(d)	§ 23.785(c)
§ 23.785(g)	§ 23.785(c)	§ 23.785(i)
§ 23.785(h)	§ 23.785(e)	§ 23.785(d)
§ 23.785(i)	§ 23.785(a)	§ 23.785(j)
§ 23.785(j)	§ 23.785(i)	§ 23.785(l)
§ 23.785(k)	§ 23.785(h)	N/A
§ 23.785(l)	N/A	§ 23.785(k)
§ 23.785(m)	§ 23.785(j)	§ 23.785(e)
§ 23.785(n)	N/A	§ 23.785(f)

Proposal 1–6. Notice No. 86–19 proposed to amend § 23.787 to increase the static strength requirements for cargo compartments and resulted from conference proposals 288, 289, 518, and 524 of the Small Airplane Airworthiness Review Conference. It was a consensus at the conference that cargo restraints should be designed to the ultimate static load factors of § 23.561 to protect occupants forward of the cargo during emergency landing conditions. For designs that carry cargo in the same compartment with occupants, the GASP proposed that these compartments have adequate strength to retain cargo in conditions which could result in occupant exposure to the dynamic conditions of proposed § 23.562(b)(2). Since dynamic testing of seats evaluates specific occupant injury criteria, the FAA considers dynamic testing of items of mass to be unnecessary because only retention of these items is a safety concern. Therefore, the ultimate static load factors of § 23.561(b)(3) are referenced in § 23.787(e).

One commenter suggests that proposed § 23.787 require that the strength of the structure forming the partition between the occupants and cargo be substantiated for a cargo load of maximum weight weight when considering the ultimate static load factors of § 23.561. The FAA agrees that adding a reference to the maximum cargo weight adds clarity to the intent of the rule, and paragraphs (c) and (e) of the final rule include requirements for evaluation at the maximum allowed cargo weight for the compartment.

Several editorial comments were received with regard to references to the paragraphs of 23.561 in proposed changes to § 23.787. They have been considered in this final rule.

Section 23.787(g), added with Amendment No. 23–34, contains specific requirements for commuter category airplanes. Paragraph (1) of § 23.787(g) requires that the cargo or baggage compartments of commuter category airplanes be evaluated for a 9g ultimate forward static load factor. Since proposed § 23.787(c) of the notice states substantively equivalent requirements for normal, utility, and acrobatic category airplanes § 23.787(c) of this final rule is applicable to all Part 23 airplanes; and § 23.787(g)(1), added by Amendment No. 23–34, is removed.

Paragraph (2) of § 23.787(g) states the specific requirements for baggage compartments of commuter category airplanes. These requirements are retained in § 23.787(g) of this final rule. A reference to § 23.787(c) and (e) is added to § 23.787(g) so that the baggage compartments in commuter category airplanes will be designed to protect occupants from injury during an emergency landing. The title of § 23.787 is amended in this final rule to include a reference to baggage compartments since certain requirements of this section are applicable to baggage compartments.

Proposal 1–7. In Notice No. 86–19, the FAA proposed changes to § 23.807 based on a number of issues raised by proposals 290, 297, and 517 at the Small Airplane Airworthiness Review Conference. One issue discussed at the conference concerned the number and locations of emergency exists required for normal, utility, or acrobatic category airplanes. One conference proposal suggested that all airplanes with a seating capacity of two or more, excluding airplanes with canopies, have at least one emergency exit on the opposite side of the cabin from the main external passenger door specified in §23.783(a). A second conference proposal recommended one emergency exist adjacent to the pilot on the pilot's side of the airplane. The consensus at the conference was that § 23.807(a)(1) should be revised substantively as stated in the first proposal, and that the current rules adequately address the issue of the second proposal. Notice No. 86–19 proposed changes to §23.807(a)(1) which were substantially the same as the first conference proposal.

A second issue, concerning type and operation of emergency exits, was addressed by three conference proposals. The first proposal recommended that § 23.807(b) require an exit area of 388 square inches in place of the current requirement that a 19-by-26-inch ellipse pass through the emergency exit opening. The proposal stated that the most critical dimension, width or height, must be no less than 19 inches. As a result of discussion at the conference, the word "critical" was changed to "minimum" in the notice. The second proposal recommended that emergency exits be openable from outside the airplane. The problem of providing security for airplanes with emergency exits, openable from the outside, was discussed at the conference, and conference attendees discussed ways to provide both security and emergency egress provisions. The third proposal addressed the use of canopies as an acceptable emergency exit. This proposal would clarify that a canopy may be used as an emergency exit and is subject to the rules applicable to an emergency exit. As a result of these suggestions, changes to paragraphs (a) and (b) of § 23.807 were proposed in Notice No. 86–19.

The third emergency exit issue addressed at the conference concerned marking and identification of these exits. Notice No. 86–19 proposed a new § 23.807(c) which stated external marking requirements for emergency

exits. The proposed requirements were stated in objective terms as discussed at the conference.

One commenter to Notice No. 86–19 agrees with the requirements in proposed § 23.807(b) that emergency exits be openable from both the inside and outside and supports the use of auxiliary locking devices that must be designed to be overridden by the operation of the internal opening means. However, the commenter is concerned that the proposed exit area requirement of 388 square inches allows an emergency exit size which does not comply with the current 19-by-26-inch ellipse requirement. The commenter requests that the FAA provide test evidence that such an exit provides an equivalent evacuation rate. As a result of this comment, the FAA reviewed the regulatory history and human factors data concerning emergency exit size and the associated effects on evacuation from small airplanes. In the past, emergency exits with total open area equal to or greater than the area of a 19-by-26-inch ellipse, but not providing unobstructed passage of the ellipse, have been approved by equivalent level of safety findings. In regard to this issue, published test data indicate that reducing the maximum (26-inch) dimension of the emergency exit while maintaining the same minimum (19-inch) dimension may significantly reduce the emergency flow rate through the exit. Since these data indicate that the proposed rule change may reduce the level of safety with regard to egress from emergency exits, the FAA is retaining the emergency exit size requirements of § 23.807.

One commenter agrees with the proposal but wants the FAA to explain what is meant by a "conspicuous visual identification scheme" in proposed § 23.807(c). In Notice No. 86–19, the FAA proposed requirements to allow the maximum compatibility between the desire for an aesthetic appearance and the need for maximizing the efforts of rescue personnel to locate emergency exits quickly. Advisory Circular 23.807(c), dated January 20, 1984, has provided guidance for marking emergency exits on a voluntary basis. Since this guidance material already exists, the FAA concludes that the proposed requirements are adequately detailed.

Several commenters suggest editorial changes to proposed § 23.807, and the FAA has considered these comments in this final rule. In addition, the FAA recognizes that the Part 25 counterparts of several of the rules, which Notice No. 86–19 proposed to locate in § 23.807, are in other sections of Part 25. In accordance with FAA policy of placing similar requirements in like numbered sections of Parts 23 and 25 of the Federal Aviation Regulations (FAR), the requirements in proposed § 23.807(c) are moved to a new § 23.811, titled "Emergency exit marking." Also, the emergency exist marking requirements of § 23.807(c)(3) which are unique to commuter category airplanes are moved to § 23.811(b) is this final rule. In addition, the requirements of § 23.807(d)(4) are moved to a new § 23.813, titled "Emergency exit access", is this final rule.

One commenter suggests that the regulatory references in the notice should be crosschecked with the latest revisions of Part 23. As a result of reviewing the FAR, the FAA identified several sections of Part 23 which need to be changed for compatibility with the new requirements for dynamic testing of set/restraint systems. The regulatory changes identified by this review are not substantive but provide consistency with the other changes made by this amendment. This review resulted in several additions to this final rule. Section 23.2 is revised to delete the reference to § 23.785(g) and (h) and, instead, states these previously incorporated-by-reference occupant protection requirements for restraint systems. Section 3.967 is revised so that paragraph (e)(1) refers to § 23.561(b)(2). Section 23.1411 is revised so that paragraph (b)(2) refers to § 23.561(b)(3). Section 23.1413 is revised to include only the requirement that each safety belt and shoulder harness be equipped with a metal-to-metal latching device since the requirements of paragraph (a) of existing § 23.1413 are redundant to the requirements in paragraphs (a) and (b) § 23.785 of this final rule, and the requirements of paragraph (b) of existing § 23.1413 are not compatible with the requirements of § 23.785(m)(2).

