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AUSTIN, TX

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Contents

Federal Register

Vol. 61, No. 233

Tuesday, December 3, 1996

Separate Parts In This Issue

Reader Aids
Additional information, including a list of public laws, telephone numbers, reminders, and finding aids, appears in the Reader Aids section at the end of this issue.

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CFR PARTS AFFECTED IN THIS ISSUE

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Rules and Regulations

Federal Register
Vol. 61, No. 233
Tuesday, December 3, 1996

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 543, 544, 545, 552, 556, and 575

[No. 96–112]

RIN 1550–AA87

Corporate Governance

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS or Office) is today issuing a final rule amending its corporate governance regulations and policy statements to update, reorganize and substantially streamline them.

This final rule follows a detailed review of each pertinent regulation and policy statement in the Code of Federal Regulations (CFR) to determine whether it is necessary, imposes the least possible burden consistent with safety and soundness, and is written in a clear and straightforward manner. Today's final rule is issued pursuant to the Regulatory Reinvention Initiative of the Vice President's National Performance Review (Reinvention Initiative) and section 303 of the Riegle Community Development and Regulatory Improvement Act of 1994 (CDRIA) which requires OTS and the other Federal banking agencies to review, streamline, and modify regulations and policies to improve efficiency, reduce unnecessary costs, and remove inconsistent, outmoded, and duplicative requirements.

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT: David Permut, Counsel (Banking and Finance), Business Transactions Division, (202) 906–7505; or Mary Jo Johnson, Project Manager, Supervision Policy (202) 906–5739; or Valerie J. Lithotomos, Counsel (Banking and Finance), Regulations and Legislation Division, (202) 906–6439, Chief Counsel's Office, 1700 G Street NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

In a comprehensive review of its regulations, beginning in the spring of 1995, pursuant to the Vice President's Reinvention Initiative and section 303 of CDRIA,[1] OTS identified numerous obsolete or redundant regulations that could quickly be repealed. On December 27, 1995, OTS published a final rule in the Federal Register repealing eight percent of its regulations.[2] As part of its review, OTS also identified several key areas in its regulations for a more intensive, systematic regulatory burden review. Certain areas—lending and investment authority, corporate governance, subsidiaries and equity investments, and conflicts of interest, corporate opportunity and hazard insurance—were chosen for intensive review because they are vital to the thrift industry, had not been developed on an interagency basis,[3] and had not been substantially reviewed or amended in recent years.

Earlier this year, OTS proposed a comprehensive streamlining of its lending and investment regulations[4] and, subsequently, OTS published a final lending and investment rule on September 30, 1996.[5] Proposals regarding subsidiaries and equity investments[6] and conflicts of interest, corporate opportunity and hazard insurance[7] were also issued this summer. The final rule regarding conflicts of interest, corporate opportunity and hazard insurance was published in the Federal Register on November 27, 1996. The final rule regarding subsidiaries and equity investments is imminent.

On June 25, 1996, OTS also issued a notice of proposed rulemaking to streamline its charter and bylaw regulations (corporate governance).[8] The proposal resulted from an intensive review by OTS staff. OTS also sought industry input regarding staff's initial recommendations through an industry focus group meeting among representatives of seven savings associations and an industry trade association.

Today's final rule is quite similar to the proposal. It reduces the number of charter and bylaw regulations and policy statements from 33 to 21, a reduction of 36 percent. In addition, deletion of the model bylaws from the CFR will remove 10 pages of CFR text. This information will be moved to the Application Processing Regulatory Handbook (Handbook) as guidance. The Handbook is sent to all OTS regulated institutions and is available to the public. The model bylaws will also be available through PUBLIFAX at (202) 906–5660 and from fee service providers on CD Rom.

The general tenor of the changes being made today can be summarized in three points. First, we are removing a number of duplicative or outdated corporate governance regulations. By clearing out the deadwood, OTS hopes to reduce compliance costs. Second, we are updating the regulations to reflect modern trends toward greater flexibility in corporate governance. Third, we are adding clarifying language to various regulations to respond to frequently recurring corporate governance questions asked by institutions. Taken together, these changes should significantly reduce regulatory burden. This final rule is the first major update of the corporate governance regulations in over a decade.[9]

[1] 12 U.S.C. 4803(a)(1).

[2] 60 FR 66866 (December 27, 1995).

[3] Interagency regulations are being reviewed through the Federal Financial Institutions Examination Counsel.

[4] 61 FR 1162 (January 17, 1996).

[5] 61 FR 50951 (September 30, 1996).

[6] 61 FR 29976 (June 13, 1996).

[7] 61 FR 30190 (June 14, 1996).

[8] 61 FR 32713 (June 25, 1996).

[9] For an extensive discussion of the history of the current and previous corporate governance regulations, see the discussion in the proposal. 61 FR 32713, 32715 (June 25, 1996).

II. Summary of Comments and Description of the Final Rule

A. General Discussion of the Comments

The public comment period on the June 25 proposal closed on August 26, 1996. Seven commenters responded. Three savings associations, one savings and loan holding company on behalf of its affiliated savings associations, one financial institutions trade group, one law firm, and one private citizen submitted comments. The comments were generally favorable. Specific comments addressing various sections are discussed, where appropriate, in the section-by-section analysis below.

B. Section-by-Section Analysis

1. Existing Corporate Governance Sections

a. Part 544—Charter and Bylaws

Section 544.1 Federal Mutual Charter

This section contains the required charter for Federal mutual associations. In its proposed rulemaking, OTS solicited comment on alternative proposals. One option was to move the mutual charter (as well as the charter for stock associations and the model bylaws for both) from the regulations to the Handbook. The other option was to retain the charters (and model bylaws) in the regulations, but update them.

Most commenters responded to this aspect of the proposal. Only one commenter generally supported moving the charters and bylaws to the Handbook. Four commenters expressed concern that moving the charters and model bylaws into the Handbook would remove the opportunity for notice and comment under the Administrative Procedure Act (APA) when changes are made to these documents. One commenter stated that weakening the APA requirements will jeopardize the mutual charter and enhance the possibility of hostile activity against mutuals by takeover interests. One commenter stated that if the OTS believes that reasons of safety and soundness warrant maintaining regulatory requirements over the forms of charters and bylaws, then those requirements should remain in the CFR. After considering these comments, OTS has decided to retain the charters in the CFR and to amend them, as proposed. As for the model bylaws, however, OTS is moving them to the Handbook because the model bylaws are intended to serve only as guidance to institutions. Critical bylaw issues are addressed in the regulations described below. These regulations, rather than the model bylaws, will serve as binding norms. Any institution which adopts the model bylaws will be deemed to comply with the regulations.

The changes to the mutual charter are as follows:

Section 1. Corporate Title. Section 1 establishes the corporate title of the Federal association. The words ''hereby chartered'' are removed as unnecessary verbiage.

Section 2. Office. This section designates the location of the association's home office. The section is being revised to indicate that the street address of the home office need not be stated in the charter. It is sufficient to indicate the city and state where the home office is located.

Section 6. Members. This section identifies the association's members and describes their rights. OTS is streamlining this section by moving the third and fourth sentences to the introductory paragraph of the regulation. These two sentences instruct institutions that wish to adopt the charter, but are currently operating under old charters conferring membership rights on borrowers, to grandfather the membership rights of their existing borrowers.

The sixth sentence of section 6, dealing with proxies, is removed because it also appears in the bylaws. The seventh and eighth sentences, dealing with quorums, is moved to the bylaws because matters regarding member meetings are more fully and appropriately addressed there.

Section 7. Directors. This section provides that a Federal mutual association may have from 5 to 15 directors. To further streamline the charter, bracketed references to ''trustees'' are removed, and a single sentence is added to the introductory instructions indicating that institutions may substitute the term ''trustee'' for the term ''director'' where appropriate. Similar changes are made throughout the charter (and the model bylaws) for mutual associations.

The third and fifth sentences (providing that directors shall be members of the association and addressing staggered terms for directors) are moved to the bylaw section dealing with directors. The fourth sentence (regarding vacancies on the board) is moved to the bylaw section on resignations, removals and (newly added) vacancies. The last sentence, in brackets, is also moved to the bylaw section on directors. This sentence authorizes state savings banks that convert to Federal mutual associations to grandfather their existing provisions for electing directors for a limited period of time. OTS believes each of these matters is more appropriately addressed in the bylaws, where related issues are already addressed. Presenting related requirements in a single place should make the bylaws more user friendly.

Section 9. Amendment of charter. Section 9 describes the procedures for amending the association's charter. References to §§ 544.2 or 544.3 are removed as unnecessary verbiage. Section 9 is also revised to reflect the fact that ''preapproved'' charter amendments (§ 544.2) will now be truly preapproved. Institutions are no longer required to submit these amendments to OTS for ''preliminary'' approval. (See discussion of § 544.2 below.)

Finally, the signature blocks of the charter are modified to include a date to clarify when a charter is effective.

Section 544.2 Charter amendments

Paragraphs (a) and (b) describe the filing requirements for amending Federal mutual charters. OTS is removing, from paragraphs (a)(2)(i) and (ii), the requirement that institutions certify that amendments they propose are permissible under all applicable laws. This certification is unnecessary because the legality of a proposed amendment is reviewed by OTS staff as part of the application process and its deletion will reduce regulatory burden. In addition, paragraph (b) is revised to indicate that preapproved charter amendments no longer require advance submissions to OTS. Instead, preapproved amendments are now deemed approved when adopted by the institution and must simply be filed with OTS within 30 days after adoption.

A new preapproved charter amendment is added to § 544.2 that authorizes Federal mutual associations to amend their charters to raise the cap on the maximum number of votes any member can cast up to 1,000. Mutual charters generally authorize depositors to cast one vote for every $100 of deposits, subject to a cap that has historically tracked the limit on deposit insurance. Thus, 1,000 votes is the standard cap under the current mutual charter (§ 544.1). However, many institutions operate under charters adopted before the cap was raised to 1,000. Making the 1,000 cap a preapproved amendment enables institutions to update their cap without filing an application and paying an application fee. This is the most frequently requested amendment for Federal mutual associations. One commenter suggested removing the cap entirely, but the OTS has determined that the existing cap has worked well in preventing unauthorized changes of

control of mutual associations. For example, if an institution had no cap on votes, an investor with more than 10% of the deposits in the institution conceivably could exercise control over the institution without regulatory approval. OTS believes it is appropriate for the voting rights of mutuals to be distributed broadly across the membership base.

OTS also is removing from § 544.2 an obsolete preapproved amendment authorizing institutions to issue Mutual Capital Certificates (MCCs). Institutions generally no longer issue MCCs.[10] Elimination of outdated matter such as this should make the regulations less confusing and easier to use.

Paragraph 544.2(c) details the procedures an institution must follow when it wants OTS to reissue its charter to reflect amendments to the charter. The wording of this section is conformed to the wording of the corresponding stock charter section at § 552.4(d). No substantive change results. Paragraph (c) is also amended to remove the delegation of authority to the Chief Counsel to execute reissued charters. This change was proposed as part of a continuing effort to remove delegations from the regulations. Delegated authority to execute reissued charters will be preserved via an internal OTS document.

Section 544.3 Adoption of a New Federal Charter by a Federal Savings Association

This section details the procedures that a Federal mutual savings and loan association would use to amend its charter to read in the form of a Federal mutual savings bank, or vice versa. This section has become obsolete. Today, the charters for both types of institution are identical, except for a possible difference in corporate title. A simple corporate title change can be used to redesignate an institution as a ''savings bank'' or ''savings and loan association.'' Thus, § 544.3 is repealed. Corresponding changes are made to §§ 543.1(b) and 543.14.

Section 544.5 Federal Mutual Savings Association Bylaws

This section describes the requirements for the bylaws of a Federal mutual association. A nonsubstantive change is made to paragraph (a) to conform its language regarding procedures for bylaw amendments to similar language that appears in § 544.5(b)(16).

Paragraph (b)(1) contains the annual meeting requirements for Federal mutual associations. This paragraph is amended to allow meetings not only at the main office, but also at any other convenient place the board of directors may designate, and to permit the association to hold its annual meeting within 150 days of the end of the association's fiscal year. The current requirement is 120 days. Both changes provide additional flexibility for Federal mutual associations.

Paragraph (b)(2) addresses special meetings of members. It provides, *inter alia*, that the holders of ten percent or more of a mutual association's voting capital may call a special meeting. Institutions frequently ask for clarification of the meaning of ''voting capital,'' since the term is no longer defined by the Home Owners' Loan Act (HOLA). As proposed, OTS is clarifying that voting capital means all FDIC-insured deposits held by a savings association. In response to a comment, OTS has also added a phrase to indicate that voting capital will be determined as of the voting record date.

Paragraphs (b)(3) and (4), which discuss notice requirements for meetings of members and the fixing of the record date for determining which members are entitled to vote, respectively, are amended to indicate the circumstances under which adjournment of a meeting of members requires the issuance of new notices and the fixing of a new record date. These are frequently asked questions.

OTS also proposed a new paragraph (b)(5), to be titled ''Member Quorum.'' [11] This paragraph, which is being added as proposed, contains certain quorum provisions previously found in the charter (as discussed above), as well as clarification of what items of business may be considered at a meeting held after adjournment. The agency believes that quorum issues are more appropriately addressed in the bylaws, where other rules governing member meetings already appear. The new paragraph also clarifies, in response to a comment, that the directors are elected by a plurality of votes in an election of directors.

Current paragraph (b)(5), on voting by proxy, is moved to (b)(6) and is amended to permit proxies to be given telephonically or electronically as long as the holder uses a procedure for verifying the identity of the member.[12] Telephonic and electronic proxies enable institutions to gather proxies and conduct corporate business more rapidly and have become an accepted part of corporate democracy. In addition, in response to frequent questions, OTS proposed to describe voting procedures applicable to joint accounts and accounts held by fiduciaries on behalf of others. These procedures will be included in the model bylaws being moved to the Handbook, rather than in the regulations. Moreover, the procedures will be slightly modified, in response to a comment, to clarify that Individual Retirement Accounts and Keogh accounts may be voted by an institution if no other instructions are received. In addition, the procedures governing joint voting of shares will be modified to parallel the provisions of the stock bylaws, also in response to a comment.

Current paragraph (b)(6), which references § 545.131 regarding communication with other members, becomes (b)(7). In addition, the paragraph is amended to reflect the relocation of § 545.131 to Part 544, and to extend the privacy rights now guaranteed to depositors of Federal stock institutions (§ 552.11(d)) to the depositors of Federal mutual institutions. The privacy rights of the members of mutual institutions will not prevent the internal use of member information by those institutions.

Current paragraph (b)(7), regarding the number of directors, becomes (b)(8). In addition, the paragraph is amended to clarify that the bylaws must specify the precise number of directors (rather than a range). This number is chosen by the institution within the range specified in the charter and may be changed by the institution from time to time by amending its bylaws. One commenter requested that the OTS allow a range of directors, as some state codes allow. OTS has determined, however, that specificity is needed in the bylaws to determine quorum requirements. Paragraph (b)(8) also contains three provisions being moved from section seven of the charter. One provision requires that directors be members of their association; a second provision, modified in response to a comment, allows, but does not require that directors serve staggered terms; and a third provision permits state savings banks that convert to Federal mutual

[10] An institution may still choose to issue MCCs, provided the institution makes any necessary amendments to its charter and bylaws (which are no longer preapproved) and follows the procedures specified at 12 CFR 563.74.

[11] All subsequent paragraphs will be renumbered accordingly. However, only those paragraphs being substantively changed are discussed herein.

[12] One example of a verification procedure is for the institution receiving the proxy by facsimile to compare the signature on the proxy to a signature that the institution has on file.

associations to grandfather their method of electing directors for a limited time.

Current paragraph (b)(9), which addresses the duties of officers, employees and agents and their indemnification, becomes (b)(10). In addition, a sentence on the removal of officers is added to answer a frequently asked question. The sentence states: ''Any officer may be removed by the board of directors with or without cause, but such removal, other than for cause, shall be without prejudice to the contractual rights, if any, of the person so removed.''

Current paragraph (b)(10), on the resignation or removal of directors, becomes (b)(11). A cross reference to the definition of ''cause,'' which appears elsewhere in the regulations, is added in response to a frequently asked question concerning the circumstances under which shareholders can remove directors for ''cause.'' Paragraph (b)(11) is also expanded to authorize boards of directors to fill vacancies under the flexible rules that now apply to stock associations.

Current paragraph (b)(12), discussing execution of instruments, is removed in its entirety. OTS has determined that this is not an item that it needs to regulate. For guidance purposes, however, current provisions in the model bylaws on the execution of instruments will remain.

Current paragraph (b)(13), discussing procedures for nominating directors, is expanded to clarify the scope of the requirement that the names of nominees be posted at least 15 days before an election, under certain circumstances. New language confirms that the requirement does not apply to a nominee substituted as a result of death or other incapacity of another nominee. From time to time, institutions have sought clarification on this issue.

Current paragraph (b)(15), discussing the corporate seal, is removed in its entirety. OTS has determined this is not an area it needs to regulate. Current provisions in the model bylaws remain, for guidance purposes.

Current paragraph (b)(16), which sets forth procedures for amending the bylaws, becomes (b)(15) and is amended to make it easier for a board that fails to meet its quorum requirement solely due to vacancies on the board to amend its bylaws. The new language specifies that, in the absence of a quorum due solely to vacancies, the affirmative vote of a majority of the sitting board may amend the bylaws.

Current paragraph (b)(17), on miscellaneous topics, becomes (b)(16) and is amended to remove the reference to provisions regarding ''emergency preparedness.'' Emergency preparedness provisions will also no longer be part of the model bylaws.

Paragraphs (c)(1) and (c)(2) discuss the filing procedures for bylaw amendments. OTS proposed to remove the requirement that applications for bylaw amendments contain certifications that the proposed amendments comport with all laws. As noted above in the discussion on charter amendments, the certification requirement is unnecessary because the legality of proposed amendments are reviewed by OTS staff as part of the application process and its deletion will reduce regulatory burden. Accordingly, the certification requirement is dropped. In addition, paragraph (c)(1) is revised to indicate that the model bylaws can now be found in the Handbook, which is available from OTS. The current appendix to part 544, which contains the model bylaws, is removed. Subsection (c)(1)(ii) has been redesignated as (c)(1)(i)(B) and modified to indicate OTS considers proposed bylaw amendments regarding indemnification, conflicts of interest, and limitations on director or officer liability to raise significant issues of law or policy and, thus, require OTS review. A new subparagraph is added to explain the application process for amendments raising issues of law or policy.

Paragraph (c)(1)(iii) is revised to indicate that the model bylaws, if adopted verbatim, are effective when adopted and must simply be filed with OTS within 30 days after adoption. This change was proposed because OTS has determined that over 90 percent of the bylaws applications filed in recent years are for standard provisions that do not require agency review.

A new paragraph (c)(3) is added to allow mutuals to adopt additional corporate governance procedures to the extent such procedures: (i) Are not inconsistent with the HOLA, applicable Federal statutes and regulations, OTS policies, or safety and soundness; and (ii) do not touch upon certain key areas, such as OTS policies and regulations on indemnification, conflict of interest, limitation of director or officer liability, or other matters of safety and soundness. Subject to these qualifications, this new provision allows Federal mutual associations to designate, *en bloc* or on a piecemeal basis, any of the corporate governance procedures from the laws of the state where the main office of the institution is located.[13] No preapproval is necessary if all provisions in question meet the applicable criteria; instead an institution must submit notice of the provisions it has chosen to the OTS Regional Office within 30 days of adoption. All commenters who addressed this issue were in favor of the more flexible corporate governance structure.

Paragraph (d), which addresses the effective date of all other bylaw amendments (*i.e.*, amendments that are not preapproved or do not meet the standards just described), is amended to comport with a similar provision for Federal stock associations. The change is intended to clarify the circumstances under which an amendment may be rejected by OTS, by cross referencing the standards that appear in paragraph (c)(1).

Section 544.8 References to Old and New Charters; Rules Applicable to Trustees of Federal Mutual Savings Banks

OTS proposed to remove this section, which indicates that trustees will be treated as if they are directors for purposes of the regulations. The same point is made in the introductory instructions to the charter and model bylaws. It does not need to be repeated here. Thus, the section is removed.

Section 544.9 Obsolete Charter Provision for Charter B Associations

This section provides that institutions that still operate under the old Charter B are not bound by section 10 of that charter. Section 10 of Charter B purports to limit the authority of an institution to invest in consumer loans and corporate debt securities. As proposed § 544.9, which affects very few institutions, is moved from the regulations into the Handbook. The authority of Charter B associations to invest in consumer loans and corporate debt securities is governed by current Federal statutory limits, not section 10 of their charter.

Section 544.8 Communication Between Members of a Federal Mutual Savings Association

OTS proposed to move the rules governing communications between members of Federal mutual associations, which now appear in § 545.131, to part 544. This is where users of the regulations would most likely look for guidance on such

[13] We note, however, that silence in a particular area in a state's law may not, for these purposes, be construed as authorizing adoption of procedures in that area. It should also be noted that when adopting provisions from any of the alternative sources, a mutual may adopt only provisions of state law specifically intended for mutual institutions and a stock institution may adopt only provisions intended for stock corporations.

matters. Accordingly, current § 545.131 becomes new § 544.8.

Appendix to Part 544

As indicated above, OTS proposed to eliminate the appendix to part 544, which contained the model bylaws. These bylaws are moved to the Handbook, with changes to be made to conform the model bylaws to the amendments to the bylaws regulations described above. The revised Handbook will be available from OTS in the near future, as well as through fee services on CD ROM. The revised model bylaws are already available through PUBLIFAX at (202) 906–5660.

b. Part 552—Incorporation, Organization, and Conversion of Federal Stock Associations

Section 552.2 Corporate Title

OTS proposed to remove this section, which merely reminds institutions that § 543.1 regarding corporate titles for Federal associations applies to Federal stock associations. Section 543.1, as currently written, clearly governs corporate titles for all Federal associations. Accordingly, § 552.2 is removed.

Section 552.2–5 Conversion from Federal Mutual to Federal Stock Charter

This section authorizes Federal mutual associations to convert to Federal stock associations and provides for issuance of a stock charter upon completion of the conversion. These matters are also covered, in greater detail, by OTS conversion regulations. OTS, therefore, proposed to, and does, remove this section.

Section 552.3 Charters for Federal Stock Associations

This section contains the required charter for Federal stock associations. For the reasons stated above in the discussion of § 544.1, OTS has decided not to move the charter into the Handbook. OTS will make the following changes to the Federal stock charter, as proposed:

Section 2. Office. This section designates the location of the association's home office. The section is being revised to indicate that the street address of the home office need not be stated in the charter. It is sufficient to indicate the city and state where the home office is located.

Section 5. Capital stock. Section 5 describes the rules governing the capital stock of a Federal stock association, including the types of stock it may issue, the consideration to be paid, and voting rights. Several changes have been made. First, the section is amended to permit the issuance of ''no par'' stock. The decision whether stock should have a stated par value is a matter of internal corporate governance that raises no supervisory or safety and soundness issues.

Second, the final sentence of the first paragraph is revised to reflect more current accounting terminology. The term ''retained earnings'' is substituted for ''surplus,'' and the phrase ''common stock or paid-in capital accounts'' is substituted for ''stated capital.''

Third, the second paragraph is revised to clarify that a Federal stock association may issue stock to officers, directors, and controlling persons in connection with its initial organization, without a shareholder vote.

Fourth, the second sentence of the third paragraph is revised to clarify that a Federal stock charter may be amended to eliminate cumulative voting.

Section 7. Directors. This section specifies that the number of directors of a stock association shall be fixed in the bylaws and shall not be fewer than five nor more than fifteen. However, provision is made for the Director of OTS to approve a larger or smaller board of directors. OTS has made a technical amendment to this section to specify that approval of a larger or smaller board can be given either by the Director ''or his or her delegate.''

Section 8. Amendment of charter. Section 8 describes the procedure for amending an association's charter. This section is revised to indicate that preapproved charter amendments become effective once they have been approved by the association's board of directors and shareholders, without any need for ''preliminary approval'' or any additional approval from OTS. (*See* discussion below of § 552.4.)

In addition, OTS proposed to clarify the general rule that charter amendments require approval by only a majority of the votes eligible to be cast at a shareholders' meeting. Language is added indicating that this general rule does not apply in those instances where an association's charter specifies that a supermajority vote is required. (*See* discussion of § 552.4 below.)

Finally, the signature blocks of the charter are modified to include a date to indicate when a charter is effective.

Section 552.4 Charter Amendments

Paragraphs (a) and (b) set forth the filing requirements for amendments to Federal stock charters. In paragraph (a), OTS has made the same changes regarding certification requirements as discussed above in connection with the corresponding provisions for mutual associations (§ 544.2(a)). Thus, stock associations are no longer required to certify that proposed amendments comport with all applicable laws.

Paragraph (b) sets forth a list of preapproved charter amendments. OTS has added descriptive titles to each of the preapproved amendments. The titles correspond, when applicable, to the titles of similar preapproved charter provisions for Federal mutual associations. Paragraph (b) is also revised to indicate that preapproved charter amendments are effective when adopted and must simply be filed with OTS within 30 days after adoption.

Paragraph (b)(3), which contains a preapproved amendment for institutions that wish to change from a Federal stock savings and loan association charter to a Federal stock savings bank charter, is removed for the same reasons described above with regard to § 544.3.[14]

Current paragraph (b)(4), which permits changes to the authorized number of shares and the par or stated value of such shares, becomes (b)(3). Additional nonsubstantive changes have been made to clarify the language of this provision.

Current paragraph (b)(5), which permits institutions to modify section 5 of the charter so as to authorize the issuance of preferred stock, becomes (b)(4) and includes the same changes to section 5 of the charter as were discussed above for section 552.3. In addition, the reference to the Resolution Trust Corporation is deleted, because that agency no longer exists.

A new preapproved charter amendment is added, as new paragraph (b)(6), to authorize institutions to prohibit cumulative voting for directors. The standard charter for Federal stock associations provides for cumulative voting for directors. Federal associations frequently apply to amend their charters to prohibit cumulative voting, and OTS routinely approves these applications. Adding this provision to the list of preapproved amendments will save associations that wish to make this change the time and expense of filing an application.

Paragraph (c) states OTS policy on antitakeover provisions in charter amendments. OTS proposed to expand this provision to state the two basic standards OTS uses when reviewing proposed antitakeover amendments. First, the proposed amendment must be consistent with applicable statutes, regulations and OTS policies. Second, such amendments must be adopted by a percentage of the shareholder vote at

[14] Subsequent paragraphs will be renumbered accordingly. However, only those paragraphs being substantively changed are discussed below.

least equal to the highest percentage that would be required to take any action under the antitakeover provision. While several commenters objected to this clarification, OTS notes that these are not new standards; OTS already employs them when reviewing antitakeover amendments. Stating these standards in the regulations will enable institutions to present applications that conform to OTS requirements, thereby saving them time and expense. Accordingly, the proposed changes have been made.

Section 552.5 Bylaws

This section presents the requirements for the bylaws of a Federal stock association. A technical amendment is made to paragraph (a) to confirm that shareholder votes to approve bylaw amendments must occur ''at a legal meeting'' [15] of shareholders.

Paragraph (b) discusses the application and notice procedures applicable to bylaw amendments. This paragraph is amended to remove the requirement that associations certify that bylaw amendments comport with applicable law. Revisions are also made to indicate that the model bylaws, if adopted verbatim, are approved when adopted and must simply be filed with OTS within 30 days after adoption. Paragraph (b) also indicates that the model bylaws will be in the revised Handbook and made available by OTS. Subsection (b)(1)(iii) is also modified, in the same way the corresponding mutual subsection is modified, to indicate to those contemplating bylaw changes, that OTS considers amendments regarding indemnification, conflicts of interest, and limitations on director or officer liability to raise significant issues requiring OTS review. A new subparagraph is added to explain the application process for such issues of law or policy.

A new paragraph (b)(3) is added to allow the adoption of additional corporate governance procedures to the extent such procedures: (i) Are not inconsistent with the Home Owner's Loan Act, applicable Federal statutes and regulations, OTS policies, or safety and soundness concerns; and (ii) do not touch upon certain key areas, such as OTS policies and regulations on indemnification, conflict of interest, limitation of director or officer liability, or other matters of safety and soundness. Subject to these qualifications, this new provision allows Federal stock associations to designate, *en bloc* or on a piecemeal basis, any of the corporate governance procedures from: the laws of the state where the main office of the institution is located; the laws of the state where the institution's holding company, if any, is located; Delaware General Corporation Law; or the Model Business Corporation Act.[16] No preapproval is necessary if all provisions in question meet the applicable criteria; instead an institution must submit to the OTS Regional Office the provisions it has chosen within 30 days of adoption. All commenters who addressed this issue were generally in favor of the more flexible corporate governance structure.

OTS proposed to add a new paragraph (d) confirming that the authority of a Federal stock association to engage in any transaction is determined by the association's charter and bylaws in effect at the time of the transaction. Subsequent amendments do not retroactively affect this determination. A similar regulatory provision is already in effect for Federal mutual associations (§ 544.6). Accordingly, the paragraph is added as proposed.

Section 552.6 Shareholders

This section contains certain corporate governance requirements regarding shareholder meetings. Paragraph (a), which contains rules regarding the time and place of shareholder meetings, is amended in two respects. First, the requirement that shareholder meetings be held in the state of an association's principal place of business is removed. Instead, associations may hold shareholder meetings at any convenient place the board of directors designates. Second, the time frame within which an association must hold its annual shareholders meeting is extended from 120 to 150 days of the end of the association's fiscal year. These are the same changes made for Federal mutual associations (§ 544.5(b)(1)).

Paragraph (b) states the notice requirements for shareholder meetings. This paragraph is amended to waive the shareholder notice requirements for wholly-owned institutions.

Paragraph (d)(1), which addresses access to shareholder lists, is revised to clarify that shareholder lists are available only to shareholders ''of record'' and their agents. In addition, the paragraph is amended to waive its application to wholly-owned institutions.

Paragraph (e), regarding shareholder quorum requirements, is amended to confirm that, whenever a quorum is present, the affirmative vote of the majority of shares entitled to vote at shareholder meetings shall constitute an act of the shareholders, absent a supermajority voting requirement. The amended paragraph also clarifies, in response to a comment, that directors are elected by a plurality of votes in an election of directors.

Paragraph (f), which addresses proxies, is amended in the same manner as the Federal mutual bylaws at § 544.5(b)(6) to allow proxies to be gathered electronically or telephonically. Subparagraph (f)(3), which addresses cumulative voting, is removed, but remains in the model bylaws as guidance for any association that continues to use cumulative voting. In addition, OTS is not adding paragraph (f)(4) as proposed. Instead, the proposed language, which describes voting procedures applicable to stock held by fiduciaries on behalf of others and stock held jointly, will be included in the model bylaws in the Handbook, rather than in the regulations. The language will be modified as described in the corresponding section of the Federal mutual bylaws.

A new paragraph (h) is added confirming that, if an association's bylaws so provide, shareholder action may be taken by unanimous written consent in lieu of a shareholder meeting. At times, this may allow associations to obtain shareholder approval more rapidly and with less expense.

Section 552.6–1 Board of Directors

This section addresses corporate governance matters involving directors. Paragraph (a) is amended to provide that directors need not be stockholders unless the bylaws so require.

Paragraph (b) sets forth the number and term of directors. This paragraph is amended to clarify that the bylaws of a Federal stock association must specify an exact number of positions on an association's board of directors, not simply a range. The rationale for this position is explained in the corresponding section for Federal mutual associations. The number is selected by the institution within a range prescribed in the charter. OTS also proposed to amend paragraph (b) to exempt wholly-owned stock associations from the requirement that their directors be elected to staggered terms. In response to a comment, OTS

[15] A ''legal meeting'' means a duly constituted meeting of the institution.

[16] We note, however, that silence in a particular area in a state's law or in the Model Business Corporation Act may not, for these purposes, be construed as authorizing adoption of procedures in that area. It should also be noted that when adopting provisions from any of the alternative sources, a stock institution may adopt only provisions state law intended for stock institutions and a mutual institution may adopt only provisions intended for a mutual corporation.

has decided to allow any association to elect not to have a staggered board.

Paragraph (c), regarding regular meetings of the board, is expanded to confirm that the board of directors has authority to determine the place, frequency, time, and notice procedures for its meetings. These matters need not be specified in the bylaws.

Paragraph (e), which covers director vacancies, is amended to clarify that a director appointed to fill a vacancy may serve ''only'' until the next election of directors. This is not a substantive change. The word ''only'' is being added for emphasis and clarity.

Paragraph (f), concerning removal of directors, is retitled ''Resignation or removal of directors'' to conform to the title for the same provision for Federal mutual associations. In addition, the paragraph is amended to confirm, as is already the case, that shareholders may remove a director in the midst of his or her term ''only'' for cause. A cross reference to the existing regulatory definition of ''cause'' is added to answer a frequently asked question.

Paragraph (k), on age limitations for directors, is revised to indicate that any age limitation provision must conform to applicable Federal law, rules, or regulations. These rules would include laws such as the Age Discrimination in Employment Act and the Employee Retirement Income Security Act (ERISA).

Section 552.6–2 Officers

This section addresses corporate governance matters involving officers. Paragraph (a) is amended to remove the requirement that the president always be a director and that either the president or the chair of the board of directors always be the chief executive officer.

Paragraph (c), on age limitations for officers, is revised to indicate that any age limitation on service by officers must conform to applicable Federal law, rules, or regulations.

Section 552.8 Savings Deposits

This section contains instructions to Federal stock associations regarding the types of savings deposits they may accept, preservation of those accounts when a former mutual association adopts a stock charter, rights of account holders in the event of liquidation, and forms of certificates to use for accounts. OTS proposed to remove this section from the regulations. The provisions of this section are either self-evident or addressed by other statutes and regulations and general contract law. Under the conversion regulations, all converting mutual institutions are required to notify their accountholders that all the rights they enjoyed as accountholders, except voting and ownership of the institution, carry over to the converting association. Accordingly, § 522.8 is removed as proposed.

Section 552.11 Books and Records

This section describes a Federal stock association's obligations with respect to books and records. Paragraph (b) is amended to make clear that shareholders' inspection rights extend only to nonconfidential portions of an institution's books and records.

Appendix to Part 552

As indicated above, OTS has moved the model bylaws for Federal stock associations, which currently appear in the appendix to Part 552, into the Handbook. Changes will be made to conform the model bylaws to the amendments to the bylaw regulations described above. In addition, OTS proposed to modify the model bylaws to indicate that procedures other than Robert's Rules of Order may be used for shareholder meetings, as long as the board of directors adopts alternative written procedures. This change will also be made. As indicated above, a revised Handbook will be available from OTS. The revised model bylaws are already available through PUBLIFAX at (202) 906–5660.

c. Part 575—Mutual Holding Companies

Section 575.9 Charters and Bylaws for Mutual Holding Companies and Their Savings Association Subsidiaries

This section describes the required charter and bylaws for Federal mutual holding companies. Paragraph (a)(1) contains the prescribed charter. The following changes are made to the charter:

Section 1. Corporate Title. Section 1 contains the corporate title of the Federal mutual holding company. The words ''hereby chartered'' are deleted as unnecessary verbiage.

Section 5. Members. This section identifies the mutual holding company's members and defines their rights. The sixth, seventh, and eighth sentences of this section, addressing proxies and quorums, are removed because these matters are now covered by the bylaw requirements applicable to mutual holding companies. As a result of this change, proxy and quorum issues are now addressed in a single place in the corporate documents of mutual holding companies.

Section 6. Directors. This section provides that a Federal mutual holding company may have from 5 to 15 directors. In addition, OTS has made technical changes to conform the wording of this section to the corresponding section of the charter for Federal mutual associations.

Section 8. Amendment of charter. Section 8 describes the procedures for amending the mutual holding company's charter. These procedures are modified to indicate that preapproved charter amendments are effective once approved by members of the mutual holding company. Other amendments will continue to require advance OTS approval.

Paragraph (a)(2) of § 575.9 provides that mutual holding companies may adopt the same preapproved charter amendments as are specified for mutual savings associations, subject to certain specified exclusions. Paragraph (a)(2) is updated to conform to the changes proposed for the list of preapproved charter amendments for mutual associations.

Paragraph (a)(4) specifies that Federal mutual holding companies shall be subject to the same rules regarding bylaws as apply to Federal mutual associations, with certain exceptions. This paragraph is amended to indicate that the model bylaws may be found in a revised Handbook to be made available from OTS.

A technical amendment is made to paragraph (a)(5), which requires mutual holding companies to make their charter and bylaws available to members. The cross reference to § 545.131 is changed to reflect the movement of this section to Part 544.

d. Miscellaneous Technical Changes

Section 543.1(b) Title Change

This section prescribes the rules for corporate titles for Federal savings associations. This section is amended to delete cross references to sections being removed by this final rule.

Section 543.14 Continuity of Existence

This section, which confirms that the corporate existence of converting associations continues, notwithstanding the conversion, is amended to delete a cross reference to a section being removed by this final rule.

Section 556.1 Directors

This policy statement, which describes OTS policy on the number of directors necessary for a quorum and the directors' power to fill vacancies, is removed because both subjects are thoroughly covered by the bylaw regulations.

Section 556.17 Effect of Loan Participation on Status of Borrowing Members

This policy statement provides guidance regarding various issues that arise when determining the identity of the borrowing members of a Federal mutual savings association. For example, this section indicates that sale of a whole loan by a savings association to a third party terminates the borrower's membership rights in the association. As proposed, this policy statement is moved from the regulations into Handbook guidance. One commenter requested clarification on borrower membership if a loan is sold when the servicing rights are retained by the selling association. Retention of servicing rights, without more, will not cause the loan to be deemed to be owned by the selling association. Thus, such borrowers would not have voting or ownership rights in the selling association.

III. Disposition of Corporate Governance Regulations

The following chart gives an overview of the changes made to OTS's corporate governance regulations.

Original provision	Comment
§ 543.1(b)	Amended to delete references.
§ 543.14	Amended to delete references.
§ 544.1	Amended.
§ 544.1, Section 2	Revised for clarification
§ 544.1, Section 6	Moved portion to § 544.5 for clarification.
§ 544.1, Section 7	Moved portion to § 544.5 for clarification.
§ 544.1, Section 9	Removed need for preliminary approval.
§ 544.2(a)(2)	Eliminated need for management certification.
§ 544.2(b)	Eliminated need for prior notice requirement.
§ 544.2(b)(4)	Removed existing paragraph and added new preapproved amendment raising the cap to 1,000 votes.
§ 544.2(c)	Removed delegation.
§ 544.3	Removed.
§ 544.5(a)	Revised for clarification.
§ 544.5(b) (1) and (2)	Amended for flexibility; changed annual meeting date.
§ 544.5(b) (3) and (4)	Adjournment provisions added.
New § 544.5(b)(5)	Added new paragraph on member quorum and clarified.
§ 544.5(b) (5) through (11).	Redesignated (b) (6) to (12).
§ 544.5(b)(6)	Amended to add privacy rights.
§ 544.5(b)(7)	Amended for clarification.
§ 544.5(b)(9)	Amended.
§ 544.5(b)(10)	Amended to add guidance on vacancies.
§ 544.5(b)(12)	Removed.
§ 544.5(b)(13)	Amended to add guidance on nominee substitution.
§ 544.5(b)(15)	Removed.
§ 544.5(b)(16)	Revised for clarification.
§ 544.5(b)(17)	Amended to delete emergency preparedness.
§ 544.5(c)	Eliminated need for management certification.
§ 544.5(c)(1)(ii)	New paragraph added to explain application process.
§ 544.5(c)(1)(iii)	Eliminated need for prior notice requirement.
§ 544.5(c)(3)	New paragraph to provide alternative corporate governance procedures.
§ 544.5(d)	Reduced filing requirement.
§ 544.8	Removed.
§ 544.9	Removed.
Part 544 Appendix	Conformed to proposed changes and moved to Handbook.
§ 545.131	Moved to Part 544.
§ 552.1	Removed.
§ 552.2	Removed.
§ 552.2–5	Removed.
§ 552.3	Amended.
§ 552.3, Section 2	Revised for clarity.
§ 552.3, Section 8	Removed need for preliminary approval.
§ 552.4(a)(2)	Eliminated need for management certification.
§ 552.4(b)	Eliminated need for prior notice requirement.
§ 552.4(b)(3)	Removed.
§ 552.4(b) (4) through (6).	Redesignated (b) (3) to (5).
New § 552.4(b)(6)	Added new preapproved amendment.
§ 552.4(c)	Amended for clarification.
§ 552.5(b)	Eliminated need for management certification.
§ 552.5(b)(1)(ii)	New paragraph added to explain application process.
§ 552.5(b)(1)(iii)	Eliminated need for prior notice requirement.
§ 552.5(b)(3)	New paragraph to provide alternative corporate governance procedures.
§ 552.5(d)	Added new paragraph for clarification.
§ 552.6(a)	Amended for flexibility; changed annual meeting date.
§ 552.6(b)	Amended shareholder meeting requirements.
§ 552.6(d)	Amended for clarification.
§ 552.6(e)	Amended to add guidance on certain voting requirements.
§ 552.6(f)(1)	Amended for flexibility.
§ 552.6(f)(3)	Removed.
New § 552.6(h)	Added section on informal action.
§ 552.6–1(a)	Amended for flexibility.
§ 552.6–1(b)	Removed necessity for staggered board of directors. Also amended to specify number of directors.
§ 552.6–1(f)	Amended to clarify where ''cause'' is defined.
§ 552.6–1(k)	Amended to add guidance.
§ 552.6–2(a)	Amended to remove provision requiring president to be a director.
§ 552.8	Removed.
§ 552.11(b)	Amended for clarification.
Part 552 Appendix	Conformed to proposed changes and moved to Handbook.
§ 556.1	Removed.
§ 556.17	Moved to Handbook.
§ 575.9	Amended.
§ 575.9 Section 8	Removed need for preliminary approval.
§ 575.9 (a)(2) and (a)(4).	Amended.

IV. Administrative Procedure Act

This final rule results from the notice of proposed rulemaking OTS published on June 25, 1996. In addition to the regulatory language proposed in that notice, OTS is today deleting several bylaw regulations previously located in Part 544 and Part 552, as described

above. Pursuant to section 553(b) of the Administrative Procedure Act, OTS hereby finds that good cause exists not to publish the deletions for public notice and comment. The bylaw regulations deleted by this final rule are either unnecessary or are deleted as a result of moving the model bylaws into the Handbook. Also, deleting these regulations reduces regulatory burden. Thus, notice and opportunity to comment are unnecessary.

V. Paperwork Reduction Act of 1995

The reporting requirements contained in this final rule have been submitted to and approved by the Office of Management and Budget under OMB Control Nos. 1550–0017 and 1550–0018, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Paperwork Reduction Project (1550), Washington, DC 20503, with copies to OTS, 1700 G Street, NW., Washington, DC 20552.

Respondents are not required to respond to the foregoing collection of information unless it displays a currently valid OMB control number.

VI. Executive Order 12866

The Director of OTS has determined that this final rule does not constitute a ''significant regulatory action'' for the purposes of Executive Order 12866.

VII. Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, OTS certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The final rule does not impose additional burdens or requirements upon small entities and lowers several paperwork and other burdens on all savings associations.

VIII. Unfunded Mandates Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act), requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, Section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. As discussed in this preamble and the preamble of the proposal, this final rule reduces regulatory burden and updates, reorganizes and substantially streamlines corporate governance regulations and policy statements. OTS has determined that the final rule will not result in expenditures by state, local, or tribal governments or by the private sector of $100 million or more. Accordingly, a budgetary impact statement is not required under section 202 of the Unfunded Mandates Act of 1995.

IX. Effective Date

Two statutes affect the effective date of OTS regulations. Section 302 of CDRIA delays the effective date of regulations promulgated by the Federal banking agencies that impose additional reporting, disclosure, or new requirements to the first day of the first calendar quarter following publication of the final rule. CDRIA does not apply to this final rule because it imposes no new burden. It reduces regulatory burden in the corporate governance area and provides additional flexibility to both stock and mutual institutions. The second statute, the Administrative Procedure Act[17] (APA), generally requires a 30-day delay in effective date for final rules. The APA provides that an agency may waive this delay where a regulation relieves regulatory restrictions. Here, because this rule reduces regulatory burden, the OTS believes there is good cause to waive the normal 30-day delay of effective date. This will make the effective date of this final rule the first day of the first calendar quarter following publication of the final rule.

List of Subjects

12 CFR Parts 543 and 544

Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 545

Accounting, Consumer protection, Credit, Electronic Funds transfers, Investments, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 552

Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 556

Savings associations.

12 CFR Part 575

Administrative practice and procedure, Capital, Holding companies, Reporting and recordkeeping requirements, Savings associations, Securities.

Accordingly, the Office of Thrift Supervision amends chapter V, title 12, Code of Federal Regulations, as set forth below.

[17] 5 U.S.C. 553(d).

PART 543—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL MUTUAL ASSOCIATIONS

1. The authority citation for part 543 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

§ 543.1 [Amended]

2. Section 543.1 is amended in paragraph (b) by removing the phrase ''only pursuant to a charter change under § 544.3 or § 552.4 of this chapter''.

§ 543.14 [Amended]

3. Section 543.14 is amended by removing the phrase ''or under § 544.3 of this chapter''.

PART 544—CHARTER AND BYLAWS

4. The authority citation for part 544 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

5. Section 544.1 is amended by revising the introductory text, and sections 1, 2, 6, 7 and 9 and the signature blocks at the end of the charter to read as follows:

§ 544.1 Federal mutual charter.

A Federal mutual savings association shall have a charter in the following form, which may include any of the additional provisions set forth in § 544.2 of this Part, if such provisions are specifically requested. A charter for a Federal mutual savings bank shall substitute the term ''savings bank'' for ''association.'' The term ''trustee'' may be substituted for the term ''director.'' Associations adopting this charter with existing borrower members must grandfather those borrower members who were members as of the date of issuance of the new charter by the Office. Such borrowers shall have one vote for the period of time such borrowings are in existence.

Federal Mutual Charter

Section 1. Corporate title. The full corporate title of the Federal savings association is _____.

Section 2. Office. The home office shall be located in _____ [city, state].

* * * * *

Section 6. Members. All holders of the association's savings, demand, or other authorized accounts are members of the association. In the consideration of all

questions requiring action by the members of the association, each holder of an account shall be permitted to cast one vote for each $100, or fraction thereof, of the withdrawal value of the member's account. No member, however, shall cast more than 1000 votes. All accounts shall be nonassessable.

Section 7. Directors. The association shall be under the direction of a board of directors. The authorized number of directors shall not be fewer than five nor more than fifteen persons, as fixed in the association's bylaws, except that the number of directors may be decreased to a number less than five or increased to a number greater than fifteen with the prior approval of the Director of the Office or his or her delegate.

* * * * *

Section 9. Amendment of charter. Adoption of any preapproved charter amendment shall be effective after such preapproved amendment has been approved by the members at a legal meeting. Any other amendment, addition, change, or repeal of this charter must be approved by the Office prior to approval by the members at a legal meeting, and shall be effective upon filing with the Office in accordance with regulatory procedures.

Attest: _____
Secretary of the Association

By: _____
President or Chief Executive Officer of the Association

Attest: _____
Secretary of the Office of Thrift Supervision

By: _____
Director of the Office of Thrift Supervision

Effective Date: _____

6. Section 544.2 is amended by revising paragraph (a)(2), the third sentence of the introductory text to paragraph (b), paragraph (b)(4), and paragraph (c) to read as follows:

§ 544.2 Charter amendments.

(a) * * *

(2) *Form of filing*—(i) *Application requirement.* If the proposed charter amendment would: render more difficult or discourage a merger, proxy contest, the assumption of control by a mutual account holder of the association, or the removal of incumbent management; or involve a significant issue of law or policy; then, the association shall file the proposed amendment and obtain the prior approval of the OTS.

(ii) *Notice requirement.* If the proposed charter amendment does not involve a provision that would be covered by paragraph (a)(2)(i) of this section and is permissible under all applicable laws, rules and regulations, then the association shall submit the proposed amendment to the OTS, at least 30 days prior to the effective date of the proposed charter amendment.

(b) * * * In addition, notwithstanding anything in paragraph (a) of this section to the contrary, the following charter amendments, including the adoption of the Federal mutual charter as set forth in § 544.1 of this part, shall be effective and deemed approved at the time of adoption, if adopted without change and filed with OTS, within 30 days after adoption, provided the association follows the requirements of its charter in adopting such amendments:

* * * * *

(4) *Maximum number of votes.* A Federal mutual savings association may amend its charter by substituting _____ votes per member in section 6. [Fill in a number from 50 to 1000.]

(c) *Reissuance of charter.* A Federal mutual savings association that has amended its charter may apply to have its charter, including the amendments, reissued by the Office. Such request for reissuance should be filed in accordance with § 516.1(c) of this chapter and, contain signatures required under § 544.1 of this part, together with such supporting documents as may be needed to demonstrate that the amendments were properly adopted.

§ 544.3 [Removed]

7. Section 544.3 is removed.

8. Section 544.5 is amended by:

a. Revising paragraph (a);

b. Removing the words ''[trustee]'' and ''[trustees]'' wherever they appear in paragraph (b);

c. Revising the second sentence of paragraph (b)(1);

d. Adding a separate new sentence at the end of each of paragraphs (b)(2), (b)(3) and (b)(4);

e. Removing paragraphs (b)(12) and (b)(15);

f. Redesignating paragraphs (b)(5) through (b)(11) as paragraphs (b)(6) through (b)(12), and paragraphs (b)(16) and (b)(17) as paragraphs (b)(15) and (b)(16), respectively;

g. Adding a new paragraph (b)(5);

h. Revising newly designated paragraphs (b)(6), (b)(7), (b)(8) and the second sentence of paragraph (b)(10)(i);

i. Adding a sentence at the end of newly designated paragraph (b)(10)(ii);

j. Revising newly designated paragraph (b)(11), the last sentence of paragraph (b)(13), and newly designated paragraphs (b)(15), and (b)(16);

k. Redesignating paragraphs (c)(1) introductory text, (c)(1)(i) through (c)(1)(iii), and (c)(1) concluding text as paragraphs (c)(1)(i) introductory text, (c)(1)(i)(A) through (c)(1)(i)(C) and (c)(1)(iii), respectively, adding a new paragraph (c)(1)(ii), revising newly designated paragraph (c)(1)(i) introductory text, revising newly designated paragraph (c)(1)(i)(B), and by revising newly designated paragraph (c)(1)(iii); and

l. Revising paragraph (c)(2), adding a new paragraph (c)(3), and revising the last sentence of paragraph (d).

The additions and revisions read as follows:

§ 544.5 Federal mutual savings association bylaws.

(a) *General.* A Federal mutual savings association shall operate under bylaws that contain provisions that comply with all requirements specified by the OTS in this section and that are not otherwise inconsistent with the provisions of this section, the association's charter, and all other applicable laws, rules, and regulations *provided that,* a bylaw provision inconsistent with the provisions of this section may be adopted with the approval of the OTS. Bylaws may be adopted, amended or repealed by a majority of the votes cast by the members at a legal meeting or a majority of the association's board of directors. The bylaws for a Federal mutual savings bank shall substitute the term ''savings bank'' for ''association''. The term ''trustee'' shall be substituted for the term ''director''.

(b) * * *

(1) * * * Such meeting shall be held, as designated by its board of directors, at a location within the state that constitutes the principal place of business of the association, or at any other convenient place the board of directors may designate, and at a date and time within 150 days after the end of the association's fiscal year. * * *

(2) * * * For purposes of this section, ''voting capital'' means FDIC-insured deposits as of the voting record date.

(3) * * * When any meeting is adjourned for 30 days or more, notice of the adjournment and reconvening of the meeting shall be given as in the case of the original meeting.

(4) * * * The same determination shall apply to any adjourned meeting.

(5) *Member quorum.* Any number of members present and voting, represented in person or by proxy, at a regular or special meeting of the members shall constitute a quorum. A majority of all votes cast at any meeting of the members shall determine any question, unless otherwise required by regulation. At any adjourned meeting, any business may be transacted that might have been transacted at the meeting as originally called. Members present at a duly constituted meeting may continue to transact business until adjournment.

(6) *Voting by proxy.* Procedures shall be established for voting at any annual or special meeting of the members by proxy pursuant to the rules and regulations of the Office, including the placing of such proxies on file with the secretary of the association, for verification, prior to the convening of such meeting. Proxies may be given telephonically or electronically as long as the holder uses a procedure for verifying the identity of the member. All proxies with a term greater than eleven months or solicited at the expense of the association must run to the board of directors as a whole, or to a committee appointed by a majority of such board.

(7) *Communications between members.* Provisions relating to communications between members shall be consistent with § 544.8 of this part. No member, however, shall have the right to inspect or copy any portion of any books or records of a Federal mutual savings association containing:

(i) A list of depositors in or borrowers from such association;

(ii) Their addresses;

(iii) Individual deposit or loan balances or records; or

(iv) Any data from which such information could be reasonably constructed.

(8) *Number of directors, membership.* The bylaws shall set forth a specific number of directors, not a range. The number of directors shall be not fewer than five nor more than fifteen, unless a higher or lower number has been authorized by the Director of the Office or his or her designee. Each director of the association shall be a member of the association. Directors may be elected for periods of one to three years and until their successors are elected and qualified, but if a staggered board is chosen, provision shall be made for the election of approximately one-third or one-half of the board each year, as appropriate. State-chartered savings banks converting to Federal savings banks may include alternative provisions for the election and term of office of directors so long as such provisions are authorized by the Office, and provide for compliance with the standard provisions of this section no later than six years after the conversion to a Federal savings association.

* * * * *

(10) *Officers, employees, and agents.* (i) * * * The officers of the association shall consist of a president, one or more vice presidents, a secretary, and a treasurer or comptroller, each of whom shall be elected annually by the board of directors. * * *

(ii) * * * Any officer may be removed by the board of directors with or without cause, but such removal, other than for cause, shall be without prejudice to the contractual rights, if any, of the person so removed.

* * * * *

(11) *Vacancies, resignation or removal of directors.* Members of the association shall elect directors by ballot: Provided, that in the event of a vacancy on the board, the board of directors may, by their affirmative vote, fill such vacancy, even if the remaining directors constitute less than a quorum. A director elected to fill a vacancy shall be elected to serve only until the next election of directors by the members. The bylaws shall set out the procedure for the resignation of a director, which shall be by written notice or by any other procedure established in the bylaws. Directors may be removed only for cause as defined in § 563.39 of this chapter, by a vote of the holders of a majority of the shares then entitled to vote at an election of directors.

* * * * *

(13) * * * However, if such provision is made for prior submission of nominations by a member, then the bylaws must provide for a nominating committee, which, except in the case of a nominee substituted as a result of death or other incapacity, must submit nominations to the secretary and have such nominations similarly posted at least 15 days prior to the date of the annual meeting.

* * * * *

(15) *Amendment.* Bylaws may include any provision for their amendment that would be consistent with applicable law, rules, and regulations and adequately addresses its subject and purpose.

(i) Amendments shall be effective:

(A) After approval by a majority vote of the authorized board, or by a majority of the vote cast by the members of the association at a legal meeting; and

(B) After receipt of any applicable regulatory approval.

(ii) When an association fails to meet its quorum requirement, solely due to vacancies on the board, the bylaws may be amended by an affirmative vote of a majority of the sitting board.

(16) *Miscellaneous.* The bylaws may also address the subject of age limitations for directors or officers as long as they are consistent with applicable Federal law, rules or regulations, and any other subjects necessary or appropriate for effective operation of the association.

(c) *Form of filing*—(1) *Application requirement.* (i) Any bylaw amendment shall be submitted to the OTS if it would:

* * * * *

(B) Involve a significant issue of law or policy, including indemnification, conflicts of interest, and limitations on director or officer liability; or

* * * * *

(ii) Applications submitted under paragraph (c)(1)(i) of this section shall be subject to the applications processing procedures set forth at § 516.2 of this chapter.

(iii) For purposes of this paragraph (c), bylaw provisions that adopt the language of the model bylaws set forth in OTS's Application Processing Handbook, if adopted without change, and filed within 30 days after adoption, are effective upon adoption.

(2) *Filing requirement.* If the proposed bylaw amendment does not involve a provision that would be covered by paragraph (c)(1) or (c)(3) of this section, then the association shall submit the amendment to the OTS at least 30 days prior to the date the bylaw amendment is to be adopted by the association.

(3) *Corporate governance procedures.* A Federal mutual association may elect to follow the corporate governance procedures of the laws of the state where the main office of the institution is located, provided that such procedures may be elected only to the extent not inconsistent with applicable Federal statutes, regulations, and safety and soundness, and such procedures are not of the type described in paragraph (c)(1) of this section. If this election is selected, a Federal mutual association shall designate in its bylaws the provision or provisions from the body of law selected for its corporate governance procedures, and shall file a copy of such bylaws, which are effective upon adoption, within 30 days after adoption. The submission shall indicate, where not obvious, why the bylaw provisions meet the requirements stated in paragraph (c)(1) of this section.

(d) *Effectiveness.* * * * This automatic effective date does not apply if, prior to the expiration of such 30-day period, the OTS notifies the association that such amendment is rejected or that such amendment requires an application to be filed pursuant to paragraph (c)(1) of this section.

§§ 544.8–544.9 [Removed]

9. Sections 544.8 and 544.9 are removed.

Appendix to Part 544 [Removed]

10. The Appendix to Part 544 is removed.

PART 545—OPERATIONS

11. The authority citation for part 545 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1828.

§ 545.131 [Redesignated as § 544.8]

12. Section 545.131 is redesignated as § 544.8.

PART 552—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL STOCK ASSOCIATIONS

13. The authority citation for part 552 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

§§ 552.1–552.2 [Removed]

14. Sections 552.1 and 552.2 are removed.

§ 552.2–5 [Removed]

15. Section 552.2–5 is removed.

16. Section 552.3 is amended in the Federal Stock Charter by:

a. revising Section 2;

b. revising, in Section 5, the first and last sentences in the first paragraph, the second paragraph, and the second sentence of the third paragraph;

c. revising Section 7;

d. revising Section 8;

e. revising the signature blocks at the end of the charter.

The revisions read as follows:

§ 552.3 Charters for Federal stock associations.

* * * * *

Federal Stock Charter

* * * * *

Section 2. Office. The home office shall be located in _____ [city, state].

* * * * *

Section 5. Capital stock. The total number of shares of all classes of the capital stock that the association has the authority to issue is _____, all of which shall be common stock of par [or if no par is specified then shares shall have a stated] value of _____ per share. * * * In the case of a stock dividend, that part of the retained earnings of the association that is transferred to common stock or paid-in capital accounts upon the issuance of shares as a stock dividend shall be deemed to be the consideration for their issuance.

Except for shares issued in the initial organization of the association or in connection with the conversion of the association from the mutual to stock form of capitalization, no shares of capital stock (including shares issuable upon conversion, exchange, or exercise of other securities) shall be issued, directly or indirectly, to officers, directors, or controlling persons of the association other than as part of a general public offering or as qualifying shares to a director, unless the issuance or the plan under which they would be issued has been approved by a majority of the total votes eligible to be cast at a legal meeting.

* * * Each holder of shares of common stock shall be entitled to one vote for each share held by such holder, except as to the cumulation of votes for the election of directors, unless the charter provides that there shall be no such cumulative voting.

* * *

* * * * *

Section 7. Directors. The association shall be under the direction of a board of directors. The authorized number of directors, as stated in the association's bylaws, shall not be fewer than five nor more than fifteen except when a greater or lesser number is approved by the Director of the Office, or his or her delegate.

Section 8. Amendment of charter. Except as provided in Section 5, no amendment, addition, alteration, change or repeal of this charter shall be made, unless such is proposed by the board of directors of the association, approved by the shareholders by a majority of the votes eligible to be cast at a legal meeting, unless a higher vote is otherwise required, and approved or preapproved by the Office.

Attest: _____
Secretary of the Association

By: _____
President or Chief Executive Officer of the Association

Attest: _____
Secretary of the Office of Thrift Supervision

By: _____
Director of the Office of Thrift Supervision

Effective Date: _____

17. Section 552.4 is amended by:

a. removing at the end of paragraph (a)(1) the semicolon and the word ''and'', and by adding in lieu thereof a period;

b. revising paragraph (a)(2);

c. revising the last sentence of the introductory text of paragraph (b);

d. adding headings to paragraphs (b)(1) and (b)(2);

e. removing paragraph (b)(3);

f. redesignating paragraph (b)(4) as paragraph (b)(3) and revising it;

g. redesignating paragraph (b)(5) as paragraph (b)(4) and revising the introductory text;

h. revising the first and last sentences of the first paragraph in Section 5 of newly designated paragraph (b)(4);

i. revising the first sentence of the second paragraph in Section 5 of newly designated paragraph (b)(4);

j. revising the introductory text of the third paragraph in Section 5 of newly designated paragraph (b)(4);

k. amending newly designated paragraph (b)(4) by revising paragraph (ii) of the third paragraph in Section 5;

l. amending newly designated paragraph (b)(4) by revising the last sentence of paragraph A. of the fourth paragraph in Section 5;

m. redesignating paragraph (b)(6) as paragraph (b)(5) and revising it;

n. adding a new paragraph (b)(6);

o. adding a heading to paragraph (b)(8); and

p. revising paragraph (c);

The additions and revisions read as follows:

§ 552.4 Charter amendments.

(a) * * *

(2) *Form of filing*—(i) *Application requirement.* If the proposed charter amendment would render more difficult or discourage a merger, tender offer, or proxy contest, the assumption of control by a holder of a block of the association's stock, the removal of incumbent management, or involve a significant issue of law or policy, the association shall file the proposed amendment and shall obtain the prior approval of the OTS; and

(ii) *Notice requirement.* If the proposed charter amendment does not involve a provision that would be covered by paragraph (a)(2)(i) of this section and such amendment is permissible under all applicable laws, rules or regulations, then the association shall submit the proposed amendments to the OTS, at least 30 days prior to the date the proposed charter amendment is to be mailed for consideration by the association's shareholders.

(b) * * * In addition, the following charter amendments, including the adoption of the Federal stock charter as set forth in § 552.3 of this part, shall be approved at the time of adoption, if adopted without change and filed with OTS within 30 days after adoption, provided the association follows the requirements of its charter in adopting such amendments:

(1) *Title change.* * * *

(2) *Home office.* * * *

(3) *Number of shares of stock and par value.* A Federal stock association may amend Section 5 of its charter to change the number of authorized shares of stock, the number of shares within each class of stock, and the par or stated value of such shares.

(4) *Capital stock.* A Federal stock association may amend its charter by revising Section 5 to read as follows:

Section 5. The total number of shares of all classes of capital stock that the association has the authority to issue is _____, of which _____ shall be common stock of par [or if no par value is specified the stated] value of _____ per share and of which [list the number of each class of preferred and the par or if no par value is specified the stated value per share of each such class]. * * * In the case of a stock dividend, that part of the retained earnings of the association that is transferred to common stock or paid-in capital accounts upon the issuance of shares

as a stock dividend shall be deemed to be the consideration for their issuance.

Except for shares issued in the initial organization of the association or in connection with the conversion of the association from the mutual to the stock form of capitalization, no shares of capital stock (including shares issuable upon conversion, exchange, or exercise of other securities) shall be issued, directly or indirectly, to officers, directors, or controlling persons of the association other than as part of a general public offering or as qualifying shares to a director, unless their issuance or the plan under which they would be issued has been approved by a majority of the total votes eligible to be cast at a legal meeting. * * *

Nothing contained in this section 5 (or in any supplementary sections hereto) shall entitle the holders of any class of a series of capital stock to vote as a separate class or series or to more than one vote per share, except as to the cumulation of votes for the election of directors, unless the charter otherwise provides that there shall be no such cumulative voting: *Provided*, That this restriction on voting separately by class or series shall not apply:

* * * * *

(ii) To any provision that would require the holders of preferred stock, voting as a class or series, to approve the merger or consolidation of the association with another corporation or the sale, lease, or conveyance (other than by mortgage or pledge) of properties or business in exchange for securities of a corporation other than the association if the preferred stock is exchanged for securities of such other corporation: *Provided*, That no provision may require such approval for transactions undertaken with the assistance or pursuant to the direction of the Office or the Federal Deposit Insurance Corporation;

* * * * *

A. *Common stock.* * * * Each holder of shares of the common stock shall be entitled to one vote for each share held by each holder, except as to the cumulation of votes for the election of directors, unless the charter otherwise provides that there shall be no such cumulative voting.

* * * * *

(5) *Limitations on subsequent issuances.* A Federal stock association may amend its charter to require shareholder approval of the issuance or reservation of common stock or securities convertible into common stock under circumstances which would require shareholder approval under the rules of the New York or American Stock Exchange if the shares were then listed on the New York or American Stock Exchange.

(6) *Cumulative voting.* A Federal stock association may amend its charter by substituting the following sentence for the second sentence in the third paragraph of Section 5: ''Each holder of shares of common stock shall be entitled to one vote for each share held by such holder and there shall be no right to cumulate votes in an election of directors.''

* * * * *

(8) *Anti-takeover provisions following mutual to stock conversion.* * * *

(c) *Anti-takeover provisions.* The Office may grant approval to a charter amendment not listed in paragraph (b) of this section regarding the acquisition by any person or persons of its equity securities provided that the association shall file as part of its application for approval an opinion, acceptable to the OTS, of counsel independent from the association that the proposed charter provision would be permitted to be adopted by a corporation chartered by the state in which the principal office of the association is located. Any such provision must be consistent with applicable statutes, regulations, and OTS policies. Further, any such provision that would have the effect of rendering more difficult a change in control of the association and would require for any corporate action (other than the removal of directors) the affirmative vote of a larger percentage of shareholders than is required by this Part, shall not be effective unless adopted by a percentage of shareholder vote at least equal to the highest percentage that would be required to take any action under such provision.

* * * * *

18. Section 552.5 is amended by:

a. revising the second sentence of paragraph (a);

b. redesignating paragraphs (b)(1) introductory text, (b)(1)(i), (b)(1)(ii), and (b)(1) concluding text as paragraphs (b)(1)(i) introductory text, (b)(1)(i)(A), (b)(1)(i)(B), and (b)(1)(iii), respectively, adding a new paragraph (b)(1)(ii), and by revising newly designated paragraphs (b)(1)(i) introductory text, (b)(1)(i)(B) and (b)(1)(iii);

c. revising paragraph (b)(2);

d. adding a new paragraph (b)(3); and

e. adding a new paragraph (d).

The additions and revisions read as follows:

§ 552.5 Bylaws.

(a) * * * Bylaws may be adopted, amended or repealed by either a majority of the votes cast by the shareholders at a legal meeting or a majority of the board of directors. * * *

(b) * * * (1) *Application requirement.* (i) Any bylaw amendment shall be submitted to the OTS for approval if it would:

* * * * *

(B) Be inconsistent with §§ 552.6, 552.6–1, 552.6–2, and 552.6–3 of this part, with applicable laws, rules, regulations or the association's charter or involve a significant issue of law or policy, including indemnification, conflicts of interest, and limitations on director or officer liability.

(ii) Applications submitted under paragraph (b)(1)(i) of this section shall be subject to the applications processing procedures set forth at § 516.2 of this chapter.

(iii) Bylaw provisions that adopt the language of the model bylaws set forth in the OTS's Application Processing Handbook, if adopted without change, and filed with OTS within 30 days after adoption, are effective upon adoption.

(2) *Filing requirement.* If the proposed bylaw amendment does not involve a provision that would be covered by paragraph (b)(1) or (b)(3) of this section and is permissible under all applicable laws, rules, or regulations, then the association shall submit the amendment to the OTS at least 30 days prior to the date the bylaw amendment is to be adopted by the association.

(3) *Corporate governance procedures.* A Federal stock association may elect to follow the corporate governance procedures of: The laws of the state where the main office of the association is located; the laws of the state where the association's holding company, if any, is incorporated or chartered; Delaware General Corporation law; or The Model Business Corporation Act, provided that such procedures may be elected to the extent not inconsistent with applicable Federal statutes and regulations and safety and soundness, and such procedures are not of the type described in paragraph (b)(1) of this section. If this election is selected, a Federal stock association shall designate in its bylaws the provision or provisions from the body or bodies of law selected for its corporate governance procedures, and shall file a copy of such bylaws, which are effective upon adoption, within 30 days after adoption. The submission shall indicate, where not obvious, why the bylaw provisions meet the requirements stated in paragraph (b)(1) of this section.

* * * * *

(d) *Effect of subsequent charter or bylaw change.* Notwithstanding any subsequent change to its charter or bylaws, the authority of a Federal stock association to engage in any transaction shall be determined only by the association's charter or bylaws then in effect, unless otherwise provided by Federal law or regulation.

19. Section 552.6 is amended by:

a. revising the first and last sentences in paragraph (a);

b. adding a sentence at the end of paragraph (b);

c. revising paragraph (d)(1);
d. adding a sentence at the end of paragraph (e);
e. adding two sentences after the first sentence in paragraph (f)(1);
f. removing paragraph (f)(3); and
g. adding paragraph (h).
The additions and revisions read as follows:

§ 552.6 Shareholders.

(a) *Shareholder meetings.* An annual meeting of the shareholders of the association for the election of directors and for the transaction of any other business of the association shall be held annually within 150 days after the end of the association's fiscal year. * * * All annual and special meetings of shareholders shall be held at such place as the board of directors may determine in the state in which the association has its principal place of business, or at any other convenient place the board of directors may designate.

(b) * * * Notwithstanding anything in this section, however, a Federal stock association that is wholly owned shall not be subject to the shareholder notice requirement.

* * * * *

(d) *Voting lists.* (1) At least 20 days before each meeting of the shareholders, the officer or agent having charge of the stock transfer books for the shares of the association shall make a complete list of the stockholders of record entitled to vote at such meeting, or any adjournments thereof, arranged in alphabetical order, with the address and the number of shares held by each. This list of shareholders shall be kept on file at the home office of the association and shall be subject to inspection by any shareholder of record or the stockholder's agent during the entire time of the meeting. The original stock transfer book shall constitute *prima facie* evidence of the stockholders entitled to examine such list or transfer books or to vote at any meeting of stockholders. Notwithstanding anything in this section, however, a Federal stock association that is wholly owned shall not be subject to the voting list requirements.

* * * * *

(e) * * * If a quorum is present, the affirmative vote of the majority of the shares represented at the meeting and entitled to vote on the subject matter shall be the act of the stockholders, unless the vote of a greater number of stockholders voting together or voting by classes is required by law or the charter. Directors, however, are elected by a plurality of the votes cast at an election of directors.

(f) *Shareholder voting.*—(1) * * * Proxies may be given telephonically or electronically as long as the holder uses a procedure for verifying the identity of the shareholder. A proxy may designate as holder a corporation, partnership or company as defined in Part 574 of this chapter, or other person. * * *

* * * * *

(h) *Informal action by stockholders.* If the bylaws of the association so provide, any action required to be taken at a meeting of the stockholders, or any other action that may be taken at a meeting of the stockholders, may be taken without a meeting if consent in writing has been given by all the stockholders entitled to vote with respect to the subject matter.

20. Section 552.6–1 is amended by:
a. adding a sentence at the end of paragraph (a);
b. revising paragraph (b);
c. adding a sentence after the first sentence in paragraph (c);
d. revising the second sentence of paragraph (e);
e. revising the heading of paragraph (f) and paragraph (f)(1); and
f. revising paragraph (k).
The additions and revisions read as follows:

§ 552.6–1 Board of directors.

(a) * * * Directors need not be stockholders unless the bylaws so require.

(b) *Number and term.* The bylaws shall set forth a specific number of directors, not a range. The number of directors shall be not fewer than five nor more than fifteen, unless a higher or lower number has been authorized by the Director of the Office or his or her delegate. Directors shall be elected for a term of one to three years and until their successors are elected and qualified. If a staggered board is chosen, the directors shall be divided into two or three classes as nearly equal in number as possible and one class shall be elected by ballot annually. In the case of a converting or newly chartered association where all directors shall be elected at the first election of directors, if a staggered board is chosen, the terms shall be staggered in length from one to three years.

(c) * * * The board of directors shall determine the place, frequency, time and procedure for notice of such meetings.

* * * * *

(e) * * * A director elected to fill a vacancy shall be elected to serve only until the next election of directors by the shareholders. * * *

(f) *Removal or resignation of directors.* (1) At a meeting of shareholders called expressly for that purpose, any director may be removed only for cause, as defined in § 563.39 of this chapter, by a vote of the holders of a majority of the shares then entitled to vote at an election of directors. Associations may provide for procedures regarding resignations in the bylaws.

* * * * *

(k) *Age limitation on directors.* A Federal association may provide a bylaw on age limitation for directors. Bylaws on age limitations must comply with all Federal laws, rules and regulations.

21. Section 552.6–2 is amended by revising the first and fifth sentences of paragraph (a); by removing the third and fourth sentences of paragraph (a), and revising paragraph (c) to read as follows:

§ 552.6–2 Officers.

(a) *Positions.* The officers of the association shall be a president, one or more vice presidents, a secretary, and a treasurer or comptroller, each of whom shall be elected by the board of directors. * * * The offices of the secretary and treasurer or comptroller may be held by the same person and the vice president may also be either the secretary or the treasurer or comptroller. * * *

* * * * *

(c) *Age limitation on officers.* A Federal association may provide a bylaw on age limitation for officers. Bylaws on age limitations must comply with all Federal laws, rules, and regulations.

§ 552.8 [Removed]

22. Section 552.8 is removed.

§ 552.11 [Amended]

23. Section 552.11 is amended by adding the phrase ''nonconfidential portions of'' in paragraph (b) between the words ''times,'' and ''its'' in the first sentence.

Appendix to Part 552 [Removed]

24. The Appendix to part 552 is removed.

PART 556—STATEMENTS OF POLICY

25. The authority citation for part 556 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1464, 1701j–3; 15 U.S.C. 1693–1693r.

§§ 556.1 and 556.17 [Removed]

26. Sections 556.1 and 556.17 are removed.

PART 575—MUTUAL HOLDING COMPANIES

27. The authority citation for part 575 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 1828, 2901.

28. Section 575.9 is amended by:

a. revising Section 1 of the Charter in paragraph (a)(1);

b. removing, in Section 5 of the Charter in paragraph (a)(1), the sixth, seventh, and eighth sentences in the last paragraph;

c. revising Section 6 of the Charter in paragraph (a)(1);

d. revising Section 8 of the Charter in paragraph (a)(1);

e. revising the signature blocks at the end of the Charter in paragraph (a)(1);

f. revising paragraph (a)(2);

g. revising the last sentence of paragraph (a)(4); and

h. revising the last sentence of paragraph (a)(5).

The revisions read as follows:

§ 575.9 Charters and bylaws for mutual holding companies and their savings association subsidiaries.

(a) *Charters and bylaws for mutual holding companies*—(1) *Charters.* * * *

Charter

Section 1: Corporate title. The name of the mutual holding company is _____ (the ''Mutual Company'').

* * * * *

Section 6. Directors. The Mutual Company shall be under the direction of a board of directors. The authorized number of directors shall not be fewer than five nor more than fifteen, as fixed in the Mutual Company's bylaws, except that the number of directors may be decreased to a number less than five or increased to a number greater than fifteen with the prior approval of the Director of the Office or his or her delegate.

* * * * *

Section 8. Amendment. Adoption of any preapproved charter amendment shall be effective after such preapproved amendment has been approved by the members at a legal meeting. Any other amendment, addition, change, or repeal of this charter must be approved by the Office prior to approval by the members at a legal meeting and shall be effective upon filing with the Office in accordance with regulatory procedures.

Attest: _____
Secretary of the Association

By: _____
President or Chief Executive Officer of the Association

Attest: _____
Secretary of the Office of Thrift Supervision

By: _____
Director of the Office of Thrift Supervision

Effective Date: _____

(2) *Charter amendments.* The rules and regulations set forth in § 544.2 of this chapter regarding charter amendments and reissuances of charters (including delegations and filing instructions) shall be applicable to mutual holding companies to the same extent as if mutual holding companies were Federal mutual savings associations, except that, with respect to the pre-approved charter amendments set forth in § 544.2 of this chapter, §§ 544.2(b)(1) and (b)(3) of this chapter shall not apply to mutual holding companies, and mutual holding companies changing their corporate title pursuant to § 544.2(b)(2) of this chapter shall be required to comply with § 575.9(a)(3) of this part as well as § 543.1(b) of this chapter.

* * * * *

(4) * * * The model bylaws for Federal mutual savings associations set forth in the OTS Applications Processing Handbook shall also serve as the model bylaws for mutual holding companies, except that the term ''association'' each time it appears therein shall be replaced with the term ''Mutual Company''; section 11(e) (extending leniency to borrowing members) and section 11(f) (rejection of applications for accounts or membership) shall be removed and the remaining paragraphs of section 11 redesignated accordingly.

(5) * * * Mutual holding companies shall also be subject to the provisions of § 544.8 of this chapter.

* * * * *

Dated: November 20, 1996.

By the Office of Thrift Supervision.

Nicolas P. Retsinas,

Director.

[FR Doc. 96–30262 Filed 12–2–96; 8:45 am]

BILLING CODE 6720–01–U

FEDERAL HOUSING FINANCE BOARD

12 CFR Parts 910 and 912

[No. 96–79]

Regulations Governing Book-Entry Federal Home Loan Bank Securities

AGENCY: Federal Housing Finance Board.

ACTION: Interim final rule with request for comments.

SUMMARY: The Federal Housing Finance Board is adopting an interim final rule amending its regulations governing procedures for maintaining book-entry (uncertificated) Federal Home Loan Bank securities within the Federal Reserve Banks' system of accounts. This action is being taken in conjunction with similar amendments being made by the Department of Treasury to its regulations governing Federal Reserve Bank book-entry procedures for Treasury securities, and by the regulators of other government sponsored enterprises for which the Federal Reserve Banks maintain book-entry securities. These amendments are intended to update the regulations to eliminate the need to treat book-entry securities as if they were certificated securities and to conform more closely to the manner in which book-entry securities are treated under the laws of the majority of the states (as set forth in Article 8 of the Uniform Commercial Code, as revised in 1994).

DATES: The interim final rule will become effective on January 1, 1997. The Finance Board will accept comments on the interim final rule in writing on or before February 3, 1997.

ADDRESSES: Mail comments to Elaine A. Baker, Executive Secretary, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

FOR FURTHER INFORMATION CONTACT: Eric M. Raudenbush, Attorney-Advisor, Office of General Counsel, 202/408–2932, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

SUPPLEMENTARY INFORMATION:

I. Background

Subsections (b) and (c) of section 11 of the Federal Home Loan Bank Act (Bank Act) authorize the issuance of consolidated Federal Home Loan Bank (FHLBank) debentures or bonds (collectively, ''FHLBank securities''), which are the joint and several obligations of the FHLBanks, upon terms and conditions established by the Federal Housing Finance Board (Finance Board). *See* 12 U.S.C. 1431(b), (c). The Finance Board has set forth the terms and conditions regarding the issuance of FHLBank securities in part 910 of its regulations. 12 CFR part 910. Although, under the Bank Act, the Finance Board is designated as the ''issuer'' of FHLBank securities, it has delegated the issuance of FHLBank securities, along with such other ministerial functions as the servicing of the FHLBank securities, to the Office of Finance (OF) (a joint office of the FHLBanks) pursuant to section 2B(b)(1) of the Bank Act, 12 U.S.C. 1422b(b)(1), part 941 of the Finance Board's regulations, 12 CFR part 941, and periodic resolutions of the Board of Directors of the Finance Board.