Economic Impact

This amendment upgrades airworthiness standards to enhance the crashworthiness of airplanes certificated to Part 23. These upgraded standards, which are based on proposals submitted to the Small Airplane Airworthiness Review Conference apply only to airplanes for which an application for a type certificate under Part 23 is made after the effective date of this amendment.

Two of the revisions contained in this amendment impose dynamic testing standards to determine the adequacy of energy absorbing seats and torso restrain systems on occupant movement resulting from sudden deceleration forces on normal, utility, and acrobatic category airplanes which are likely to be experienced in accidents. Two other revisions pertain to doors and emergency exits will facilitate emergency egress from airplanes sustaining heavy ground impact damage. Another three revisions are of an organizational rather than substantive nature and will not have any economic impacts. The economic impact of this amendment was estimated by the FAA with the assistance of a research firm, which relied heavily on General Aviation Manufacturers Association (GAMA) information pertaining to expected costs and National Transportation Safety Board (NTSB) data pertaining to expected benefits. The estimation procedure quantified the costs and benefits expected to result from this amendment based upon the official FAA forecast of airplane production and a more conservative forecast that projects a continuation of the depressed condition of this industry. The effect of using the more conservative forecast is to reduce substantially the magnitude of both the expected total costs and benefits of this amendment for which quantification of these impacts was possible, reflecting the considerably smaller number of affected airplanes. The use of the more conservative forecast does not alter the general results of the analysis with regard to the overall combined economic impact of this amendment, although the effects on the cost-effectiveness of the individual proposals differed.

Using the FAA production forecast, the total expected quantified benefits for the two revisions aimed at occupant energy-absorbing seats and torso restraint systems (benefits cannot be quantified for the others) are estimated to be approximately $30.5 million on a discounted basis over a 20-year period, considerably higher than the expected associated costs, which are estimated at about $17.1 million. The use of the more conservative production forecast results in an estimate of about $4.3 million for the discounted benefits of this amendment and expected costs of about $4.0 million. Benefits cannot be quantified for the other substantive revisions because of insufficient accident data.

One of the two revisions directed at occupant restraint, which will require a shoulder harness capable of satisfying a dynamic test at all seats in new type certificated normal, utility, and acrobatic category airplanes, is similar to an airworthiness standard recently adopted by the FAA in Amendment 23–

32. That recently adopted rule imposes a shoulder harness requirement at all seats of normal, utility, and acrobatic category airplanes manufactured after December 12, 1986, and requires the shoulder harness to satisfy static strength requirements. Because the requirements in Amendment 23–32 apply to all normal, utility, and acrobatic category airplanes with a seating configuration of nine or less excluding pilot seats, regardless of the date of type certification and type certification basis, its implementation has the effect of minimizing any costs pertaining to should harnesses that can be attributed to this amendment. The dynamic test is a more stringent one because the basic seat structure and its attachment to the cabin floor must be designed so as to afford greater occupant protection through energy absorption, a requirement whose incremental costs have been attributed to a separate revision contained in this amendment that pertains only to seat strength.

The benefits of the shoulder harness requirements in this amendment are not totally eliminated, however, because it requires that these harnesses pass a dynamic test with seat systems as a whole to protect occupants, as noted above. In contrast, the recently adopted rule only required static strength evaluation of the shoulder harness which less accurately represents the loads on occupants resulting from survivable airplane accidents. The full extent of those incremental benefits cannot be quantified, however, because the benefits for the two revisions pertaining to seat systems are interdependent. The benefits estimated for the seat revisions were found to be directly proportional to the rate of shoulder harness usage. These benefits are estimated over a 20-year period, compared with the 10-year period used for estimating costs, in order to capture all of the benefits that can be attributed to seats installed near the end of the initial 10-year period.

For the purpose of this analysis, the quantified benefits for the seat system improvements are attributed solely to the revision requiring energy-absorbing seats, recognizing that the shoulder harness amendment is likely to produce additional benefits that appear difficult if not impossible to quantify. The cost-effectiveness of the seat amendment (based on the FAA production forecast) is contingent upon the assumption that over 56 percent of the occupants would use shoulder harnesses. The required rate of shoulder harness usage increases to 93 percent based on the more conservative forecast.

The benefits of this amendment pertaining to door and emergency exit requirements, as well as cargo restraint, cannot be precisely quantified because of a lack of detail in the historical accident data although an expected range of benefits in terms of fatalities prevented was estimated. Accidents involving post-crash fires were regarded as being the most relevant for assessing the benefits because fatalities caused by this type of accident are more likely to have resulted from evacuation problems than impact forces. A "breakeven" analysis of the number of fatalities that would have to be prevented to offset the costs of these proposals ($1.6 million for cargo restraint requirements, $10.2 million for the door requirements and $17.1 million for the emergency exit requirements based on the FAA forecast) was performed to provide an indication of the expected relationship between the costs and benefits that were estimated in this amendment. This comparison revealed a strong probability that this amendment would prevent a substantially greater number of fatalities than would be required to offset their costs based on the most realistic assumptions regarding the effectiveness of the revised requirements. More specifically, the benefits estimated for this amendment ranged from about 17 to 50 fatalities prevented on an annual basis based on an intermediate assumption pertaining to effectiveness (see Table 1), far in excess of the "breakeven point" of 5.5 fatalities prevented (see Regulatory Evaluation). The "breakeven point" declines to only one fatality prevented when the more conservative production forecast is used.

TABLE 1

[Number of Fatalities Expected to be Prevented by Door and Emergency Exit Requirements Under Various Assumptions [1]]

	Percent of Fatalities in Accidents Involving Post-Crash Fires Attributable Solely to Egress Problems		
	25 percent	50 percent	75 percent
Effectiveness of Door and Emergency Exit Requirements in Preventing Fatalities:			
25 percent	8	17	25
50 percent	17	33	50
75 percent	25	50	75

[1] The numbers in this table are based on an expected annual average of 133 fatalities (derived from the FAA's Accident/Incident Data System).
Source: Office of Aviation Policy and Plans, FAA.

Trade Impact

This amendment will have little or no impact on trade for both U.S. firms doing business in foreign countries and foreign firms doing business in the United States. In the United States, foreign manufacturers would have to meet U.S. requirements, and thus they would gain no competitive advantage. In foreign countries, U.S. manufacturers would not be bound by Part 23 requirements and would not be compelled to implement these requirements.

Final Regulatory Determination

The FAA has also determined that this amendment will not have a significant economic impact on a substantial number of small entities. The FAA's criteria for a Part 23 airplane manufacturer is one employing less than 75 employees, a substantial number is a number which is not less than 11 and which is more than one-third of the small entities subject to this amendment, and a significant impact is one having an annual cost of more than $14,258 per manufacturer.

A review of domestic Part 23 airplane manufacturing companies indicates that only six companies meet the size threshold of 75 employees or less. This amendment to 14 CFR Part 23 will, therefore, not affect a substantial number of small entities.

Federalism Implications

The regulations set forth in this amendment are promulgated pursuant to the authority in the Federal Aviation Act of 1958, as amended (49 U.S.C. 1301, *et seq.*), which statute is construed to

preempt state law regulating the same subject. Thus, in accordance with Executive Order 12612, it is determined that such regulations do not have federalism implications warranting the preparation of a Federalism Assessment.

Conclusion

For reasons discussed earlier in the preamble, the FAA has determined that this document: (1) Involves a regulation that is not major under the provisions of Executive Order 12291, and (2) is not significant under the provisions of DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). I certify that under the criteria of the Regulatory Flexibility Act, this rule will not have a significant economic impact, positive or negative, on a substantial number of small entities. In addition, this rule will have little or no impact on trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Air transportation, Safety.

Adoption of the Amendment

Accordingly, 14 CFR Part 23 is amended as follows:

PART 23—AIRWORTHINESS STANDARDS: NORMAL, UTILITY, ACROBATIC, AND COMMUTER CATEGORY AIRPLANES

1. The authority citation for Part 23 continues to read as follows:

Authority: 49 U.S.C. 1344, 1354(a), 1355, 1421, 1423, 1425, 1428, 1429, 1430; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983).

2. Section 23.2 is revised to read as follows:

§ 23.2 Special retroactive requirements.

(a) Notwithstanding §§ 21.17 and 21.101 of this chapter and irrespective of the type certification basis, each normal, utility, and acrobatic category airplane having a passenger seating configuration, excluding pilot seats, of nine or less, manufactured after December 12, 1986, or any such foreign airplane for entry into the United States must provide a safety belt and shoulder harness for each forward- or aft-facing seat which will protect the occupant from serious head injury when subjected to the inertia loads resulting from the ultimate static load factors prescribed in § 23.561(b)(2) of this part, or which will provide the occupant protection specified in § 23.562 of this part when that section is applicable to the airplane. For other seat orientations, the seat/restraint system must be designed to provide a level of occupant protection equivalent to that provided for forward- or aft-facing seats with a safety belt and shoulder harness installed.

(b) Each shoulder harness installed at a flight crewmember station, as required by this section, must allow the crewmember, when seated with the safety belt and shoulder harness fastened, to perform all functions necessary for flight operations.

(c) For the purpose of this section, the date of manufacture is:

(1) The date the inspection acceptance records, or equivalent, reflect that the airplane is complete and meets the FAA approved type design data; or

(2) In the case of a foreign manufactured airplane, the date the foreign civil airworthiness authority certifies the airplane is complete and issues an original standard airworthiness certificate, or the equivalent in that country.

3. Section 23.561 is amended by revising paragraphs (b) and (d) to read as follows:

§ 23.561 General.

* * * * *

(b) The structure must be designed to protect each occupant during emergency landing conditions when—

(1) Proper use is made of the seats, safety belts, and shoulder harnesses provided for in the design;

(2) The occupant experiences the static inertia loads corresponding to the following ultimate load factors—

(i) Upward, 3.0g for normal, utility, and commuter category airplanes, or 4.5g for acrobatic category airplanes;

(ii) Forward, 9.0g;

(iii) Sideward, 1.5g; and

(3) The items of mass within the cabin, that could injure an occupant, experience the static inertia loads corresponding to the following ultimate load factors—

(i) Upward, 3.0g;

(ii) Forward, 18.0g; and

(iii) Sideward, 4.5g.

* * * * *

(d) If it is not established that a turnover is unlikely during an emergency landing, the structure must be designed to protect the occupants in a complete turnover as follows:

(1) The likelihood of a turnover may be shown by an analysis assuming the following conditions—

(i) Maximum weight;

(ii) Most forward center of gravity position;

(iii) Longitudinal load factor of 9.0g;

(iv) Vertical load factor of 1.0g; and

(v) For airplanes with tricycle landing gear, the nose wheel strut failed with the nose contacting the ground.

(2) For determining the loads to be applied to the inverted airplane after a turnover, an upward ultimate inertia load factor of 3.0g and a coefficient of friction with the ground of 0.5 must be used.

* * * * *

4. New § 23.562 is added to read as follows:

§ 23.562 Emergency landing dynamic conditions.

(a) Each seat/restraint system for use in a normal, utility, or acrobatic category airplane must be designed to protect each occupant during an emergency landing when—

(1) Proper use is made of seats, safety belts, and shoulder harnesses provided for in the design; and

(2) The occupant is exposed to the loads resulting from the conditions prescribed in this section.

(b) Each seat/restraint system, for crew or passenger occupancy in a normal, utility, or acrobatic category airplane, must successfully complete dynamic tests or be demonstrated by rational analysis supported by dynamic tests, in accordance with each of the following conditions. These tests must be conducted with an occupant simulated by an anthropomorphic test dummy (ATD) defined by 49 CFR Part 572, Subpart B, or an FAA-approved equivalent, with a nominal weight of 170 pounds and seated in the normal upright position.

(1) For the first test, the change in velocity may not be less than 31 feet per second. The seat/restraint system must be oriented in its nominal position with respect to the airplane and with the horizontal plane of the airplane pitched up 60 degrees, with no yaw, relative to the impact vector. For seat/restraint systems to be installed in the first row of the airplane, peak deceleration must occur in not more than 0.05 seconds after impact and must reach a minimum of 19g. For all other seat/restraint systems, peak deceleration must occur in not more than 0.06 seconds after impact and must reach a minimum of 15g.

(2) For the second test, the change in velocity may not be less than 42 feet per second. The seat/restraint system must be oriented in its nominal position with respect to the airplane and with the vertical plane of the airplane yawed 10 degrees, with no pitch, relative to the impact vector in a direction that results in the greatest load on the shoulder harness. For seat/restraint systems to be

installed in the first row of the airplane, peak deceleration must occur in not more than 0.05 seconds after impact and must reach a minimum of 26g. For all other seat/restraint systems, peak deceleration must occur in not more than 0.06 seconds after impact and must reach a minimum of 21g.

(3) To account for floor warpage, the floor rails or attachment devices used to attach the seat/restraint system to the airframe structure must be preloaded to misalign with respect to each other by at least 10 degrees vertically (i.e., pitch out of parallel) and one of the rails or attachment devices must be preloaded to misalign by 10 degrees in roll prior to conducting the test defined by paragraph (b)(2) of this section.

(c) Compliance with the following requirements must be shown during the dynamic tests conducted in accordance with paragraph (b) of this section:

(1) The seat/restraint system must restrain the ATD although seat/restraint system components may experience deformation, elongation, displacement, or crushing intended as part of the design.

(2) The attachment between the seat/restraint system and the test fixture must remain intact, although the seat structure may have deformed.

(3) Each shoulder harness strap must remain on the ATD's shoulder during the impact.

(4) The safety belt must remain on the ATD's pelvis during the impact.

(5) The results of the dynamic tests must show that the occupant is protected from serious head injury.

(i) When contact with adjacent seats, structure, or other items in the cabin can occur, protection must be provided so that the head impact does not exceed a head injury criteria (HIC) of 1,000.

(ii) The value of HIC is defined as—

$$HIC = \left\{ (t_2 - t_1) \left[\frac{1}{(t_2 - t_1)} \int_{t_1}^{t_2} a(t)\,dt \right]^{2.5} \right\}_{Max}$$

Where: t_1 is the initial integration time, expressed in seconds, t_2 is the final integration time, expressed in seconds, $(t_2 - t_1)$ is the time duration of the major head impact, expressed in seconds, and $a(t)$ is the resultant deceleration at the center of gravity of the head form expressed as a multiple of g (units of gravity).

(iii) Compliance with the HIC limit must be demonstrated by measuring the head impact during dynamic testing as prescribed in paragraphs (b)(1) and (b)(2) of this section or by a separate showing of compliance with the head injury criteria using test or analysis procedures.

(6) Loads in individual shoulder harness straps may not exceed 1,750 pounds. If dual straps are used for retaining the upper torso, the total strap loads may not exceed 2,000 pounds.

(7) The compression load measured between the pelvis and the lumbar spine of the ATD may not exceed 1,500 pounds.

(d) An alternate approach that achieves an equivalent, or greater, level of occupant protection to that required by this section may be used if substantiated on a rational basis.

5. Section 23.783 is amended by revising paragraph (c) and adding new paragraphs (d) and (e) to read as follows:

§ 23.783 Doors.

* * * * *

(c) Each external passenger or crew door must comply with the following requirements:

(1) There must be a means to lock and safeguard the door against inadvertent opening during flight by persons, by cargo, or as a result of mechanical failure.

(2) The door must be openable from the inside and the outside when the internal locking mechanism is in the locked position.

(3) There must be a means of opening which is simple and obvious and is arranged and marked inside and outside so that the door can be readily located, unlocked, and opened, even in darkness.

(4) The door must meet the marking requirements of § 23.811 of this part.

(5) The door must be reasonably free from jamming as a result of fuselage deformation in an emergency landing.

(6) Auxiliary locking devices that are actuated externally to the airplane may be used but such devices must be overridden by the normal internal opening means.

(d) In addition, each external passenger or crew door, for a commuter category airplane, must comply with the following requirements:

(1) Each door must be openable from both the inside and outside, even though persons may be crowded against the door on the inside of the airplane.

(2) If inward opening doors are used, there must be a means to prevent occupants from crowding against the door to the extent that would interfere with opening the door.