Since 1977, the OF has issued domestic FHLBank securities

exclusively in ''book-entry'' form; that is, as uncertificated securities recorded as entries on the computerized system of accounts maintained by the Federal Reserve Banks (Reserve Banks), acting as fiscal agents of the FHLBanks. This arrangement between the FHLBanks and the Reserve Banks exists pursuant to a 1973 agreement which, as permitted under section 15 of the Bank Act, 12 U.S.C. 1435, authorizes the Reserve Banks to issue book-entry FHLBank securities; to maintain related book-entry accounts; to pay principal and interest due on book-entry FHLBank securities; and otherwise to service such FHLBank securities.

At the time this agreement was consummated, the former Federal Home Loan Bank Board (FHLBB)—the Finance Board's predecessor as regulator of the FHLBanks—promulgated regulations governing the rights and obligations of the FHLBanks, the Reserve Banks, and other persons with respect to the issuance and servicing of book-entry FHLBank securities and the operation of the associated FHLBank book-entry system. *See* 12 CFR 506a (1974); 38 FR 10969 (1973) (proposed rule); 38 FR 26355 (1973) (final rule). These regulations, and those of other government sponsored enterprises (GSEs) having similar book-entry arrangements with Reserve Banks, are patterned after part 306 of the regulations of the Department of Treasury, 31 CFR part 306 (1996), which govern Reserve Bank book-entry procedures for Treasury securities. Responsibility for the FHLBB book-entry regulations was transferred to the Finance Board by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), Pub. L. 101–73, section 401(h), 103 Stat. 356 (1989), and the regulations were redesignated as part 912 of the Finance Board's regulations.

Like those underlying the analogous Department of Treasury regulations, the legal concepts upon which part 912 is based have become outdated. At the time that these regulations were developed, the United States government securities market was in a state of transition between one in which most securities existed in definitive form (that is, the traditional certificate) to one in which securities are maintained almost exclusively within computerized book-entry systems. This is evidenced by the fact that current part 912 and the parallel regulations contained provisions regarding the conversion of definitive securities into book entry securities. Because, as mentioned, all definitive FHLBank securities have reached maturity, new part 912 contains no such ''conversion'' provisions.

Corresponding law (including state laws based on the Uniform Commercial Code (UCC)) at the time current part 912 was promulgated assumed that possession and delivery of physical certificates were the key elements in the securities holding system. This led the Department of Treasury, the FHLBB, and other GSE regulators to premise their regulations upon the ''bearer-definitive security fiction,'' which deems each book-entry security to be the equivalent of a bearer-definitive security. Despite the usefulness of the bearer-definitive fiction, its shortcomings have become increasingly apparent over the past 25 years, as the rules based on this fiction have been found to leave many unanswered questions regarding transactions and rights in book-entry securities.

In addition, the rules have proved inadequate to deal with the tiered system of accounts in which book-entry securities are held. Each interest in a book-entry security must be credited to the account of a Reserve Bank ''participant''—that is, an entity having an account with a Reserve Bank. Persons or entities, including securities broker-dealers, who wish to acquire an interest in book-entry securities, but who do not have an account with a Reserve Bank, must do so through a Reserve Bank participant. Non-participant broker-dealers who deal in book-entry securities through a participant may, in turn, hold these securities for other persons or entities who otherwise lack access to the securities markets. Accordingly, a Reserve Bank most likely will have no information regarding the beneficial owners of interests in book-entry securities, but, instead, will consider the participants in whose Reserve Bank accounts the book-entry securities are held to be the ''owners'' of the interests therein.

Since 1985, the Department of Treasury has been working to develop a new book-entry regulation that does not rely on the bearer-definitive fiction and that effectively addresses the tiered system of accounts in which book-entry securities are held. The Department of Treasury published proposed rules amending its regulations governing the book-entry system for Treasury securities (called ''Treasury/Reserve Automated Debt Entry System'' or ''TRADES'') in March 1986 (51 FR 8846), November 1986 (51 FR 43027) and April 1992 (57 FR 12244). After publication of the latter proposed rule, the Department of Treasury decided to defer publication of a final rule, or additional proposed rules, pending the completion of a planned revision of Article 8 of the UCC, governing investment securities, in order to coordinate the concepts contained in the new TRADES regulation with those set forth in the revised version of Article 8.

The revised version of Article 8 of the UCC (Revised Article 8) was ratified by the American Law Institute and the National Conference of Commissioners on Uniform State Laws in 1994. Thereafter, the Department of Treasury, in March 1996, published a fourth proposed TRADES rule, *see* 61 FR 8420, that incorporates many of the concepts regarding transactions and rights in book-entry securities that are set forth in Revised Article 8 and that defers to state law modeled after Revised Article 8 in many circumstances. A largely similar final rule was published in August 1996, *see* 61 FR 43626, the substantive provisions of which will take effect on January 1, 1997.

In order to ensure uniformity in the treatment of book-entry government securities, the regulators of GSEs that maintain book-entry securities at Reserve Banks also are promulgating new regulations to govern their respective book-entry systems. These regulations will parallel the new TRADES regulation, with modifications appropriate to the particular GSE and government securities to which such regulations will apply, and will most likely become effective simultaneously with the new TRADES regulation.

As part of this effort, the Finance Board is now adopting an interim final rule amending part 912 of its regulations, governing book-entry FHLBank securities. Because new part 912 is based upon the new TRADES regulation and because the Department of Treasury has published extensive commentary in its proposed and final rules regarding the TRADES regulation, the Finance Board has not set forth here a comprehensive analysis of part 912. Instead, the Finance Board is including here concise summaries of each section of new part 912, which address the manner in which the new provisions will effect the FHLBank book-entry system specifically. Those wishing to review a more complete explanation of the nuances of the book-entry regulation and the principles underlying it are referred to the preambles of the proposed and final TRADES rules, as well as the official Department of Treasury Commentary on the TRADES regulation, which will be published as Appendix B to 31 CFR part 357 (and which was published as part of the final TRADES rule at 61 FR 43631).

Although new part 912 is intended to provide a legal framework for all book-entry FHLBank securities, it is not a codification of all laws that could affect interests in book-entry FHLBank securities. In general, the regulation provides that (with some exceptions regarding security interests) Federal law will govern the rights and obligations of the FHLBanks and the Reserve Banks arising from book-entry FHLBank securities and the book-entry system, and that state law (to the extent that states have adopted Revised Article 8) will govern all other rights and obligations. The regulation also sets forth the substantive Federal law that applies to the rights and obligations of the FHLBanks and the Reserve Banks arising from book-entry FHLBank securities and the book-entry system. The most prominent aspect of the substantive law set forth therein is that neither the FHLBanks nor the Reserve Banks are liable to persons having or claiming interests in book-entry securities that are below the participant level in the tiered system of ownership; that is, the FHLBanks and Reserve Banks need only recognize Reserve Bank participants as holders of interests in book-entry FHLBank securities.

II. Section-by-Section Analysis

Section 912.1 contains definitions for use in part 912. Section 912.2(a) provides that, with the exception of certain security interests addressed in § 912.2(b) (discussed below), the rights and obligations of the FHLBanks and the Reserve Banks with respect to the FHLBank book-entry system and the FHLBank securities maintained therein are governed solely and exclusively by Federal law, which is defined to include: part 912, book-entry FHLBank securities offering notices, and Reserve Bank Operating Circulars. The governing Federal law set forth in § 912.2 relates only to the matters set forth therein; other laws, such as tax, banking, and securities laws remain applicable and could affect the holders of book-entry FHLBank securities.

Section 912.2(b) provides an exception to the rule of Federal preemption set forth in § 912.2(a), stating that security interests in book-entry FHLBank securities in favor of a Reserve Bank that have not been recorded on the books of the Reserve Bank, as described in § 912.4(c)(1), shall be governed by: (i) the law of the state in which the head office of the Reserve Bank maintaining the participant's account is located, if the security interest is from a participant; or (ii) the law of the state to be determined as specified in § 912.3 (discussed below), if the security interest is from a person other than a participant. By implication, security interests in favor of a Reserve Bank that have been recorded on the books of the Reserve Bank in accordance with § 912.4(c)(1) are governed by Federal law, as set forth in § 912.2(a). Thus, claims against the FHLBanks and Reserve Banks made by participants, or any other person claiming an interest in a book-entry FHLBank security, other than claims involving Reserve Bank security interests that have not been recorded on the books of the Reserve Bank, are governed solely and exclusively by Federal law.

Section 912.2(c) provides that, if the application of the jurisdictional rule set forth in the first sentence of § 912.2(b) would result in the application of the law of a state that has not adopted Revised Article 8, that state's law will be read as if it had adopted Revised Article 8. This limited rule of Federal preemption is included in order to ensure that matters involving book-entry FHLBank securities will be treated similarly regardless of the state having jurisdiction over the matter. As of November 1, 1996, 29 states have adopted Revised Article 8 and others are expected to follow. If and when all states adopt Revised Article 8, the Finance Board expects that this provision, and the similar provision contained in § 912.3(d), will be repealed. In the meantime, as provided in § 912.9(b), the Finance Board will defer to determinations of the Department of Treasury regarding whether particular states may be deemed to have adopted Revised Article 8 for purposes of part 912. With regard to the TRADES regulation, the Department of Treasury intends to publish such determinations in the Federal Register, as necessary. *See* 61 FR 43633–34.

Section 912.3 is a choice of law rule governing the substantive matters set forth in § 912.3(a)—which are meant to be coextensive with those matters covered by Revised Article 8 with respect to a person's interest in a book-entry FHLBank security, other than interests connected with a person's relationship with the Reserve Banks or the FHLBanks, which are governed by Federal law, as provided in § 912.2. Section 912.3(b) adopts Revised Article 8's general choice of law rule, providing that the law applicable to the securities intermediary will govern matters involving an interest in a book-entry FHLBank security held through that intermediary. Section 912.3(c) also parallels Revised Article 8 by excepting from the general rule the determination of whether security interests are perfected automatically or by filing a financing statement and providing that this issue is to be resolved by reference to the law of the state in which the debtor is located.

Section 912.3(d) is analogous to § 912.2(c), providing that if the application of the jurisdictional rule set forth in § 912.3(b) would result in the application of the law of a state that has not adopted Revised Article 8, that state's law will be read as if it had adopted Revised Article 8.

Section 912.4(a) provides that a participant's securities entitlement is created when a Reserve Bank indicates by book-entry that a book-entry FHLBank security has been credited to the participant's securities account. The nature of the participant's ''securities entitlement''—that is, the nature of its interest in a book-entry FHLBank security—once it is created, must be determined by reference to Federal law with respect to the participant's rights against and obligations to its Reserve Bank and the FHLBanks, as provided in § 912.2, or to applicable state law with respect to the participant's rights against and obligations to all other persons, as provided in § 912.3. Section 912.4(b) provides that a security interest in favor of the United States government to secure deposits of public money has priority over the interests of any other person in a book-entry FHLBank security.

Section 912.4(c)(1) provides that, where required by Federal law or regulation or pursuant to a specific agreement with a Reserve Bank, a security interest in book-entry FHLBank securities in favor of a Reserve Bank or other person may be created and perfected by a Reserve Bank marking its books to record the security interest. However, neither the FHLBanks nor the Reserve Banks have any obligation to agree to record a security interest in book-entry FHLBank securities on the books of a Reserve Bank, except as required by Federal law or regulation. A security interest created and perfected as specified in § 912.4(c)(1) has priority over all other interests in the book-entry FHLBank security, except an interest of the United States government, as described in § 912.4(b).

Section 912.4(c)(2) provides that a security interest in a book-entry FHLBank security may be perfected by any method available under applicable state law, as determined under §§ 912.2(b) or 912.3, and that the priority of such security interests shall be governed by such applicable law. If a person perfects a security interest pursuant to § 912.4(c)(2), obligations of the FHLBanks and the Reserve Banks

with respect to that security interest are limited, absent a specific agreement made by the FHLBanks or Reserve Banks pursuant to § 912.4(c)(1). In other words, although security interests in a book-entry FHLBank security perfected under applicable state law may be valid, neither the FHLBanks nor a Reserve Bank have any obligation to recognize any such interests, other than those of the participant in whose securities account the interest is maintained; a creditor's recourse will be solely against the debtor participant or other third party.

Section 912.5(a) sets forth the general rule that, with limited exceptions, the FHLBanks and the Reserve Banks will recognize the interest in a book-entry FHLBank security only of a participant in whose securities account such interest is maintained. As noted above, book-entry FHLBank securities are held via a tiered system of ownership. The records of a Reserve Bank reflect only the ownership interests of participants. Participants frequently will hold interests in book-entry FHLBank securities for the benefit of their customers (which may include broker-dealers and other securities intermediaries) who, in certain cases, in turn will hold interests in FHLBank securities for the benefit of their customers. Accordingly, neither the FHLBanks nor a Reserve Bank would know the identity or recognize a claim of a participant's customer if that customer were to present it to the FHLBanks or a Reserve Bank. Under the regulation, persons at levels below the participant level must present their claims to their securities intermediary; neither the FHLBanks not the Reserve Banks are liable for any such claims.

Section 912.5(b)(1) sets forth a corollary to the rule set forth in § 912.5(a), providing that the FHLBanks discharge their payment responsibilities with respect to a book-entry FHLBank security when a Reserve Bank credits the funds account of a participant with amounts due on that security, or makes payment in some other manner specified by the participant. Section 912.5(b) establishes the mechanism for payment of book-entry FHLBank securities at maturity or upon redemption. Contrary to the practice with definitive securities, no act of presentment is required by the participant.

Section 912.6 authorizes the Reserve Banks, as fiscal agents of the FHLBanks, to operate the book-entry system for the FHLBanks. Section 912.7 provides that the FHLBanks and the Reserve Banks are not liable for actions taken in reliance on a tender, transaction request form, Transfer Message, or other written instrument, or evidence submitted in support thereof. Section 912.8 makes clear where certain legal process should be directed, although it makes clear that the regulations do not establish whether a Reserve Bank is required to honor any such order or notice.

Section 912.9(a) references, for interpretive purposes, the Commentary that the Department of Treasury has appended to its TRADES regulation, so as to provide a comprehensive background to the matters contained in part 912 and to ensure that it is applied in similar fashion to the TRADES regulation. Section 912.9(b) defers to the Department of Treasury determinations regarding whether particular states may be deemed to have adopted Revised Article 8 for purposes of part 912.

Section 912.10 merely restates the substance of section 15 of the Bank Act, 12 U.S.C. 1435, which provides that FHLBank securities are not obligations of the United States and are not guaranteed by the United States.

III. Procedural Requirements

This interim final rule does not meet the criteria for a ''significant regulatory action'' under Executive Order 12866.

The Finance Board finds that the notice and comment procedure required by the Administrative Procedures Act is unnecessary, impracticable, and contrary to the public interest in this instance. *See* 5 U.S.C. 553(b)(3)(B). The Treasury TRADES regulation on which this rule is based has been published, in various forms, as a proposed rule four times and as a final rule once. In each instance, the TRADES regulation was accompanied by extensive commentary addressing the background and provisions of the TRADES regulation. Accordingly, the Finance Board has concluded that publication of new part 912 for notice and comment is unnecessary given its similarity to the TRADES regulation and is impracticable given the compelling reasons for setting the effective date of the regulation at January 1, 1997, when the TRADES regulation and those of the other GSEs will most likely become effective. Nevertheless, because the Finance Board believes public comments aid in effective rulemaking, it will accept written comments on the interim final rule on or before February 3, 1997.

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, do not apply.

There are no collections of information contained in this interim final rule. Therefore, the Paperwork Reduction Act does not apply.

List of Subjects

12 CFR Part 910

Federal home loan banks, Government securities.

12 CFR Part 912

Federal home loan banks, Federal Reserve System, Government securities, electronic funds transfer.

Accordingly, the Federal Housing Finance Board hereby amends title 12, chapter IX of the Code of Federal Regulations, to read as follows:

PART 910—CONSOLIDATED BONDS AND DEBENTURES

1. The authority citation for part 910 is revised to read as follows:

Authority: 12 U.S.C. 1422b, 1431.

2. Section 910.3 is revised to read as follows:

§ 910.3 Transactions in consolidated bonds.

The general regulations of the Department of Treasury now or hereafter in force governing transactions in United States securities, except 31 CFR part 357, regarding book-entry procedure, are hereby incorporated into this part, so far as applicable and as necessarily modified to relate to consolidated Federal Home Loan Bank bonds, as the regulations of the Board for similar transactions in consolidated Federal Home Loan Bank bonds. The book-entry procedure for consolidated Federal Home Loan Bank bonds is contained in part 912 of this subchapter.

3. Part 912 is revised to read as follows:

PART 912—BOOK-ENTRY PROCEDURE FOR FEDERAL HOME LOAN BANK SECURITIES

Sec.

Authority: 12 U.S.C. 1422a, 1422b, 1431, 1435.

§ 912.1 Definitions.

For purposes of this part, unless the context otherwise requires or indicates:

(a) *Adverse Claim* means a claim that a claimant has a property interest in a Book-entry Federal Home Loan Bank Security and that it is a violation of the rights of the claimant for another Person to hold, transfer, or deal with the Security.

(b) *Book-entry Federal Home Loan Bank Security* means a Federal Home Loan Bank Security maintained in the book-entry system of the Federal Reserve Banks.

(c) *Entitlement Holder* means a Person to whose account an interest in a Book-entry Federal Home Loan Bank Security is credited on the records of a Securities Intermediary.

(d) *Federal Home Loan Bank Security* means a consolidated bond, debenture, note, or other obligation of the Federal Home Loan Banks issued under authority of section 11 of the Federal Home Loan Bank Act (12 U.S.C. 1431).

(e) *Federal Reserve Bank* means the a Federal Reserve Bank or branch, acting as fiscal agent of the Federal Home Loan Banks, unless otherwise indicated.

(f) *Federal Reserve Bank Operating Circular* means the publication issued by each Federal Reserve Bank that sets forth the terms and conditions under which the Federal Reserve Bank maintains Book-entry Securities accounts and transfers Book-entry Securities.

(g) *Funds account* means a reserve and/or clearing account at a Federal Reserve Bank to which debits or credits are posted for transfers against payment, Book-entry Securities transaction fees, or principal and interest payments.

(h) *Participant* means a Person that maintains a Participant's Securities Account with a Federal Reserve Bank.

(i) *Participant's Securities Account* means an account in the name of a Participant at a Federal Reserve Bank to which Book-entry Federal Home Loan Bank Securities held for a Participant are or may be credited.

(j) *Person* means and includes an individual, corporation, company, governmental entity, association, firm, partnership, trust, estate, representative, and any other similar organization, but does not mean or include the United States, a Federal Home Loan Bank, or a Federal Reserve Bank.

(k) *Revised Article 8* means Uniform Commercial Code, Revised Article 8, Investment Securities (with Conforming and Miscellaneous Amendments to Articles 1, 3, 4, 5, 9, and 10) 1994 Official Text. Copies of this publication are available from the Executive Office of the American Law Institute, 4025 Chestnut Street, Philadelphia, PA 19104, and the National Conference of Commissioners on Uniform State Laws, 676 North St. Clair Street, Suite 1700, Chicago, IL 60611.

(l) *Securities Intermediary* means:

(1) A Person that is registered as a ''clearing agency'' under the federal securities laws; a Federal Reserve Bank; any other person that provides clearance or settlement services with respect to a Book-entry Federal Home Loan Bank Security that would require it to register as a clearing agency under the federal securities laws but for an exclusion or exemption from the registration requirement, if its activities as a clearing corporation, including promulgation of rules, are subject to regulation by a federal or state governmental authority; or

(2) A Person (other than an individual, unless such individual is registered as a broker or dealer under the federal securities laws) including a bank or broker, that in the ordinary course of its business maintains securities accounts for others and is acting in that capacity.

(m) *Security Entitlement* means the rights and property interest of an Entitlement Holder with respect to a Book-entry Federal Home Loan Bank Security.

(n) *State* means any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, or any other territory or possession of the United States.

(o) *Transfer Message* means an instruction of a Participant to a Federal Reserve Bank to effect a transfer of a Book-entry Federal Home Loan Bank Security, as set forth in Federal Reserve Bank Operating Circulars.

§ 912.2 Law governing rights and obligations of Federal Home Loan Banks and Federal Reserve Banks; rights of any Person against Federal Home Loan Banks and Federal Reserve Banks.

(a) Except as provided in paragraph (b) of this section, the rights and obligations of the Federal Home Loan Banks and the Federal Reserve Banks with respect to: A Book-entry Federal Home Loan Bank Security or Security Entitlement and the operation of the Book-entry system, as it applies to Federal Home Loan Bank securities; and the rights of any Person, including a Participant, against the Federal Home Loan Banks and the Federal Reserve Banks with respect to: A Book-entry Federal Home Loan Bank Security or Security Entitlement and the operation of the Book-entry system, as it applies to Federal Home Loan Bank Securities; are governed solely by regulations of the Federal Housing Finance Board, including the regulations of this part 912, the applicable offering notice, applicable procedures established by the Federal Home Loan Banks, and Federal Reserve Bank Operating Circulars.

(b) A security interest in a Security Entitlement that is in favor of a Federal Reserve Bank from a Participant and that is not recorded on the books of a Federal Reserve Bank pursuant to § 912.4(c)(1), is governed by the law (not including the conflict-of-law rules) of the jurisdiction where the head office of the Federal Reserve Bank maintaining the Participant's Securities Account is located. A security interest in a Security Entitlement that is in favor of a Federal Reserve Bank from a Person that is not a Participant, and that is not recorded on the books of a Federal Reserve Bank pursuant to § 912.4(c)(1), is governed by the law determined in the manner specified in § 912.3.

(c) If the jurisdiction specified in the first sentence of paragraph (b) of this section is a State that has not adopted Revised Article 8, then the law specified in the first sentence of paragraph (b) of this section shall be the law of that State as though Revised Article 8 had been adopted by that State.

§ 912.3 Law governing other interests.

(a) To the extent not inconsistent with this part 912, the law (not including the conflict-of-law rules) of a Securities Intermediary's jurisdiction governs:

(1) The acquisition of a Security Entitlement from the Securities Intermediary;

(2) The rights and duties of the Securities Intermediary and Entitlement Holder arising out of a Security Entitlement;

(3) Whether the Securities Intermediary owes any duties to an adverse claimant to a Security Entitlement;

(4) Whether an Adverse Claim can be asserted against a Person who acquires a Security Entitlement from the Securities Intermediary or a Person who purchases a Security Entitlement or interest therein from an Entitlement Holder; and

(5) Except as otherwise provided in paragraph (c) of this section, the perfection, effect of perfection or non-perfection, and priority of a security interest in a Security Entitlement.

(b) The following rules determine a ''Securities Intermediary's jurisdiction'' for purposes of this section:

(1) If an agreement between the Securities Intermediary and its Entitlement Holder specifies that it is governed by the law of a particular jurisdiction, that jurisdiction is the Securities Intermediary's jurisdiction.

(2) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify the governing law as provided in paragraph (b)(1) of this section, but expressly specifies that the securities account is maintained at an office in a particular jurisdiction, that jurisdiction is the Securities Intermediary's jurisdiction.

(3) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify a jurisdiction as provided in paragraph (b)(1) or (b)(2) of this section, the Securities Intermediary's jurisdiction is the jurisdiction in which is located the office identified in an account statement as the office serving the Entitlement Holder's account.

(4) If an agreement between the Securities Intermediary and its Entitlement Holder does not specify a jurisdiction as provided in paragraph (b)(1) or (b)(2) of this section and an account statement does not identify an office serving the Entitlement Holder's account as provided in paragraph (b)(3) of this section, the Securities Intermediary's jurisdiction is the jurisdiction in which is located the chief executive office of the Securities Intermediary.

(c) Notwithstanding the general rule in paragraph (a)(5) of this section, the law (but not the conflict-of-law rules) of the jurisdiction in which the Person creating a security interest is located governs whether and how the security interest may be perfected automatically or by filing a financing statement.

(d) If the jurisdiction specified in paragraph (b) of this section is a State that has not adopted Revised Article 8, then the law for the matters specified in paragraph (a) of this section shall be the law of that State as though Revised Article 8 had been adopted by that State. For purposes of the application of the matters specified in paragraph (a) of this section, the Federal Reserve Bank maintaining the Securities Account is a clearing corporation, and the Participant's interest in a Federal Home Loan Bank Book-entry Security is a Security Entitlement.

§ 912.4 Creation of Participant's Security Entitlement; security interests.

(a) A Participant's Security Entitlement is created when a Federal Reserve Bank indicates by book entry that a Book-entry Federal Home Loan Bank Security has been credited to a Participant's Securities Account.

(b) A security interest in a Security Entitlement of a Participant in favor of the United States to secure deposits of public money, including, without limitation deposits to the Treasury tax and loan accounts, or other security interest in favor of the United States that is required by Federal statute, regulation, or agreement, and that is marked on the books of a Federal Reserve Bank is thereby effected and perfected, and has priority over any other interest in the Securities. Where a security interest in favor of the United States in a Security Entitlement of a Participant is marked on the books of a Federal Reserve Bank, such Reserve Bank may rely, and is protected in relying, exclusively on the order of an authorized representative of the United States directing the transfer of the Security. For purposes of this paragraph (b), an ''authorized representative of the United States'' is the official designated in the applicable regulations or agreement to which a Federal Reserve Bank is a party, governing the security interest.

(c)(1) The Federal Home Loan Banks and the Federal Reserve Banks have no obligation to agree to act on behalf of any Person or to recognize the interest of any transferee of a security interest or other limited interest in a Security Entitlement in favor of any Person except to the extent of any specific requirement of Federal law or regulation or to the extent set forth in any specific agreement with the Federal Reserve Bank on whose books the interest of the Participant is recorded. To the extent required by such law or regulation or set forth in an agreement with a Federal Reserve Bank, or the Federal Reserve Bank Operating Circular, a security interest in a Security Entitlement that is in favor of a Federal Reserve Bank or a Person may be created and perfected by a Federal Reserve Bank marking its books to record the security interest. Except as provided in paragraph (b) of this section, a security interest in a Security Entitlement marked on the books of a Federal Reserve Bank shall have priority over any other interest in the Securities.

(2) In addition to the method provided in paragraph (c)(1) of this section, a security interest in a Security Entitlement, including a security interest in favor of a Federal Reserve Bank, may be perfected by any method by which a security interest may be perfected under applicable law as described in § 912.2(b) or § 912.3. The perfection, effect of perfection or non-perfection, and priority of a security interest are governed by that applicable law. A security interest in favor of a Federal Reserve Bank shall be treated as a security interest in favor of a clearing corporation in all respects under that law, including with respect to the effect of perfection and priority of the security interest. A Federal Reserve Bank Operating Circular shall be treated as a rule adopted by a clearing corporation for such purposes.

§ 912.5 Obligations of the Federal Home Loan Banks; No Adverse Claims.

(a) Except in the case of a security interest in favor of the United States or a Federal Reserve Bank or otherwise as provided in § 912.4(c)(1), for the purposes of this part 912, the Federal Home Loan Banks and the Federal Reserve Banks shall treat the Participant to whose Securities Account an interest in a Book-entry Federal Home Loan Bank Security has been credited as the person exclusively entitled to issue a Transfer Message, to receive interest and other payments with respect thereof and otherwise to exercise all the rights and powers with respect to the Security, notwithstanding any information or notice to the contrary. Neither the Federal Reserve Banks nor the Federal Home Loan Banks are liable to a Person asserting or having an Adverse Claim to a Security Entitlement or to a Book-entry Federal Home Loan Bank Security in a Participant's Securities Account, including any such claim arising as a result of the transfer or disposition of a Book-entry Federal Home Loan Bank Security by a Federal Reserve Bank pursuant to a Transfer Message that the Federal Reserve Bank reasonably believes to be genuine.

(b) The obligation of the Federal Home Loan Banks to make payments of interest and principal with respect to Book-entry Federal Home Loan Bank Securities is discharged at the time payment in the appropriate amount is made as follows:

(1) Interest on Book-entry Federal Home Loan Bank Securities is either credited by a Federal Reserve Bank to a Funds Account maintained at the Federal Reserve Bank or otherwise paid as directed by the Participant.

(2) Book-entry Federal Home Loan Bank Securities are paid, either at maturity or upon redemption, in accordance with their terms by a Federal Reserve Bank withdrawing the securities from the Participant's Securities Account in which they are maintained and by either crediting the amount of the proceeds, including both principal and interest, where applicable, to a Funds Account at the Federal Reserve Bank or otherwise paying such

principal and interest as directed by the Participant. No action by the Participant is required in connection with the payment of a Book-entry Federal Home Loan Bank Security, unless otherwise expressly required.

§ 912.6 Authority of Federal Reserve Banks.

(a) Each Federal Reserve Bank is hereby authorized as fiscal agent of the Federal Home Loan Banks to perform functions with respect to the issuance of Book-entry Federal Home Loan Bank Securities, in accordance with the terms of the applicable offering notice and with procedures established by the Federal Home Loan Banks; to service and maintain Book-entry Federal Home Loan Bank Securities in accounts established for such purposes; to make payments of principal, interest and redemption premium (if any), as directed by the Federal Home Loan Banks; to effect transfer of Book-entry Federal Home Loan Bank Securities between Participants' Securities Accounts as directed by the Participants; and to perform such other duties as fiscal agent as may be requested by the Federal Home Loan Banks.

(b) Each Federal Reserve Bank may issue Operating Circulars not inconsistent with this part 912, governing the details of its handling of Book-entry Federal Home Loan Bank Securities, Security Entitlements, and the operation of the book-entry system under this part 912.

§ 912.7 Liability of Federal Home Loan Banks and Federal Reserve Banks.

The Federal Home Loan Banks and the Federal Reserve Banks may rely on the information provided in a tender, transaction request form, other transaction documentation, or Transfer Message, and are not required to verify the information. The Federal Home Loan Banks and the Federal Reserve Banks shall not be liable for any action taken in accordance with the information set out in a tender, transaction request form, other transaction documentation, or Transfer Message, or evidence submitted in support thereof.

§ 912.8 Notice of attachment for Book-entry Federal Home Loan Bank Securities.

The interest of a debtor in a Security Entitlement may be reached by a creditor only by legal process upon the Securities Intermediary with whom the debtor's securities account is maintained, except where a Security Entitlement is maintained in the name of a secured party, in which case the debtor's interest may be reached by legal process upon the secured party. These regulations do not purport to establish whether a Federal Reserve Bank is required to honor an order or other notice of attachment in any particular case or class of cases.

§ 912.9 Reference to certain Department of Treasury commentary and determinations.

(a) The Department of Treasury TRADES Commentary (Appendix B to 31 CFR part 357) addressing the Department of Treasury regulations governing book-entry procedure for Treasury Securities is hereby referenced, so far as applicable and as necessarily modified to relate to Book-entry Federal Home Loan Bank Securities, as an interpretive aid to this part 912.

(b) Determinations of the Department of Treasury regarding whether a State shall be considered to have adopted Revised Article 8 for purposes of 31 CFR part 357, as published in the Federal Register or otherwise, shall also apply to this part 912.

§ 912.10 Obligations of United States with respect to Federal Home Loan Bank Securities.

Federal Home Loan Bank Securities are not obligations of the United States and are not guaranteed by the United States.

By the Board of Directors of the Federal Housing Finance Board.

Dated: November 7, 1996.

Bruce A. Morrison,

Chairman.

[FR Doc. 96–30454 Filed 12–2–96; 8:45 am]

BILLING CODE 6725–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93G–0017]

Listing of Color Additives Exempt From Certification; Ferrous Lactate; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 4, 1996, for the final rule that appeared in the Federal Register of August 2, 1996 (61 FR 40317), and amended the color additive regulations to provide for the safe use of ferrous lactate for the coloring of ripe olives.

DATES: Effective date confirmed: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 2, 1996 (61 FR 40317), FDA amended 21 CFR part 73 to add a new § 73.165 to provide for the use of ferrous lactate for the coloring of ripe olives.

FDA gave interested persons until September 3, 1996, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the Federal Register of August 2, 1996, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, notice is given that no objections or requests for a hearing were filed in response to the August 2, 1996, final rule. Accordingly, the amendments promulgated thereby became effective September 4, 1996.

Dated: November 21, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–30730 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 961030301–6301–01]

RIN 0651–AA55

Changes in Signature and Filing Requirements for Correspondence Filed in the Patent and Trademark Office

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Correcting amendment.

SUMMARY: This document contains a further correction to the final regulations which were published Friday, October 22, 1993 (58 FR 54494). The regulations related to the changes in signature and filing requirements for correspondence filed in the Patent and Trademark Office. The correction re-inserts part of a rule (37 CFR 1.741) that was inadvertently deleted when the rule was amended.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Karin Tyson by telephone at (703) 305–9285; by mail marked to her attention and addressed to the Assistant Commissioner for Patents, Box COMMENTS—PATENTS, Washington, D.C. 20231; or by fax marked to her attention at (703) 308–6916.

SUPPLEMENTARY INFORMATION:

Background

The final regulation that is the subject of this correction was revised to change ''Certificate of Mailing'' to ''Certificate of Mailing or Transmission'' in 37 CFR 1.741(a) as published at 58 FR 54494 (October 22, 1993), corrected at 58 FR 64154 (December 6, 1993), and in the Official Gazette of the Patent and Trademark Office at 1156 Off. Gaz. Pat. Office 61 (November 16, 1993), corrected at 1157 Off. Gaz. Pat. Office 87 (December 28, 1993).

Need for Correction

As published, the final regulation inadvertently deleted the last sentence of the first paragraph of paragraph (a) of Rule 741 and paragraphs (a)(1)–(a)(6).

Paperwork Reduction Act Statement

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number.

OMB has approved the collection of the information required by this rule under OMB # 0651–0020.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Freedom of Information, Inventions and patents, Reporting and record keeping requirements.

PART 1—RULES OF PRACTICE IN PATENT CASES

Accordingly, 37 CFR part 1 is corrected by making the following correcting amendment:

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. In § 1.741, paragraph (a) is revised to read as follows:

§ 1.741 Filing date of application.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the ''Certificate of Mailing or Transmission'' procedures of 37 CFR 1.8 or ''Express Mail'' provisions of 37 CFR 1.10. A complete application shall include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under 35 U.S.C. 156 subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

* * * * *

Dated: November 26, 1996.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 96–30751 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD033–7157; FRL–5650–8]

Approval and Promulgation of Air Quality Implementation Plans; Maryland 1990 Base Year Emission Inventory; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; correcting amendment.

SUMMARY: This action corrects the citation of a direct final rule, which was published on Friday, September 27, 1996 (61 FR 50715). This action pertains to the Maryland 1990 base year emission inventory for ozone.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 566–2182.

SUPPLEMENTARY INFORMATION:

Background

On October 31, 1995 (60 FR 55321) EPA published a direct final rule approving a State Implementation Plan (SIP) revision submitted by Maryland pertaining to the 1990 base year emission inventory for carbon monoxide for the Baltimore Metropolitan Statistical Area (40 CFR 52.1075(a)).

On January 30, 1996 (61 FR 2931) EPA published a direct final rule approving a SIP revision submitted by Maryland pertaining to the 1990 base year emission inventory for carbon monoxide for the Washington Metropolitan Statistical Area (§ 52.1075(b)).

On September 27, 1996 (61 FR 50715) EPA published a direct final rule approving a SIP revision submitted by Maryland pertaining to the Maryland 1990 base year emission inventory for ozone.

Need for Correction

As published, the direct final rule contains errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication on September 27, 1996 (61 FR 50717, FR Doc. 96–24524), Part 52, § 52.1075 is being amended by revising the section heading to ''1990 Base Year Emission Inventory'' and adding a third paragraph (c).

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by

Executive Order 12898 (59 FR 7629, February 16, 1994).

Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.).*

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of this rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Dated: October 31, 1996.

Stanley L. Laskowski,

Acting Regional Administrator, Region III.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Part 52, Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart V—Maryland

2. Section 52.1075 is amended by revising the heading and adding paragraph (c) to read as follows:

§ 52.1075 1990 base year emission inventory.

* * * * *

(c) EPA approves as a revision to the Maryland State Implementation Plan the 1990 base year emission inventories for the Maryland ozone nonattainment areas: Baltimore nonattainment areas, Cecil County, and Kent and Queen Anne's Counties submitted by the Secretary of Maryland Department of Environment on March 21, 1994. This submittal consists of the 1990 base year point, area, non-road mobile, biogenic and on-road mobile source emission inventories for the following pollutants: volatile organic compounds (VOC), carbon monoxide (CO), and oxides of nitrogen (NO_X).

[FR Doc. 96–30476 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[Region II Docket No. 144, NY21–1–6732(c); FRL–5657–8]

Approval and Promulgation of Implementation Plans; New York; Withdrawal of Direct Final Rule Regarding Transportation Control Measures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On October 1, 1996, EPA published approval of a State Implementation Plan (SIP) revision submitted by New York (61 FR 51214), which addressed the need for transportation control measures (TCMs) to offset growth in emissions from growth in vehicle miles traveled as required by the Clean Air Act. This action was published without prior proposal because EPA anticipated no adverse comments. Because EPA received adverse comments on this action, EPA is withdrawing the approval of New York's request to revise its SIP for ozone, announced in the October 1, 1996 direct final rule. EPA will now proceed with rulemaking based on a proposed rule pertaining to the same TCMs, which was published on the same date (61 FR 51257).

EFFECTIVE DATE: This action is effective December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Linda Kareff, Environmental Protection Agency, Region 2 Office, 290 Broadway, New York, New York 10007–1866, (212) 637–3741 or kareff.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On October 1, 1996, EPA published direct final approval of a revision to New York's SIP for ozone, submitted by New York on November 15, 1992 and supplemented on November 5, 1993 (61 FR 51215). The intended effect of this action was to address the need for TCMs to offset growth in emissions from growth in vehicle miles traveled as required by the Clean Air Act. EPA published this direct final rulemaking without prior proposal because the Agency viewed it as a noncontroversial revision and anticipated no adverse comments. The direct final rule was published in the Federal Register with a provision for a 30 day comment period.

A proposed rule pertaining to the same TCMs for New York was also published in the Federal Register on October 1, 1996 (61 FR 51257). EPA announced that the direct final rule would be withdrawn in the event that adverse comments were submitted to EPA within 30 days of publication of the rule in the Federal Register (61 FR 51214). EPA received adverse comments. Therefore, EPA is withdrawing the October 1, 1996 direct final approval of New York's SIP revision. Comments received during the 30 days after October 1, 1996 will be addressed in a subsequent rulemaking action based on the proposed rule. As stated in the October 1, 1996 notice, this withdrawal action does not establish an additional comment period.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen Oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 20, 1996.

Herbert Barrack,

Acting Regional Administrator.

For the reasons set out in the preamble, 40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart HH—New York

§ 52.1683 [Amended]

2. Section 52.1683 is amended by removing paragraph (c).

[FR Doc. 96–30750 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1–279]

Organization and Delegation of Powers and Duties Delegations of Authority to the Maritime Administrator

AGENCY: Office of the Secretary, DOT.

ACTION: Final Rule.

SUMMARY: The Secretary of Transportation (Secretary) hereby delegates to the Maritime Administrator authority of the Secretary from the Maritime Security Act of 1996, Public Law 104–239. This amendment adds a new paragraph 1.66(v) to reflect this delegation of authority.

EFFECTIVE DATE: This rule becomes effective December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Richard Weaver, Chief, Division of Management and Organization, Maritime Administration, MAR–318, Room 7225, 400 Seventh Street, S.W., Washington, DC 20590, (202) 366–2811.

SUPPLEMENTARY INFORMATION: Public Law 104–239, the Maritime Security Act of 1996, directs the Secretary of Transportation (Secretary) to enter into agreements with owners and operators of U.S.-flag commercial vessels for access to a fleet of modern commercial ships, along with the sophisticated intermodal transportation system supporting it. The Act also extends to seafarers certified by the Secretary the same basic reemployment rights that apply to reserve members of the U.S. Armed Forces in time of war or national emergency. This amendment to 49 CFR Part 1 delegates the Secretary's authorities related to the above responsibilities to the Maritime Administrator.