(3) Auxiliary locking devices may be used.

(e) Each external door on a commuter category airplane, each external door forward of any engine or propeller on a normal, utility, or acrobatic category airplane, and each door of the pressure vessel on a pressurized airplane must comply with the following requirements:

(1) There must be a means to lock and safeguard each external door, including cargo and service type doors, against inadvertent opening in flight, by persons, by cargo, or as a result of mechanical failure or failure of a single structural element, either during or after closure.

(2) There must be a provision for direct visual inspection of the locking mechanism to determine if the external door, for which the initial opening movement is not inward, is fully closed and locked. The provisions must be discernible, under operating lighting conditions, by a crewmember using a flashlight or an equivalent lighting source.

(3) There must be a visual warning means to signal a flight crewmember if the external door is not fully closed and locked. The means must be designed so that any failure, or combination of failures, that would result in an erroneous closed and locked indication is improbable for doors for which the initial opening movement is not inward.

6. Section 23.785 is revised to read as follows:

§ 23.785 Seats, berths, litters, safety belts, and shoulder harnesses.

(a) Each seat/restraint system and the supporting structure must be designed to support occupants weighing at least 215 pounds when subjected to the maximum load factors corresponding to the specified flight and ground load conditions, as defined in the approved operating envelope of the airplane. In addition, these loads must be multiplied by a factor of 1.33 in determining the strength of all fittings and the attachment of—

(1) Each seat to the structure; and
(2) Each safety belt and shoulder harness to the seat or structure.

(b) Each forward-facing or aft-facing seat/restraint system in normal, utility, or acrobatic category airplanes must consist of a seat, safety belt, and shoulder harness that are designed to provide the occupant protection provisions required in § 23.562 of this part. Other seat orientations must provide the same level of occupant protection as a forward-facing or aft-facing seat with a safety belt and shoulder harness, and provide the protection provisions of § 23.562 of this part.

(c) For commuter category airplanes, each seat and the supporting structure must be designed for occupants weighing at least 170 pounds when subjected to the inertia loads resulting from the ultimate static load factors prescribed in § 23.561(b)(2) of this part, and each occupant must be protected from serious head injury when subjected to the inertia loads resulting from these load factors by a safety belt and shoulder harness for the front seats; and a safety belt, or a safety belt and shoulder harness, for each seat other than the front seats.

(d) Each restraint system must have a single-point release for occupant evacuation.

(e) The restraint system for each crewmember must allow the crewmember, when seated with the safety belt and shoulder harness fastened, to perform all functions necessary for flight operations.

(f) Each pilot seat must be designed for the reactions resulting from the application of pilot forces to the primary flight controls as prescribed in § 23.395 of this part.

(g) There must be a means to secure each safety belt and shoulder harness, when not in use, to prevent interference with the operation of the airplane and with rapid occupant egress in an emergency.

(h) Unless otherwise placarded, each seat in a utility or acrobatic category airplane must be designed to accommodate an occupant wearing a parachute.

(i) The cabin area surrounding each seat, including the structure, interior walls, instrument panel, control wheel, pedals, and seats within striking distance of the occupant's head or torso (with the restraint system fastened) must be free of potentially injurious objects, sharp edges, protuberances, and hard surfaces. If energy absorbing designs or devices are used to meet this requirement, they must protect the occupant from serious injury when the occupant is subjected to the inertia loads resulting from the ultimate static load factors prescribed in § 23.561(b)(2) of this part, or they must comply with the occupant protection provisions of § 23.562 of this part, as required in paragraphs (b) and (c) of this section.

(j) Each seat track must be fitted with stops to prevent the seat from sliding off the track.

(k) Each seat/restraint system may use design features, such as crushing or separation of certain components, to reduce occupant loads when showing compliance with the requirements of § 23.562 of this part; otherwise, the system must remain intact.

(l) For the purposes of this section, a front seat is a seat located at a flight crewmember station or any seat located alongside such a seat.

(m) Each berth, or provisions for a litter, installed parallel to the longitudinal axis of the airplane, must be designed so that the forward part has a padded end-board, canvas diaphragm, or equivalent means that can withstand the load reactions from a 215-pound occupant when subjected to the inertia loads resulting from the ultimate static load factors of § 23.561(b)(3) of this part. In addition—

(1) Each berth or litter must have an occupant restraint system and may not have corners or other parts likely to cause serious injury to a person occupying it during emergency landing conditions; and

(2) Occupant restraint system attachments for the berth or litter must withstand the inertia loads resulting from the ultimate static load factors of § 23.561(b)(3) of this part.

(n) Proof of compliance with the static strength requirements of this section for seats and berths approved as part of the type design and for seat and berth installations may be shown by—

(1) Structural analysis, if the structure conforms to conventional airplane types for which existing methods of analysis are known to be reliable;

(2) A combination of structural analysis and static load tests to limit load; or

(3) Static load tests to ultimate loads.

7. Section 23.787 is amended by revising the section heading and by revising paragraphs (c), (e), and (g) to read as follows:

§ 23.787 Baggage and cargo compartments.

* * * * *

(c) There must be a means to protect occupants from injury by the contents of any baggage or cargo compartment, located aft of the occupants and separated by structure, when the ultimate forward inertia load factor is 9% and assuming the maximun allowed baggage or cargo weight for the compartment.

* * * * *

(e) Designs which provide for baggage or cargo to be carried in the same compartment as passengers must have a means to protect the occupants from injury when the cargo is subjected to the inertia loads resulting from the ultimate static load factors of § 23.561(b)(3) of this part, assuming the maximum allowed baggage or cargo weight for the compartment.

* * * * *

(g) Baggage compartments used in commuter category airplanes must also meet the requirements of paragraphs (a), (b), (d), and (f) of this section.

8. Section 23.807 is amended by removing paragraphs (d)(3) andm (d)(4) and revising paragraphs (a)(1) and (b) introductory text, to read as follows:

§ 23.807 Emergency exits.

(a) * * *

(1) For all airplanes with a seating capacity of two or more, excluding airplanes with canopies, at least one emergency exit on the opposite side of the cabin from the main door specified in § 23.783 of this part.

* * * * *

(b) *Type and operation.* Emergency exits must be movable windows, panels, canopies, or external doors, openable from both inside and outside the airplanes, that provide a clear and unobstructed opening large enough to admit a 19-by-26-inch ellipse. Auxiliary locking devices used to secure the airplane must be designed to be overridden by the normal internal opening means. In addition, each emergency exit must—

* * * * *

9. New § 23.811 is added to read as follows:

§ 23.811 Emergency exit marking.

(a) Each emergency exit and external door in them passenger compartment must be externally marked and readily identifiable from outside the airplane by—

(1) A conspicuous visual identification scheme; and

(2) A permanent decal or placard on or adjacent to the emergency exit which shows the means of opening the emergency exit, including any special instructions, if applicable.

(b) In addition, for commuter category airplanes, these exits and doors must be internally marked with the word "exit" by a sign which has white letters 1 inch

high on a red background 2 inches high, be self-illuminated or independently, internally electrically illuminated, and have a minimum brightness of at least 160 microlamberts. The color may be reversed if the passenger compartment illumination is essentially the same.

10. New § 23.813 is added to read as follows:

§ 23.813 Emergency exit access.

For commuter category airplanes, access to window-type emergency exits may not be obstructed by seats or seat backs.

11. Section 23.967 is amended by revising paragraph (e)(1) to read as follows:

§ 23.967 Fuel tank installation.

* * * * *

(e) * * *

(1) When subjected to the inertia loads resulting from the ultimate static load factors prescribed in § 23.561(b)(2) of this part; and

* * * * *

12. Section 23.1411 is amended by revising paragraph (b)(2) to read as follows:

§ 23.1411 General

* * * * *

(b) * * *

(2) Protect the safety equipment from damage caused by being subjected to the inertia loads resulting from the ultimate static load factors specified in § 23.561(b)(3) of this part.

13. Section 23.1413 is revised to read as follows:

§ 23.1413 Safety belts and harnesses.

Each safety belt and shoulder harness must be equipped with a metal-to-metal latching device.

Issued in Washington, DC, on August 8, 1988.

T. Allan McArtor,

Administrator.

[FR Doc. 88-18267 Filed 8-12-88; 8:45 am]

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Part VI

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 2, 14, 15, and 52
Federal Acquisition Regulation; Late Bids and Proposals—Composite Case; Proposed Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 14, 15, and 52

Federal Acquisition Regulation (FAR); Late Bids and Proposals—Composite Case

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to Federal Acquisition Regulation (FAR) Parts 2, 14, and 52 to (1) correct language in the current 5-day late bid rule concerning acceptable evidence to establish the date of mailing of a late bid, modification, or withdrawal sent by registered or certified mail; (2) provide a 2-day late bid rule for bids mailed by U.S. Postal Service Express Mail Next Day Service; (3) provide separate late bid rules for bids outside the U.S. and Canada; and (4) allow contracting officers the option of permitting the use of facsimile equipment for the submission of bids, acknowledgements of amendments to solicitations, and modifications or withdrawals of bids. Corresponding changes pertinent to contracting by negotiation are also proposed in Parts 15 and 52.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before October 14, 1988 to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets, NW, Room 4041, Washington, DC 20405.

Please cite FAR Case 85–16 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Margaret A. Willis, FAR Secretariat, Room 4041, GS Building, Washington, DC 20405, (202) 523–4755.

SUPPLEMENTARY INFORMATION:

A. Background

The proposed revisions to correct language in the current 5-day late bid rule concerning acceptable evidence to establish the day of mailing of a late bid, modification, or withdrawal sent by registered or certified mail were published in the **Federal Register** as a proposed rule on March 23, 1985 (50 FR 11522). Comments received in response to the referenced proposed rule have been considered in the formulation of the language set forth in this proposed rule.

The provision of a 2-day late bid rule for bids mailed by U.S. Postal Service Express Mail Next Day Service is based on recommendations made by the Office of Federal Procurement Policy (OFPP) and the General Accounting Office (GAO) that consideration be given to include express mail in the late bids/offers provisions, along with registered and certified mail. The OFPP and GAO recommendations were not adopted at the time they were made, in view of the then limited availability of U.S. Postal Service Express Mail Next Day Service. Subsequent expansion of such services, however, has resulted in a favorable reconsideration of the recommendations.

The provision of separate late bid rules for bids outside the United States and Canada is based on a comment received in response to the publication of the proposed rule in the **Federal Register** on March 23, 1985. The recommendation pointed out that the 5-day late bid rule is inappropriate with respect to bids mailed to contracting offices outside the United States and Canada. Consequently, FAR revisions are proposed to (1) limit applicability of the 5-day late bid rule to bids submitted to contracting offices in the United States and Canada, and (2) establish, for bids submitted to contracting offices outside the United States and Canada, a rule that limits acceptance of late bids to those whose late receipt is due solely to mishandling by the Government at the Government installation.

The provision of an option that permits contracting officers to authorize the use of facsimile equipment for the submission of bids, acknowledgements of amendments to solicitations, and modifications or withdrawals of bids, is based on a 4-month test in response to an inquiry from a member of the public. The 4-month test was conducted to determine the practicality of prospective contractors submitting certain contractual documents by facsimile in addition to telegram. Comments from interested parties indicated that facsimile transmission of the documents is highly acceptable because of its convenience, accuracy, and low cost.

The corresponding changes proposed with respect to FAR Parts 15 and 52 are intended to adjust coverage pertaining to contracting by negotiation to the extent feasible to be consistent with the changes proposed with respect to sealed bidding.

B. Regulatory Flexibility Act

Public comments are not necessary because this proposed rule does not have a significant cost or administrative impact on contractors and does not have a significant effect beyond the internal operating procedures of the Government. However, any public comments received will be considered in the formulation of a final rule.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the proposed rule does not impose recordkeeping or information collection requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, et seq.

List of Subjects in 48 CFR Parts 2, 14, 15, and 52

Government procurement.

Dated: August 5, 1988.

Harry S. Rosinski,

Acting Director, Office of Federal Acquisition and Regulatory Policy.

Therefore, it is proposed that 48 CFR Parts 2, 14, 15, and 52 be amended as set forth below:

1. The authority citation for Parts 2, 14, 15, and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2473(c).

PART 2—DEFINITIONS OF WORDS AND TERMS

2. Section 2.101 is amended by alphabetically adding a definition "Facsimile" to read as follows:

2.101 Definitions

* * * * *

"Facsimile" means electronic equipment that communicates and reproduces both printed and handwritten material. If used in conjunction with a reference to a document, e.g., facsimile bid, the term refers to a document (in the example given, a bid) that has been transmitted to and received by the Government via facsimile.

* * * * *

PART 14—SEALED BIDDING

3. Section 14.201–6 is amended by revising paragraphs (c)(3) and (r); by reserving paragraph (u); and by adding

paragraphs (c)(4), (v), and (w) to read as follows:

14.201-6 Solicitation provisions.

* * * * *

(c) * * *

(3) 52.214-7, Late Submissions, Modifications, and Withdrawals of Bids, for solicitations issued in the United States and Canada for submission of bids to a contracting office in the United States or Canada.

(4) 52.214-32, Late Submissions, Modifications, and Withdrawals of Bids (Overseas), for solicitations under which bids are to be submitted to a contracting office outside the United States or Canada.

* * * * *

(r) The contracting officer shall insert the provision at 52.214-23, Late Submissions, Modifications, and Withdrawals of Technical Proposals under Two-Step Sealed Bidding, in solicitations for technical proposals in step one of two-step sealed bidding issued in the United States and Canada for submission of technical proposals to a contracting office in the United States or Canada.

* * * * *

(u) [Reserved]

(v) The contracting officer shall insert the provision at 52.214-33, Late Submissions, Modifications, and Withdrawals of Technical Proposals under Two-Step Sealed Bidding (Overseas), in solicitations for technical proposals in step one of two-step sealed bidding under which technical proposals are to be submitted to a contracting office outside the United States or Canada.

(w) The contracting officer shall insert the provision at 52.214-31, Facsimile Bids, in solicitations if facsimile bids are authorized (see 14.202-7).

4. Section 14.202-7 is added to read as follows:

14.202-7 Facsimile bids.

Unless prohibited or otherwise restricted by agency procedures, contracting officers may authorize facsimile bids (see 14.201-6(w)). In determining whether or not to authorize facsimile bids, the contracting officer shall consider factors such as—

(a) Anticipated bid size and volume;

(b) Urgency of the requirement;

(c) Frequency of price changes;

(d) Availability, reliability, speed, and capacity of the receiving facsimile equipment; and

(e) Adequacy of administrative procedures and controls for receiving, identifying, recording, and safeguarding facsimile bids, and ensuring their timely delivery to the bids opening location.

5. Section 14.301 is amended by revising paragraph (a); by redesignating existing paragraph (c) as (d); and by adding new paragraph (c) to read as follows:

14.301 Responsiveness of bids.

(a) To be considered for award, a bid (including, if authorized by the solicitation, facsimile bids) (see 14.301(c)) must comply in all material respects with the invitation for bids. Such compliance enables bidders to stand on an equal footing and maintains the integrity of sealed bidding system.

* * * * *

(c) Facsimile bids shall not be considered unless permitted by the invitation (see 14.202-7).

* * * * *

6. Section 14.303 is amended by revising paragraph (a) to read as follows:

14.303 Modifications or withdrawal of bids.

(a) Bids may be modified or withdrawal by written or telegraphic notice received in the office designated in the invitation for bids not later than the exact time set for opening of bids. Unless proscribed by agency regulations, a telegraphic modification or withdrawal of a bid received in such office by telephone from the receiving telegraph office shall be considered. However, the message shall be confirmed by the telegraph company by sending a copy of the written telegram that formed the basis for the telephone call. If the solicitation authorizes facsimile bids, bids may be modified or withdrawn via facsimile received at any time before the exact time set for receipt of bids, subject to the conditions specified in the provision prescribed in 14.201-6(w). Modifications received by telephone (including a record of those telephoned by the telegraph company) or facsimile shall be sealed in an envelope by a proper official. The official shall write on the envelope (1) the date and time of receipt and by whom and (2) the number of the invitation for bids, and shall sign the envelope. No information contained in the envelope shall be disclosed before the time set for bid opening.