Since this amendment relates to departmental management, organization, procedure, and practice, notice and comment are unnecessary, and the rule may become effective in fewer than 30 days after publication in the Federal Register.

List of Subjects in 49 CFR Part 1

Authority delegations (Government agencies), Organizations and functions (Government agencies).

In consideration of the foregoing, part 1 of title 49, Code of Federal Regulations, is amended as follows:

PART 1—[AMENDED]

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

Authority: 49 U.S.C. 322; Pub. L. 101–552, 28 U.S.C. 2672, 31 U.S.C. 3711(a)(2).

2. Section 1.66 is amended by adding a new paragraph (v), to read as follows:

§ 1.66 Delegations to Maritime Administrator.

* * * * *

(v) Carry out the responsibilities and exercise the authorities of the Secretary of Transportation under the Maritime Security Act of 1996, Public Law 104–239;

* * * * *

Issued at Washington, DC, this 22nd day of November 1996.

Federico Peña,

Secretary of Transportation.

[FR Doc. 96–30724 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–62–P

Research and Special Programs Administration

49 CFR Parts 106 and 190

[Docket RSP–2; Admt. Nos. 106–12, 190–8]

RIN 2137–AC 94

Pipeline Safety Rulemaking Procedures

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Correction of amendment number of final rule document.

SUMMARY: This action corrects the amendment number of the Final Rule document published in the Federal Register on Friday, September 27, 1996 (61 FR 50908). In the document heading on page 50908, the amendment number ''Amdt. 190–1'' is changed to read ''Amdt. 190–8.'' The Final Rule replicates in 49 CFR Part 190 its rulemaking procedures presently found in 49 CFR Part 106.

EFFECTIVE DATE: October 1, 1996.

FOR FURTHER INFORMATION CONTACT: Paul Sanchez (202) 366–4400.

Issued in Washington, DC on November 26, 1996.

Richard B. Felder,

Associate Administrator for Pipeline Safety.

[FR Doc. 96–30699 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–60–P

Proposed Rules

Federal Register
Vol. 61, No. 233
Tuesday, December 3, 1996

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 ENERGY

Federal Energy Regulatory Commission, DOE

18 CFR Parts 4 and 375

[Docket No. RM95–16–000]

Regulations for the Relicensing of Hydroelectric Projects; Notice of Proposed Rulemaking

November 26, 1996.

AGENCY: Federal Energy Regulatory Commission, Doe.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to revise its procedural regulations governing applications for licenses for hydroelectric projects. The proposed regulations respond to a petition for rulemaking filed by the National Hydropower Association and are intended to offer an alternative administrative process whereby in appropriate circumstances the pre-filing consultation process and the environmental review process can be integrated. This alternative process is designed to be tailored to the facts and circumstances of the particular proceeding. The proposed regulations would not delete or replace any existing regulations.

DATES: Comments on the Notice of Proposed Rulemaking are due February 3, 1997 and March 3, 1997 for reply comments. Comments should be filed with the Office of the Secretary and should refer to Docket No. RM95–16–000.

ADDRESSES: Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Edward Abrams, Office of Hydropower Licensing, 888 First Street, N.E., Washington, DC 20426, (202) 219–2773.

Merrill Hathaway, Office of the General Counsel, 888 First Street, N.E., Washington, DC 20426, (202) 208–0825.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in Room 2A, 888 First Street, N.E., Washington, DC 20426. The last page of Appendix A consists of a flow chart that is not being published in the Federal Register but is available from the Commission's Public Reference Room.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397 if dialing locally or 1–800–856–3920 if dialing long distance. To access CIPS, set your communications software to use 19200, 14400, 12000, 9600, 7200, 4800, 2400 or 1200bps, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this document will be available on CIPS indefinitely in ASCII and WordPerfect 5.1 format for one year. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in Room 2A, 888 First Street, N.E., Washington, DC 20426.

The Commission's bulletin board system also can be accessed through the FedWorld system directly by modem or through the Internet. To access the FedWorld system by modem:

Dial (703) 321–3339 and logon to the FedWorld system.
After logging on, type: /go FERC

To access the FedWorld system through the Internet, a telnet application must be used either as a stand-alone or linked to a Web browser:

Telnet to: fedworld.gov
Select the option: [1] FedWorld
Logon to the FedWorld system
Type: /go FERC

Or:

Point your Web Browser to: http://www.fedworld.gov
Scroll down the page to select FedWorld Telnet Site
Select the option: [1] FedWorld
Logon to the FedWorld system
Type: /go FERC

I. Introduction

The Federal Energy Regulatory Commission (Commission) is proposing to revise its procedural regulations governing applications for licenses for hydroelectric projects. The proposed regulations respond to a petition for rulemaking filed by the National Hydropower Association (NHA) and are intended to offer an alternative administrative process whereby in appropriate circumstances the pre-filing consultation process and the environmental review process can be integrated. This alternative process is designed to be tailored to the facts and circumstances of the particular proceeding. The proposed regulations would not delete or replace any existing regulations.

II. Reporting Burden

The regulations proposed herein would not impose any new information collection requirements.

III. Background

A. Order Nos. 513 and 533 Proceedings

The Commission last made comprehensive revisions of its procedural regulations governing hydropower applications in two major rulemakings. In Order Nos. 513 and 513–A,[1] the Commission revised its regulations governing the relicensing of hydropower projects to implement provisions added to the Federal Power Act (FPA)[2] by the Electric Consumers Protection Act of 1986 (ECPA).[3] The Commission adopted more detailed regulations for applicants for new licenses to conduct pre-filing consultation with resource agencies, to specify the information to be contained in the applications, and to set forth procedures for processing and considering the applications. These regulations are principally contained in 18 C.F.R. Part 16. In Order Nos. 533 and

[1] Order No. 513 (1989), 54 FR 23756 (June 2, 1989), FERC Stats & Regs., Regulations Preambles 1986–1990 ¶ 30,854; Order No. 513–A (1989), 55 FR 4 (January 2, 1990), FERC Stats & Regs., Regulations Preambles 1986–1990 ¶ 30,869.

[2] 16 U.S.C. §§ 791a–825r.

[3] Pub. L. No. 99–495, 100 Stat. 1243 (Oct. 16, 1986).

533–A,[4] the Commission adopted further revisions to its procedural regulations for all applications for hydropower licenses, implemented other provisions of ECPA, especially Section 10(j) of the FPA, and streamlined the hydropower licensing process by making it more efficient, fairer, and more understandable for all participants. In the rule, the Commission codified and improved many of its regulations governing pre-filing consultation and hearing practices, explaining how most hydropower proceedings are conducted by notice and comment rather than by trial-type hearings. This rulemaking established deadlines for participation in hydropower proceedings, clarified a number of Commission practices in the conduct of such proceedings,[5] required the Commission to resolve disputes concerning necessary scientific studies in the pre-filing consultation process for hydropower applicants, and provided greater opportunities for the public and Indian tribes to participate in the proceedings.

In one important respect, however, the Commission took no action in these rulemakings in response to comments made by some resource agencies and citizens' groups. They believed that in the revised regulations the Commission should have integrated the environmental review process pursuant to the National Environmental Policy Act of 1969 (NEPA)[6] with the pre-filing consultation process required of hydropower applicants. The Commission stated that this was not the Commission's historical practice, and that the results of the pre-filing consultation process and the comments, recommendations, conditions, and prescriptions of concerned parties were a necessary predicate to a successful NEPA review by the Commission of a hydropower application.

B. Implementation of Energy Policy Act of 1992

In section 2403 of the Energy Policy Act of 1992,[7] Congress authorized the Commission, in preparing a NEPA document in hydropower licensing proceedings, subject to certain conditions, to permit the applicant or its contractor or consultant to prepare an Environmental Assessment (EA) or a contractor or consultant chosen by the Commission and funded by the applicant to prepare an Environmental Impact Statement (EIS).[8] The provision left untouched the Commission's own responsibilities under NEPA.

The Commission has implemented this provision of the Act by permitting hydropower applicants to explore alternative licensing procedures. The Commission has received from potential hydropower applicants requests for guidance as to whether they could submit an EA or an EIS as part of their license applications. Applicants have asked whether they could integrate the NEPA process with the Commission's pre-filing consultation process, obtain greater involvement of Commission staff in this effort, and substitute such actions and the resulting NEPA document for the requirements for pre-filing consultation and filings set forth in the Commission's regulations.

The Commission's staff has responded to such requests on a case-by-case basis.[9] Staff advised potential applicants that it could not participate unless entities that might reasonably have an interest in the contemplated hydropower application are invited to participate in the pre-filing process. Such entities included all resource agencies, Indian tribes, local governments, citizens groups, and members of the general public affected by the proposed project. Staff advised that following this process requires a number of waivers of the Commission's regulations, in order to achieve the purposes of the Act. The principal waivers required are:

(1) the requirement for the applicant to file Exhibit E, containing environmental information[10]—the draft NEPA document prepared by the applicant or contractor or consultant, together with additional information, satisfies this requirement;

(2) the provision allowing parties to request additional scientific studies after the application is tendered for filing[11]—the waiver procedures move this opportunity forward in time;

(3) the requirement for issuing a notice that the application is ready for environmental analysis[12]—integrating preparation of the draft NEPA document with the pre-filing consultation process should ensure that the necessary environmental data concerning the application have already been developed prior to filing; and

(4) the requirement for the applicant to document the pre-filing process in detail[13]—this is replaced by periodic reports during the pre-filing process that are available to the public.

Before staff acts on a potential applicant's request for waiver of these regulatory requirements, the applicant must demonstrate that a cooperative atmosphere exists regarding the participation of concerned entities in the pre-filing process and that the applicant has reached an agreement with such entities on accepted procedures. Staff has advised the participants on procedures that have worked in similar circumstances to produce good NEPA documents or that show promise of working in this respect. Staff's objective has been to encourage the participants to focus analysis on a preferred environmental alternative and, insofar as possible, reach agreement on the issues raised by the application.[14]

The applicant is also required to develop a communications protocol, governing how the participants, including Commission staff, may communicate with each other during the pre-filing process. Oversight and technical committees may be formed. At least three public notices are required during this process, each of which consists of notice placed in the Federal

[4] Order No. 553 (1991), 56 FR 23108 (May 20, 1991), FERC Stats & Regs., Regulations Preambles 1991–1996 ¶ 30,921; Order No. 553–A (1991), 56 FR 61137 (December 2, 1991), FERC Stats. & Regs., Regulations Preambles 1991–1996 ¶ 30,932.

[5] These related to the requirements governing pre-filing consultation for applicants for amendment of licenses, when a water quality certification must be obtained, and how the Commission begins its review of hydropower applications.

[6] 42 U.S.C. §§ 4321–4307a.

[7] Pub. L. No. 102–486, 106 Stat. 2776, 2905–21. Codified at 42 U.S.C. §§ 13201–13556 (Supp. 1993).

[8] Section 2403 provides:

(a) ENVIRONMENTAL IMPACT STATEMENTS.—Where the Federal Energy Regulatory Commission is required to prepare a draft or final environmental impact statement . . . in connection with an application for a [hydropower] license . . ., the Commission may permit, at the election of the applicant, a contractor, consultant, or other person funded by the applicant and chosen by the Commission . . ., to prepare such statement for the Commission. . . . Nothing herein shall affect the Commission's responsibility to comply with the National Environmental Policy Act of 1969.

(b) ENVIRONMENTAL ASSESSMENTS.—Where an environmental assessment is required . . . in connection with an application for a [hydropower] license . . ., the Commission may permit an applicant, or a contractor, consultant or other person selected by the applicant, to prepare such environmental assessment. The Commission shall institute procedures, including pre-application consultations, to advise potential applicants of studies or other information foreseeably required by the Commission. The Commission may allow the filing of such applicant-prepared environmental assessment as part of the application. Nothing herein shall affect the Commission's responsibility to comply with the National Environmental Policy Act of 1969.

[9] The Office of Hydropower Licensing has developed ''Guidelines for the Applicant Prepared Environmental Assessment (APEA) Process.'' *See* Appendix A.

[10] *E.g.*,18 CFR 4.51(f).

[11] 18 CFR 4.32(b)(7).

[12] 18 CFR 4.34(b).

[13] *E.g.*, 18 CFR 4.38.

[14] The alternative process is designed to facilitate the negotiation of settlements in appropriate cases, that could be submitted to the Commission with the application as an offer of settlement.

Register by the Commission, notice placed in local newspapers by the potential applicant, and notice mailed directly to a mailing list of interested entities.[15] These notices are typically given: (1) at the beginning of the pre-filing process, when the applicant releases its initial information package, which may include a schedule for the first NEPA scoping meeting;[16] (2) when the results of the applicant's scientific studies are available, which may be combined with additional NEPA scoping and study requests; and (3) when the preliminary draft environmental document and related application have been prepared.

Prior to the signing of the communications protocol, staff has not communicated with any interested entity other than on procedural matters. Once the protocol is executed, pursuant to its provisions staff may enter into substantive discussions with any entity on the merits of the potential applicant's proposal, so long as the results of those discussions are subsequently made available in the relevant public files. These consist of the Commission's files for the project in question and a file maintained by the potential applicant.

For the majority of the many applications for new license currently undergoing pre-filing consultation, the applicants are using the process set forth in the Commission's rules. In 20 proceedings where a potential applicant is seeking a new or original license, the staff's alternative pre-filing procedures are being explored or are in use. In one proceeding, use of the alternative process has already resulted in an order issuing a license.[17] In most of the pending proceedings the applicant or its agent is preparing an EA; in some of the cases a contractor funded by the applicant is preparing an EIS. Some of the proceedings involve multiple projects on the same river basin.

C. NHA Petition for Rulemaking

On July 10, 1995, NHA filed a Petition for Rulemaking Regarding Regulations for the Relicensing of Hydroelectric Projects.[18] In its petition, NHA described its consultation with a large number of entities on how to improve the Commission's regulations in this area. NHA expressed its views on problems it perceives in the existing process for relicensing hydroelectric projects and proposed a comprehensive regulatory scheme for that purpose, which would replace the existing regulations governing the preparation, filing, and hearing process for hydropower applications for new licenses.

As described by NHA, its proposal is intended to integrate the application preparation process under the FPA with the environmental review process under NEPA, to provide an earlier start to the NEPA process, to involve Commission staff prior to the filing of an application, and to afford resource agencies and the public greater opportunity to participate in the pre-filing process. The goal is to shorten and simplify relicensing proceedings, which NHA claimed take too long to complete and impose unnecessary burdens on the participants, by eliminating repetitious steps in the pre-filing and post-filing stages. NHA also sought to promote settlements and to allow greater communication among parties and Commission staff by relaxing restrictions on *ex parte* communications. NHA proposed a ''collaborative option'' by which participants could agree to an alternative process for preparing and evaluating a hydropower application for new license.

NHA proposed 49 pages of regulatory text, which would substitute for sections in Parts 4 and 16 of the Commission's rules governing relicensing proceedings. NHA's proposed regulations specify 52 steps in such proceedings, through the filing of a final license application. The applicant would prepare and file with the Commission a Notice of Intent Package, an Initial Information Package, a study plan, and an application for new license. Under detailed guidelines, the Commission would give public notice of each of these filings, review them to determine their adequacy, and either accept or reject them.[19]

Under NHA's proposed regulations, a proceeding before the Commission would begin no later than the filing of the Initial Information Package, when interested persons could formally intervene in the proceeding as parties under § 385.214 of the Commission's rules.[20] The applicant's Initial Information Package would be ''comprised primarily of baseline data from the exhibits in [existing] 18 CFR § 4.51.''[21] These requirements were spelled out in section 19 of NHA's proposal, describing seven required ''schedules'' containing detailed information on the project, its operation and resource utilization, need for power and alternative sources of power, costs and financing, the environment, design drawings and other information showing the safety and adequacy of project structures, and a project map.

The environmental schedule would contain seven major elements, including a description of the locale and reports on water use and quality; fish, wildlife, and botanical resources; historic and archeological resources; recreational resources; socio-economic impacts; and land management and aesthetics. This information would describe not only the existing project and its impacts but also mitigation and other measures proposed for the new license period. Unlike existing § 4.51 and similar regulations (including § 16.8) now governing the preparation of license applications, no consultation with resource agencies, Indian tribes, or the public would be required in the preparation of these proposals of the applicant.

Under NHA's proposed rules, the Commission would conduct the NEPA process beginning immediately after the receipt of the Initial Information Package. The rules specify deadlines for the Commission and all participants defining ''the latest point at which a decision or action should be taken * * *''[22] The Commission would be required to publish public notice of the Initial Information Package within 30 days of its filing and at the same time issue and serve on each interested person a copy of ''Scoping Document I,'' pursuant to NEPA. This document would include: (1) a description of the scoping process, the project and its history; (2) a discussion of the applicant's proposal, reasonable alternatives, and competing proposals; (3) a discussion of resource and environmental issues (including cumulative impacts, other relevant projects and alternatives); (4) a schedule for preparing the NEPA document; (5) an outline for the final scoping document; and (6) a mailing list of recipients with intervenors identified.[23]

[15] The mailing list is developed by the applicant under the guidance of Commission staff. The list will include federal and state resource agencies, Indian tribes, local governments, environmental groups and others that may be affected by the proposed hydropower project. The mailing list may expand as a result of responses to the applicant's initial pre-filing consultation meeting and public notices, including local newspaper notice.

[16] Scoping is the formal process to solicit comments to help determine the environmental issues and how they should be addressed in an EIS or EA.

[17] *See* Georgia Power Company, 74 FERC ¶ 62,146 (1996) (Sinclair Project No. 1951). No requests for rehearing were filed.

[18] NHA is an association that represents the hydropower industry.

[19] See NHA Petition, Draft Regulations, at sections 6, 7, 18, 23, 24, 27, and 29.

[20] *Id.* at 5, section 8(c).

[21] *Id.* at 13.

[22] *Id.* at 33, section 22(b) (emphasis in original).

[23] *Id.* at 35, section 24.

Sixty days would be allowed for filing comments on Scoping Document I, and within 45 days the Commission would be required to hold a site visit and public scoping meeting.[24] Within 45 days of the completion of the public comment period on Scoping Document I, the Commission would be required to issue Scoping Document II, reviewing all the issues identified and the comments provided.[25] This document would identify all the data needs that must be satisfied by studies to be conducted by the applicant. Persons would have 45 days to file comments on Scoping Document II, including requests for additional or alternative studies. Not less than 14 days after issuance of Scoping Document II, the Commission would be required to issue public notice of a final public scoping meeting.

Within 30 days after the final scoping meeting, the Commission would be required to issue a final scoping document, which would ''identify all reasonable alternatives that need to be considered, identify cumulative effects and significant issues that need to be addressed in the environmental review process, document issues that were found not to be significant, and list all study and additional information requirements * * *'' [26] At this point, applicants would have the right to elect to prepare an EA or to have a contractor prepare an EIS.[27]

Pursuant to a set of detailed deadlines, NHA would allow a period of 150 days for the applicant to prepare a study plan, comments on it to be filed, and the Commission to resolve any disputes and review the plan.[28] Agencies and citizens groups would have the burden of asking the Commission to resolve any dispute over the adequacy of the applicant's study plan.[29] If the agencies or groups failed to request such a resolution, they would waive any right to raise this issue subsequently in the relicensing proceeding. The Commission would have 60 days after the filing of the Final Study Plan for the first year's study to resolve any disputes presented to the Commission over the plan and to accept, reject, or modify the plan accordingly.[30] The applicant would be required to submit a report summarizing the results of each study completed at the conclusion of the first year's study, and the Commission would hold a meeting to discuss the report.[31] Similar steps would be required in reference to a study plan for the second year, with further restrictions on the ability of others to request additional studies, and deadlines for the Commission to resolve any disputes presented to it.

The final stage of NHA's rulemaking proposal would require the applicant to prepare a ''final license application'' for filing with the Commission.[32] This application would incorporate the Notice of Intent Package, the Initial Information Package, the scoping documents and the study reports made in the pre-filing process. This information would be updated as necessary, and recommendations of agencies or citizens groups that were rejected would be explained.[33] This filing would ''constitute the complete application upon which the Commission will base its decision to accept, reject, or accept with modifications the final application submitted by the Applicant.'' [34]

NHA's proposed rules would also require the Commission to make more information about the relicensing process available on the Commission Issuance Posting Systems (CIPS); [35] provide that the Commission's *ex parte* rule, § 385.2201, does not apply to the proposed hydropower proceeding until after the filing of a final license application; [36] and give an applicant the right to elect a collaborative option, by which the applicant and interested parties may jointly design rules—different from the detailed rules proposed by NHA—to govern a hydropower proceeding.[37]

NHA acknowledged that there are a number of relevant subject areas, where it has not proposed regulations, that require further analysis. These areas include: [38]

(1) the impact of the relicensing process on small hydropower projects;

(2) the interaction of the Commission's process with administrative processes of other agencies, such as those conducted pursuant to the Endangered Species Act,[39] and FPA sections 4(e) and 18;

(3) how to integrate cumulative impact analysis into an accelerated NEPA process;

(4) how to evaluate the appropriateness of the time deadlines proposed for comment and Commission action; and

(5) how to develop transition provisions regarding ongoing licensing proceedings.

D. Comments Received on NHA's Petition

On October 31, 1995, the Commission issued a notice of NHA's petition and invited comment on it.[40] The Commission received 43 comments and four reply comments. The commenters are listed in Appendix B.

A number of licensees of hydropower projects [41] and other industry associations [42] filed comments supportive of NHA's petition. A number of state agencies filed comments supporting NHA.[43] A number of federal agencies supported NHA's petition,[44] but other federal agencies, while approving of a Commission rulemaking that would integrate the NEPA and pre-filing consultation processes, objected to the short time frames and other aspects of NHA's proposed rules.[45]

Many hydropower licensees filed comments critical of various aspects of NHA's petition, supporting the goal of greater integration of the NEPA and pre-filing processes but asking for more flexibility in the proposed rules in order to accommodate different circumstances.[46] Questions about the appropriateness of the time frames established in NHA's proposal were raised,[47] and the Commission was asked

[24] *Id.* at 37, section 26.

[25] *Id.* at 37, section 27.

[26] *Id.* at 39, section 31.

[27] *Id.* at 39, section 32.

[28] *Id.* at 40–47, sections 34–37.

[29] NHA's proposed rules do not recognize any right of Indian tribes to dispute the adequacy of the applicant's study plan.

[30] NHA Petition, Draft Regulations, at 43, section 34(e).

[31] *Id.* at 45, section 35(g).

[32] *Id.* at 47–48, section 38.

[33] As in the pre-filing process, NHA's proposed regulations do not recognize any role for Indian tribes.

[34] NHA Petition, Draft Regulations, at 47, section 38(b).

[35] *Id.* at 6, section 9(a).

[36] *Id.* at 6, section 10.

[37] *Id.* at 6–7, section 12.

[38] NHA Petition at 12.

[39] 16 U.S.C. § 1531, *et seq.*

[40] The notice was published in the Federal Register on November 8, 1995 (60 FR 56278). On January 4, 1996, the Commission issued a notice extending the deadline for comments and reply comments to February 5 and March 4, 1996, respectively.

[41] *E.g.*, Comments of Adirondack Hydro Development Corp., Alabama Power Co., Idaho Power Co., Minnesota Power & Light Co., Montana Power Co., Pacific Gas and Electric Co., and Southern California Edison Co.

[42] *E.g.*, Comments of American Public Power Association and Edison Electric Institute.

[43] *E.g.*, Comments of Idaho Public Utilities Commission and State of Washington, Department of Ecology.

[44] Comments of the U.S. Environmental Protection Agency and the U.S. Department of Energy.

[45] Comments of U.S. Department of Agriculture and U.S. Department of Commerce.

[46] Comments of Duke Power Co., Georgia Power Co., Nebraska Public Power District, and Niagara Mohawk Power Co.

[47] Comments of Public Utility District No. 2 of Grant County.

to codify the alternative procedures staff had used on a case-by-case basis.[48] Some licensees believed that NHA's Initial Information Package was too detailed, amounting to a draft license application.[49]

New England Power Company opposed adoption of NHA's proposed rule, except in situations where the parties agreed on such an approach as an alternative. The company doubted that NHA's proposal would help when there was no such consensus, especially in light of the importance of other related legal processes, such as those involving fishway prescriptions under section 18 of the FPA and certifications under section 401 of the Clean Water Act.[50] New England Power did not believe that the Commission would have the resources to be as involved in the pre-filing process as NHA's proposed rule would require. The company thought that NHA did not recognize the importance of the flexible, case-by-case procedures the Commission's staff had been using in recent years when there was a consensus supporting this approach.

Some commenters characterized NHA's petition as discouraging competing relicense applications, because the petition would seriously delay a potential competitor's access to project information that section 15(b)(2) of the FPA requires the incumbent licensee to make available, and that the potential competitor needs in order to decide whether to file an application.[51]

A number of state agencies opposed adoption of NHA's proposed rule as unnecessary.[52] They objected to its rigidity and to many of its features that in their view favored the applicant at the expense of other participants. They considered NHA's time deadlines on participants in the process unreasonable and opposed the elimination of draft applications and the shifting of responsibility from the applicant to others. A number of federal agencies, while supporting the goal of greater integration of the pre-filing and NEPA processes, made similar criticisms of NHA's petition and reminded the Commission of its trust responsibilities for Indian tribes, which they asserted NHA ignored.[53]

Citizens' groups were very much opposed to adoption of the regulations NHA proposed.[54] These commenters asked the Commission to continue its current practice of flexibly implementing the existing hydropower procedural regulations.

Hydro Reform Coalition (HRC) stated that the Commission's current procedural regulations for hydropower applications were adopted for good reasons, to cure real problems in the licensing process, have been working reasonably well and are not the chief cause of any delays encountered in the process.[55] Rather, HRC asserted that applicants have brought such delays on themselves by not conducting adequate studies of a project's resource impacts and not filing required information with their applications. Other delays are necessary to allow sufficient time to address such critical issues as cumulative impacts. HRC stated: ''NHA's package of changes drastically alters the equities of the relicensing process in favor of a front-end loaded, fast track, where licensees gain at the expense of all other participants—resource agencies, conservation groups, competing applicants * * *.'' [56]

HRC noted that a hydropower licensing proceeding is a learning process for most parties, who do not have the information and knowledge of the applicant. It takes some time for them to learn about and evaluate the proposed project's resource impacts so that they can usefully participate in the process and assist the Commission in considering reasonable alternatives and in compiling an adequate record for a decision in the public interest. While the current procedural regulations allow this process to unfold, in HRC's view NHA's proposal would replace them with new regulations designed to curtail this process and serve the interests of the license applicants.[57]

IV. Discussion

A. NHA's Petition

The Commission recognizes that the present procedures for licensing hydroelectric projects are complicated and can result in lengthy proceedings. We agree with NHA that every effort should be made to lessen the burden of such proceedings on the participants. To a considerable extent, however, we believe the burdens are an unavoidable product resulting from statutory mandates and the often conflicting objectives of the large number of parties, including state and federal agencies with overlapping roles, Indian tribes, and citizens' groups, interested in the licensing process. Nevertheless, we believe there continues to be room for taking reasonable measures to improve the efficiency of the process, while remaining faithful to the statutory mandates and public interest the Commission serves. Our hope is that the licensing process can be both expedited in time and improved in results, while treating all parties fairly.

We commend NHA and the other representatives of the hydropower industry who devoted substantial time and effort in evaluating the Commission's hydropower licensing procedures. We appreciate NHA's consultation with other participants in the licensing process and the submission of a petition for rulemaking, and we welcome the comments of all those who responded. We believe that the comments show that everyone who has studied and addressed this subject shares common goals, making licensing proceedings more efficient while maintaining procedures that will protect the participatory rights of interested parties and compile an adequate record for decision.

A critical difference between the avenues explored by the Commission staff in light of the Energy Policy Act and by NHA is in their basic design. The staff process was designed to supplement and not replace the existing procedures in licensing proceedings and can be flexibly applied on a case-by-case basis, with the alternative procedures tailored to the expressed needs and desires of the participants. This process places a lot of responsibility on the participants to come together and reach

[48] Comments of Power Authority of the State of New York.

[49] Comments of Georgia Power Co. and Safe Harbor Water Power Corp.

[50] 33 U.S.C. § 1341(a)(1).

[51] Comments of the Confederated Tribes of the Warm Springs Reservation and the City of Santa Clara, California, Holyoke Gas & Electric Dept., and the Northern California Power Agency.

Section 15(b)(2) of the FPA provides that, at the time an existing licensee notifies the Commission whether it intends to file an application for a new license (which shall be at least 5 years before the expiration of the existing license), the existing licensee must make publicly available such information about construction and operation of the project as the Commission shall require. The Commission's regulations implementing this provision (18 CFR 16.7) require extensive and detailed information about the project.

[52] *E.g.*, State of Washington Department of Fish and Wildlife and State of Wisconsin Department of Natural Resources.

[52] Comments of the U.S. Department of the Interior, Fish and Wildlife Service, and Bureau of Indian Affairs.

[54] Comments of the Adirondack Mountain Club, the Defenders of Wildlife, and the Hydropower Reform Coalition, which includes American Rivers, American Whitewater Affiliation, Appalachian Mountain Club, Conservation Law Foundation, Michigan Hydro Relicensing Coalition, Natural Heritage Institute, New England F.L.O.W., New York Rivers United, River Alliance of Wisconsin, Trout Unlimited, and Sierra Club Legal Defense Fund.

[55] HRC at 3–8. HRC pointed to many recent relicense proceedings, primarily involving some kind of cooperative approach, that were expeditiously conducted under the current regulations.

[56] HRC at 4.

[57] HRC at 8.

a consensus on how the environmental impacts of the applicant's proposal should be evaluated. If such a consensus cannot be achieved, the standard procedures set forth in the Commission's regulations must be followed by the applicant.

NHA has proposed enactment of comprehensive generic procedures that would apply to all relicensing proceedings, regardless of whether such a consensus exists and the prospect for success. NHA's proposal would require the Commission's staff to be involved in developing every application for a new license and to render decisions on the details of the steps required in that development. The Commission does not have the resources to carry out such an open-ended mandate. Furthermore, if, as NHA proposed, Commission staff assumed the role of decisionmaker in pre-filing consultation for all proceedings, concerned parties (including the applicant) could be discouraged from trying to form a consensus on how to study and resolve critical issues in a mutually satisfactory manner.

We share with the critics of NHA's petition a concern that NHA's proposed regulations would not improve hydropower licensing proceedings. In effect, NHA's proposal would eliminate the pre-filing consultation process. NHA would have an applicant for a new license develop a detailed package, called the ''Initial Information Package,'' that is for all intents and purposes a draft license application. We think such proposals are best developed based on prior consultation with affected resource agencies, Indian tribes, and the public. Before doing such consultation and conducting the studies that are required as part of the pre-filing process, an applicant cannot know in detail what mitigation and enhancement measures it should propose.

To require the Commission staff to step in to direct every hydropower relicensing proceeding prior to any pre-filing consultation would consume too much of the Commission's limited resources without providing any assurance that the process would be improved. The Commission did not have the resources to undertake this role in the past; we certainly do not have the resources to do so now, a time when federal agencies are being called upon to tighten their budgets.

NHA has described as critical its proposal to waive the *ex parte* rule prior to the filing of what it calls the ''final license application'' with the Commission. But its proposal would have the Commission conducting a proceeding prior to that time, with the intervention of parties, and NHA itself also recognized that the proceeding may be highly contentious. Under those circumstances, it would be unwise and may be unlawful for the Commission to consider itself and its advisory staff as not subject to any *ex parte* restraint.

We also share the concern of those who question how NHA's proposal would afford potential competitors the timely access to project information that section 15(b)(12) of the FPA calls for.

Nor has NHA justified the short time frames it sets for responses and decisions during its proposed hydropower process. The periods allowed are much shorter than similar time frames in the existing regulations, whose deadlines have been considered strict by various participants in the licensing process. Any successful process will necessarily require more flexibility than may be contemplated in NHA's proposal.

NHA's proposed rules might also not result in a more efficient proceeding if other state or federal agencies with related statutory responsibilities, such as Clean Water Act certification, do not wish to participate in the accelerated NEPA process that NHA would require in all cases. Lacking a consensus for an alternative approach to front-load the NEPA process would risk wasting a large amount of resources by all participants and might require the NEPA process to be repeated, once the other agencies decided how they wished to proceed in reference to the applicant's proposal. The Commission cannot by rule mandate a positive spirit of mutual understanding and cooperation among the applicant, resource agencies, Indian tribes, and the public, or fully integrate related processes that occur under separate statutes.[58]

We do, however, believe there is considerable merit in the part of NHA's proposal called a ''collaborative option.'' This appears to be similar to the alternative procedures that the Commission's staff has been using on a case-by-case basis at the request of license applicants, where there is a consensus among the interested entities that such an approach would be fruitful. If an applicant is willing to devote itself to working on a cooperative basis with all the entities interested in its proposed hydropower project, including affected resource agencies, Indian tribes, and the public, and those entities have a similar attitude and commitment, the Commission is willing to commit its staff to active involvement in the proceeding prior to the filing of an application, to the extent our limited resources permit. In such cases, the staff's participation has been more as a resource and guide to the parties rather than as a decisionmaker.

Such an approach, tailored to the needs and requirements of the particular circumstances and facts presented, has worked in many cases and in our view offers the best hope of achieving the goal of expediting the licensing process in a way that is fair to all parties and in the public interest. Such proceedings can front-load not only NEPA, but also the completion of other processes related to hydropower licensing that are not in the Commission's control, such as state water quality certification for the project.

In the following section, we describe the Commission's proposed rule on this alternative process. The proposed rule is intended to refine, clarify, and codify the alternative procedures that the Commission's staff has evolved over the past few years on a case-by-case basis. By articulating these procedures in the form of a notice of proposed rulemaking, we are providing a forum in which all interested persons will have an opportunity to comment on them, in light of experience with the alternative procedures as well as with the existing procedures. This rulemaking should provide an opportunity to consider how the alternative procedures have worked to date, and how they might be refined to improve the efficiency of the licensing process while preserving the rights of all of the participants in it.

B. Proposed Rule

We propose to codify an alternative process that affords case-by-case flexibility and opportunity for continued innovation for all concerned. We recognize that some of the procedures that participants may agree to use and that the Commission may approve in individual cases might well be similar to those that NHA has proposed in generic form. The proposal would leave intact the existing pre-filing and hearing procedures for use in all proceedings where there is neither a consensus on suitable alternative procedures nor any reasonable prospect for their success in expediting the proceeding.

We see no reason to restrict the proposal to applicants for new licenses, but, consistent with Commission practice and the Energy Policy Act,

[58] NHA has also not explained its apparent omission of Indian tribes from its proposed rules. The Commission included the tribes in the pre-filing consultation process in recognition of their special interests and status. NHA claimed that it consulted with Indian tribes in developing its proposal, but NHA did not identify them or their positions.

would extend the ability to apply for this option to all applicants for licenses, whether original, new or subsequent, and to amendments to existing licenses where pre-filing consultation is required (pursuant to § 4.38(a)(4) of the regulations).[59]

The Commission proposes to revise § 4.34 of the regulations, governing the hydropower hearing process, to add a new subsection (i). Under this subsection, a potential applicant could request that it be permitted to conduct the pre-filing consultation and hearing processes pursuant to an alternative procedure. Under this procedure, the pre-filing consultation process and the NEPA process would be integrated and the applicant or its contractor or consultant would prepare a preliminary draft environmental assessment or a contractor or consultant chosen by the Commission and funded by the applicant would prepare a preliminary draft environmental impact statement, to be filed with the application.

In appropriate circumstances, the Commission could approve the request and participate in the alternative process, if the applicant demonstrated that it had reached out to interested entities and a consensus exists supporting the use of alternative procedures. The requester would also have to submit a communications protocol, supported by interested entities, that would describe how the applicant and other participants in the pre-filing consultation process, including Commission staff, would communicate concerning the merits of the applicant's proposal.

The alternative process would integrate the NEPA process and the pre-filing consultation process. The applicant, contractor or consultant would be required to conduct an initial information meeting, to scope environmental issues, to complete scientific studies and release them, to conduct further scoping if appropriate, and to prepare the preliminary draft environmental document for filing with the Commission. The process would allow for public participation, and public notice would be given of critical stages (including the filing of the request for alternative procedures) by the Commission in the Federal Register and by the applicant in a local newspaper.

Every quarter, the applicant would be required to report to the Commission on the progress of the pre-filing consultation process. Public files of relevant documents would be maintained by the Commission and the applicant. The Commission's file would contain summary information while the applicant's file would contain all relevant information compiled during the process.

Under the alternative process, the applicant could substitute a draft NEPA document for Exhibit E to its application, and the applicant would not need to document all the details of the pre-filing consultation process. Requests for scientific studies would be due during the pre-filing process, and requests for additional studies could be made after filing of the application only upon a showing that it was not possible to request them during the pre-filing process. Preliminary fish and wildlife recommendations, prescriptions, mandatory conditions, and comments would be due during the pre-filing period, to be finalized after the filing of the application. No notice that the application is ready for environmental analysis would be given by the Commission after filing of the application.

The proposed rule would also reserve the Commission's authority, upon request and on a case-by-case basis, to participate in the pre-filing consultation process and assist in the integration of this process with the NEPA process where, *e.g.*, the applicant, contractor or consultant funded by the applicant would not prepare an environmental assessment or environmental impact statement. In such cases, the Commission could approve suitable modifications to the procedures otherwise applicable during the pre-filing and post-filing periods, similar to those made for alternative procedures set forth in the proposed rule.

The Commission invites comment on all aspects of its proposal, as described above. The Commission particularly invites comment on what should happen if the consensus for use of alternative procedures disappears prior to the filing of an application. Should the Commission still allow alternative procedures to be followed in such a situation? If not, what procedures should apply?

Would any transition provisions be necessary for the proposed rule, so as not to upset applications currently being prepared pursuant to staff-granted waivers?

The Commission also proposes to add a new § 375.314(u) to its regulations, to clarify and codify the authority of the Director of the Office of Hydropower Licensing to approve the use of the alternative procedures and to assist in the pre-filing consultation process. In appropriate cases, for example, the Director could decide to actively assist a potential applicant in the pre-filing consultation process, including the preparation of a NEPA document.

V. Environmental Analysis

Commission regulations describe the circumstances where preparation of an environmental assessment or an environmental impact statement will be required.[60] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment.[61] No environmental consideration is necessary for the promulgation of a rule that is clarifying, corrective, or procedural, or that does not substantially change the effect of legislation or regulations being amended.[62]

This proposed rule is procedural in nature. It proposes alternative procedures that participants to a hydroelectric licensing proceeding may wish to use. Thus, no environmental assessment or environmental impact statement is necessary for the requirements proposed in the rule.

VI. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980 (RFA) [63] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. Pursuant to section 605(b) of the RFA, the Commission hereby certifies that the proposed regulations, if promulgated, will not have a significant economic impact on a substantial number of small entities.

The procedures proposed herein are purely voluntary in nature, and are designed to reduce burdens on small entities (as well as large entities) rather than to increase them. More fundamentally, the alternative process we are proposing herein would be purely voluntary. The procedures proposed herein would be a potential alternative to the procedures currently prescribed in our regulations, and would not be adopted unless all of the persons and entities interested in the proceeding affirmatively agreed to use them. Under this approach, each small entity would be able to evaluate for itself whether the alternative procedures would be beneficial or burdensome, and could decline to agree to their adoption

[59] By revising § 4.34 of the regulations, which governs the hearing process for all hydropower applications, the proposal would apply to all licensing proceedings, including those subject to Part 16.

[60] Regulations Implementing National Environmental Policy Act, 52 FR 47897 (Dec. 17, 1987), codified at 18 CFR Part 380.

[61] 18 CFR 380.4(a)(2)(ii).