* * * * *

7. Section 14.304-1 is amended by revising paragraphs (a)(1), (a)(2), and (b); by redesignating existing paragraph (d) as (e); and by adding new paragraphs (a)(3) and (d) to read as follows:

14.304-1 General.

* * * * *

(a) * * *

(1) It was sent to a contracting office in the United States or Canada by registered or certified mail not later than 5 calendar days before the bid receipt date specified;

(2) It was sent by mail (or, if authorized by the solicitation, was sent by telegram or via facsimile) and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation; or

(3) It was sent to a contracting office in the United States or Canada by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee not later than 5:00 PM at the place of mailing 2 U.S. Federal working days prior to the date specified for receipt of bids. The term "U.S. Federal Working Days" excludes weekends and U.S. Federal holidays.

(b) The only acceptable evidence to establish the date of mailing of a late bid, modification, or withdrawal sent to a contracting office in the United States or Canada either by registered or certified mail is a U.S. or Canadian Postal Service postmark both on the envelope or wrapper and on the original receipt from the U.S. or Canadian Postal Service. If both postmarks do not show a legible date, the bid, modification, or withdrawal shall be deemed to have been mailed late. (The term "postmark" means a printed, stamped, or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable without further action as having been supplied and affixed on the date of mailing by employees of the U.S. or Canadian Postal Service. Therefore, bidders should request the postal clerk to place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.)

* * * * *

(d) The only acceptable evidence to establish the date of mailing of a late bid, modification, or withdrawal sent by Express Mail Next Day Service-Post Office to Addressee is the date entered by the post office receiving clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envolope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the same meaning as defined in paragraph (b) of the subsection, excluding postmarks of the Canadian Postal Service. Therefore, bidders would request the postal clerks to place a legible and hand cancellation

bull's-eye postmark on both the receipt and the envelope or wrapper.

* * * * *

8. Section 14.304–2 is revised to read as follows:

14.304–2 Notification to late bidders.

When a bid, modification of bid, or withdrawal of bid is received late and it is clear from available information that it cannot be considered, the contracting officer shall promptly notify the bidder accordingly. However, when a late bid, modification of bid, or withdrawal of bid is transmitted to a contracting office in the United States or Canada by registered or certified mail or by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee and is received before award, the bidder shall be promptly notified substantially as follows:

Your bid in response to Invitation for Bids Number ____ dated ____ for ____ [insert subject matter or short title] was received after the time for opening specified in the Invitation. Accordingly, you bid will not be opened or considered for award unless there is received from you by ____ [insert date] the original post office receipt for (insert one of the following, as appropriate):

(i) Registered or certified mail showing a date of mailing not later than the fifth calendar day before the date specified for opening (e.g., a bid submitted in response to a solicitation requiring receipt of bids by the 20th of the month must have been mailed by the 15th or earlier); or

(ii) U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee showing a date of mailing not later than 5:00 PM 2 Federal working days prior to the date specified for opening.

PART 15—CONTRACTING BY NEGOTIATION

9. Section 15.402 is amended by adding paragraph (i) to read as follows:

15.402 General.

* * * * *

(i) Unless prohibited or otherwise restricted by agency procedures, contracting offices may authorize fascimile proposals (see 15.407 (i)). In determining whether or not to authorize facsimile proposals, the contracting officer shall consider such factors as—

(1) Anticipated proposal size and volume;

(2) Urgency of the requirement;

(3) Frequency of price changes;

(4) Availability, reliability, speed, and capacity of the receiving facsimile equipment; and

(5) Adequacy of administrative procedures and controls for receiving, identifying, recording, and safeguarding facsimile proposals, and ensuring their timely delivery to the proposal opening location.

10. Section 15.407 is amended by revising paragraphs (c)(6) and (c)(8); by adding and reserving paragraph (i); and by adding paragraphs (c)(9) and (j) to read as follows:

15.407 Solicitation provisions.

* * * * *

(c) * * *

(6) 52.215–10, Late Submissions, Modifications, and Withdrawals of Proposals, for solicitations issued in the United States and Canada for submission of offers to a contracting office in the United States or Canada;

* * * * *

(8) 52.215–12, Restriction on Disclosure and Use of Data; and

(9) 52.215–36, Late Submissions, Modifications, and Withdrawals of Proposals (Overseas), for solicitations under which offers are to be submitted to a contracting office outside the United States or Canada.

* * * * *

(i) [Reserved]

(j) The contracting officer shall insert the provisions at 52.215–18, Facsimile Proposals, in solicitations if facsimile proposals are authorized (see 15.402(i)).

11. Section 15.412 is amended by revising paragraph (e) to read as follows:

15.412 Late proposals and modifications.

* * * * *

(e) When a late proposal or modification is transmitted to a contracting office in the United States or Canada by registered or certified mail or by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee and is received before award, the offeror shall be promptly notified substantially in accordance with the notice in 14.304–2, appropriately modified to relate to proposals.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

12. Section 52.214–5 is revised to read as follows:

52.214–5 Submission of Bids.

As prescribed in 14.201–6(c)(1), insert the following provision:

SUBMISSION OF BIDS (AUG 1988)

(a) Bids and bid modifications shall be submitted in sealed envelopes or packages (unless submitted by electronic means) (1) addressed to the office specified in the solicitation number, and name and address of the bidder.

(b) Telegraphic bids will not be considered unless authorized by the solicitation; however, bids may be modified or withdrawn by written or telegraphic notice, if such notice is received by the time specified for receipt of bids.

(c) Facsimile bids will not be considered unless authorized by the solicitation.

(End of provision)

13. Section 52.214–7 is revised to read as follows:

52.214–7 Late Submissions, Modifications, and Withdrawals of Bids.

As prescribed in 14.201–6(c)(3), insert the following provision:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF BIDS (AUG 1988)

(a) Any bid received at the office designated in the solicitation after the exact time specified for receipt will not be considered unless it is received before award is made and it—

(1) Was sent by registered or certified mail not later than the fifth calendar day before the date specified for receipt of bids (e.g., a bid submitted in response to a solicitation required receipt of bids by the 20th of the month must have been mailed by the 15th);

(2) Was sent by mail or, if authorized by the solicitation, was sent by telegram or via facsimile and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation; or

(3) Was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5:00 P.M. at the place of mailing 2 U.S. Federal working days prior to the date specified for receipt of bids. The term "U.S. Federal working days" excludes weekends and U.S. Federal holidays.

(b) Any modification or withdrawal of a bid is subject to the same conditions as in paragraph (a) of this provision.

(c) The only acceptable evidence to establish the date of mailing of a late bid, modification, or withdrawal sent either by registered or certified mail is the U.S. or Canadian Postal Service postmark both on the envelope or wrapper and on the original receipt from the U.S. or Canadian Postal Service. If both postmarks do not show a legible date, the bid, modification, or withdrawal shall be processed as if mailed late. "Postmark" means a printed, stamped, or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable without further action as having been supplied and affixed by employees of the U.S. or Canadian Postal Service on the date of mailing. Therefore, bidders should request the postal clerks to place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.

(d) The only acceptable evidence to establish the time of receipt at the

Government installation is the time/date stamp of that installation on the bid wrapper or other documentary evidence of receipt maintained by the installation.

(e) The only acceptable evidence to establish the date of mailing of a late bid, modification, or withdrawal sent by Express Mail Next Day Service-Post Office to Addressee is the date entered by the post office receiving clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark has the same meaning as defined in paragraph (c) of this provision, excluding postmarks of the Canadian Postal Service. Therefore, bidders should request the postal clerks to place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.

(f) Notwithstanding paragraph (a) of this provision, a late modification of an otherwise successful bid that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(g) Bids may be withdrawn by written notice or telegram (including mailgram) received at any time before the exact time set for receipts of bids. If the solicitation authorizes facsimile bids, bids may be withdrawn via facsimile received at any time before the exact time set for receipt of bids, subject to the conditions specified in the provision entitled "Facsimile Bids." A bid may be withdrawn in person by a bidder or its authorized representative if, before the exact time set for receipt of bids, the identity of the person requesting withdrawal is established and the person signs a receipt for the bid.

(End of provision)

14. Section 52.214–23 is revised to read as follows:

52.214–23 Late Submissions, Modifications, and Withdrawals of Technical Proposals under Two-Step Sealed Bidding.

As prescribed in 14.201–6(r), insert the following provision:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF TECHNICAL PROPOSALS UNDER TWO-STEP SEALED BIDDING (AUG 1988)

(a) Any technical proposal under step one of two-step sealed bidding received at the office designated in this solicitation after the exact time specified for receipt will not be considered unless it is received before the invitation for bids in step two is issued and it—

(1) Was sent by registered or certified mail not later than the 5th calendar day before the date specified for receipt of technical proposals (e.g., technical proposal submitted in response to a solicitation requiring receipt of technical proposals by the 20th of the month must have been mailed by the 15th);

(2) Was sent (i) by mail, or (ii) if authorized, by telegram (including mailgram) or via facsimile, and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation;

(3) Was sent by U.S. Postal Service Express Mail Next Day Service-Post Office To Addressee, not later than 5:00 P.M. at the place of mailing 2 U.S. Federal working days prior to the date specified for receipt of technical proposals. The term "U.S. Federal working days" excludes weekends and U.S. Federal holidays; or

(4) Is the only technical proposal received.

(b) Any modification of a technical proposal is subject to the same conditions as in paragraph (a) of this provision except that (i) the use of a telegram (or mailgram) is authorized, and (ii) if the solicitation authorizes facsimile bids, technical proposals may be modified via facsimile received at any time before the exact time set for receipt of bids under step two, subject to the conditions specified in the provision entitled "Facsimile Bids."

(c) Technical proposals may be withdrawn by written notice or telegram (including mailgram) received at any time before the exact time set for receipt of bids under step two. If the solicitation authorizes facsimile bids, technical proposals may be withdrawn via facsimile received at any time before the exact time set for receipt of bids under step two, subject to the conditions specified in the provision entitled "Facsimile Bids." Technical proposals may be withdrawn in person by the submitter or the submitter's authorized representative if, before the exact time set for receipt of bids in step two, the identity of the person requesting withdrawal is established and that person signs a receipt for the technical proposal.

(d) The only acceptable evidence to establish the date of mailing of a late technical proposal, modification, or withdrawal of technical proposal sent either by registered or certified mail is the U.S. or Canadian Postal Service postmark both on the envelope or wrapper and on the original receipt from the U.S. or Canadian Postal Service. If both postmarks do not show a legible date, the technical proposal, modification, or withdrawal of technical proposal shall be processed as if mailed late. "Postmark" means a printed, stamped, or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable without further action as having been supplied and affixed by employees of the U.S. or Canadian Postal Service on the date of mailing. Therefore, submitters of technical proposals should request the postal clerks to place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.

(e) The only acceptable evidence to establish the time of receipt at the Government installation is the time/date stamp of that installation on the proposal wrapper or other documentary evidence of receipt maintained by the installation.

(f) The only acceptable evidence to establish the date of mailing of a late technical proposal, modification, or withdrawal sent by Express Mail Next Day Service-Post Office to Addressee is the date entered by the post office receiving clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the same meaning as defined in paragraph (d) of this provision, excluding postmarks of the Canadian Postal Service. Therefore, submitters of technical proposals should request the postal clerks to place a legible hand cancellation bull's-eye postmark on both the receipt and the envelope or wrapper.

(End of provision)

15. Sections 52.214–31, 52.214–32, and 52.214–33 are added to read as follows:

52.214–31 Facsimile Bids.

As prescribed in 14.201–6(w), insert the following provision:

FACSIMILE BIDS (AUG 1988)

(a) Definition. "Facsimile bid," as used in this solicitation, means a bid that is transmitted to and received by the Government via electronic equipment that communicates and reproduces both printed and handwritten material.

(b) Bidders may submit facsimile bids as responses to this solicitation. These responses must arrive at the place and by the time, specified in the solicitation.

(c) Facsimile bids that fail to furnish required representations or information, or that reject any of the terms, conditions, and provisions of the solicitation, may be excluded from consideration.

(d) Facsimile bids must contain the required signatures.

(e) The bidder must promptly submit the complete signed bid in confirmation of the facsimile bid.

(f) Facsimile receiving data and compatibility characteristics are as follows:

(1) Telephone number of receiving facsimile equipment:

_____

(2) Compatibility characteristics of receiving facsimile equipment (e.g., make and model number, receiving speed, communications protocol):

_____

_____

(g) If the bidder chooses to transmit a facsimile bid, the Government will not be responsible for any failure attributable to the transmission or receipt of the facsimile bid including, but not limited to, the following:

(1) Receipt of garbled or incomplete bid.

(2) Availability or condition of the receiving facsimile equipment.

(3) Incompatibility between the sending and receiving equipment.

(4) Delay in transmission or receipt of bid.

(5) Failure of the bidder to properly identify the bid.

(6) Illegibility of bid.

(7) Security of bid data.

(End of provision)

52.214–32 Late Submissions, Modifications, and Withdrawals of Bids (Overseas).

As prescribed in 14.201–6(c)(4), insert the following provision:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF BIDS (OVERSEAS) (AUG 1988)

(a) Any bid received at the office designated in the solicitation after the exact time specified for receipt will not be considered unless it is received before award is made and it was sent by mail or, if authorized by the solicitation, was sent by telegram or via facsimile, and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation.

(b) Any modification or withdrawal of a bid is subject to the same conditions as in paragraph (a) of this provision.

(c) The only acceptable evidence to establish the time of receipt at the Government installation is the time/date stamp of the installation on the bid wrapper or other documentary evidence of receipt maintained by the installation.

(d) Notwithstanding paragraph (a) of this provision, a late modification of an otherwise successful bid that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(e) Bids may be withdrawn by written notice or telephone (including mailgram) received at any time before the exact time set for receipt of bids. If the solicitation authorizes facsimile bids, bids may be withdrawn via facsimile received at any time before the exact time set for receipt of bids, subject to the conditions specified in the provision entitled "Facsimile Bids." A bid may be withdrawn in person by a bidder or its authorized representative if, before the exact time set for receipt of bids, the identity of the person requesting withdrawal is established and that person signs a receipt for the bid.

(End of provision)

52.214-33 Late Submissions, Modifications, and Withdrawals of Technical Proposals under Two-Step Sealed Bidding (Overseas).

As prescribed in 14.201-6(v), insert the following provision:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF TECHNICAL PROPOSALS UNDER TWO-STEP BIDDING (OVERSEAS) (AUG 1988)

(a) Any technical proposal under step one of two-step sealed bidding received at the office designated in this solicitation after the exact time specified for receipt will not be considered unless it is received before the invitation for bids in step two is issued and it—

(1) Was sent: (i) By mail, or (ii) if authorized by the solicitation, was sent by telegram (including mailgram) or via facsimile, and it is determined by the Government that the late receipt was due solely to mishandling by the Government at the Government installation; or

(2) Is the only technical proposal received.

(b) Any modification of a technical proposal is subject to the same conditions as in paragraph (a) of this provision, except that (i) the use of a telegram (or mailgram) is authorized, and (ii) if the solicitation authorizes facsimile bids, technical proposals may be modified via facsimile received at any time before the exact time set for receipt of bids under step two, subject to the conditions specified in the provision entitled "Facsimile Bids."

(c) Technical proposals may be withdrawn by written notice (including facsimile) or telegram (including mailgram) received at any time before the exact time set for receipt of bids under step two. If the solicitation authorizes facsimile bids, technical proposals may be withdrawn via facsimile received at any time before the exact time set for receipt of bids under step two, subject to the conditions specified in the provision entitled "Facsimile Bids." Technical proposals may be withdrawn in person by the submitter or the submitter's authorized representative if, before the exact time set for receipt of bids in step two, the identity of the person requesting withdrawal is established and that person signs a receipt for the technical proposal.

(d) The only acceptable evidence to establish the time of receipt at the Government installation is the time/date stamp of that installation on the proposal wrapper or other documentary evidence of receipt maintained by the installation.

16. Section 52.215-9 is revised to read as follows:

52.215-9 Submission of Offers.

As prescribed in 15.407(c)(5), insert the following provision in requests for proposals:

SUBMISSION OF OFFERS (AUG 1988)

(a) Offers and modifications thereof shall be submitted in sealed envelopes or packages (1) addressed to the office specified in the solicitation and (2) showing the time specified for receipt, the solicitation number, and the name and address of the offeror.