[62] 18 CFR 380.4.

[63] 5 U.S.C. §§ 601–612.

if they appeared to be burdensome. Under these circumstances, the economic impact of the proposed rule would be either neutral or beneficial to the small entities affected by it.

VII. Information Collection Requirements

The Office of Management and Budget's (OMB)[64] regulations require that OMB approve certain information collection requirements imposed by agency rules. The regulations proposed in this Notice do not require the collection or filing of any information, nor would they amend any existing information collection requirement.

VIII. Comment Procedure

The Commission invites interested persons to submit written comments on the matters proposed in this notice. An original and 14 copies of the written comments must be filed with the Commission no later than February 3, 1997, for comments and March 3, 1997, for reply comments. Comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, and should refer to Docket No. RM95–16–000.

Written comments will be placed in the public files of the Commission and will be available for inspection at the Commission's Public Reference Room, at 888 First Street, N.E., Washington, D.C. 20426, during regular business hours.

List of Subjects

18 CFR Part 4

Electric power, Reporting and recordkeeping requirements.

18 CFR Part 375

Authority delegations (Government agencies), Seals and insignia, Sunshine Act.

By direction of the Commission.

Lois D. Cashell,

Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 4 and 375 of chapter I, title 18, *Code of Federal Regulations*, as set forth below.

PART 4—LICENSES, PERMITS, EXEMPTIONS, AND DETERMINATION OF PROJECT COSTS

1. The authority citation for part 4 continues to read as follows:

Authority: 16 U.S.C. 791a-825r, 2601–2645; 42 U.S.C. 7101–7352.

[64] 5 CFR 1320.13.

2. In § 4.34, the heading is revised and a new paragraph (i) is added to read as follows:

§ 4.34 Hearings on applications; consultation on terms and conditions; motions to intervene; alternative procedures.

* * * * *

(i) *Alternative procedures.* (1) An applicant may submit to the Commission a request to approve the use of alternative procedures for pre-filing consultation and the filing and processing of an application for an original, new or subsequent hydropower license, or for the amendment of a license that is otherwise subject to the provisions of § 4.38.

(2) The goal of such alternative procedures shall be to:

(i) Integrate the pre-filing consultation process with the environmental review process;

(ii) Facilitate the greater participation of the public and Commission staff in the pre-filing consultation process;

(iii) Allow for the preparation of an environmental assessment by an applicant or its contractor or consultant or of an environmental impact statement by a contractor or consultant chosen by the Commission and funded by the applicant; and

(iv) Encourage the applicant and interested persons to narrow any areas of disagreement and promote settlement of the issues raised by the hydropower proposal.

(3) A potential hydropower applicant requesting the use of alternative procedures must:

(i) Demonstrate that a reasonable effort has been made to contact all resource agencies, Indian tribes, citizens' groups and others affected by the applicant's proposal, and that a consensus exists that the use of alternative procedures is appropriate under the circumstances; and

(ii) Submit a communications protocol, supported by interested entities, governing how the applicant and other participants in the pre-filing consultation process, including the Commission staff, may communicate with each other regarding the merits of the applicant's proposal.

(4) As appropriate, the alternative procedures shall include provision for an initial information meeting, the scoping of environmental issues, the analysis of completed scientific studies and further scoping, and the preparation of a preliminary draft environmental assessment or environmental impact statement and related application.

(5) The Commission will give public notice inviting comment on the applicant's request to use alternative procedures.

(6) If the Commission accepts the use of alternative procedures, the following provisions will apply.

(i) To the extent feasible under the circumstances of the proceeding both the Commission and the applicant will give public notice at each of the stages described in paragraph (i)(4) of this section. The applicant will also send notice of these stages to a mailing list approved by the Commission.

(ii) Every quarter, the applicant shall furnish the Commission with a report summarizing the progress made in the pre-filing consultation process and referencing the applicant's public file, where additional information on that process can be obtained.

(iii) At a suitable location, the applicant will maintain a public file of all relevant documents, including scientific studies, correspondence, and minutes of meetings, compiled during the pre-filing consultation process. The Commission will maintain a public file of the applicant's initial proposal and information package, scoping documents, periodic reports on the pre-filing consultation process, and the preliminary draft environmental document.

(iv) An applicant authorized to use alternative procedures may substitute a preliminary draft environmental document and specified additional material instead of Exhibit E to its application and need not document the pre-filing consultation process.

(v) The procedures approved may require all resource agencies, Indian tribes, citizens groups, and interested persons to submit to the applicant requests for scientific studies during the pre-filing consultation process, so long as additional requests may be made to the Commission for good cause after the filing of the application, explaining why it was not possible to request the study during the pre-filing period.

(vi) During the pre-filing process the Commission may require the filing of preliminary fish and wildlife recommendations, prescriptions, mandatory conditions, and comments, to be finalized after the filing of the application; no notice that the application is ready for environmental analysis need be given by the Commission after the filing of an application pursuant to these procedures.

(7) The Commission may participate in the pre-filing consultation process and assist in the integration of this process and the environmental review process in appropriate cases where the applicant, contractor or consultant

funded by the applicant is not preparing a preliminary draft environmental assessment or environmental impact statement, but where staff assistance is available and will expedite the proceeding.

PART 375—THE COMMISSION

3. The authority citation for part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

4. In § 375.314, paragraph (u) is added to read as follows:

§ 375.314 Delegations to the Director of the Office of Hydropower Licensing.

* * * * *

(u) Approve, on a case-specific basis, the use of alternative procedures for the development of an application for an original, new or subsequent license or of an application for a license amendment subject to the pre-filing consultation process, and assist in the pre-filing consultation process.

Note: The appendices will not appear in the *Code of Federal Regulations.*

Appendix A—Guidelines for the Applicant Prepared Environmental Assessment (APEA) Process

(November 26, 1996—Office of Hydropower Licensing Division of Project Review)

Section 2403(b) of the Energy Policy Act of 1992 (Act) allows an applicant to file a draft environmental assessment (DEA), pursuant to the National Environmental Policy Act of 1969 (NEPA),[65] with its license application. The Act also requires the Federal Energy Regulatory Commission (Commission) to institute procedures to advise applicants who choose this route. This document provides general advice consistent with the statutory provisions.

We've divided the process into three stages, consistent with the Commission's three stage consultation regulations. In each stage, we: 1) highlight the objective; and 2) discuss the major milestones and work products. The process, as outlined by the bullet items and arrows, provides a framework for applicants, consultants, Commission staff and other interested entities to complete the process successfully. The guidance herein is intended to be flexibly administered, to suit the circumstances of specific cases.

Applicant Prepared EA (APEA) Process

Commission Staff Goal: 1) front-load NEPA review and other licensing requirements (i.e., 401 water quality certification, section 106—historic preservation consultation, section 7—endangered species consultation, etc.) by providing oversight for an applicant who prepares a DEA during the prefiling consultation period; 2) facilitate a process whereby the draft EA fully evaluates and balances the interests of all stakeholders involved; and 3) expedite the licensing process.

Stage 1 Consultation

Stage 1 Consultation sets the tone for the process and has two important features: participation in the activities ancillary to the licensing process and the beginning of NEPA scoping, including a site visit. Part of the licensing process includes the applicant inviting the federal, state, and local agencies, nongovernmental organizations (NGOs), and other interested members of the public to participate in the process. Once the applicant has gathered a group to participate, the applicant and participants should prepare a communications protocol and a request for waiver of specific three-stage consultation regulations. If a federal land managing agency is involved and desires cooperating agency status in the Commission's NEPA document, a Letter of Understanding (LOU) should be prepared by staff.

NEPA scoping and a site visit may begin in Stage 1. Basically, there are two options: 1) the applicant can begin the NEPA scoping by combining the 1st Stage joint agency and public meeting [required in 18 C.F.R. § 4.38(b)(3) and 16.8] with a NEPA scoping meeting; or 2) the applicant can hold the 1st Stage meeting and postpone NEPA scoping until Stage 2. The Commission and the Council on Environmental Quality (CEQ) prefer to scope the issues as early as possible.

There are advantages and disadvantages of beginning NEPA scoping at the 1st Stage consultation meeting. The advantage is that the applicant and participants can focus on identifying the issues up-front to develop study plans for the project. This may help eliminate the ''cart before the horse'' syndrome where the applicant is requested to study everything to find out if it's an issue. Another advantage is that the applicant can ask for input regarding project alternatives and ask the meeting participants to provide information, such as existing studies, that other agencies or NGOs might have. Most APEA efforts have completed NEPA scoping in Stage 1.

It may not be possible to combine NEPA scoping with the 1st Stage consultation meeting, because the participants may not be able to identify the issues owing to a lack of data.

Consider combining the NEPA scoping and 1st Stage joint meeting when:

1) applicants ask to begin the APEA process at the beginning of Stage 1, and

2) project issues and potential impacts are fairly well-known. This option is most appropriate for relicenses or unlicensed projects (UL's).

Here Are the Milestones and Work Products for Stage 1 Consultation

- Applicant decides to do APEA—preferably at the preliminary permit stage (original license) or at the notice of intent to file stage (relicense) or earlier.[66]
- Applicant generates a project mailing list (federal, state, local agencies, NGOs, and any other interested entities, such as property owners along the river).
- Applicant writes to the Commission (cc: the mailing list) requesting that the Commission agree to advise it in the APEA process.
- Commission responds to the applicant's letter and specifies staff's role in the process. Staff sends samples of communications protocol, if one hasn't been proposed, as well as samples of other EAs, scoping documents, etc.

==> Commission staff are selected to advise applicant

- Applicant requests a waiver of certain regulations (such as a waiver allowing the filing of the DEA in lieu of an exhibit E), as appropriate.
- The applicant, Commission staff, and other participants develop a Communications protocol (merits and procedures discussions) and a timeline (milestones). Participants are encouraged to sign the communications protocol. The applicant mails a copy of these documents to the mailing list.
- If applicable, the Commission or applicant will executes a Letter of Understanding (LOU) with cooperating federal managing agencies.
- Applicant mails Initial Stage Consultation Document (ISCD). The ISCD must be comprehensive and contain adequate information to provide a basis for participants to comment and make recommendations concerning study plans, etc.

BASED ON THE AMOUNT OF AVAILABLE PROJECT INFORMATION, THE COMMISSION STAFF WILL ADVISE THE APPLICANT TO: (A) HOLD THE 1ST STAGE MEETING ONLY; OR (B) COMBINE THE 1ST STAGE AND NEPA SCOPING MEETINGS.

(A) Applicant holds joint agency and public meeting within 60 days of mailing the ISCD; conducts a site visit; Applicant requests that the agencies, NGOs provide initial study needs.

==> Comments from agencies/NGOs on the ISCD are due 60 days after joint meeting. Agencies, NGOs, and the public should request initial studies.

- Applicant, agencies, or NGOs can, if needed, request dispute resolution on study requests.

(B) Applicant prepares Scoping Document 1 (SD1)[67] and mails 30 days before joint agency/public meeting. Applicant can attach Scoping Document I to the ISCD and mail together.

==> Commission issues a notice of scoping.

==> Applicant holds NEPA scoping meetings (public and agency); conducts site visit.

==> Comments from agencies/NGOs on the ISCD and SDI are due 60 days after joint meeting. This includes requests for initial studies.

- Applicant, agencies, or NGOs can, if needed, request dispute resolution on study requests.
- Applicant issues Scoping Document II (SDII).

[65] National Environmental Policy Act of 1969, as amended.

[66] Applicant and interested stakeholders can request to meet with staff to discuss the process.

[67] SDI can be very brief since the ISCD will provide a great deal of information.

• Applicant should apply for the 401 WQC so that the WQC agency can determine whether it requires any additional information to act on water quality certification.

Stage 2 Consultation

Several activities occur during Stage 2: 1) data collection and analysis [1–2 field seasons]; 2) scoping [if not completed in Stage 1]; 3) final request for additional studies pursuant to 18 C.F.R. Section 4.32 (b)(7); 4) development of the preliminary DEA and draft license application; 5) request for agency/NGO/public preliminary recommendations, terms and conditions; and 6) issuance of the draft license application and preliminary DEA for comment [as required in 18 C.F.R. § 4.38(c)(4); § 16.8].

Here Are the Milestones and Work Products for Stage 2

• Applicant will copy Commission and all participants on study plans (Commission staff reviews, advises, comments).
• Applicant completes first field season of studies.

IF NEPA SCOPING WASN'T DONE IN STAGE 1, PROCEED WITH (A); IF NEPA SCOPING WAS DONE IN STAGE 1, FOLLOW (B).

(A) Applicant provides study results to all interested participants along with SD1.

==> In SD1, applicant issues a request for any further study recommendations.

• Applicant holds a Scoping meeting and site visit 30 days after mailing SDI.
• Comments on scoping and additional study requests are due to the Applicant, with a copy to the Commission staff, 60 days after SD1 is mailed; 30 days after the NEPA scoping meeting.
• If a dispute regarding an additional study request can not be resolved, an applicant, agency, or NGO may request dispute resolution.

(B) Since scoping meetings were held in Stage 1, the Applicant mails study results to all participants for 60-day review.

==> Applicant issues a request for any further study recommendations 30 days after study results have been mailed and allows 60 days after issuance of that letter for agencies, NGOs, public, to request additional studies, if needed.

• If a dispute regarding an additional study request can not be resolved, an applicant, agency, or NGO may request dispute resolution.

ALL APPLICANTS FOLLOW THE STEPS OUTLINED BELOW

• Second field season of studies, if needed.
• Applicant begins preparing draft license application and preliminary DEA (PDEA).
• Applicant requests preliminary terms and conditions from the stakeholders to analyze in the PDEA.
• Applicant presents and analyzes its proposal for licensing/relicensing the project in the PDEA along with any preliminary terms and conditions, prescriptions and recommendations from the participants and sends to all participants for review and comment.[68] The PDEA should contain the results of any additional studies that were completed in stage 2.

==>NOTE: The PDEA must include the applicant's proposal and reasonable alternatives.

==> Commission issues a notice of availability of the PDEA with a request for preliminary terms and conditions, prescriptions and recommendations.

• The applicant will incorporate comments, preliminary terms and conditions and recommendations from the participants into the DEA and final license application.

==> Comments from agencies, NGOs, and the public are due to the applicant 90 days from mailing the draft license application and PDEA.

• Hold a meeting, if needed, (not later than 60 days from the disagreeing parties' letter) to discuss the applicant's proposal, analyses, etc., that were presented in the PDEA and discuss any changes (such as settlement agreements, the preliminary conditions and recommendations) to be incorporated and analyzed in the DEA and final license application.
• Prepare final application and DEA.

Stage 3 Consultation

At this stage, the Commission staff conducts an independent analysis and makes a recommended decision.

Here Are the Milestones for Stage 3

• Applicant files license application and DEA with Commission, and distributes it to the mailing list.

==> Staff reviews the application and DEA for adequacy.

• The Commission issues a notice of acceptance, provides opportunity for interested entities to request intervenor status, and requests final terms, conditions [including final 401 WQC conditions] recommendations, and 4(e) conditions if applicable, from participants.

==> 60-day period to file a motion to intervene with the Commission.

==> 105-day comment period (60 days for agency final recommendations; 45 days for the applicant's response to agency final recommendations.

==> This 60-day recommendation period is also an opportunity for agencies, NGOs, and other interested entities to comment on the applicant's license application and DEA.

• Commission staff receives final agency terms and conditions, prescriptions and participants' final recommendations.

[68] To allow sufficient time for the applicant to evaluate and balance the participants' recommendations and preliminary terms and conditions, the applicant should mail the PDEA about 8 months prior to the deadline date for filing the final license application and DEA with the Commission.

• Commission staff modifies the DEA in light of responses to final agency and participants' recommendations.

==> Staff completes comprehensive development analysis; writes Finding of Significant Impact or of No Significant Impact.

• Commission issues staff DEA.

==> 30-day comment period on the DEA or 45 days comment if section 10(j) issues apply.

• Commission staff revises DEA in light of comments received and the results of section 10(j) negotiations, if applicable.
• Commission issues Final EA.
• Commission requests Final 4(e) conditions, if applicable.[69]
• License order issued.[70] Note: The Applicant-Prepared EA Process flow chart that follows is not being published in the Federal Register but is available from the Commission's Public Reference Room.

Note: The Applicant-Prepared EA Process flow chart that follows is not being published in the Federal Register but is available from the Commission's Public Reference Room.

Appendix B—Commenters

U.S. Department of Agriculture, U.S. Forest Service
U.S. Department of Commerce, National Marine Fisheries Service
U.S. Department of Energy
U.S. Department of the Interior, Bureau of Indian Affairs
U.S. Department of the Interior, U.S. Fish and Wildlife Service
U.S. Environmental Protection Agency
Environmental Council of States
Idaho Public Utility Commission
Minnesota Department of Natural Resources
Washington Department of Ecology
Washington Department of Fish and Wildlife
Wisconsin Department of Natural Resources
Confederated Tribes of the Warm Springs Reservation of Oregon
National Hydropower Association
Edison Electric Institute
American Public Power Association
Western Urban Water Coalition
Northwest Hydroelectric Association
Association of California Water Agencies
Hydro Reform Coalition
Adirondack Mountain Club
Defenders of Wildlife
Denver Water Department
Nebraska Public Power District
New York State Power Authority
Sacramento Municipal Power District
Santa Clara County, Holyoke Gas & Electric Company, and California Water Agency
Alabama Power Company
Duke Power Company
Georgia Power Company
Idaho Power Company
Minnesota Power & Light Company

[69] Some 4(e) agencies have a practice of providing only preliminary terms and conditions before a final NEPA document is issued. However, Staff will work with cooperating agencies with the goal of expediting final 4(e) conditions so that they may be incorporated into the Final EA, rather than have those conditions provided afterward.

[70] Assumes 401 WQC has been received/waived and no intervenors in opposition.

Montana Power Company
Niagara Mohawk Power Company
New England Power Services
Pacific Gas & Electric Company
Portland General Electric Company
Safe Harbor Power Company
Southern California Edison Company
Washington Water Power Company
TAPOCO
Adirondack Hydro Development Corporation

Reply comments were filed by NHA, Hydro Reform Coalition, Georgia Power, and Niagara Mohawk.

[FR Doc. 96–30715 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 122

Addition of Midland International Airport to List of Designated Landing Locations for Private Aircraft

AGENCY: Customs Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations by adding the user-fee airport at Midland, Texas (Midland International Airport) to the list of designated airports at which private aircraft arriving in the Continental U.S. via the U.S./Mexican border, the Pacific Coast, the Gulf of Mexico, or the Atlantic Coast from certain locations in the southern portion of the Western Hemisphere must land for Customs processing. This proposed amendment is made to improve the effectiveness of Customs enforcement efforts to combat the smuggling of drugs by air into the United States. This proposed amendment, if adopted, would also improve service to the community, by relieving congestion at Presidio-Lely International, Del Rio International, and Eagle Pass Municipal Airports, which are also located in Texas.

DATES: Comments must be received on or before February 3, 1997.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to U.S. Customs Service, Office of Regulations and Rulings, Regulations Branch, Franklin Court, 1301 Constitution Avenue, NW., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, located at Franklin Court, 1099 14th St., NW, Suite 4000, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Gay Laxton, Passenger Operations Division, Office of Field Operations, (202) 927–5709.

SUPPLEMENTARY INFORMATION:

Background

As part of Customs efforts to combat drug-smuggling efforts, Customs air commerce regulations were amended in 1975 to impose special reporting requirements and control procedures on private aircraft arriving in the Continental United States from certain areas south of the United States. T.D. 75–201. Thus, since 1975, commanders of such aircraft have been required to furnish Customs with timely notice of their intended arrival, and certain private aircraft have been required to land at certain airports designated by Customs for processing. In the last twenty years the list of designated airports for private aircraft has changed and the reporting requirements and control procedures—now contained in Subpart C of Part 122 of the Customs Regulations (19 CFR Subpart C, Part 122)—have been amended, as necessary.

Specifically, § 122.23 (19 CFR 122.23) provides that subject aircraft arriving in the Continental U.S. must furnish a notice of intended arrival to the designated airport located nearest the point of crossing. Section 122.24(b) provides that, unless exempt, such aircraft must land at the designated airport for Customs processing and delineates the airports designated for private aircraft reporting and processing purposes. There are currently 30 designated airports listed at § 122.24(b).

Community officials from Midland, Texas, have written Customs requesting that the user-fee airport there (Midland International Airport) be added to Customs list of airports designated for private aircraft reporting and processing. The request is based both on considerations of the strategic location of the airport—between the communities of El Paso and Laredo, Texas—and because the airport has become a modern, well-equipped airport that can accommodate corporate aircraft.

Customs has determined that the addition of Midland International Airport to the list of designated landing sites for private aircraft will improve the effectiveness of Customs drug-enforcement programs relative to private aircraft arrivals, as Midland is adjacent to the Southwest Border of the U.S. and is on a regularly traveled flight path. Further, the designation would enhance the efficiency of the Customs Service, as the airport is close to the normal work location for inspectional personnel assigned to the Del Rio-Eagle Pass-El Paso-Laredo-Presidio Ports-area. In this regard, it is pointed out that the private aircraft processing services Customs provides at the Presidio, Del Rio, and Eagle Pass Airports will continue; designating Midland International Airport is meant to provide an alternative airport to these other airports in order to relieve air traffic congestion at those locations.

Although notice of this proposed designation is not required to be published in the Federal Register, comments are solicited from interested parties concerning whether or not the Midland International Airport should be designated as an airport for the landing of private aircraft.

Comments

Before adopting this proposal as a final rule, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1099 14th St., NW, 4th floor, Washington, DC.

Inapplicability of the Regulatory Flexibility Act and Executive Order 12291

This proposed amendment seeks to expand the list of designated airports at which private aircraft may land for Customs processing. Although this document is being issued with notice for public comment, because it relates to agency management and organization, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Agency organization matters such as this document are exempt from consideration under E.O. 12866.

Drafting Information

The principal author of this document was Gregory R. Vilders, Regulations Branch.

List of Subjects in 19 CFR Part 122

Air carriers, Air transportation, Aircraft, Airports, Customs duties and inspection, Drug traffic control, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Security measures.

Proposed Amendment to the Regulations

For the reasons stated above, it is proposed to amend part 122, Customs Regulations (19 CFR part 122), as set forth below:

PART 122—AIR COMMERCE REGULATIONS

1. The authority citation for Part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1433, 1436, 1459, 1590, 1594, 1623, 1624, 1644; 49 U.S.C. App. 1509.

§ 122.24 [Amended]

2. In § 122.24, paragraph (b) is amended by adding, in appropriate alphabetical order, ''Midland, TX'' in the column headed ''Location'' and, on the same line, ''Midland International Airport.'' in the column headed ''Name''.

Samuel H. Banks,

Acting Commissioner of Customs.

Approved: November 8, 1996.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–30722 Filed 12–2–96; 8:45 am]

BILLING CODE 4820–02–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 96–6]

''Best Edition'' of Published Copyrighted Works for the Collections of the Library of Congress

AGENCY: Copyright Office, Library of Congress.

ACTION: Proposed rule; Extension of filing period.

SUMMARY: The Copyright Office is extending the filing period for comments on proposed amendments to the regulations governing the deposit of the ''best edition'' of published motion pictures. This extension will provide interested parties with adequate time to comment.

DATES: Filings should be received by January 14, 1997.

ADDRESSES: By mail: Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20023. By hand: Office of the General Counsel, U.S. Copyright Office, James Madison Memorial Building, Room 407, First and Independence Avenue, S.E.

FOR FURTHER INFORMATION CONTACT: Marilyn J. Kretsinger, Acting General Counsel, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380, Telefax (202) 707–8366.

SUPPLEMENTARY INFORMATION: On November 15, 1996 (61 FR 58497), the Copyright Office published a Notice of Proposed Rulemaking to amend the regulations regarding the deposit of the ''best edition'' of published motion pictures. The purpose of the proposed rule is to remove the ''most widely distributed gauge'' as a selection faction of the ''best edition'' and add new videotape formats to the prioritized list of material preferences based on current industry practices.

Although the Office meant the comment period to last at least six weeks, the Notice inadvertently set a deadline of December 6, 1996, for comments. Interested parties have asked about an extension of the comment period, and the Office has decided to extend the deadline to January 14, 1997.

Dated: November 26, 1996.

Marilyn J. Kretsinger,

Acting General Counsel.

[FR Doc. 96–30590 Filed 12–2–96; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[MO 013–1013; FRL–5658–3]

Approval and Promulgation of Implementation Plans and State Operating Permit Programs; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed full approval.

SUMMARY: The EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the state of Missouri to update references and modify the Missouri intermediate operating permit program. The EPA is also proposing to grant full approval of an operating permit program submitted by the state of Missouri for the purpose of complying with Federal requirements for an approvable state program to issue operating permits to all major stationary sources and to certain other sources.

DATES: Comments must be received on or before January 2, 1997.

ADDRESSES: Comments may be mailed to Joshua A. Tapp, U.S. Environmental Protection Agency, Region VII, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Joshua Tapp at (913) 551–7606.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Title V of the 1990 Clean Air Act Amendments (sections 501–507 of the Clean Air Act (''the Act'')), and implementing regulations at 40 Code of Federal Regulations (CFR) Part 70, require that states develop and submit operating permit programs to the EPA by November 15, 1993, and that the EPA act to approve or disapprove each program within one year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the Part 70 regulations, which together outline criteria for approval or disapproval. Additionally, section 502(g) of the Act and the Part 70 regulations outline criteria for granting interim approval where a program substantially, but not fully, meets the requirements of the Act and Part 70. The EPA may grant interim approval to such a program for a period of up to two years.

On January 13, 1995, the state of Missouri submitted an operating permits program to the EPA. Supplemental submissions were made by the state on August 14, 1995; September 19, 1995; and October 16, 1995. On April 11, 1996, Region VII determined that Missouri's program contained the minimum elements required for interim approval as specified in 40 CFR 70.4(d). The rationale for the EPA's determination that interim approval is appropriate is contained in the December 15, 1995, Federal Register document (60 FR 64404) which proposed interim approval of the program. In that document, the Region identified the revisions that were required in order for Region VII to be able to grant full approval. The state was required to adopt and submit these revisions to the EPA within 12 months of the effective date of the notice of final interim approval which published on April 11, 1996.

The EPA is also proposing to approve revisions submitted pursuant to section 110 of the Act to update references in rule 10 CSR 10–6.020, and to modify permit provisions in rule 10 CSR 10–6.065 with regard to the Missouri intermediate operating permit program. Specifically, the revisions to rule 10 CSR 10–6.020 update a reference to the Standard Industrial Classification Manual and revise Table 2 entitled, ''List of Named Installations'' so that it is consistent with applicable EPA regulations.

With regard to rule 10 CSR 10–6.065, Missouri submitted revisions that delete the following language from subsection (3)(E): ''However, for insignificant activities which are exempt because of size or production rate, a list of these activities must be included in the application.'' The requirement for listing insignificant activities relates to the Title V program, and Missouri has retained this provision for its Title V applications. Such a provision is not relevant to the SIP-based Federally approved operating permit programs as defined by the EPA in a June 28, 1989, Federal Register document (54 FR 27274). The SIP-based program is a mechanism for restricting total emissions at a source, and all emissions (including those from insignificant activities) must be considered under Missouri's rules in calculating potential emissions at a source. However, such activities are not required to be explicitly listed in the intermediate permit application. Therefore, the EPA is proposing approval of this modification.

The state of Missouri also revised subsection (g) of the basic operating permit program which is contained in section 4 of rule 10 CSR 10–6.065. This program is not a Federally approved program. The EPA is, therefore, not taking action on Missouri's revision to subsection 4(g) of rule 10 CSR 10–6.065.

II. Final 40 CFR Part 70 Action and Implications

A. Missouri's Submission and EPA-Requested Modifications

The December 15, 1995, Federal Register document proposing interim approval of the Missouri program discussed two rules which are a part of the operating permit program that require revisions in order for the program to qualify for full Part 70 approval. These rules are 10 CSR 10–6.020, ''Definitions and Common Reference Tables,'' and 10 CSR 10–6.065, ''Operating Permits.''

In order qualify for full approval, Missouri made the required program revisions in its August 6, 1996, submittal. Specifically, MDNR made the following revisions to rule 10 CSR 10–6.020, ''Definitions and Common Reference Tables.'' Paragraph (2)(I)7 was updated to reference the current Standard Industrial Classification Manual. And, subsection (3)(B), Table 2—List of Named Installations, was revised to make it consistent with the list in the definition of major source in 40 CFR 70.2.

MDNR made the following revisions to rule 10 CSR 10–6.065, ''Operating Permits.'' Paragraph (1)(D)2 was revised to clarify the meaning of ''fugitive air pollutant'' as it relates to Part 70 installations. Subsection (3)(D) was revised to clarify Part 70 applicability with respect to emissions from exempt installations and emission units. Subpart (6)(C)1.C.(II)(b) was revised to clarify the retention of records requirements in permits, consistent with 40 CFR 70.6(a)(3). Part (6)(C)1.G.(I) was revised to clarify the general requirements for permit compliance and noncompliance, consistent with 70.6(a)(6). Subparagraph (6)(C)4.A. was revised to correct a citation error, and to clarify that the requirement for the EPA and affected state review applies to general permits, consistent with 70.6(d)(1). Part (6)(C)7.B.(IV) was revised to make the emergency provision notice consistent with 70.6(g)(3). Paragraph (6)(C)8 was revised to clarify the meaning of the term ''emissions allowable under the permit.'' Part (6)(E)5.B.(I), minor permit modification criteria, was revised to be consistent with 70.7(e)(2)(i)(A)(3). Part (6)(E)5.B.(I) was also revised by the addition of subpart (b) which incorporates economic incentive provisions consistent with 70.7(e)(2)(i)(B). Subpart (6)(E)5.C.(I)(b) was revised to correct the threshold for group processing of minor permit modifications so that it is consistent with 70.7(e)(2)(i)(B). Subpart (6)(E)5.D.(II)(a), significant permit modification procedures, was revised so that it is consistent with 70.4(b)(2) and 70.5(c). And finally, minor citation corrections were made to part (6)(B)3.I.(IV), subpart (6)(E)5.B.(II)(a), part (6)(E)5.C.(V), and subparagraph (6)(E)6.C.

Missouri has the authority to issue a variance from state requirements under section 643.110 of the state statutes. This provision was not included by the state in its operating permit program submittal, and the EPA regards this provision as wholly external to the program submitted for approval under Part 70, and consequently is not taking action on this provision of state law. The EPA has no authority to approve provisions of state law, such as the variance provision referred to, which are inconsistent with the Act. The EPA does not recognize the ability of a permitting authority to grant relief from the duty to obtain or comply with a Federally enforceable Part 70 permit, except where such relief is granted through the procedures allowed by Part 70. A Part 70 permit may be issued or revised (consistent with Part 70 permitting procedures) to incorporate those terms of a variance that are consistent with applicable requirements. A Part 70 permit may also incorporate, via Part 70 permit issuance or modification procedures, the schedule of compliance set forth in a variance. However, the EPA reserves the right to pursue enforcement of applicable requirements, notwithstanding the existence of a compliance schedule in a permit to operate. This is consistent with 70.5(c)(8)(iii)(C), which states that a schedule of compliance ''shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based.''

The technical support document (TSD) for the interim approval describes in detail the criteria for Federal approval of a Part 70 program and how the Missouri program meets these criteria. The TSD for the final interim approval also describes in detail the revisions to these rules which are required for full approval of the program. The reader should refer to this document which is located in the public docket for further information.

B. Proposed Full Part 70 Approval

The EPA is proposing to grant full approval to the operating permit program submitted by the state of Missouri on August 6, 1996, with supplemental information submitted on August 14, 1995; September 19, 1995; and October 16, 1995. The state of Missouri has demonstrated that its program meets the required elements for full approval as specified in 40 CFR Part 70.

1. Regulations. This proposed approval of the Missouri operating permits program includes the following regulations, solely as they relate to the Missouri Part 70 operating permit program: 10 CSR 10–6.065, Operating Permits; 10 CSR 10–6.110, Submission of Emission Data, Emission Fees and Process Information; and 10 CSR 10–6.020, Definitions and Common Reference Tables.

2. Jurisdiction. The scope of the Part 70 program on which the EPA is proposing action in this document applies to all Part 70 sources (as defined in the approved program), within the state of Missouri, except sources of air pollution, if any, over which an Indian Tribe has jurisdiction. See 59 FR 55813, 55815–55818 (November 9, 1994). The term ''Indian Tribe'' is defined under the Act as ''any Indian Tribe, Band, Nation, or other organized group or community, including any Alaska Native village, which is federally recognized as eligible for the special programs and services provided by the

United States to Indians, because of their status as Indians.'' See section 302(r) of the CAA; 59 FR 43956, 43962 (August 25, 1994); 58 FR 54364 (October 21, 1993).

3. CAA section 112(l). Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by the EPA as they apply to Part 70 sources. Section 112(l)(5) requires that the state's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under Part 70. The EPA granted full approval to the state's program under section 112(l)(5) and 40 CFR 63.91 in an April 11, 1996, Federal Register document (61 FR 16063). This approval gives the state the authority to receive delegation of section 112 standards for both Part 70 and non-Part 70 sources.

4. CAA section 112(g). The EPA issued an interpretive document on February 14, 1995 (60 FR 8333), which outlines the EPA's revised interpretation of 112(g) applicability. The document postpones the effective date of 112(g) until after the EPA has promulgated a rule addressing that provision. The document sets forth in detail the rationale for the revised interpretation.

The section 112(g) interpretive notice explains that the EPA is still considering whether the effective date of section 112(g) should be delayed beyond the date of promulgation of the Federal rule so as to allow states time to adopt rules implementing the Federal rule, and that the EPA will provide for any such additional delay in the final section 112(g) rulemaking. Unless and until the EPA provides for such an additional postponement of section 112(g), Missouri must have a Federally enforceable mechanism for implementing section 112(g) during the period between promulgation of the Federal section 112(g) rule and adoption of implementing Federal regulations.

The EPA is aware that Missouri lacks a program designed specifically to implement section 112(g). However, Missouri does have a program for review of new and modified hazardous air pollutant sources that can serve as an adequate implementation vehicle during the transition period, because it would allow Missouri to select control measures that would meet the maximum achievable control technology, as defined in section 112, and incorporate these measures into a federally enforceable preconstruction permit.

The EPA granted approval to Missouri's preconstruction permitting program under the authority of Title V and Part 70 in an April 11, 1996, Federal Register document (61 FR 16063). This approval was granted solely for the purpose of implementing section 112(g) to the extent necessary during the transition period between 112(g) promulgation and adoption of a state rule implementing the EPA's section 112(g) regulations. Although section 112(l) generally provides authority for approval of state air programs to implement section 112(g), Title V and section 112(g) provide for this limited approval because of the direct linkage between the implementation of section 112(g) and Title V. The scope of this approval was narrowly limited to section 112(g) and does not confer or imply approval for purposes of any other provision under the Act (e.g., section 110). That approval will be without effect if the EPA decides in the final section 112(g) rule that sources are not subject to the requirements of the rule until state regulations are adopted. The duration of that approval is limited to 18 months following promulgation by the EPA of the 112(g) rule to provide adequate time for the state to adopt regulations consistent with the federal requirements.

III. Administrative Requirements

A. Docket

Copies of the state submittal and other information relied upon for the proposed full approval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, the EPA in the development of this proposed full approval. The docket is available for public inspection at the location listed under the ADDRESSES section of this document.

B. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5. U.S.C. 600 et seq., the EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, the EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, the EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves preexisting requirements under state or local law, and imposes no new Federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: November 20, 1996.

Dennis Grams,

Regional Administrator.

[FR Doc. 96–30742 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 82

[FRL–5657–9]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency.

ACTION: Notice of response to petition.

SUMMARY: This action notifies the public that the Agency received a petition pursuant to section 612(d) of the Clean Air Act, under the Significant New Alternatives Policy (SNAP) Program, and that EPA has responded to the petition. The petition requested that EPA take several specific actions. EPA had already implemented certain requests prior to receipt of the petition, and will not take the other requested actions. SNAP implements section 612 of the amended Clean Air Act of 1990, which requires EPA to evaluate substitutes for ozone-depleting Substances (ODS) and to regulate the use of substitutes where other alternatives exist that reduce overall risk to human health and the environment. Through these evaluations, EPA generates lists of acceptable and unacceptable substitutes for each of the major industrial use sectors.

EPA has listed several refrigerants as acceptable substitutes for CFC–12 in motor vehicle air conditioning (MVAC), provided they are used in accordance with several requirements. We have worked with the MVAC industry to minimize the mixing of refrigerants and to ensure that the recycled supply of CFC–12 is protected from contamination. Contaminated refrigerant poses numerous technical problems, and may damage both the vehicle's air conditioner and equipment in shops that service such vehicles.

The Association of International Automobile Manufacturers petitioned EPA to take additional steps to prevent the mixing of refrigerants. In general, AIAM believes that only HFC–134a should be used as a retrofit refrigerant. EPA has expressed the belief that HFC–134a is a good choice when a retrofit kit exists that is warranted by the manufacturer. However, some kits are quite expensive, and for many cars, they do not even exist. Therefore, EPA's position has been that other alternatives have an important role to play. Therefore, we will continue to review alternative refrigerants and impose conditions on their use to eliminate the mixing of refrigerants. The petition is file number VI–D–197, and the response is file number VI–C–18.

ADDRESSES: Information relevant to this notice is contained in Air Docket A–91–42, Central Docket Section, South Conference Room 4, U.S. Environmental Agency, 401 M Street, S.W., Washington, D.C. 20460. Telephone: (202) 260–7548. The docket may be inspected between 8:00 a.m. and 5:30 p.m. weekdays. As provided in 40 CFR part 2, a reasonable fee may be charged for photocopying.

FOR FURTHER INFORMATION CONTACT: Rey Forte at (202) 233–9134 or fax (202) 233–9577, U.S. EPA, Stratospheric Protection Division, 401 M Street S.W., Mail Code 6205J, Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION: Contact the Stratospheric Protection Hotline at 1–800–296–1996, Monday-Friday, between the hours of 10:00 a.m. and 4:00 p.m. (Eastern Standard Time) weekdays.

For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the SNAP final rulemaking published in the Federal Register on March 18, 1994 (59 FR 13044). Federal Register notices can be ordered from the Government Printing Office Order Desk (202) 783–3238; the citation is the date of publication. This notice may also be obtained on the World Wide Web at http://www.epa.gov/docs/ozone/title6/snap/.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: November 22, 1996.

Mary D. Nichols,

Assistant Administrator for Air and Radiation.

[FR Doc. 96–30743 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR PART 1

[MM Docket No. 87–268, FCC 96–465]

Technical Standards for Digital Television

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This Public Notice provides an opportunity for public comment on the appended agreement submitted to the Commission on November 27, 1996, by a number of parties representing a diverse range of interests concerning technical standards for digital Television (DTV). The agreement addresses issues raised in the Fifth Further Notice of Proposed Rule Making in this proceeding. Copies of this agreement are available for public inspection in the docket file in the Commission's Public Reference Room, room 239, 1919 M Street, NW., Washington, DC, and on the Commission's internet site accessed at ''www.fcc.gov.'' Interested parties are invited to submit comments on this proposal by Friday, December 6, 1996. The Commission contemplates action on the issue by end of 1996.

DATES: Comments are due on or before December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Roger Holberg, (202) 418–2130, Gordon Godfrey (202) 418–2900, or Saul Shapiro (202) 418–2600.

SUPPLEMENTARY INFORMATION:

[MM Docket No. 87–268]

The Commission Seeks Comment on Digital TV Standards Agreement

Technical Standards for Digital Television

On November 27, 1996, a number of parties representing a diverse range of interests submitted to the Commission the attached agreement on the issue of technical standards for digital television (DTV). The agreement addresses issues raised in the Fifth Further Notice of Proposed Rule Making in MM Docket No. 87–268, 61 FR 26864 (May 29, 1996). Copies of the agreement are available for public inspection in the docket file in the Commission's Public Reference Room, room 239, 1919 M St. NW., Washington, DC, and on the Commission's internet site accessed at ''www.fcc.gov.'' Interested parties are invited to submit comments on this proposal by Friday, December 6, 1996. This public notice elicits comment only on matters concerning the elements of the ATSC digital television standard. The Commission does not contemplate any extension on the comment period, and there will be no reply comment filing period. The Commission contemplates action on the issue of technical standards for DTV by the end of 1996.

Federal Communication Commission.

William F. Caton,

Acting Secretary.

November 27, 1996.

The Honorable Susan Ness,

Commissioner, Federal Communications Commission, 1919 M Street, N.W., Room 832, Washington, D.C. 20554.

Dear Commissioner Ness: As we reported to you yesterday, broadcasters, computer

industry representatives (''CICATS''), receiver manufacturers, and the Film Coalition have engaged in lengthy and numerous discussions over the past four weeks concerning the proposed DTV standard. The first three of these groups have reached the following agreement:

(1) The FCC should adopt no later than December 31, 1996, the voluntary ATSC DTV Standard (A/53), except for the video format constraints described in Table 3, including the aspect ratios (''the FCC standard''). The ATSC DTV Standard, including the Table 3 video format constraints, remains unchanged.

(2) The FCC's Report and Order adopting the FCC standard should include language clarifying that data broadcasting is a permitted use under the standard. Data broadcasting is defined as the transmission of any type of data other than real-time video and audio programming.

(3) The parties agree that the FCC standard provides for extensibility of services and that this extensibility feature can be used as long as such services comply with the FCC standard. Video and audio services may be enhanced by providing augmentation data in the manner described in ATSC ''Guide to the Use of the ATSC Digital Television Standard,'' A/54, Section 8.1.1.3. See Attachment A hereto.

(4) Subject to applicable legal restrictions, if any, neither CICATS nor its member companies nor their representatives will directly or indirectly seek to oppose or delay—before the FCC, by judicial review, legislatively or otherwise—final adoption of the positions urged by broadcasters and consumer electronics manufacturers in MM Docket No. 87–268 to the extent such positions are not inconsistent with this letter. Nor will they support efforts in Congress or elsewhere for auctioning of spectrum allocated or to be allocated for digital television in MM Docket No. 87–268 or other proceedings related to the launch of digital television. After December 31, 1997, CICATS and its member companies may address other spectrum issues, provided that they do not support efforts for the auctioning of spectrum MM Docket NO. 87–268 or other proceedings related to the launch of digital television. The purpose of this understanding is to further the common goal of expeditious launch of digital television and is not intended to impose restrictions with respect to future regulatory or legislative issues.

In addition, consistent with the target date recognized in your letter to us, the parties will no longer be bound by this agreement if the FCC standard is not adopted by the FCC by December 31, 1996.

The parties agreed beforehand to maintain the confidentiality of the positions taken by them in the discussions, if not agreed to as part of a final resolution of the DTV standard issue. All parties continue to be bound by that agreement.

Respectfully submitted,

Broadcasters Caucus,

Michael J. Sherlock (NBC),

Chairman.

Consumer Electronics Manufacturers Association,

Gary J. Shapiro,

President.

Computer Industry Coalition on Advanced Television Service,

Paul E. Misener,

Intel Corporation.

cc: Chairman Reed E. Hundt
Commissioner James H. Quello
Commissioner Rachelle B. Chong
Honorable Larry Irving
Secretary, FCC (for filing in MM Docket No. 87–268)

Attachment A

Because there will be possibilities for future services that we cannot anticipate today, it is extremely important that the transport architecture provide open-ended extensibility of services. New elementary bit streams could be handled at the transport layer without hardware modification by assigning new packet IDs (''PIDs'') at the transmitter and filtering out these new PIDs in the bit stream at the receiver. Backward compatibility is assured when new bit streams are introduced into the transport system as existing decoders will automatically ignore new PIDs.

[FR Doc. 96–30838 Filed 11–29–96; 10:54 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 111496C]

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Request for joint management; request for public comments.

SUMMARY: NMFS announces that the Secretary of Commerce (Secretary) has been asked by the New England Fishery Management Council (NEFMC) to allow the Atlantic mackerel, squid, and butterfish fisheries to be managed jointly by the NEFMC and the Mid-Atlantic Fishery Management Council (MAFMC). The MAFMC is currently responsible for the Fishery Management Plan for Atlantic Mackerel, Squid, and Butterfish (FMP). Public comments are solicited concerning the request for joint management.

DATES: Comments must be submitted by January 2, 1997.

ADDRESSES: Comments should be directed to Dr. Andrew A. Rosenberg, Regional Administrator, Northeast Region, NMFS, 1 Blackburn Drive, Gloucester, MA 01930. Please label the envelope ''Joint SMB Management.''

FOR FURTHER INFORMATION CONTACT: Myles Raizin, Fishery Policy Analyst, 508–281–9104.

SUPPLEMENTARY INFORMATION:

Background

Soon after the passage of the original Magnuson Fishery Conservation and Management Act in 1976, the Secretary, pursuant to his authority under section 304(f), designated species-specific management responsibilities to the Fishery Management Councils (Councils). The MAFMC was given the authority to manage the Atlantic mackerel, *Illex* and *Loligo* squids, and butterfish fisheries. In 1979, NMFS approved separate fishery management plans for the three species. In 1981, the three plans were merged into the present FMP.

At its June 1996 meeting, the NEFMC passed a motion to request the Secretary to make the FMP a joint plan between the NEFMC and the MAFMC and to designate the MAFMC as the lead Council. While recognizing the need to conserve these resources, the NEFMC believes that there are access issues concerning all of these fisheries that only can be resolved fairly through joint management. The NEFMC's main concern focused on a proposal for resubmission to the Secretary of a management measure that would implement a permit moratorium on the fishery for *Illex*. Additionally, the NEFMC believes that there is enough uncertainty about the stock structure of *Illex* to warrant a closer look at how the resource should be managed in different areas along the coast and how seasonal restrictions would substantially increase the overall yield and economic value of the fishery.

In conjunction with this request for joint management, the NEFMC requested NMFS to halt all rulemaking associated with the FMP. NMFS will not take such action, because it is inappropriate to interfere with the MAFMC's statutory mandate to develop fishery management plans and amendments to manage the fisheries for which they are responsible. Furthermore, there is no legal mechanism to bring rulemaking under the Magnuson-Stevens Fishery Conservation and Management Act, as amended, (Magnuson-Stevens Act) to a

halt. The Magnuson-Stevens Act contains a statutory time period for the review and implementation of a fishery management plan or amendment that is submitted to the Secretary by a Council. This can only be modified or halted by a legislative revision to the Magnuson-Stevens Act.

Public comments are requested on the NEFMC's request for joint designation of this FMP. Comments will be reviewed and considered prior to the Secretary's decision on this request.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 25, 1996.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–30687 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–22–F

50 CFR Part 679

[I.D. 111896B]

RIN 0648–AF81

Fisheries of the Exclusive Economic Zone Off Alaska; Scallop Fishery; Vessel Moratorium

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: NMFS announces that the North Pacific Fishery Management Council (Council) has submitted Amendment 2 to the Fishery Management Plan for the Scallop Fishery off Alaska for Secretarial review. Amendment 2 would establish a temporary moratorium on the entry of additional vessels into the scallop fishery off Alaska. Comments from the public are requested.

DATES: Comments on Amendment 2 must be received on or before February 3, 1997.

ADDRESSES: Comments on Amendment 2 should be submitted to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668, Attn: Lori Gravel, or delivered to the Federal Building, 709 West 9th Street, Juneau, AK.

Copies of Amendment 2 and the Environmental Assessment/ Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for the amendment are available from the North Pacific Fishery Management Council, 605 West Fourth Avenue, Anchorage, AK 99501-2252; telephone 907-271-2809.

FOR FURTHER INFORMATION CONTACT: Kent Lind, 907-586-7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires that each regional fishery management council submit any fishery management plan (FMP) or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, immediately publish a notice that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period in determining whether to approve the FMP or amendment.

Amendment 2 would establish a temporary vessel moratorium, which would remain in effect for 3 years from the date of implementation or until repealed or replaced by a permanent limited access program. Scallop moratorium permits would be issued to the person who was the most recent owner of a qualifying vessel at the time of qualification. Vessels would qualify for inclusion in the moratorium if they made a legal landing of scallops during 1991, 1992, or 1993, or during any 4 years between 1980 and 1990. The purpose of Amendment 2 is to curtail increases in fishing capacity and to provide stability for industry while the Council and NMFS develop a limited access program for this fishery.

NMFS will consider the public comments received during the comment period in determining whether to approve the proposed amendment. A proposed rule to implement Amendment 2 has been submitted for Secretarial review and approval. NMFS expects to publish proposed regulations to implement Amendment 2 shortly for public review and comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 26, 1996.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–30688 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 61, No. 233
Tuesday, December 3, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Availability for Licensing and Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of availability and intent.

SUMMARY: Notice is hereby given that U.S. Patent Application Serial No. 08/654,654, ''Preparation of Secondary Ether Fatty Acids and Esters from their Hydroxy Acid Equivalents,'' filed May 29, 1996, is available for licensing and that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant an exclusive license to The Fanning Corporation of Chicago, Illinois.

DATES: Comments must be received on or before March 3, 1997.

ADDRESSES: Send comments to: USDA, ARS, Office of the Director, National Center for Agricultural Utilization Research, Room 2042, 1815 N. University Street, Peoria, Illinois 61604.

FOR FURTHER INFORMATION CONTACT: Andrew Watkins of the National Center for Agricultural Utilization Research at the Peoria address given above; telephone: 309–681–6545.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as The Fanning Corporation has submitted a complete and sufficient application for a license. The prospective 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 prospective exclusive license may be granted unless, within ninety days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

R.M. Parry, Jr.,
Assistant Administrator.
[FR Doc. 96–30681 Filed 12–2–96; 8:45 am]
BILLING CODE 3410–03–M

Notice of Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service intends to grant to The Fanning Corporation of Chicago, Illinois, an exclusive license for U.S. Patent Application Serial No. 08/534,810, filed September 27, 1995, entitled ''Method for the Development of Delta Lactones and Hydroxy Acids from Unsaturated Fatty Acids and their Glycerides.'' Notice of Availability for U.S. Patent Application Serial No. 08/534,810 was published in the Federal Register on July 18, 1996.

DATES: Comments must be received on or before February 3, 1997.

ADDRESSES: Send comments to: USDA, ARS, Office of the Director, National Center for Agricultural Utilization Research, Room 2042, 1815 N. University Street, Peoria, Illinois 61604.

FOR FURTHER INFORMATION CONTACT: Andrew Watkins of the National Center for Agricultural Utilization Research at the Peoria address given above; telephone: 309–681–6545.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as The Fanning Corporation has submitted a complete and sufficient application for a license. The prospective 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 prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

R.M. Parry, Jr.,
Assistant Administrator.
[FR Doc. 96–30682 Filed 12–2–96; 8:45 am]
BILLING CODE 3410–03–M

Forest Service

Willamette Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Willamette PIEC Advisory Committee will meet on Thursday, December 12, 1996. The meeting will be held at the USDI Salem BLM; 1717 Fabry Road SE; Salem, Oregon 97306; phone (503) 375–5642. The meeting is scheduled to begin at 9:00 a.m. and conclude at approximately 12:00 NOON. Topics tentatively scheduled on the agenda include: (1) PAC Meeting Frequency; (2) Proposed topics for 1997 PAC Meetings, (3) Public Forum; (4) Jobs in the Woods Program, FY 1997; (5) Watershed Analysis and Assessments in 1997; (6) Information sharing.

The meeting is open to the public and opportunity will be available to address the Advisory Committee during the public forum. Time allotted for individual presentations to the committee will be limited to 3–5 minutes each. Written comments are encouraged and can be submitted prior to the meeting.

FOR FURTHER INFORMATION CONTACT:

For more information regarding this meeting, contact Designated Federal Official Neal Forrester; Willamette National Forest, 211 East Seventh Avenue; Eugene, Oregon 97401; (541) 465–6924.

Dated: November 26, 1996.

Harold Legard,
Acting Forest Supervisor.
[FR Doc. 96–30701 Filed 12–2–96; 8:45 am]
BILLING CODE 3410–11–M

Natural Resources Conservation Service

Perry Ridge Shoreline Protection (PCS–26), Calcasieu Parish, LA

AGENCY: Natural Resources Conservation Service USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40CFR Part 1500); and the Natural Resources Conservation Service Regulations (7CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Perry Ridge Shoreline Protection (PCS–26), Calcasieu Parish, Louisiana.

FOR FURTHER INFORMATION CONTACT: Donald W. Gohmert, State Conservationist, Natural Resources Conservation Service, 3737 Government Street, Alexandria, Louisiana, 71302, telephone (318) 473–7751.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Donald W. Gohmert, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The purpose of the project is to ensure the stability of 1,203 acres of interior marsh by providing bank protection of the critical area located along the north GIWW bankline and preventing additional breaching. The planned works of improvement include the placement of 12,000 linear feet of rock dike on critical areas within a 4.25 mile reach between Perry Ridge and the Vinton Drainage Canal.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Bennett C. Landreneau, Assistant State Conservationist/Water Resources, Natural Resources Conservation Service, 3737 Government Street, Alexandria, Louisiana, 71302, telephone (318) 473–7756.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the Federal Register.

Dated: November 7, 1996.

Donald W. Gohmert,

State Conservationist.

(This activity is listed in the Catalog of Federal Domestic Assistance under NO.10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.)

[FR Doc. 96–30664 Filed 12–2–96; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Producing Firms for Determination of Eligibility to Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration (EDA).

ACTION: To give firms an opportunity to comment.

Petitions have been accepted for filing on the dates indicated from the firms listed below.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD 09/25/96–11/21/96

Firm name	Address	Date petition accepted	Product
Hudson Standard Corporation	90 South Street, Newark NJ 07114	09/27/96	Electric household appliances—table ranges, waffle irons, broilers, toaster, and convection ovens.
Agora Sales, Inc	2101 28th Street North, St. Petersburg FL 33713.	09/30/96	Bags with textile outer surface of man made fibers.
Shiloh Lure Company	302 W. First Street, Montrose MO 64770.	10/01/96	Fishing lures.
Adcom	11 Elkins Road, East Brunswick NJ 08816.	10/01/96	Electric power amplifiers for home and consumer use.
Rich-Mar Corporation	P.O. Box 879, Route 9, Inola OK 74036	10/01/96	Therapeutic ultrasonic appliances, muscle stimulators and gels.
Warrior Enterprises, Inc	5103 E Roadrunner, Mesa AZ 85205	10/03/96	Remanufactured engine accessories for civil aircraft.
Ver-Sa-Til Associates, Inc	18400 West 77th Street, Chanhassen MN 55317.	10/03/96	Machined metal components of computer floppy disk drives, automobile and defense systems.
The Kraissl Company, Inc	299 Williams Avenue, Hackensack NJ 07601.	10/03/96	Heavy duty simplex and duplex strainers and filters for protecting equipment in pipeline service.
Kozak Auto Dry Wash, Inc	6 South Lyon Street, Batavia NY 14020	10/03/96	Cleaning cloths of heavy napped cotton chemically treated to clean automotive finishes and furniture.
Molded Products, Inc	11524 East 58th Street, Tulsa OK 74146.	10/15/96	Rack and pinion rubber boots, seals, brackets and diaphragms.
Saco Brick Company	102 Industrial Park Road, Saco MA 04072.	10/17/96	Foundation concrete blocks, paving stones and bricks, and masonry products.
J&C Ferrara Company, Inc	104 Richards Avenue, North Attleboro MA 02761.	10/18/96	Precious metal jewelry—platinum, gold, and sterling silver charms, earrings, rings used with gems.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD 09/25/96–11/21/96—Continued

Firm name	Address	Date petition accepted	Product
Atlas Plastic Products Corporation	10550 72nd Street, N. #504, Largo FL 33777.	10/21/96	Injection molds for plastic parts and plastic resins.
Leader Manufacturing Company, Inc	3693 Forest Park Boulevard, St. Louis MO 63108.	10/21/96	Headwear.
Purethane, Inc	One Purethane Place, West Branch IA 52358.	10/23/96	Urethane arm and wrist rests for furniture, appliance handles and urethane and vinyl automotive components.
Chiles Power Supply Company dba Heatway.	3131 W. Chestnut Expressway, Springfield MO 65802.	10/23/96	Underground/subfloor radiant, hydronic heating systems and supplies.
Bassett Woodworks	11905 Golden Gate Road, El Paso TX 79936.	10/23/96	Cabinets of wood for permanent installation.
United States Forgecraft Corporation	P.O. Box 387, Fort Smith AR 72902	10/25/96	Forged and electro-plated safety clasps, made of high quality metals.
Manufacturing Group of America, Inc	2841 Pierce Street, Dallas TX 75233	10/25/96	Wood cabinets.
Land and Sky Manufacturing, Inc	5410 N W 44th Street, Lincoln NE 68524.	10/29/96	Waterbed heaters, and vinyl waterbed mattresses.
Cert-C, Inc. dba Flint River Manufacturing Company.	1454 Williamson Road, Griffin GA 30223.	10/31/96	Sports caps of cotton, man-made material and wool.
Northern Laminate Sales, Inc	11 Industrial Way, Atkinson NH 02116	10/28/96	Copper clad laminated and punched boards.
Bayer Clothing Group, Inc	RD #4, Box 91B, Clearfield PA 16830	11/07/96	Men's tailored suits, sportcoats and slacks of wool/synthetic blend.
OK Filter Company, Inc	104 N. Cherokee, Catoosa OK 74015	11/08/96	Air filters commercial and industrial.
Andrews Knitting Mills, Inc	3560 Huffman Road East, St. Paul MN 55110.	11/15/96	Custom knit garment trim—cuffs, waistbands, collars, etc.
Spyrotech Corporation	4930 Superior Street, Suite D, Lincoln NE 68529.	11/15/96	Gold shafts, industrial rolls, shafts and tubing for tent poles and bike frames, and pipes for oil drills.
Marlow Industries, Inc	10451 Vista Park Road, Dallas TX 75238.	11/12/96	Hybrid integrated circuits.
German Machine, Inc	245 Hollenbeck Street, Rochester NY 14621.	11/13/96	Cylindrical metal rollers, and pins used in office equipment and parts for film guides and blood analysers.

The petitions were submitted pursuant to Section 251 of the Trade Act of 1974 (19 U.S.C. 2341). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Trade Adjustment Assistance Division, Room 7023, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.

Dated: November 25, 1996.

Lewis R. Podolske,

Director, Trade Adjustment Assistance Division.

[FR Doc. 96–30772 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–24–M

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 353.22 or 355.22 of the Department of Commerce's (the Department) regulations (19 CFR 353.22/355.22), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity To Request a Review

Not later than December 31, 1996, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in December for the following periods:

Antidumping Proceedings		Period
BRAZIL: A–351–602	Certain Carbon Steel Butt-Weld Pipe Fittings	12/1/95–11/30–96

Antidumping Proceedings		Period
BRAZIL: A–351–824	Silcomanganese	12/1/95–11/30/96
CANADA: A–122–047	Elemental Sulphur	12/1/95–11/30/96
GERMANY: A–428–062	Animal Glue and Inedible Gelatin	12/1/95–11/30/96
INDIA: A–533–808	Stainless Steel Wire Rods	12/1/95–11/30/96
JAPAN: A–588–809	Business Telephone Systems	12/1/95–11/30/96
JAPAN: A–588–405	Cellular Mobile Telephones and Subassemblies	12/1/95–11/30/96
JAPAN: A–588–811	Drafting Machines and Parts Thereof	12/1/95–11/30/96
JAPAN: A–588–046	Polychloroprene Rubber	12/1/95–11/30/96
JAPAN: A–588–068	Steel Wire Strand	12/1/95–11/30/96
MEXICO: A–201–504	Cooking Ware	12/1/95–11/30/96
NEW ZEALAND: A–614–502	Low-Fuming Brazing Copper Rod & Wire	12/1/95–11/30/96
SOUTH KOREA: A–580–501	Photo Albums	12/1/95–11/30/96
SOUTH KOREA: A–580–810	Welded Stainless Steel Pipes	12/1/95–11/30/96
SWEDEN: A–401–603	Seamless Stainless Steel Hollow Products	12/1/95–11/30/96
TAIWAN: A–583–806	Business Telephone Systems	12/1/95–11/30/96
TAIWAN: A–583–605	Butt-Weld Pipe Fittings	12/1/95–11/30/96
TAIWAN: A–583–508	Porcelain-On-Steel Cooking Ware	12/1/95–11/30/96
TAIWAN: A–583–815	Welded Stainless Steel Pipes	12/1/95–11/30/96
THE PEOPLE'S REPUBLIC OF CHINA: A–570–827	Cased Pencils	12/1/95–11/30/96
THE PEOPLE's REPUBLIC OF CHINA: A–570–506	Porcelain-on-Steel Cooking Ware	12/1/95–11/30/96
THE PEOPLE'S REPUBLIC OF CHINA: A–570–82	Silicomanganese	12/1/95–11/30/96

Countervailing Duty Proceedings		Period
MEXICO: C–201–505	Porcelain-On-Steel Cookware	1/1/95–12/31/95

Suspension Agreements: None

In accordance with sections 353.22(a) and 355.22(a) of the regulations, an interested party as defined by section 353.2(k) may request in writing that the Secretary conduct an administrative review. The Department has changed its requirements for requesting reviews for countervailing duty orders and suspension agreements. Pursuant to 19 CFR 355.22(a), an interested party must specify the individual producers or exporters covered by the order or suspension agreements for which they are requesting a review (Interim Regulations, 60 FR 25130, 25137 (May 11, 1995)). Therefore, for antidumping and countervailing duty reviews, and suspension agreements, the interested party must specify for which individual producers or exporters covered by an antidumping finding, antidumping or countervailing duty order or suspension agreement it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales or merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Shelia Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 353.31(g) or 355.31(g) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the Federal Register a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation,'' for requests received by December 31, 1996. If the Department does not receive, by December 31, 1996, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: November 27, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for Group III.

[FR Doc. 96–30878 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–M

[A–570–849, A–823–808, A–821–808, and A–791–804]

Initiation of Antidumping Duty Investigations: Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China, Ukraine, the Russian Federation, and the Republic of South Africa

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Robin Gray at (202) 482–0196 and Elizabeth Patience at (202) 482–0195, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Initiation of Investigation

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (''the Act'') by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department's regulations are to

the current regulations, as amended by the interim regulations published in the Federal Register on May 11, 1995 (60 FR 25130).

The Petitions

On November 5, 1996, the Department of Commerce (''the Department'') received petitions filed in proper form from Geneva Steel Company (Geneva) and Gulf States Steel, Inc. (Gulf States) (''petitioners''), domestic producers of certain cut-to-length carbon steel plate (CTL plate). The Department received amended petitions on November 14 and 15, 1996.

In accordance with section 732(b) of the Act, petitioners alleged that imports of CTL plate from the People's Republic of China (China), Ukraine, the Russian Federation (Russia), and the Republic of South Africa (South Africa) are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to a U.S. industry.

The Department finds that petitioners have standing to file the petitions because they are interested parties, as defined under section 771(9)(C) of the Act.

Determination of Industry Support for the Petitions

Section 732(c)(4)(A) of the Act requires the Department to determine, prior to the initiation of an investigation, that a minimum percentage of the domestic industry supports an antidumping petition. A petition meets these minimum requirements if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

We received submissions from two importers, Ranger Steel Supply Corporation (Ranger) and Klockner Steel Trade (Klockner), alleging that these petitions were not filed on behalf of the domestic carbon steel plate industry. Moreover, Klockner, in filing its notice of appearance in the Chinese, Russian and Ukrainian proceedings, contended that there are 38 domestic firms that may have produced plate in 1992. Therefore, the importer questions whether petitioners identified all domestic plate producers in the petitions. Klockner's support for this assertion is based on a list of companies, prepared by the International Trade Commission for the 1992 carbon flat-rolled steel investigations, that produce, in general, carbon flat-rolled steel products which, depending on the producer, may or may not include plate. Independent sources readily available to the Department indicate that the domestic producers originally identified in the petition are the only producers of carbon steel plate in the United States. *See* Metal Bulletin Books, *Iron and Steel Works of the World* (11th ed., 1994).

On November 18, 1996, counsel for Ranger submitted additional arguments on all four petitions contending that the petitions do not have industry support. Ranger argues that petitioners failed to demonstrate on the face of the petitions that Geneva and Gulf States account for more than 50 percent of total domestic production. Ranger also contends that the Department must determine through polling that domestic producers supporting the petitions account for more than 50 percent of the production of CTL plate produced by that portion of the industry expressing a view on the petitions.

On November 14, 1996, petitioners submitted amended petitions for the four countries with letters of support for the petitions from Bethlehem Steel Corporation and U.S. Steel Group, a unit of USX Corporation. Letters of support were also submitted to the Department by the United Steelworkers of America on November 13, 1996. Based on the production data we collected from domestic steel-producing companies, Geneva, Gulf States, Bethlehem and USX account for significantly more than 50 percent of total production of the domestic like product. Because the amended petitions now establish sufficient support of domestic producers within the meaning of 732(c)(4)(D), the Department is not required to poll or rely on other information to determine if there is support for the petition. The Department received no expressions of opposition to the petitions from any U.S. producers or workers. Accordingly, the Department determines that the petitions have been filed on behalf of the domestic industry in accordance with sections 732(c)(4)(A) and 732(c)(4)(D) of the Act.

Scope of the Investigation

The scope of these investigations includes hot-rolled iron and non-alloy steel universal mill plates (i.e., flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm and of a thickness of not less than 4 mm, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain iron and non-alloy steel flat-rolled products not in coils, of rectangular shape, hot-rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 mm or more in thickness and of a width which exceeds 150 mm and measures at least twice the thickness. Included as subject merchandise in this petition are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been ''worked after rolling'')—for example, products which have been bevelled or rounded at the edges. This merchandise is currently classifiable in the Harmonized Tariff Schedule of the United States (HTS) under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000. Excluded from subject merchandise within the scope of this petition is grade X–70 plate. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

South Africa

Export Price and Normal Value

The petitioners based export price on the customs values derived from the IM–145 monthly import statistics for HTS subheading 7208.51.0060 and 7208.52.0000, published by the U.S. Department of Commerce, for the month of July 1996. These customs values correspond to the month the available home market price lists were in effect. The customs values, which represent the f.o.b. South Africa price of the subject CTL plate, were adjusted for foreign inland freight, based on the freight charges by one South African producer. We find the customs values a reasonable basis for export prices because (1) the HTS subheadings contain only CTL plate and no other products, and (2) the customs values reported for IM–145 are based on the transaction value of the merchandise.

The petitioners based normal value on July 1996 prices between a South African producer and its customers obtained from a market researcher. The gross home market prices were adjusted

downward for discounts and value-added tax. The petitioners converted the unit prices in South African rand to U.S. dollars using the exchange rates that were in effect on or about the time the home market sales occurred.

Based on comparisons of export price to normal value, the estimated dumping margins for certain CTL plate from South Africa range from 6.66 percent to 33.87 percent.

China

Export Price

Petitioners based export price on two methods: 1) the import values declared to the U.S. Customs Service; and 2) actual U.S. selling prices obtained by Geneva. Petitioners used the HTS categories which contained only subject merchandise, as follows: 7208.51.0060, 7208.52.0000, 7208.40.3030, and 7208.53.0000. Petitioners deducted foreign inland freight from the FAS customs values in order to obtain ex-factory prices. In order to calculate foreign inland freight, petitioners used Chilean rail rates. Petitioners explained that the only reasonably-available public rates were from Chile and the United States. Because Chile's GNP is closer to China's, Chile's transport rates were used in petitioners' calculations. Based on the information presented by petitioners, we believe that their use of Chilean rail rates is acceptable for purposes of initiation of this investigation.

Normal Value

Petitioners asserted that China is a non-market economy country (NME) to the extent that sales or offers for sale of such or similar merchandise in China or to third countries do not permit calculation of normal value under 19 C.F.R. 353.46, 353.49 or 353.53. Petitioners, therefore, constructed a normal value based on the factors of production methodology pursuant to 19 U.S.C. 1677b(c). In previous investigations, the Department has determined that China is an NME. *See, e.g., Final Determination of Sales at Less than Fair Value: Bicycles From the People's Republic of China*, 61 FR 19026 (April 30, 1996). In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for China has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the normal value of the product was appropriately based on the producers' factors of production, valued in a surrogate market economy country in accordance with section 773(c) of the Act.

In the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of China's NME status and the granting of separate rates to individual exporters. *See, e.g., Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the PRC*, 59 FR 22585 (May 2, 1994).

For their normal value calculation, petitioners based the factors of production, as defined by section 773(c)(3) of the Act (raw materials, labor, energy and capital cost), for CTL plate on petitioners' own usage inputs and amounts, adjusted for known differences in production efficiencies on the basis of available information. Petitioners asserted that no detailed information is available regarding the quantities of inputs used by plate producers in China. Thus, they have assumed, for purposes of the petition, that producers in China use the same inputs in the same quantities as petitioners, except where a variance from petitioners' cost model can be justified on the basis of available information. Petitioners argued that the use of their own factors is conservative because the U.S. steel industry is more efficient and technologically-advanced than the Chinese steel industry. Petitioners cited four different sources to support this contention. Based on the information provided by petitioners, we believe that petitioners' use of its own adjusted factors of production is appropriate for purposes of initiation of this investigation. *See, Initiation of the Antidumping Duty Investigations of Melamine Institutional Dinner Products from Indonesia, Taiwan, and the People's Republic of China*, 61 FR 8039 (March 31, 1996).

In accordance with section 773(c)(4) of the Act, petitioners then valued the factors of production, where possible, on reasonably available surrogate country data. Petitioners selected Indonesia as the primary surrogate. Petitioners argued that Indonesia is an acceptable surrogate country because its level of economic development is comparable to that of China and it is a significant producer of comparable merchandise (in accordance with 773(c)(4) of the Act). *See, Final Determination of Sales at Less-Than-Fair-Value: Disposable Pocket Lighters from the People's Republic of China* 60 FR 22359 (May 5, 1996). Petitioners stated that because the per-capita gross national product (GNP) of Indonesia and China are relatively close, the two countries may be considered economically comparable. Based on the information provided by petitioners, we believe that petitioners' use of Indonesia as a surrogate country is appropriate for purposes of initiation of this investigation.

Petitioners were unable to obtain port unloading charges for Indonesia and, therefore, chose the lowest charge applicable in Brazil based on a publicly-available news article. Petitioners chose Brazilian values because they were the only reasonably available figures for a country with a per-capita GNP similar to China's. Petitioners were also unable to find data on factory overhead, selling, general & administrative (SG&A) expenses, and profit from Indonesia. Therefore, petitioners used overhead, SG&A and profit percentages used by the Department in a recent results of review (*Preliminary Results of Review: Sebacic Acid from the People's Republic of China*, 61 FR 46440 (September 3, 1996)) where India was the surrogate country in order to value these factors. Based on the information provided by petitioners, we believe that their use of the noted Brazilian and Indian surrogate values are acceptable for purposes of initiation of this investigation.

Based on comparisons of export price to the factors of production, the calculated dumping margins for CTL plate from China ranged from 10.01–45.84 percent.

Russia

Export Price

Petitioners based export price on two methods: (1) The import values declared to the U.S. Customs Service; and (2) actual U.S. selling prices known to petitioners. In order to ensure a fair comparison, petitioners used the HTS categories which contained only subject merchandise, as follows: 7208.51.0060, 7208.52.0000, 7208.40.3030, and 7208.53.0000. Petitioners deducted foreign inland freight from the customs values in order to obtain ex-factory prices. In order to calculate foreign inland freight, petitioners used U.S. barge rates and Chilean rail rates because they were the only appropriate public figures reasonably available to the petitioners. Petitioners explained that they could only find barge rates for the United States that revealed the distances needed to permit calculation of a rate in dollars-per-ton. Further, they could only find data on rail rates from Chile and the United States which would permit the calculation of rail freight costs in such terms. They used the Chilean rail rate because Chilean per-capita GNP is much closer to Russia's than is the United States'.

Based on the information presented by petitioners, we believe that their use of U.S. barge and Chilean rail rates is acceptable for purposes of initiation of this investigation.

Normal Value

Petitioners asserted that Russia is a non-market economy country (NME) to the extent that sales or offers for sale of such or similar merchandise in Russia or to third countries do not permit calculation of normal value under 19 CFR 353.46, 353.49 or 353.53. Petitioners, therefore, constructed a normal value based on the factors of production methodology pursuant to 19 U.S.C. 1677b(c). In previous investigations, the Department has determined that Russia is an NME. *See, e.g., Pure Magnesium and Alloy Magnesium from the Russian Federation,* 60 FR 16440 (March 30, 1995). In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for Russia has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the normal value of the product is appropriately based on factors of production, valued in a surrogate market economy country in accordance with section 773(c) of the Act.

In the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of Russia's NME status and the granting of separate rates to individual exporters. *See, e.g., Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the PRC,* 59 FR 22585 (May 2, 1994).

For the normal value calculation, petitioners based the factors of production, as defined by section 773(c)(3) of the Act (raw materials, labor, energy and capital cost), for CTL plate on petitioners' own usage inputs and amounts, adjusted for known differences in production efficiencies on the basis of available information. Petitioners asserted that no detailed information is available regarding the quantities of inputs used by plate producers in Russia. Thus, they have assumed, for purposes of the petition, that producers in Russia use the same inputs in the same quantities as petitioners, except where a variance from petitioners' cost model can be justified on the basis of available information. Petitioners argued that the use of their own factors is conservative because the U.S. steel industry is more efficient and technologically-advanced than the Russian steel industry. Petitioners cited three different sources to support this contention. Based on the information provided by petitioners, we believe that petitioners' use of its own adjusted factors of production is appropriate for purposes of initiation of this investigation.

In accordance with section 773(c)(4) of the Act, petitioners valued these factors, where possible, on reasonably available, published surrogate country data. Petitioners selected Turkey as their primary surrogate. Petitioners stated that the per-capita GNP of Turkey differs only slightly from Russia's and, thus, maintain that Turkey is the most suitable surrogate, amongst the potential surrogates, because it is at a level of comparable economic development and is also a significant producer of comparable merchandise (in accordance with section 773(c)(4) of the Act). *See, Final Determination of Sales at Less-than-Fair-Value of Ferrovanadium and Nitrided Vanadiam From the Russian Federation,* 60 FR 27957 (May 26, 1996). Based on the information provided by petitioners, we believe that petitioners' use of Turkey as a surrogate country is appropriate for purposes of initiation of this investigation.

Petitioners state that they were unable to find publicly-available information on port unloading charges in Turkey and, therefore, chose the lowest charge applicable in Brazil as a surrogate value, based on a published news article. Petitioners were also unable to find a published source for the number of man-hours used to produce a ton of any steel product in Russia or Turkey, and, therefore, used a labor-per-ton figure for Mexico, based on a published news article, as the surrogate value. Petitioners chose values from Brazil and Mexico, respectively, as surrogates because the information was reasonably available and the per-capita GNPs of these countries were most comparable to Russia's. Finally, petitioners valued Russian consumption rates for fuel, energy, and raw materials at 20 percent above petitioners' based on a publicly-available news article. Based on the information provided by petitioners, we believe that their use of the noted surrogate values is acceptable for purposes of initiation of this investigation.

Based on comparisons of export price to the factors of production, the calculated dumping margins for CTL plate from Russia ranged from 139.97–230.38 percent.

Ukraine

Export Price

Petitioners based export price on two methods: (1) The import values declared to the U.S. Customs Service; and (2) actual U.S. selling prices known to petitioners. In order to ensure a fair comparison, petitioners used the HTS categories which contained only subject merchandise, as follows: 7208.51.0060, 7208.52.0000, 7208.40.3030, and 7208.53.0000. Petitioners deducted foreign inland freight from the customs values in order to obtain ex-factory prices. In order to calculate foreign inland freight, petitioners used U.S. barge rates and Chilean rail rates because they were the only appropriate, public figures reasonably available to the petitioners. Petitioners explained that they could only find barge rates for the United States that revealed the distances needed to permit calculation of a rate in dollars-per-ton. Further, they could only find data on rail rates from Chile and the United States which would permit the calculation of rail freight costs in such terms. They used the Chilean rail rate because Chilean per-capita GNP is much closer to Ukraine's than is the United States'. Based on the information presented by petitioners, we believe that their use of U.S. barge and Chilean rail rates is acceptable for purposes of initiation of this investigation.

Normal Value

Petitioners alleged that Ukraine is an NME to the extent that sales or offers for sale of such or similar merchandise in Ukraine or to third countries does not permit calculation of normal value under 19 CFR 353.46, 353.49 or 353.53. Petitioners, therefore, constructed a normal value based on the factors of production methodology pursuant to 19 U.S.C. 1677b(c). In previous investigations, the Department has determined that Ukraine is an NME. *See, e.g., Final Determinations of Sales at Less Than Fair Value: Ferrosilicon from Kazakhstan and Ukraine; and Postponement of Final Determination; Ferrosilicon from the Russian Federation,* 58 FR 13050 (March 9, 1993). In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for Ukraine has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the normal value of the product is appropriately based on the producers' factors of production valued in a

surrogate market economy country in accordance with section 773(c) of the Act.

In the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of Ukraine's NME status and the granting of separate rates to individual exporters. *See, e.g., Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the PRC,* 59 FR 22585 (May 2, 1994).

For the normal value calculation, petitioners based the factors of production, as defined by section 773(c)(3) of the Act (raw materials, labor, energy, and capital costs), for CTL plate on petitioners' own usage amounts, adjusted for known differences in production efficiencies on the basis of available information. Petitioners asserted that no detailed information is available regarding the quantities of inputs used by plate producers in Ukraine. Thus, they have assumed, for purposes of the petition, that producers in Ukraine use the same inputs in the same quantities as petitioners, except where a variance from petitioners' cost model can be justified on the basis of available information. Petitioners argued that the use of their own data is conservative because the U.S. steel industry is more efficient and technologically-advanced than the Ukrainian steel industry. Petitioners cited two different sources to support this contention. Based on the information provided by petitioners, we believe that petitioners' use of its own adjusted factors of production is appropriate for purposes of initiation of this investigation.

In accordance with section 773(c)(4) of the Act, petitioners valued these factors, where possible, on reasonably available, published surrogate country data. Petitioners selected Peru as their primary surrogate. Petitioners argued that Peru is an acceptable surrogate country because its level of economic development is comparable to that of Ukraine and it is a significant producer of comparable merchandise (in accordance with 773(c)(4) of the Act). *See, Preliminary Determination of Sales at Less-than-Fair-Value and Postponement of Final Determination of Silicomanganese From Ukraine* 59 FR 31201 (June 17, 1996). Petitioners stated that because the per-capita GNP of Peru and Ukraine are relatively close, the two countries may be considered economically comparable. Based on the information provided by petitioners, we believe that petitioners' use of Peru as a surrogate country is appropriate for purposes of initiation of this investigation.

Petitioners were unable to obtain port unloading charges for Peru and, therefore, chose the lowest charge applicable in Brazil based on a published news article. Petitioners were also unable to find a published source for the number of man-hours used to produce a ton of any steel product in Ukraine or Peru, and, therefore, used a labor-per-ton figure for Mexico based on a news article, as the surrogate value. Petitioners chose values from Brazil and Mexico, respectively, as surrogates because the information was reasonably available and the per-capita GNPs of these countries were most comparable to Ukraine's. Based on the information provided by petitioners, we believe that their use of the noted Brazilian and Mexican surrogate values is acceptable for purposes of initiation of this investigation.