(b) Telegraphic offers will not be considered unless authorized by the solicitation; however, offers may be modified by written or telegraphic notice, if that notice is received by the time specified for receipt of offers.

(c) Facsimile offers will not be considered unless authorized by the solicitation.

(d) Item samples, if required, must be submitted within the time specified for receipt of offers. Unless otherwise specified in the solicitation, these samples shall be: (1) Submitted at no expense to the Government and (2) returned at the sender's request and expense, unless they are destroyed during preaward testing.

(End of provision)

17. Section 52.215-10 is revised to read as follows:

52.215-10 Late Submissions, Modifications, and Withdrawals of Proposals.

As prescribed in 15.407(c)(6), insert the following provision in requests for proposals:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF PROPOSALS (AUG 1988)

(a) Any proposal received at the office designated in the solicitation after the exact time specified for receipt will not be considered unless it is received before award is made and it—

(1) Was sent by registered or certified mail not later than the fifth calendar day before the date specified for receipt of offers (e.g., an offer submitted in response to a solicitation requiring receipt of offers by the 20th of the month must have been mailed by the 15th);

(2) Was sent by mail or, if authorized by the solicitation, was sent by telegram or via facsimile, and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation;

(3) Was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5:00 p.m. at the place of mailing 2 U.S. Federal working days prior to the date specified for receipt of proposals. The term "U.S. Federal working days" excludes weekends and U.S. Federal holidays; or

(4) Is the only proposal received.

(b) Any modification of a proposal or quotation, except a modification resulting from the Contracting Officer's request for "best and final" offer, is subject to the same conditions as in subparagraphs (a) (1), (2), and (3) of this provision.

(c) A modification resulting from the Contracting Officer's request for "best and final" offer received after the time and date specified in the request will not be considered unless received before award and the late receipt is due solely to mishandling by the Government after receipt at the Government installation.

(d) The only acceptable evidence to establish the date of mailing of a late proposal or modification sent either by registered or certified mail is the U.S. or Canadian Postal Service postmark both on the envelope or wrapper and on the original receipt from the U.S. on Canadian Postal Service. If both postmarks do not show a legible date, the proposal, quotation, or modification shall be processed as if mailed late. "Postmark" means a printed, stamped, or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable without further action as having been supplied and affixed by employees of the U.S. or Canadian Postal Service on the date of mailing. Therefore, offerors or quoters should request the postal clerks to place a legible hand cancellation bull's eye postmark on both the receipt and the envelope or wrapper.

(e) The only acceptable evidence to establish the time of receipt at the Government installation is the time/date stamp of that installation on the proposal wrapper or other documentary evidence of receipt maintained by the installation.

(f) The only acceptable evidence to establish the date of mailing of a late offer, modification, or withdrawal sent by Express Mail Next Day Service-Post Office to Addressee is the date entered by the post office receiving clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on both the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the

same meaning as defined in paragraph (d) of this provision, excluding postmarks of the Canadian Postal Service. Therefore, offerors or quoters should request the postal clerks to place a legible hand cancellation bull's eye postmark on both the receipt and the envelope or wrapper.

(g) Notwithstanding paragraph (a) of this provision, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(h) Proposals may be withdrawn by written notice or telegram (including mailgram) received at any time before award. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision entitled "Facsimile Proposals." Proposals may be withdrawn in person by an offeror or an authorized representative, if the representative's identity is made known and the representative signs a receipt for the proposal before award.

(End of provision)

18. Section 52.215–18 is added to read as follows:

52.215–18 Facsimile Proposals.

As prescribed in 15.407(i), insert the following provision:

FACSIMILE PROPOSALS (AUG 1988)

(a) Definition. "Facsimile proposal," as used in this solicitation, means a proposal that is transmitted to and received by the Government via electronic equipment that communicates and reproduces both printed and handwritten material.

(b) Offerors may submit facsimile proposals as responses to this solicitation. These responses must arrive at the place, and by the time, specified in the solicitation.

(c) Facsimile proposals that fail to furnish required representations or information, or that reject any of the terms, conditions, and provisions of the solicitation, may be excluded from consideration.

(d) Facsimile proposals must contain the required signatures.

(e) The Offeror must promptly submit the complete signed proposal in confirmation of the facsimile proposal.

(f) Facsimile receiving data and compatibility characteristics are as follows:

(1) Telephone number of receiving facsimile equipment:

_____

(2) Compatibility characteristics of receiving facsimile equipment (e.g., make and model number, receiving speed, communications protocol):

_____

_____

(g) If the Offeror chooses to transmit a facsimile proposal, the Government will not be responsible for any failure attributable to the transmission or receipt of the facsimile proposal including, but not limited to the following:

(1) Receipt of garbled or incomplete proposal.

(2) Availability or condition of the receiving facsimile equipment.

(3) Incompatibility between the sending and receiving equipment.

(4) Delay in transmission or receipt of proposal.

(5) Failure of the Offeror to properly identify the proposal.

(6) Illegibility of proposal.

(7) Security of proposal data.

(End of provision)

19. Section 52.215–36 is added to read as follows:

52.215–36 Late Submission, Modifications, and Withdrawals of Proposal (Overseas).

As prescribed in 15.407(c)(9), insert the following provision in request for proposals:

LATE SUBMISSIONS, MODIFICATIONS, AND WITHDRAWALS OF PROPOSAL (OVERSEAS) (AUG 1988)

(a) Any proposal received at the Office designated in the solicitation after the exact time specified for receipt will not be considered unless it is received before award is made and it—

(1) Was sent by mail or, if authorized by the solicitation, was sent by telegram or via facsimile, and it is determined by the Government the late receipt was due solely to mishandling by the Government after receipt at the Government installation; or

(2) Is the only proposal received.

(b) Any modification of a proposal or quotation, except a modification resulting from the Contracting Officer's request for "best and final" offer, is subject to the same conditions as in subparagraph (a)(1) of this provision.

(c) A modification resulting from the Contracting Officer's request for "best and final" offer received after the time and date specified in the request will not be considered unless received before award and the late receipt was due solely to mishandling by the Government after receipt at the installation.

(d) The only acceptable evidence to establish the time of receipt at the Government installation is the time/date stamp of the installation on the proposal wrapper or other documentary evidence of receipt maintained by the installation.

(e) Notwithstanding paragraph (a) of this provision, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(f) Proposals may be withdrawn by written notice or telegram (including mailgram) received at any time before award. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile at any time before award, subject to the conditions specified in the provision entitled "Facsimile Proposals." Proposals may be withdrawn in person by an offeror or an authorized representative, if the representative's identity is made known and the representative signs a receipt for the proposal before award.

(End of provision)

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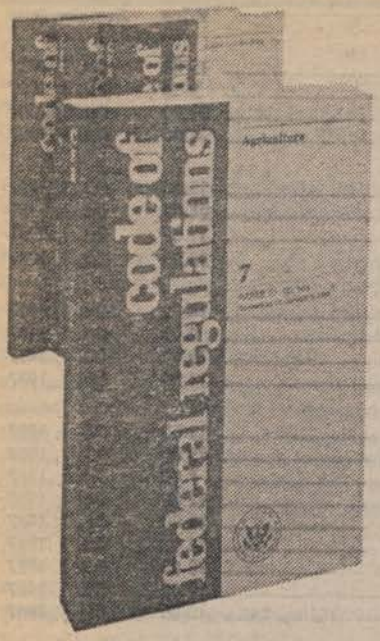
[2] No amendments to this volume were promulgated during the period Jan. 1, 1987 to Dec. 31, 1987. The CFR volume issued January 1, 1987, should be retained.

[3] No amendments to this volume were promulgated during the period Apr. 1, 1980 to March 31, 1988. The CFR volume issued as of Apr. 1, 1980, should be retained.

[4] The July 1, 1985 edition of 32 CFR Parts 1-189 contains a note only for Parts 1-39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1-39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[5] No amendments to this volume were promulgated during the period July 1, 1986 to June 30, 1988. The CFR volume issued as of July 1, 1986, should be retained.

[6] The July 1, 1985 edition of 41 CFR Chapters 1-100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.



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