Petitioners were also unable to find values for natural gas rates, factory overhead, selling, general & administrative (SG&A) expenses, and profit from Peru. Therefore, petitioners used surrogate natural gas rates from Indonesia and Turkish values for factory overhead, SG&A, and profit. Values from Indonesia and Turkey were selected on the basis that these countries were closer to Ukraine in per-capita GNP than were other countries from which values could be ascertained by petitioners. Based on the information provided by petitioners, we believe that their use of the noted Indonesian and Turkish surrogate values is acceptable for purposes of initiation of this investigation.

Based on comparisons of export price to the factors of production, the calculated dumping margins for CTL plate from Ukraine ranged from 201.61–274.82 percent.

Fair Value Comparisons

Based on the data provided by petitioners, there is reason to believe that imports of CTL plate from China, Ukraine, Russia and South Africa are being, or are likely to be, sold at less than fair value. If it becomes necessary at a later date to consider these petitions as a source of facts available, under section 776 of the Act, we may further review the calculations.

Initiation of Investigations

We have examined the petitions on CTL plate from China, Ukraine, Russia and South Africa and have found that they meet the requirements of section 732 of the Act, including the requirements concerning allegations of material injury or threat of material injury to the domestic producers of a domestic like product by reason of the complained-of imports, allegedly sold at less than fair value. In reaching this determination, we have examined the accuracy and adequacy of the evidence provided in the petitions based on information readily available to us, as required by section 732(c)(1)(A)(i). Therefore, we are initiating antidumping duty investigations to determine whether imports of CTL plate from China, Ukraine, Russia and South Africa are being, or are likely to be, sold in the United States at less than fair value. Unless extended, we will make our preliminary determination by April 14, 1997.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act, copies of the public version of the petitions have been provided to the representatives of the governments of China, Ukraine, Russia and South Africa. We will attempt to provide copies of the public versions of the petitions to the exporters named in the petitions.

International Trade Commission (ITC) Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will determine by December 20, 1996, whether there is a reasonable indication that imports of CTL plate from China, Ukraine, Russia and South Africa are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination in any of these investigations will result in the respective investigation being terminated; otherwise, these investigations will proceed according to statutory and regulatory time limits.

Dated: November 25, 1996.

Robert S. LaRussa

Acting Assistant Secretary of Import Administration

[FR Doc. 96–30756 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–412–602]

Certain Forged Steel Crankshafts From the United Kingdom; Preliminary Results of Antidumping Duty Administrative Review and Intent to Revoke Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review and intent to revoke order.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain forged steel crankshafts from the United Kingdom in response to a request by respondent British Steel Forgings (BSF), a producer. This review covers shipments of this merchandise to the United States during the period September 1, 1994 through August 31, 1995. Based upon BSF's three consecutive years of *de minimis* margins, we intend to revoke the order with respect to crankshafts from the United Kingdom, based on our preliminary determination that BSF is the only known producer of crankshafts.

We have preliminarily determined that sales have not been made below normal value (NV).

Interested parties are invited to comment on these preliminary results. Parties who submit arguments are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: David Dirstine, Lyn Johnson, or Richard Rimlinger, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482–4733.

Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulations published in the Federal Register on May 11, 1995 (60 FR 25130).

SUPPLEMENTARY INFORMATION:

Background

On September 12, 1995, the Department published in the Federal Register a notice of ''Opportunity to Request Administrative Review'' (60 FR 47349) of the antidumping duty order on certain forged steel crankshafts (crankshafts) from the United Kingdom.

In accordance with 19 CFR 353.22(a)(1)(1995), the petitioner, Krupp Gerlach Company (KGC), and BSF requested that we conduct an administrative review of BSF's sales. We published a notice of initiation of this antidumping duty administrative review on October 12, 1995 (60 FR 53164). The Department is conducting this administrative review in accordance with section 751 of the Act.

Scope of Review

Imports covered by this review are certain forged steel crankshafts. The term ''crankshafts'' as used in this review includes forged carbon or alloy steel crankshafts with a shipping weight between 40 and 750 pounds, whether machined or unmachined. These products are currently classifiable under item numbers 8483.10.10.10, 8483.10.10.30, 8483.10.30.10, and 8483.10.30.50 of the Harmonized Tariff Schedule (HTS). Neither cast crankshafts nor forged crankshafts with shipping weights of less than 40 pounds or more than 750 pounds are subject to this review. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive of the scope of the order.

This review covers one manufacturer/exporter of crankshafts, and the period September 1, 1994 through August 31, 1995.

Verification

As provided in section 776(b) of the Act, we verified information provided by the respondent by using standard verification procedures, including on-site inspection of the manufacturer's facilities, the examination of relevant sales and financial records, and the selection of original documentation containing relevant information. Our verification results are outlined in the public versions of the verification reports.

Intent To Revoke

On September 29, 1995, BSF submitted a request, in accordance with 19 CFR 353.25(b), to revoke the order covering crankshafts from the United Kingdom with respect to BSF's sales of this merchandise.

In accordance with 19 CFR 353.25(a)(2)(iii), this request was accompanied by a certification from BSF that it had not sold the relevant class or kind of merchandise at less than NV for a three-year period, including this review period, and would not do so in the future. BSF also agreed to its immediate reinstatement in the relevant antidumping order, as long as any firm is subject to this order, if the Department concludes under 19 CFR 353.22(f) that, subsequent to revocation, it sold the subject merchandise at less than NV.

In the two prior reviews of this order, we determined that BSF sold crankshafts from the United Kingdom at not less than NV. The Department conducted a verification of BSF's response for this review and preliminarily determines that BSF sold crankshafts at not less than NV during the review period. Based on BSF's three consecutive years of *de minimis* margins, we have preliminarily determined that it is not likely that BSF will in the future sell subject merchandise at less than NV. Therefore, we intend to revoke the order on crankshafts from the United Kingdom, based on our preliminary determination that BSF is the only known producer of crankshafts, if these preliminary findings are affirmed in our final results.

Foreign Like Product

In determining similar merchandise comparisons pursuant to section 771(16) of the Act, we considered the following physical characteristics, which appear in order of importance: (1) Twisted vs. untwisted; (2) number of throws; (3) forging method; (4) engine type; (5) number of bearings; (6) number of flanges; and (7) number of counterweights. We applied weight separately based on a range of plus or minus 20 percent of the weight of the U.S. model. If there were two or more potential home market matches after applying each of the matching criteria, including the 20 percent weight range, we chose the home market model that was closest in weight to the U.S. model. Our reasons for using the weight criterion are contained in the *Notice of Final Results of Antidumping Duty Administrative Review: Certain Forged Steel Crankshafts from the United Kingdom*, 60 FR 52150, 52151–152 (October 5, 1995).

United States Price (USP)

For sales made by BSF, we calculated an export price (EP), in accordance with section 772(a) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation into the United States and the constructed export price methodology was not indicated by other circumstances.

We calculated export price based on delivered prices to unrelated purchasers. We made deductions for foreign inland freight, ocean freight, marine insurance, U.S. duties, and brokerage and handling expenses in accordance with section 772(c)(2) of the Act.

Normal Value (NV)

Pursuant to section 773(a)(1)(B) of the Act, we determined that the home market (HM) is viable and an appropriate basis for calculating NV.

On March 14, 1996, KGC submitted an allegation that BSF sold subject merchandise in its home market at less than its cost of production (COP) during the period of review. After analyzing the allegation, the Department determined that reasonable grounds exist to believe or suspect that HM sales of the foreign like product were made below COP (*see* memo to Holly A. Kuga dated April 19, 1996). Accordingly, the Department conducted a sales-below-COP investigation for this review period.

In accordance with 19 CFR 353.51(c), we calculated COP as the sum of reported materials, labor, factory overhead, and general expenses, and compared COP to HM prices, net of price adjustments.

As a result of our COP investigation, we found that it was necessary to disregard certain HM sales pursuant to section 773(b)(1) of the Act. In accordance with sections 773(b)(2) (B) and (C) of the Act, we found that 20 percent or more of respondent's sales of a given product during the POR were at prices less than COP and, therefore, that below-cost sales were made within an extended period of time in substantial quantities. We also determined, based on a comparison of each below-cost price to the weighted-average COP for the period for that product, that below-cost sales were made at prices which would not permit recovery of all costs within a reasonable period of time in accordance with section 773(b)(2)(D) of the Act.

Where HM sales were used for comparisons, we calculated NV based on packed, ex-factory or delivered prices to customers in the United Kingdom. We made deductions, where appropriate, for rebates and for HM movement charges. We also made circumstances-of-sale (COS) adjustments, where appropriate, for differences in credit expenses, warranty expenses, customer-requested tooling expenses, and post-sale warehousing expenses, in accordance with 19 CFR 353.56(a).

BSF did not claim HM packing expenses since subject merchandise is loaded into reusable bins as part of the production process with no packing material expenses incurred. In accordance with section 773(a)(6)(A) of the Act, we then added U.S. packing costs to all HM prices.

BSF reported that its sales in the home and U.S. markets were made at the same level of trade and channel of distribution. Therefore, BSF did not request a level-of-trade adjustment. Our analysis and verification of BSF's response confirmed that the selling functions performed for EP and HM sales are comparable. Therefore, in accordance with section 773(a)(7)(A) of the Act, we compared sales at the same level of trade and did not make a level-of-trade adjustment to NV for these preliminary results.

For certain U.S. sales, we found no comparable home market sales after applying the model-matching methodology, the contemporaneity test, and the difference-in-merchandise (difmer) test. For these sales, we based NV on constructed value (CV), in accordance with section 773(a)(4) of the Act.

In accordance with section 773(e) of the Act, we calculated CV based on the sum of BSF's submitted cost of materials and fabrication, selling, general and administrative (SG&A) expenses, and profit, and U.S. packing costs. In accordance with section 773(e)(2)(A) of the Act, we based SG&A and profit on the amounts incurred and realized by BSF in connection with the production and sale of the foreign like product, in the ordinary course of trade, for consumption in the foreign country.

We made COS adjustments, in accordance with 19 CFR 353.56, by deducting home market direct selling expenses from CV and adding U.S. direct selling expenses to CV. These adjustments were made for differences in credit expenses, warranties, and warehousing.

Preliminary Results of the Review

We preliminarily determine that the following dumping margin exists:

Manufacturer/ exporter	Time period	Margin (per-cent)
British Steel Forgings.	09/01/94–8/31/95 ...	0.49

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice. Any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the publication of this notice, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 37 days after the date of publication. The Department will publish a notice of final results of this administrative review, which will include the results of its analysis of issues raised in any such comments.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between export price and NV may vary from the percentage stated above. Upon completion of this review, the Department will issue appraisement instructions directly to the Customs Service.

If our intent to revoke is finalized, the revocation will apply to all entries of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after September 1, 1995. The Department will then order the suspension of liquidation ended for all such entries and will instruct the Customs Service to release any cash deposit or bonds. The Department will further instruct Customs to refund with interest any cash deposits on post-September 1, 1995 entries. In addition, the Department will terminate the review covering subject merchandise from the United Kingdom sold during the period September 1, 1995, through August 31, 1996, which was initiated on October 17, 1996 (61 FR 54154).

If we do not revoke, the following deposit rates will be effective upon publication of the final results of these administrative reviews for all shipments of crankshafts from the United Kingdom entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(c) of the Act: (1) The cash deposit rate for reviewed company will be the rate established in the final results of this review (except that no deposit will be required if the margin is zero or *de minimis, i.e.*, less than 0.5 percent); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) for all other producers and/or exporters of this merchandise, the cash deposit rate shall be 6.55 percent, the adjusted ''all others'' rate from the less-than-fair-value investigation.

These deposit rates, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of

their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review, intent to revoke, and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)), 19 CFR 353.22, and 19 CFR 353.25.

Dated: November 25, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–30747 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–201–802]

Gray Portland Cement and Clinker From Mexico; Notice of Court Decision

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of court decision and suspension of liquidation.

SUMMARY: On October 24, 1996, in the case of *Cemex, S.A.* v. *United States,* Slip Op. 96–170, (Cemex), the United States Court of International Trade (the Court) affirmed the Department of Commerce's (the Department's) results of redetermination pursuant to remand of the final results of the second administrative review of the antidumping duty order on gray portland cement and clinker from Mexico. The period covered by the second review is August 1, 1991 through July 31, 1992. Consistent with the decision of the United States Court of Appeals for the Federal Circuit (Federal Circuit) in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), the Department will not order the liquidation of the subject merchandise entered or withdrawn from warehouse for consumption prior to a ''conclusive'' decision in this case.

EFFECTIVE DATE: November 3, 1996.

FOR FURTHER INFORMATION CONTACT: Robert James or John Kugelman, Office Eight, Enforcement Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5222.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 1993, the Department published in the Federal Register the final results of its second administrative review of the antidumping duty order on gray portland cement and clinker from Mexico (58 FR 47253 (September 8, 1993)). In those final results the Department set forth its determination of the weighted-average margins for the respondent Cemex for the period of review, August 1, 1991 through July 31, 1992, and announced its intent to instruct the U.S. Customs Service to assess antidumping duties on all appropriate entries.

Cemex subsequently filed suit with the Court challenging these final results. Thereafter, the Court published an Opinion dated April 24, 1995, in *Cemex, S.A.* v. *United States,* Ct. No. 93–10–00659, Slip Op. 95–72, remanding the Department's determination with instructions to: (1) Request and consider difference-in-merchandise information to determine the suitability of a price-to-price comparison of U.S. sales of Types II and V cement to home market sales of Type I cement; (2) consider an arm's-length test of transfer prices between a cement distributor and a concrete manufacturer in the United States, both related to Cemex, for allocating profit to value added during further processing in the United States; (3) examine whether the Department articulated a new policy regarding treatment of interest income ''at a critical juncture,'' thus warranting consideration of factual information submitted by Cemex but rejected as untimely new information; and (4) correct our margin calculation to include CEMEX's sales of further-manufactured merchandise. *See Cemex, S.A.* v. *United States,* Slip Op. 95–72 (CIT April 24, 1995). On February 1, 1996, the Department filed its remand results with the Court. Cemex and defendant-intervenors, The Ad-Hoc Committee of AZ–NM–TX–FL Producers of Gray Portland Cement and the National Cement Company of California, Inc., challenged certain aspects of the Department's remand results.

On August 13, 1996, the Court ordered a second remand so that the Department (1) could determine if the inclusion of non-subject merchandise in Cemex's calculation of its home market freight expenses is distortive; (2) deny, as either direct or indirect adjustments, Cemex's claimed adjustments to foreign market value for post-sale freight expenses in those cases where the expenses fail to qualify as a direct deduction from foreign market value; (3) choose an appropriate methodology for establishing duty assessment and estimated deposit rates; and (4) correct certain clerical errors discovered during the first remand proceeding. *See Cemex, S.A.* v. *United States,* Slip Op. 96–132 (CIT August 13, 1996). The Department filed its second redetermination with the Court on September 27, 1996; the Court, on October 24, 1996, affirmed the Department's remand results. *See Cemex, S.A.* v. *United States,* Slip Op. 96–170 (CIT October 24, 1996).

Suspension of Liquidation

In its decision in Timken, the Federal Circuit held that, pursuant to 19 U.S.C. 1516a(e), the Department must publish notice of a decision of the Court or Federal Circuit which is ''not in harmony'' with the Department's determination. Publication of this notice fulfills this obligation. The Federal Circuit also held that in such a case, the Department must suspend liquidation until there is a ''conclusive'' decision in the action. A ''conclusive'' decision cannot be reached until the opportunity to appeal expires or any appeal is decided by the Federal Circuit. Therefore, the Department will continue to suspend liquidation pending expiration of the period to appeal or pending a final decision of the Federal Circuit if Cemex is appealed.

Dated: November 25, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary, Enforcement Group III.

[FR Doc. 96–30746 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–580–811]

Steel Wire Rope From the Republic of Korea; Preliminary Results of Antidumping Duty Administrative Review and Intent To Revoke Antidumping Duty Order in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review and intent to revoke antidumping duty order in part.

SUMMARY: In response to requests by the petitioner, the Committee of Domestic Steel Wire Rope & Specialty Cable Manufacturers, and by Manho Rope and Wire Ltd. (Manho) and Chun Kee Steel Wire Co. Ltd. (Chun Kee), respondent manufacturers/exporters of steel wire rope, the Department of Commerce (the

Department) is conducting an administrative review of the antidumping duty order on steel wire rope from the Republic of Korea. The review covers 12 manufacturers/exporters of the subject merchandise to the United States. The review period is March 1, 1995, through February 28, 1996 (the POR).

We have preliminarily determined that sales have been made below normal value (NV). If these preliminary results are adopted in our final results of administrative review, we will instruct U.S. Customs to assess antidumping duties equal to the difference between the export price (EP) and the normal value (NV). Also, if these preliminary results are adopted in our final results of administrative review, we intend to revoke the antidumping duty order with respect to Manho and Chun Kee based on three years of sales at not less than NV. See Intent to Revoke, infra. Interested parties are invited to comment on these preliminary results. Parties who submit comments in this proceeding are requested to submit with each argument: (1) a statement of the issue, and (2) a brief summary of the argument.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas O. Barlow, Matthew Rosenbaum, or Kris Campbell, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, Washington, D.C. 20230; telephone: (202) 482–4733.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Rounds Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the current regulations, as amended by the interim regulation published in the Federal Register on May 11, 1995 (60 FR 25130).

Background

On March 26, 1993, the Department published in the Federal Register (58 FR 16398) the antidumping duty order on steel wire rope from the Republic of Korea. On March 4, 1996, the Department published a notice of ''Opportunity to Request an Administrative Review'' (61 FR 8238) of this antidumping duty order for the period March 1, 1995, through February 28, 1996. On April 1, 1996, the petitioner requested an administrative review of 12 manufacturers/exporters of steel wire rope from Korea. Manho and Chun Kee, each on April 1, 1996, also requested that the Department conduct an administrative review of their sales of subject merchandise during the POR. We published a notice of initiation of administrative review on April 25, 1996 (61 FR 18379). The Department is now conducting this review in accordance with section 751 of the Act.

Unlocated Companies

We were unable to obtain addresses for Hanboo Wire Rope and Seo Jin Wire Rope and thereafter received confirmation from the U.S. embassy in Seoul, South Korea, that these companies were closed. In accordance with our practice with respect to companies to which we cannot send a questionnaire, we are assigning to these companies the ''All Others'' rate from the less-than-fair-value (LTFV) investigation, which is 1.51 percent. *See Sweaters Wholly or in Chief Weight of Man-Made Fiber From Hong Kong; Final Results of Antidumping Duty Administrative Review*, 59 FR 13926 (March 24, 1994).

Non-Shipper

Myung Jin notified us that it did not have shipments of subject merchandise during the POR, and we confirmed this with the United States Customs Service.

Verification

In accordance with section 782(i) of the Act, we verified information provided by Chun Kee, Manho, Kumho Wire Rope Mfg., Co., Ltd. (Kumho), and Sungjin Company (Sung Jin), using standard verification procedures, including on-site inspection of the manufacturer's facilities, the examination of relevant sales and financial records, and selection of original documentation containing relevant information. Our verification results are outlined in the public versions of the verification reports.

Scope of Review

The product covered by this review is steel wire rope. Steel wire rope encompasses ropes, cables, and cordage of iron or carbon steel, other than stranded wire, not fitted with fittings or made up into articles, and not made up of brass-plated wire. Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7312.10.9030, 7312.10.9060, and 7312.10.9090.

Excluded from this review is stainless steel wire rope, i.e., ropes, cables and cordage other than stranded wire, of stainless steel, not fitted with fittings or made up into articles, which is classifiable under HTS subheading 7312.10.6000. Although HTS subheadings are provided for convenience and Customs purposes, our own written description of the scope of this review is dispositive.

Export Price

For sales to the United States, the Department used EP as defined in section 772(a) of the Act, because the subject merchandise was sold to unaffiliated U.S. purchasers prior to the date of importation and the use of constructed export price was not indicated by the facts of record.

We calculated EP based on ex-factory, f.o.b., c.i.f., c&f, or delivered to Korean port prices to unrelated purchasers in, or for exportation to, the United States. We adjusted these prices for billing adjustments, where applicable. We made adjustments, where applicable, for domestic brokerage and handling, ocean freight, marine insurance, terminal handling charges, stevedoring charges, wharfage expenses, bill of lading issuing fees, export license fees, export insurance, domestic inland freight, containerization expenses and container taxes, container freight station charges, and shoring charges in accordance with section 772(c)(2)(A) of the Act. We also added duty drawback, where applicable, for Manho and Chun Kee, pursuant to section 772(c)(1)(B) of the Act. We did not make any duty drawback adjustments for Chung Woo Rope Co., Ltd., Inc. (Chung Woo), Kumho, or Ssang Yong Steel Wire Co., Ltd., because they were unable to demonstrate a connection between payment of import duties and receipt of duty drawback on exports of steel wire rope, and because they did not demonstrate that they had sufficient imports of raw materials to account for the duty drawback received on exports of the manufactured product, consistent with our practice in the previous review (*see Steel Wire Rope From the Republic of Korea; Final Results of Antidumping Duty Administrative Review*, 61 FR 55965, 55968 (October 30, 1996) (*Steel Wire Rope II Final*)).

No other adjustments to EP were claimed or allowed.

Normal Value

Based on a comparison of the aggregate quantity of home market and U.S. sales, and absent any information that a particular market situation in the exporting country does not permit a

proper comparison, we determined that the quantity of foreign like product each respondent sold in the exporting country was sufficient to permit a proper comparison with the sales of the subject merchandise to the United States, pursuant to section 773(a) of the Act, because each company had sales in its home market which were greater than five percent of the U.S. market. Therefore, in accordance with section 773(a)(1)(B)(i) of the Act, we based NV on the prices at which the foreign like products were first sold for consumption in the exporting country.

We used sales to affiliated customers only where we determined such sales were made at arm's-length prices, *i.e.*, at prices comparable to prices at which the firm sold identical merchandise to unrelated customers.

Because we disregarded sales below the cost of production (COP) in the last completed review for Manho and Chun Kee, we had reasonable grounds to believe or suspect that sales of the foreign product under consideration for the determination of NV in this review may have been made at prices below the COP, as provided by section 773(b)(2)(A)(ii) of the Act. Therefore, pursuant to section 773(b)(1) of the Act, we initiated COP investigations of sales by Manho and Chun Kee in the home market.

In accordance with section 773(b)(3) of the Act, we calculated the COP based on the sum of the costs of materials and fabrication employed in producing the foreign like product, plus selling, general and administrative expenses (SG&A) and the cost of all expenses incidental to placing the foreign like product in condition packed ready for shipment. We relied on the home market sales and COP information provided by Manho and Chun Kee in their questionnaire responses.

After calculating COP, we tested whether home market sales of steel wire rope were made at prices below COP within an extended period of time in substantial quantities, and whether such prices permit recovery of all costs within a reasonable period of time. We compared model-specific COPs to the reported home market prices less any applicable movement charges, rebates, and direct selling expenses.

Pursuant to section 773(b)(2)(C), where less than 20 percent of respondent's sales of a given product were at prices less than COP, we did not disregard any below-cost sales of that product because we determined that the below-cost sales were not made in ''substantial quantities.'' Where 20 percent or more of a respondent's sales of a given product during the POR were at prices less than the COP, we disregarded the below-cost sales because we determined that the below-cost sales were made within an extended period of time in ''substantial quantities'' in accordance with sections 773(b)(2)(B) and (C) of the Act, and based on comparisons of price to weighted-average COPs for the POR we determined that the below-cost sales of the product were at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act. Based on this test, we disregarded below cost sales with respect to Manho and Chun Kee.

Pursuant to section 777A(d)(2) of the Act, we compared the EPs of individual transactions to the monthly weighted-average price of sales of the foreign like product. We compared EP sales to sales in the home market of identical or similar merchandise.

We based NV on the price at which the foreign like product is first sold for consumption in the exporting country, in the usual commercial quantities, in the ordinary course of trade and at the same level of trade as the EP, in accordance with section 773(a)(1)(B)(i) of the Act. We made adjustments, where appropriate, for rebates. We increased home market price by the amount of U.S. packing costs in accordance with section 773(a)(6)(A) of the Act and reduced it by the amount of home market packing costs in accordance with section 773(a)(6)(B) of the Act. We adjusted for movement expenses in accordance with section 773(a)(6)(B)(ii) of the Act. We also made adjustments, where applicable, for differences in the physical characteristics of merchandise in accordance with section 773(a)(6)(C)(ii) of the Act.

Pursuant to section 773(a)(6)(C)(iii) of the Act and 19 CFR 353.56, we made circumstance-of-sale (COS) adjustments to NV. We deducted home market credit expenses, inspection fees, warranty and servicing expenses and, where appropriate, added U.S. postage fees, U.S. letter of credit fees, U.S. bank charges, U.S. credit expenses, U.S. inspection fees, U.S. warranty and servicing expenses, and U.S. product liability insurance. Prices were reported net of value-added taxes (VAT) and, therefore, no adjustment for VAT was necessary.

In accordance with section 773(a)(4) of the Act, we used CV as NV for those U.S. sales for which we could not determine the NV based on home market sales pursuant to section 773(a)(1) of the Act either because there were no appropriate sales or because we disregarded below-cost sales pursuant to section 773(b) of the Act. We calculated CV, in accordance with section 773(e) of the Act, as the sum of the cost of manufacturing (COM) of the product sold in the United States, home market SG&A expenses, home market profit, and U.S. packing expenses. The COM of the product sold in the United States is the sum of direct material, direct labor, and variable and fixed factory overhead expenses. For home market SG&A expenses and profit, we used the actual amounts incurred and realized by the respondent in connection with the production and sale of the foreign like product in the ordinary course of trade, for consumption in the foreign country, in accordance with section 773(e)(2)(A) of the Act, unless these actual data were not available. If these actual data were not available, we used the actual amounts incurred and realized by the respondent in connection with the production and sale, for consumption in the foreign country, of merchandise that is in the same general category of products as the subject merchandise, in accordance with section 773(e)(2)(B)(i) of the Act. In accordance with section 773(a)(8) of the Act, we made COS adjustments to CV by deducting home market direct selling expenses and adding U.S. direct selling expenses.

No other adjustments were claimed or allowed.

Use of Facts Otherwise Available

We preliminarily determine, in accordance with section 776(a) of the Act, that the use of facts available is appropriate for Boo Kook Corp., Dong-Il Steel Mfg. Co., Ltd. and Yeon Sin Metal because they did not respond to our antidumping questionnaire. We find that these firms have withheld ''information that has been requested by the administering authority.'' Furthermore, we determine that, pursuant to section 776(b) of the Act, it is appropriate to make an inference adverse to the interests of these companies because they failed to cooperate by not responding to our questionnaire.

Where the Department must base the entire dumping margin for a respondent in an administrative review on facts otherwise available because that respondent failed to cooperate, section 776(b) of the Act authorizes the use of an inference adverse to the interests of that respondent in choosing the facts available. Section 776(b) of the Act also authorizes the Department to use as adverse facts available information derived from the petition, the final determination, a previous administrative review, or other information placed on the record.

Section 776(c) of the Act provides that the Department shall, to the extent practicable, corroborate that secondary information from independent sources reasonably at its disposal. The Statement of Administrative Action (SAA) provides that ''corroborate'' means simply that the Department will satisfy itself that the secondary information to be used has probative value. (*See* H.R. Doc. 316, Vol. 1, 103d Cong., 2d sess. 870 (1994).)

To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used. However, unlike other types of information, such as input costs or selling expenses, there are no independent sources for calculated dumping margins. Thus, in an administrative review, if the Department chooses as total adverse facts available a calculated dumping margin from a prior segment of the proceeding, it is not necessary to question the reliability of the margin for that time period. With respect to the relevance aspect of corroboration, however, the Department will consider information reasonably at its disposal as to whether there are circumstances that would render a margin not relevant. Where circumstances indicate that the selected margin is not appropriate as adverse facts available, the Department will disregard the margin and determine an appropriate margin (*see, e.g., Fresh Cut Flowers from Mexico; Final Results of Antidumping Duty Administrative Review,* 61 FR 6812 (Feb. 22, 1996), where the Department disregarded the highest margin as adverse best information available because the margin was based on another company's uncharacteristic business expense resulting in an unusually high margin).

In this case, we have used the highest rate from any prior segment of the proceeding, 1.51 percent, as adverse facts available. This rate is the highest available rate and, to the best of our knowledge, there are no circumstances that indicate that the selected margin is not appropriate as adverse facts available.

Intent To Revoke

Chun Kee and Manho requested, pursuant to 19 CFR 353.25(b), revocation of the order with respect to their sales of the merchandise in question and submitted the certification required by 19 CFR 353.25(b)(1). In addition, in accordance with 19 CFR 353.25(a)(2)(iii), Chun Kee and Manho have agreed in writing to their immediate reinstatement in the order, as long as any producer or reseller is subject to the order, if the Department concludes under 19 CFR 353.22(f) that Chun Kee and Manho, subsequent to revocation, sold merchandise at less than NV. Based on the preliminary results in this review and the two preceding reviews (*see Steel Wire Rope From the Republic of Korea; Final Results of Antidumping Duty Administrative Review,* 60 FR 63499 (December 11, 1995), and *Steel Wire Rope II Final*), Chun Kee and Manho have demonstrated three consecutive years of sales at not less than NV.

Given the results of the two preceding reviews, if the final results of this review demonstrate that Chun Kee and Manho sold the merchandise at not less than NV, and if we determine that it is not likely that Chun Kee and Manho will sell the subject merchandise at less then NV in the future, we intend to revoke the order with respect to merchandise produced and exported by Chun Kee and Manho.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the following margins exist for the period March 1, 1995, through February 28, 1996:

Manufacturer/exporter	Margin (percent)
Boo Kook Corporation	1.51
Chun Kee Steel & Wire Rope Co., Ltd.	0.01
Chung Woo Rope Co., Ltd.	0.24
Dong-Il Steel Manufacturing Co., Ltd	1.51
Hanboo Wire Rope, Inc.	1.51
Kumho Wire Rope Mfg. Co., Ltd.	0.01
Manho Rope & Wire, Ltd.	0.00
Myung Jin Co. [1]	1.51.
Seo Jin Rope	1.51
Ssang Yong Steel Wire Co., Ltd	0.01
Sung Jin	0.03
Yeonsin Metal	1.51

[1] No shipments subject to this review. Rate is from the last relevant segment of the proceeding in which the firm had shipments/sales.

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice. Any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the publication of this notice, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Parties who submit argument in this proceeding are requested to submit with each argument: (1) a statement of the issues, and (2) a brief summary of the arguments. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 37 days after the date of publication. The Department will issue a notice of the final results of this administrative review, which will include the results of its analysis of issues raised in any such written comments or at the hearing, within 120 days from the publication of these preliminary results.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. The Department will issue appraisement instructions directly to the Customs Service. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the determination and for future deposits of estimated duties. For duty assessment purposes, we calculated an importer-specific assessment rate by aggregating the dumping margins calculated for all U.S. sales to each importer and dividing this amount by the total quantity of subject merchandise sold to each of the respective importers. This specific rate calculated for each importer will be used for the assessment of antidumping duties on the relevant entries of subject merchandise during the POR.

Furthermore, the following deposit requirements will be effective upon completion of the final results of this administrative review for all shipments of steel wire rope from Korea entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) the cash deposit rate for the reviewed companies will be the rates established in the final results of administrative review (except that for companies whose weighted-average margins are less than 0.5 percent, *i.e.,* are *de minimis,* no cash deposit will be required); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in the original LTFV investigation or a previous review, the cash deposit will continue to be the most recent rate published in the final determination or final results for which the manufacturer or exporter received an individual rate; (3) if the exporter is not a firm covered in this review, the previous review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous reviews, the cash deposit rate will be 1.51

percent, the ''all others'' rate established in the LTFV investigation (58 FR 16398, March 26, 1993).

This notice serves as a preliminary reminder to importers of their responsibility to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) and 751(d) of the Act (19 U.S.C. 1675(a)(1)), 19 CFR 353.22, and 19 CFR 353.25.

Dated: November 26, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–30755 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–401–401]

Certain Carbon Steel Products from Sweden; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty order on certain carbon steel products from Sweden. For information on the net subsidy for the reviewed company, as well as for any non-reviewed companies, please see the *Preliminary Results of Review* section of this notice. If the final results remain the same as these preliminary results of administrative review, we will instruct the U.S. Customs Service to assess countervailing duties as detailed in the *Preliminary Results of Review* section of this notice. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Gayle Longest or Lorenza Olivas, Office of CVD/AD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: Gayle Longest (202) 482–3338 or (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On October 4, 1985, the Department published in the Federal Register (50 FR 48517) the countervailing duty order on certain carbon steel products from Sweden. On October 5, 1995, the Department published a notice of ''Opportunity to Request an Administrative Review'' (60 FR 52149) of this countervailing duty order. We received timely requests for review, and we initiated the review, covering the period January 1, 1994 through December 31, 1994, on November 16, 1995 (60 FR 57573).

In accordance with section 355.22(a) of the Department's *Interim Regulations*, this review covers only those producers or exporters for which a review was specifically requested (*see Antidumping and Countervailing Duties: Interim Regulations; Request for Comments,* (60 FR 25130; May 11, 1995) (*Interim Regulations*)). Accordingly, this review covers SSAB Svenskt Stal AB (SSAB), the sole known producer/exporter of the subject merchandise during the period of review (POR). This review also covers 10 programs.

On July 30, 1996, we extended the period for completion of the preliminary results pursuant to section 751(a)(3) of the Tariff Act of 1930, as amended (*see Certain Carbon Steel Products From Sweden; Extension of Time Limit for Countervailing Duty Administrative Review* (61 FR 39632). As explained in the memoranda from the Assistant Secretary for Import Administration to the File, dated November 22, 1995, and January 11, 1996 (both on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce), all deadlines were extended to take into account the partial shutdowns of the Federal Government from November 15 through November 21, 1995, and December 15, 1995, through January 6, 1996. Therefore, the deadline for these preliminary results is no later than November 27, 1996, and the deadline for the final results of this review is no later than 120 days from the date on which these preliminary results are published in the Federal Register.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act (URAA) effective January 1, 1995 (the Act). The Department is conducting this administrative review in accordance with section 751(a) of the Act. References to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments* (54 FR 23366; May 31, 1989) (*1989 Proposed Regulations*) are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *1989 Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the URAA. *See Advance Notice of Proposed Rulemaking for Public Comments,* (60 FR 80; Jan. 3, 1995); *Antidumping Duties; Countervailing Duties; Notice of Proposed Rulmaking and Request for Public Comments,* (61 FR 7308; February 27, 1996).

Scope of the Review

Imports covered by this review are shipments of certain carbon steel products from Sweden. These products include cold-rolled carbon steel, flat-rolled products, whether or not corrugated, or crimped: whether or not pickled, not cut, not pressed and not stamped to non-rectangular shape; not coated or pleated with metal and not clad; over 12 inches in width and of any thickness; whether or not in coils. During the review period, such merchandise was classifiable under the *Harmonized Tariff Schedule* (HTS) item numbers 7209.11.0000, 7209.12.0000, 7209.13.0000, 7209.21.0000, 7209.22.0000, 7209.23.0000, 7209.24.5000, 7209.31.0000, 7209.32.0000, 7209.33.0000, 7209.34.0000, 7209.41.0000, 7209.43.0000, 7209.44.0000, 7209.90.0000, 7211.30.5000, 7211.41.7000 and 7211.49.5000. The written description remains dispositive.

Allocation Methodology

In the past, the Department has relied upon information from the U.S. Internal Revenue Service on the industry-specific average useful life of assets in determining the allocation period for nonrecurring grant benefits. *See General Issues Appendix* appended to *Final Countervailing Duty Determination; Certain Steel Products from Austria* (58 FR 37063, 37226; July 9, 1993). However, in *British Steel plc.* v. *United States,* 879 F. Supp. 1254 (CIT 1995) (*British Steel*), the U.S. Court of International Trade (the Court) ruled against this allocation methodology. In

accordance with the Court's remand order, the Department calculated a company-specific allocation period for nonrecurring subsidies based on the average useful life (AUL) of non-renewable physical assets. This remand determination was affirmed by the Court on June 4, 1996. *British Steel,* 929 F. Supp. 426, 439 (CIT 1996).

The Department has decided to acquiesce to the Court's decision and, as such, we intend to determine the allocation period for nonrecurring subsidies using company-specific AUL data where reasonable and practicable. Specifically, the Department has preliminarily determined that it is reasonable and practicable to allocate all new nonrecurring subsidies (*i.e.*, subsidies that have not yet been assigned an allocation period) based on a company-specific AUL. However, if a subsidy has already been countervailed based on an allocation period established in an earlier segment of the proceeding, it does not appear reasonable or practicable to reallocate that subsidy over a different period of time. In other words, since the countervailing duty rate in earlier segments of the proceeding was calculated based on a certain allocation period and resulting benefit stream, redefining the allocation period in later segments of the proceeding would entail taking the original grant amount and creating an entirely new benefit stream for that grant. Such a practice may lead to an increase or decrease in the amount countervailed and, thus, would result in the possibility of over-countervailing or under-countervailing the actual benefit. The Department has preliminarily determined that a more reasonable and accurate approach is to continue using the allocation period first assigned to the subsidy. We invite the parties to comment on the selection of this methodology and provide any other reasonable and practicable approaches for complying with the Court's ruling.

In the current review, there are no new subsidies. All of the nonrecurring grants under review were provided prior to the POR; allocation periods for these grants were established during prior segments of this proceeding. Therefore, for purposes of these preliminary results, the Department is using the original allocation period assigned to each grant.

Privatization and Sale of Assets to Other Companies

SSAB is the only Swedish company that produces and exports the subject merchandise. SSAB has sold several productive units and the company was partially privatized twice, in 1987 and in 1989. During the review period, SSAB was completely privatized.

In *Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Sweden* (58 FR 37385; July 9, 1993) (*Final Determination*), the Department found that SSAB had received countervailable subsidies prior to the sale of the productive units and the two partial privatizations. Further, the Department found that a private party purchasing all or part of a government-owned company can repay prior subsidies on behalf of the company as part or all of the sales price (*see General Issues Appendix* (58 FR 37217, 37262; July 9, 1993)). Therefore, to the extent that a portion of the sales price paid for a privatized company can be reasonably attributed to prior subsidies, that portion of those subsidies will be extinguished.

To calculate a rate for the subsidies that were allocated to the spin-off, *i.e.,* a productive unit that was sold, we first determined the amount of the subsidies attributable to each productive unit by dividing the asset value of that productive unit by the total asset value of SSAB in the year of the spin-off. We then applied this ratio to the net present value (NPV), in the year of the spin-off, of the future benefit streams from all of SSAB's prior subsidies allocable to the POR. The future benefit streams at the time of the sale of each productive unit reflect the Department's allocation over time of prior subsidies to SSAB in accordance with the declining balance methodology (*see* section 355.49 of the Department's *1989 Proposed Regulations*), and reflect also the effect of prior spin-offs of SSAB productive units.

We next estimated the portion of the purchase price which represents repayment of prior subsidies by determining the portion of SSAB's net worth that was accounted for by subsidies. To do that, we divided the face value of the allocable subsidies received by SSAB in each year from fiscal year 1979 through fiscal year 1993 by SSAB's net worth in the same year. We calculated a simple average of these ratios, which was then multiplied by the purchase price of the productive unit. Thus, we determined the amount of the purchase price which represents repayment of prior subsidies. This amount was subtracted from the subsidies attributed to the productive unit at the time of sale to arrive at the amount of subsidies allocated to the productive unit being spun-off.

To calculate the subsidies remaining with SSAB after privatization, we performed the following calculations. We first calculated the NPV of the future benefit stream of the subsidies at the time of the sale of the shares. Next, we estimated the portion of the purchase price which represents repayment of prior subsidies in accordance with the methodology described in the ''Privatization'' section of the *General Issues Appendix* (58 FR 37217, 37259). This amount was then subtracted from the amount of the NPV eligible for repayment, and the result was divided by the NPV to calculate the ratio representing the amount of subsidies remaining with SSAB.

To calculate the benefit provided to SSAB in the POR, where appropriate, we multiplied the benefit calculated for 1994, adjusted for sales of productive units, by the ratio representing the amount of subsidies remaining with SSAB after privatization. We then divided the results by the company's total sales in 1994.

Analysis of Programs

I. Programs Conferring Subsidies

Programs Previously Determined to Confer Subsidies

(1) Equity Infusions

In 1981, the Government of Sweden (GOS) provided equity capital to SSAB totaling 1,125 million Swedish kronor (MSEK). Simultaneously, Granges, a private company and the only other shareholder at the time, contributed 375 MSEK. To persuade Granges to contribute this equity capital, the GOS guaranteed a specified sum to be paid to Granges in 1991. Because of this arrangement, we determined that the 375 MSEK paid by Granges was an equity infusion provided indirectly by the GOS, through Granges, specifically to SSAB. *See Final Determination* (58 FR 37385, 37387).

In the *Final Determination* and in the final determination from a previous investigation of Swedish steel, *Final Affirmative Countervailing Duty Determinations; Certain Carbon Steel Products from Sweden* (50 FR 33377; August 19, 1985) (*Final Certain Carbon Steel Products*), we determined that SSAB was unequityworthy in 1981 when it received the equity infusions, and that the two equity infusions are therefore countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

In accordance with the ''Equity'' section of the *General Issues Appendix,* we treated the equity infusions as grants. To calculate the benefit from these equity infusions for the POR, we used the grant methodology as

described in the ''Allocation Methodology'' section above. Because the Department determined in the *Final Determination* that the infusions are non-recurring subsidies, we have allocated the subsidies over 15 years, as discussed in the ''Allocation Methodology'' section above. As the discount rate, we have used SSAB's company-specific interest rate on fixed-rate long-term loans (*see* § 355.49(b)(2)(i) of the *1989 Proposed Regulations*).

We reduced the benefit from these equity infusions attributable to the POR according to the methodology outlined in the ''Privatization'' section above. We then divided the result by SSAB's total sales for 1994. On this basis, we preliminarily determine the net subsidy for equity infusions to be 0.53 percent *ad valorem*.

(2) Structural Loans

Under three separate pieces of legislation, SSAB received structural loans for investment in plant and equipment. The loans were disbursed in installments between 1978 and 1983. All three loans were outstanding during the POR.

According to the terms of the loans, all three structural loans were interest-free for three years from the date of disbursement. After that time, one loan incurred interest at a fixed rate of five percent per annum while the other two loans incurred interest at a variable rate subject to change every five years. The variable interest rate on these two loans is set at the rate of the long-term government bonds plus a 0.25 percent margin. After a five-year grace period, the principal is repaid in 20 equal installments at the end of each calendar year.

In *Final Determination* and in *Final Certain Carbon Steel Products*, we determined that these loans are countervailable because they were provided specifically to SSAB on terms inconsistent with commercial considerations. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit from the fixed-rate structural loan, we employed the long-term loan methodology described in section 355.49(c)(1) of the *1989 Proposed Regulations.* To calculate the benefits from the two variable-rate loans, we used the variable-rate long-term loan methodology described in section 355.49(d)(1) of the *1989 Proposed Regulations.* As the discount rate, we used SSAB's company-specific long-term interest rates, a benchmark previously established in the *Final Determination.*

We reduced the benefit attributable to the POR from the fixed-rate structural loan according to the methodology outlined in the ''Privatization'' section above. We then aggregated the benefits for the three loans (fixed interest rate and variable interest rate) and divided the results by SSAB's total sales for 1994. On this basis, we preliminarily determine the net subsidy from the three structural loans to be 0.27 percent *ad valorem*.

(3) Forgiven Reconstruction Loans

The GOS provided reconstruction loans to SSAB between 1979 and 1985 to cover operating losses, investment in certain plants and equipment, and for employment promotion purposes. The loans were interest free for three years, after which a fixed interest rate was charged. According to the terms of the loans, up to half of the outstanding amount of the loan can be written off after the second calendar year following the disbursement. The remainder of the loan can be written off entirely at the end of the ninth calendar year after disbursement. Pursuant to the terms of the reconstruction loans, the GOS wrote off large portions of principal and accrued interest on these loans between 1980 and 1990.

In the *Final Determination* and in *Final Certain Carbon Steel Products,* we determined that forgiveness of these loans is countervailable. There has been no new information or evidence of changed circumstances in this review to warrant reconsideration of this determination.

To calculate the benefit, we treated the written-off portions of the reconstruction loans as countervailable grants received in the years the loans were forgiven and calculated the benefit using the grant methodology as described in the ''Allocation Methodology'' section above. We reduced the benefits from these grants attributable to the POR according to the methodology outlined in the ''Privatization'' section above. We then divided the results by SSAB's total sales for 1994. On this basis, we preliminarily determine the net subsidy from the three forgiven reconstruction loans to be 1.18 percent *ad valorem*.

II. Program Preliminarily Determined Not to Confer Subsidies

(1) *Research & Development (R&D) Loans and Grants*

The Swedish National Board for Industrial and Technical Development (NUTEK) provides research and development loans and grants to Swedish industries for R&D purposes. One type of R&D loan (industrial development loans) is mostly aimed at ''new'' industries such as the biotechnical, electronic, and medical industries. Another type of R&D loan (energy efficiency loans) is directed towards big energy consumers.

The loans accrue interest equal to the official ''discount'' rate plus a premium of 3.75 percent. However, no interest or principal payments are due until the R&D project is completed. If, upon completion of a project, the company wishes to use the research results for commercial purposes, the loan must be repaid. On the other hand, if the company decides not to utilize the results and, therefore, does not claim proprietary treatment for the results, NUTEK will forgive the loan and the results of the research become publicly available.

SSAB had several R&D loans outstanding during the POR on which it did not make either principal or interest payments. However, under our current practice, we cannot determine whether SSAB has received a countervailable benefit until the research is completed and they will be able to submit information demonstrating that the research results are publicly available. It is only upon completion that it will be known (1) whether the loans are forgiven and (2) if the loans are not forgiven, whether the accrued interest is less than what would accrue if the loans are provided at commercial rates. *See Final Determination* (58 FR 37385, 37390). Therefore, we will continue to examine these R&D loans in future administrative reviews.

As explained above, NUTEK may forgive R&D loans if the companies receiving them disseminate publicly the results of the research financed by the loans. The Department's current practice is to treat forgiven R&D loans as non-countervailable if the research results are publicly available. *See Final Determination* (58 FR 37385, 37390). During the POR, three such loans to SSAB were forgiven. Official documentation from NUTEK, provided in the questionnaire response, indicates that the results of these research projects for which these three loans were made to SSAB were made publicly available. On this basis, we preliminarily determine that these three forgiven R&D loans did not confer countervailable benefits on the subject merchandise during the POR.

(2) Fund for Industry and New Business R&D

SSAB reported in its questionnaire response that SSAB Oxelosund, a subsidiary, received a conditional repayment R&D loan from the Fund for Industry and New Business (the Fund).

The Fund provides project financing to firms with a budget of at least two million Swedish kroner (MSEK), and start-up loans to new ''limited'' companies. Projects are financed through (1) conditional repayment loans, (2) capital in return for royalty, (3) project guarantees, and (4) credit guarantees for developing new products, processes and systems, and marketing. The terms and conditions of the financing depend on the type of financing provided.

In October 1992, the Fund approved a 6–MSEK conditional repayment loan for SSAB Oxelosund. Only 3 MSEK of the loan amount were disbursed. Under the terms of the loan, 50 percent of the principal was to be paid at the end of 1994, with the remaining 50 percent to be paid at the end of 1995. The loan accrued interest from the date of disbursement at a rate equal to the Central Bank's ''discount'' rate, plus a 4 percent premium, paid quarterly, for the prior quarter. Because the base rate changes quarterly, we have analyzed this loan under our variable rate loan methodology. In *Certain-Cut-to-Length Carbon Steel Plate from Sweden; Preliminary Results of Countervailing Duty Administrative Review* (60 FR 44017; August 24, 1995) (*92/93 Preliminary Results*) and Certain-Cut-to-Length Carbon Steel Plate from Sweden; Final Results of Countervailing Duty Administrative Review (61 FR 5381; February 12, 1996) (*92/93 Final Results*), the previous administrative review of this order, we found that SSAB paid a higher interest rate for this loan than it would have paid at the commercial benchmark rates. Accordingly, we determined that the program did not confer a countervailable benefit on the subject merchandise during the POR. In this review period, the entire outstanding principal and the accrued interest were paid.

During the POR, SSAB made two interest payments on the loan. The first payment was in arrears and covered the last quarter of 1993; the second payment was for interest accrued in 1994. Therefore, we selected benchmarks for both 1993 and 1994, using the same source for benchmarks established previously. *See 92/93 Preliminary Results* and *92/93 Final Results.* We compared the interest paid by the company with the amount of interest that the company would have paid on a similar loan provided at the benchmark rates, and we factored into the calculation the period of time in which the interest payment was in arrears. We found that the amount paid by the company was slightly lower than the amount that would have been paid at the commercial benchmark rate. However, the subsidy rate that would be attributable to this loan is 0.00002 percent *ad valorem*. A rate this small would not change the overall subsidy rate for SSAB. Moreover, since the principal of the loan was entirely repaid during the POR, the issue of the countervailability of the loan will not arise in subsequent administrative reviews. Since any benefit we would calculate for the loan would not affect the overall subsidy rate during the POR and since there is no possibility of future benefits from this loan, we do not consider it necessary to make a determination on the specificity of this loan program and are not including it in the calculation of these preliminary results.

III. Programs Preliminarily Found to be Not Used

We also examined the following programs and preliminarily determine that SSAB did not apply for or receive benefits under them during the POR:

A. Regional Development Grants
B. Transportation Grants
C. Location-of-industry Loans

IV. Program Preliminarily Found to be Terminated

Mining Exploration Grants

Between 1983 and 1985, SSAB received grants for exploration of new mineral deposits in its Grangesberg mines. In *Final Determination*, the Department found that these grants were countervailable, because they were provided specifically to a group of enterprises or industries (mining companies). The amounts received under this program were less than 0.5 percent of the value of SSAB's total sales for that year and were expensed in the year of receipt in accordance with the Allocation section of the *General Issues Appendix*.

In June 1993, the mining exploration grant program was terminated by the Government of Sweden under law SFS 1993:693 which eliminated Nämnden för Statens Gruvegendom, the agency that administered the program. No grants were given to SSAB under this program after 1985 and there were no residual benefits during the POR from grants previously bestowed.

Preliminary Results of Review

In accordance with section 355.22(c)(4)(ii) of the Department's *Interim Regulations*, we calculated an individual subsidy rate for each producer/exporter subject to this administrative review. For the period January 1, 1994 through December 31, 1994, we preliminarily determine the net subsidy for SSAB to be 1.98 percent *ad valorem*. If the final results of this review remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service (Customs) to assess countervailing duties for SSAB at 1.98 percent *ad valorem*. The Department also intends to instruct the Customs to collect a cash deposit of 1.98 percent of the f.o.b. invoice price on all shipments of the subject merchandise from SSAB, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

Because the URAA replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2)(B) of the Act. The requested review will normally cover only those companies specifically named. Pursuant to 19 CFR 355.22(g), for all companies for which a review was not requested, duties must be assessed at the cash deposit rate, and cash deposits must continue to be collected, at the rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. *See Federal-Mogul Corporation and The Torrington Company* v. *United States*, 822 F.Supp. 782 (CIT 1993) and *Floral Trade Council* v. *United States*, 822 F.Supp. 766 (CIT 1993) (interpreting 19 CFR 353.22(e), the antidumping regulation on automatic assessment, which is the analogue to 19 CFR 355.22(g), the countervailing duty regulation on automatic assessment). Therefore, the cash deposit rates for all companies except those covered by this review will be unchanged by the results of this review.

We will instruct Customs to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate

applicable to the company. Accordingly, the cash deposit rate that will be applied to all non-reviewed companies covered by this order is that established in the most recently completed administrative proceeding. *See Certain Carbon Steel Products From Sweden; Final Results of Countervailing Duty Administrative Review,* 61 FR at 5378. This rate shall apply to all non-reviewed companies until a review of a company assigned these rates is requested. In addition, for the period January 1, 1994 through December 31, 1994, the assessment rates applicable to all non-reviewed companies covered by this order are the cash deposit rates in effect at the time of entry.

Public Comment

Parties to the proceeding may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit written arguments in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 355.38(e).

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under § 355.38(c), are due. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1) and 19 C.F.R. § 355.22(c)(5)).

Dated: November 25, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–30754 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–401–804]

Cut-to-Length Carbon Steel Plate From Sweden; Termination of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of termination of countervailing duty administrative review.

SUMMARY: On September 17, 1996 (61 FR 48885), in response to a request from the petitioners, the Department of Commerce (the Department) initiated an administrative review of the countervailing duty order on cut-to-length carbon steel plate from Sweden. In accordance with 19 CFR 355.22(a)(5) (Interim Regulations, 60 FR 25137; May 11, 1995), the Department is now terminating this review because petitioners have withdrawn their request for review.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Gayle Longest or Lorenza Olivas, Office of CVD/AD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 30, 1996, the Department received a request for an administrative review of this countervailing duty order from the petitioners, U.S. producers of the subject merchandise, for the period January 1, 1995, through December 31, 1995. No other interested party requested a review of the countervailing duty order. On September 17, 1996, the Department published in the Federal Register (61 FR 48885) a notice of ''Initiation of Countervailing Duty Administrative Review'' initiating the administrative review of SSAB Svenskt Stal AB for that period. On November 19, 1996, the petitioners withdrew their request for review.

Section 355.22(a)(5) of the Department's interim regulations stipulates that the Secretary may permit a party that requests a review to withdraw the request not later than 90 days after the date of publication of the notice of initiation of the requested review. In this case, the petitioners have withdrawn their request for review within the 90-day period. No other interested party requested a review and we have received no other submissions regarding the petitioners' withdrawal of their request for review. Therefore, we are terminating this review of the countervailing duty order on cut-to-length carbon steel plate from Sweden.

This notice is published in accordance with 19 CFR 355.22(a)(5).

Dated: November 25, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary AD/CVD Enforcement III.

[FR Doc. 96–30752 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–351–818]

Cut-to-Length Carbon Steel Plate From Brazil; Termination of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of termination of countervailing duty administrative review.

SUMMARY: On September 15, 1995 (60 FR 47930), in response to a request from Usinas Siderurgicas de Minas Gerais, S.A. (USIMINAS), the Department of Commerce (the Department) initiated an administrative review of the countervailing duty order on cut-to-length carbon steel plate from Brazil. In accordance with 19 CFR 355.22(a)(5) (Interim Regulations, 60 FR 25137; May 11, 1995), the Department is now terminating this review because USIMINAS has withdrawn its request for review.

EFFECTIVE DATE: December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Cameron Cardozo, Office of CVD/AD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 29, 1996, the Department received a request for an administrative review of this countervailing duty order from USIMINAS, a Brazilian exporter of the subject merchandise, for the period January 1, 1995, through December 31, 1995. No other interested party requested a review of the countervailing duty order. On September 15, 1995, the Department published in the Federal Register (60 FR 47930) a notice of ''Initiation of Countervailing Duty Administrative Review'' initiating the administrative review of USIMINAS for that period. On November 18, 1996, USIMINAS withdrew its request for review.

Section 355.22(a)(5) of the Department's regulations stipulates that the Secretary may permit a party that requests a review to withdraw the request not later than 90 days after the date of publication of the notice of initiation of the requested review. In this case, USIMINAS has withdrawn its request for review within the 90-day period. No other interested party requested a review and we have received no other submissions regarding USIMINAS's withdrawal of its request for review. Therefore, we a terminating this review of the countervailing duty order on cut-to-length carbon steel plate from Brazil.

This notice is published in accordance with 19 CFR 355.22(a)(5).

Dated: November 25, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for AD/CVD Enforcement III.

[FR Doc. 96–30753 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–DS–M

National Institute of Standards and Technology

National Fire Codes: Request for Proposals for Revision of Standards

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of request for proposals.

SUMMARY: The National Fire Protection Association (NFPA) proposes to revise some of its fire safety standards and requests proposals from the public to amend existing NFPA fire safety standards. The purpose of this request is to increase public participation in the system used by NFPA to develop its standards.

The publication of this notice on behalf of NFPA is being undertaken as a public service; NIST does not necessarily endorse, approve, or recommend any of the standards referenced in the notice.

DATES: Interested persons may submit proposals on or before the dates listed with the standards.

ADDRESSES: Arthur E. Cote, P.E., Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts 02269–9101.

FOR FURTHER INFORMATION CONTACT: Arthur E Cote, P.E., Secretary, Standards Council, at above address, (617) 770–3000.

SUPPLEMENTARY INFORMATION:

Background

The National Fire Protection Association (NFPA) develops fire safety standards which are known collectively as the National Fire Codes. Federal agencies frequently use these standards as the basis for developing Federal regulations concerning fire safety. Often, the Office of the Federal Register approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Request for Proposals

Interested persons may submit amendments, supported by written data, views, or arguments to Arthur E. Cote, P.E., Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts 02269–9101. Proposals should be submitted on forms available from the NFPA Standards Administration Office.

Each person must include his or her name and address, identify the document and give reasons for the proposal. Proposals received before or by 5:00 PM local time on the closing date indicated will be acted on by the Committee. The NFPA will consider any proposal that it receives on or before the date listed with the standard.

At a later date, each NFPA Technical Committee will issue a report which will include a copy of written proposals that have been received and an account of their disposition of by the NFPA Committee as the Report on Proposals. Each person who has submitted a written proposal will receive a copy of the report.

Authority: 15 U.S.G. 272.

Dated: November 26, 1996.

Samuel Kramer,

Associate Director.

NFPA No.	Proposal title	Closing date
NFPA 13–1996	Installation of Sprinkler Systems	1/02/98
NFPA 13D–1996 ...	Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes	1/02/98
NFPA 22–1996	Water Tanks for Private Fire Protection	1/17/97
NFPA 30–1996	Flammable and Combustible Liquids Code	8/1/97
NFPA 30A–1996	Automotive and Marine Service Station Code	8/1/97
NFPA 33–1995	Spray Application Using Flammable or Combustible Materials	8/1/97
NFPA 34–1995	Dipping and Coating Processes Using Flammable or Combustible Liquids	8/1/97
NFPA 35–1995	Manufacture of Organic Coatings	12/31/96
NFPA 43D–1994 ...	Pesticides	1/17/97
NFPA 45–1996	Fire Protection for Laboratories Using Chemicals	1/02/98
NFPA 52–1995	Compressed Natural Gas (CNG) Vehicular Fuel Systems	1/17/97
NFPA 54–1996	National Fuel Gas Code	1/02/98
NFPA 59A–1996	Liquefied Natural Gas (LNG)	1/02/98
NFPA 61–1995	Fires and Dust Explosions in Agricultural and Food Products Facilities	1/02/98
NFPA 65–1993	Processing and Finishing of Aluminum	1/17/97
NFPA 70B–1994	Electrical Equipment Maintenance	1/17/97
NFPA 72–1996	National Fire Alarm Code	1/02/98
NFPA 75–1995	Electronic Computer/Data Processing Equipment	7/18/97
NFPA 80–1995	Fire Doors and Fire Windows	1/17/97
NFPA 82–1994	Incinerators and Waste and Linen Handling Systems and Equipment	1/17/97
NFPA 86–1995	Ovens and Furnaces	1/02/98
NFPA 86C–1995 ...	Industrial Furnaces Using a Special Processing Atmosphere	1/02/98
NFPA 86D–1995 ...	Industrial Furnaces Using Vacuum as an Atmosphere	1/02/98
NFPA 88A–1995	Parking Structures	1/17/97
NFPA 91–1995	Exhaust Systems for Air Conveying of Materials	7/18/97
NFPA 92B–1995	Smoke Management Systems in Malls, Atria, and Large Areas	1/17/97
NFPA 99–1996	Health Care Facilities	6/1/97
NFPA 99B–1996	Hypobaric Facilities	6/1/97
NFPA 101B–P*	Means of Egress Code	1/17/97
NFPA 102–1995	Granstands, Folding and Telescopic Seating, Tents, and Membrane Structures	4/4/97
NFPA 105–1993	Smoke-Control Door Assemblies	1/17/97

NFPA No.	Proposal title	Closing date
NFPA 110–1996	Emergency and Standby Power Systems	7/18/97
NFPA 111–1996	Stored Electrical Energy Emergency and Standby Power Systems	7/18/97
NFPA 220–1995	Types of Building Construction	1/02/98
NFPA 231–1995	General Storage	1/17/97
NFPA 231C–1995	Rack Storage of Materials	1/17/97
NFPA 231D–1994	Storage of Rubber Tires	1/17/97
NFPA 260–1994	Cigarette Ignition Resistance of Components of Upholstered Furniture	1/17/97
NFPA 261–1994	Mock-Up Upholstered Furniture Material Assemblies to Ignition by Smoldering Cigarettes	1/17/97
NFPA 262–1994	Fire and Smoke Characteristics of Wires and Cables	1/17/97
NFPA 263–1994	Heat and Visible Smoke Release Rates for Materials and Products	1/17/97
NFPA 264–1995	Heat and Visible Smoke Release Rates for Materials and Products Using an Oxygen Consumption Calorimeter.	1/17/97
NFPA 264A–1994 ..	Heat Release Rates for Upholstered Furniture Components or Composites and Mattresses Using an Oxygen Consumption Calorimeter.	1/17/97
NFPA 285–P*	Evaluation of Flammability Characteristics of Exterior Non-Load Bearing Wall Assemblies Containing Combustible Components Using the Intermediate Scale Multi-Story Test Apparatus.	1/17/97
NFPA 295–1991	Wildfire Control	1/17/97
NFPA 297–1995	Principles and Practices for Communications Systems	1/17/97
NFPA 302–1994	Pleasure and Commercial Motor Craft	1/17/97
NFPA 326–1993	Underground Storage Tanks	1/02/98
NFPA 327–1993	Cleaning or Safeguarding Small Tanks and Containers Without Entry	1/02/98
NFPA 328–1992	Flammable and Combustible Liquids and Gases in Manholes, Sewers, and Similar Underground Structures	1/02/98
NFPA 329–1992	Underground Releases of Flammable and Combustible Liquids	1/02/98
NFPA 403–1993	Aircraft Rescue and Fire Fighting Services at Airports	1/17/97
NFPA 412–1993	Aircraft Rescue and Fire Fighting Foam Equipment	1/17/97
NFPA 430–1995	Liquid and Solid Oxidizers	1/17/97
NFPA 480–1993	Magnesium Solids and Powders	1/17/97
NFPA 481–1995	Titanium	1/17/97
NFPA 490–1993	Ammonium Nitrate	1/17/97
NFPA 496–1993	Purged and Pressurized Enclosures for Electrical Equipment	1/17/97
NFPA 501C–1996	Recreational Vehicles	7/18/97
NFPA 501D–1996	Recreational Vehicle Parks and Campgrounds	7/18/97
NFPA 502–1996	Limited Access Highways, Tunnels, Bridges, Elevated Roadways, and Air Right Structures	1/17/97
NFPA 505–1996	Powered Industrial Trucks Including Type Designations, Areas of Use, Conversions, Maintenance, and Operation.	1/17/97
NFPA 512–1994	Truck Fire Protection	1/17/97
NFPA 513–1994	Motor Freight Terminals	1/17/97
NFPA 550–1995	Fire Safety Concepts Tree	1/17/97
NFPA 651–1993	Aluminum Powder	1/17/97
NFPA 655–1993	Sulfur Fires and Explosions	1/17/97
NFPA 664–1993	Wood Processing and Woodworking Facilities	1/17/97
NFPA 701–1996	Fire Tests for Flame-Resistant Textiles and Films	4/1/97
NFPA 906–1993	Fire Incident Field Notes	1/17/97
NFPA 1002–1993 ..	Fire Department Vehicle Dirver/Operator Professional Qualifications	1/17/97
NFPA 1031–1993 ..	Professional Qualifications for Fire Inspector	1/17/97
NFPA 1033–1993 ..	Professional Qualifications for Fire Investigator	1/17/97
NFPA 1035–1993 ..	Professional Qualifications for Public Fire and Life Safety Educator	1/17/97
NFPA 1124–1995 ..	Manufacture, Transportation, and Storage of Fireworks	1/17/97
NFPA 1127–1995 ..	High Power Rocketry	1/17/97
NFPA 1221–1994 ..	Public Fire Service Communication Systems	1/17/97
NFPA 1231–1993 ..	Water Supplies for Suburban and Rural Fire Fighting	1/17/97
NFPA 1420–1993 ..	Pre-Incident Planning for Warehouse Occupancies	1/17/97
NFPA 1452–1993 ..	Training Fire Service Personnel to Make Dwelling Fire Safety Surveys	1/31/97
NFPA 1470–1994 ..	Search and Rescue Training for Structural Collapse Incidents	7/18/97
NFPA 1963–1993 ..	Fire Hose Connections	1/17/97
NFPA 1975–1994 ..	Station/Work Uniforms for Fire Fighters	6/27/97
NFPA 1991–1994 ..	Vapor-Protective Suits for Hazardous Chemical Emergencies	6/27/97
NFPA 1992–1994 ..	Liquid Splash-Protective Suits for Hazardous Chemical Emergencies	6/27/97
NFPA 1993–1994 ..	Support Function Protective Clothing for Hazardous Chemical Operations	6/27/97
NFPA 8502–1995 ..	Furnace Explosions/Implosions in Multiple Burner Boilers	7/18/97
NFPA 8506–1995 ..	Heat Recovery Steam Generator Systems	1/17/97

*Proposed NEW drafts are available from the NFPA Standards Administration Department, 1 Batterymarch Park, Quincy, MA 02269.

[FR Doc. 96–30708 Filed 12–2–96; 8:45 am]
BILLING CODE 3510–13–M

National Fire Codes: Request for Comments on NFPA Technical Committee Reports

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of request for comments.

SUMMARY: The National Fire Protection Association (NFPA) revises existing standards and adopts new standards twice a year. At its Fall Meeting in November or its Annual Meeting in May, the NFPA acts on recommendations made by its technical

committees. The purpose of this notice is to request comments on the technical reports which will be presented at NFPA's 1997 Fall Meeting.

The publication of this notice by the National Institute of Standards and Technology (NIST) on behalf of NFPA is being undertaken as a public service; NIST does not necessarily endorse, approve, or recommend any of the standards referenced in the notice.

DATES: Twenty-eight reports are published in the 1997 Fall Meeting Report on Proposals and will be available on January 31, 1997. Comments received on or before April 11, 1997 will be considered by the respective NFPA Committees before final action is taken on the proposals.

ADDRESSES: The 1997 Fall Meeting Report on Proposals is available from NFPA, Publications Department, 11 Tracy Drive, Avon, MA 02322. Comments on the reports should be submitted to Arthur E. Cote, P.E., Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts 02269–9101.

FOR FURTHER INFORMATION CONTACT: Arthur E. Cote, P.E., Secretary, Standards Council, at above address, (617) 770–3000.

SUPPLEMENTARY INFORMATION:

Background

Standards developed by the technical committees of the National Fire Protection Association (NFPA) have been used by various Federal Agencies as the basis for Federal regulations concerning fire safety. The NFPA standards are known collectively as the National Fire Codes. Often, the Office of the Federal Register approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Revisions of existing standards and adoption of new standards are reported by the technical committees at the NFPA's Fall Meeting in November or at the Annual Meeting in May each year. The NFPA invites public comment on its Report on Proposals.

Request for Comments

Interested persons may participate in the revisions of these technical reports by submitting written data, views, or arguments to Arthur E. Cote, P.E., Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts 02269–9101. The 1997 Fall Report on Proposals will be available on CD–ROM (suitable for use only in Windows or Macintosh environments). It will also be available in the traditional print version. Commenters may use the forms provided for comments in the Reports on Proposals. Each person submitting a comment should include his or her name and address, identify the notice, and give reasons for any recommendations. Comments received on or before April 11, 1997, for the 1997 Fall Meeting Report on Proposals, will be considered by the NFPA before final action is taken on the proposals.

Copies of all written comments received and the disposition of those comments by the NFPA committees will be published as the 1997 Fall Meeting Report on Comments by September 26, 1997, prior to the Fall Meeting.

A copy of the Report on Comments will be sent automatically to each commenter. Action on the reports of the Technical Committees (adoption or rejection) will be taken at the Fall Meeting, November 17–19, 1997, in Kansas City, Missouri, by NFPA members.

Authority: 15 U.S.C. 272.

Dated: November 26, 1996.

Samuel Kramer,

Associate Director.

1997 FALL MEETING: REPORT ON PROPOSALS

[P = Partial revision; W = Withdrawal; R = Reconfirmation; N = New; C = Complete Revision]

Doc. No.	Title	Action
NFPA 10–1994	Standard for Portable Fire Extinguishers	P
NFPA 10R–1992	Recommended Practice for Portable Fire Extinguishing Equipment in Family Dwellings and Living Units	W
NFPA 12–1993	Standard on Carbon Dioxide Extinguishing Systems	P
NFPA 17–1994	Standard for Dry Chemical Extinguishing Systems	P
NFPA 17A–1994	Standard for Wet Chemical Extinguishing Systems	P
NFPA 25–1995	Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems	P
NFPA 37–1994	Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines	P
NFPA 55–1993	Standard for the Storage, Use, and Handling of Compressed and Liquefied Gases in Portable Cylinders	P
NFPA 58–1995	Standard for the Storage and Handling of Liquefied Petroleum Gases	P
NFPA 59–1995	Standard for the Storage and Handling of Liquefied Petroleum Gases at Utility Gas Plants	P
NFPA 68–1994	Guide for Venting of Deflagrations	P
NFPA 101A–1995 ..	Guide on Alternative Approaches to Life Safety	P
NFPA 160–P*	Standard for the Use of Flame Special Effects Before a Proximate Audience	N
NFPA 256–1993	Standard Methods of Fire Tests of Roof Coverings	P
NFPA 259–1993	Standard Test Method for Potential Heat of Building Materials	C
NFPA 266–1994	Standard Method of Test for Fire Characteristics of Upholstered Furniture Exposed to Flaming Ignition Source	P
NFPA 267–1994	Standard Method of Test for Fire Characteristics of Mattresses and Bedding Assemblies Exposed to Flaming Ignition Source.	P
NFPA 301–P*	Code for Safety to Life From Fire on Merchant Vessels	N
NFPA 650–1990	Standard for Pneumatic Conveying Systems for Handling Combustible Materials	C
NFPA 720–P*	Recommended Practice for the Installation of Household Carbon Monoxide (CO) Warning Equipment	N
NFPA 801–1995	Standard for Facilities Handling Radioactive Materials	C
NFPA 802–1993	Recommended Practice for Fire Protection for Nuclear Research and Production Reactors	W
NFPA 803–1993	Standard for Fire Protection for Light Water Nuclear Power Plants	P
NFPA 921–1995	Guide for Fire and Explosion Investigations	P
NFPA 1201–1994 ..	Standard for Developing Fire Protection Services for the Public (will be renumbered NFPA 1200)	C
NFPA 1962–1993 ..	Standard for the Care, Use and Service Testing of Fire Hose, Including Couplings and Nozzles	P
NFPA 1964–1993 ..	Standard for Spray Nozzles (Shutoff and Tip)	C
NFPA 8505–1992 ..	Recommended Practice for Stoker Operation	P

*Proposed NEW drafts are available from the NFPA Standards Administration Department, 1 Batterymarch Park, Quincy, MA 02269.

[FR Doc. 96–30709 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

[I.D. 112596A]

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Caribbean Fishery Management Council (Council) and its Administrative Committee will hold meetings.

DATES: The meetings will be held on December 11–12, 1996.

ADDRESSES: All meetings will be held at the Ponce Hilton Hotel, Ponce, Puerto Rico.

Council Address: Caribbean Fishery Management Council, 268 Muñoz Rivera Avenue, Suite 1108, San Juan, PR 00918–2577.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council; telephone: (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 90th regular public meeting to discuss the Third Amendment to the Reef Fish Fishery Management Plan, and the Queen Conch Survey, among other topics.

The Council will convene on December 11, 1996, from 9:00 a.m. to 5:00 p.m., and December 12, 1996, from 9:00 a.m. to noon, approximately.

The Administrative Committee will meet on December 10, 1996, from 2:00 p.m. to 5:00 p.m., to discuss administrative matters regarding Council operation.

The meetings are open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or requests for sign language interpretation and/or other auxiliary aids please contact Mr. Miguel A. Rolón, Executive Director, (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: November 25, 1996.

George H. Darcy,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–30760 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[I.D. 111496B]

Marine Mammals; Scientific Research Permit (P772#70)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application.

SUMMARY: Notice is hereby given that the Southwest Fisheries Science Center, NMFS, P.O. Box 271, La Jolla, CA 92038–0271, has applied in due form for a permit to take all species of cetacea, pinnipedia, sirenia and marine and sea otters for purposes of scientific research.

DATES: Written comments must be received on or before January 2, 1997.

ADDRESSES: The application and related documents are available for review upon written request or by appointment. See **SUPPLEMENTARY INFORMATION** for addresses.

Written data or views, or requests for a public hearing on this request, should be submitted to the Director, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Concurrent with the publication of this notice in the Federal Register, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR 222.23), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to obtain samples from all species of cetacea (whales, porpoises and dolphins), pinnipedia (seals and walrus), sirenia (manatees and dugongs), and marine and sea otters. Samples will be collected, imported, exported and re-imported from salvaged individuals that were: Directly taken in fisheries for such animals in countries and situations where such taking is legal; killed incidental to fishing or other operations; found dead at sea or beached; found dead of natural causes; and/or collected from captive animals.

Documentation is available at the following locations:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213 (310/980–4001);

Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Bin C15700, Seattle Washington 98115–0070 (206/526–6150);

Regional Administrator, Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298 (508/281–9250);

Regional Administrator, Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702–2432 (813/570–5301);

Regional Administrator, Alaska Region, P.O. Box 21668, Juneau, AK 99802–1668 (907/586–7221); and

U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 432, Arlington, VA 22203 (1–800–358–2104).

Dated: November 14, 1996.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

Dated: November 14, 1996.

Margaret Tieger,

Chief, Branch of Permits, Office of Management Authority, Fish and Wildlife ervice.

[FR Doc. 96–30761 Filed 12–2–96; 8:45 am]

BILLING CODE 3510–22–F

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Thursday, December 19, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C., 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Enforcement Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30842
Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 2:00 p.m., Monday, December 16, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.
STATUS: Closed
MATTERS TO BE CONSIDERED: Adjudicatory Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30843 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 2:00 p.m., Tuesday, December 10, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C. Lobby Level Hearing Room located at Room 1000.
STATUS: Open.
MATTERS TO BE CONSIDERED: Proposed amendment to Regulation 1.41; Update on Commission activities.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30844 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 2:00 p.m., Monday, December 9, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Adjudicatory Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30845 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Friday, December 27, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C., 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Surveillance Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30846 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Friday, December 20, 1996.
PLACE: 1155 21st St., NW., Washington, D.C., 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Surveillance Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30847 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Friday, December 13, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Surveillance Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30848 Filed 11–29–96; 10:15 am]
BILLING CODE 6351–01–M

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Friday, December 6, 1996.
PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.
STATUS: Closed.
MATTERS TO BE CONSIDERED: Surveillance Matters.
CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 96–30849 Filed 11–29–96;10:15 am]
BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Department of Navy, DoD

Notice of Intent to Prepare an Environmental Impact Statement and to Open Scoping for Developing Home Port Facilities for Three NIMITZ Class Nuclear-Powered Aircraft Carriers in Support of the United States Pacific Fleet

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations (40 CFR Parts 1500–1508), the Department of the Navy announces its intent to prepare an Environmental Impact Statement (EIS) and to open scoping to evaluate the environmental effects associated with developing and operating home port facilities for three nuclear-powered aircraft carriers (CVNs) in support of the U.S. Pacific Fleet.

The scope of the proposed action is to: (1) determine the appropriate home port for two CVNs that will replace two conventionally-powered aircraft carriers (CVs) that are currently homeported at Naval Air Station (NAS) North Island in the Naval Complex San Diego, CA, and (2) reevaluate the current location of one CVN homeport at Naval Station (NAVSTA) Everett in order to increase efficiency of support infrastructure, maintenance, and repair capabilities, to reduce costs, and to enhance crew quality of life. Decisions for facilities development need to be made as soon as possible to accommodate planned arrival schedules of the CVNs to the Pacific Fleet (one as early as 2001) and to gain infrastructure benefits prior to upcoming ship maintenance periods (commencing in 1999). These schedules are now sufficiently clarified to allow Navy to proceed with the proposed actions at this time.

There are three major U.S. areas of Navy concentration in the Pacific: San Diego, CA complex; Puget Sound, WA complex; and Pearl Harbor, HI complex. Naval Air Station (NAS) North Island in the San Diego Naval Complex and Puget

Sound Naval Shipyard (PSNS) Bremerton and NAVSTA Everett in the Pacific Northwest are currently designated as CVN home ports. All three locations will be considered as alternative locations for the proposed actions. Although not currently designated as a CVN home port, Pearl Harbor is capable of accommodating deep-draft ships and will also be evaluated as a potential home port.

The 1993 Defense Base Closure and Realignment Commission recommended, and the President and Congress directed the closure of NAS Alameda, CA (scheduled for 1997), and the relocation of two CVNs to fleet concentrations in San Diego, CA, and in the Pacific Northwest. Consequently, the Department of the Navy established homeporting capabilities for one nuclear-powered aircraft carrier at NAS North Island in the San Diego Naval Complex, CA (scheduled for completion in 1998), and one nuclear-powered aircraft carrier at PSNS Bremerton, WA (which has now been implemented). The proposed actions do not involve a reexamination of homeporting actions directed by the 1993 Defense Base Closure and Realignment process.

As the proposed actions could result in the aggregation of CVNs at PSNS Bremerton, consideration will be given to relocation of non-nuclear powered deep-draft Navy support ships currently homeported at PSNS Bremerton.

The EIS will analyze the potential environmental effects of the proposed actions at the alternative locations discussed above, including any associated facilities development and dredging, and other reasonable alternatives identified during the public scoping process. Environmental issues to be addressed in the EIS include: geology, topography, and soils; dredging, hydrology, and water quality; pollution prevention; biology and natural resources; noise; air quality; land use; historic and archeological resources; socioeconomics schools, and housing, transportation/circulation/parking; public facilities and recreation; safety and environmental health; aesthetics; utilities; and environmental justice. Issue analysis will include an evaluation of the direct, indirect, short-term, and cumulative impacts associated with the proposed actions. No decision to implement the proposed actions will be made until the NEPA process is complete.

ADDRESSES: The Department of the Navy will initiate a scoping process for the purpose of determining the scope of issues to be addressed and for identifying significant issues relative to these proposed actions. Public meetings to receive oral comments from the public will be held in the four primary areas of consideration (San Diego, CA; Bremerton, WA; Everett, WA; and Honolulu, HI) in January and February 1997. These meetings will be announced in the Federal Register and in local area newspapers. Navy representatives will be available at the scoping meetings to receive comments from the public regarding issues of concern. A brief presentation describing the proposed actions and the NEPA process will precede a request for public comments. It is important that federal, state, and local agencies, as well as interested organizations and individuals, take this opportunity to identify environmental concerns that they feel should be addressed during the preparation of the EIS. Agencies and the public are invited and encouraged to provide written comments in addition to, or in lieu of, oral comments at the public meetings. To be most helpful, scoping comments should clearly describe specific issues or topics that the commenter believes the EIS should address. Written comments or questions regarding the scoping process and/or the EIS should be postmarked no later than 28 February 1997 and sent to the following address.

FOR FURTHER INFORMATION CONTACT: Mr. Daniel Muslin (Code 03PL), Southwest Division, Naval Facilities Engineering Command, 1220 Pacific Highway, San Diego, CA 92132–5190; telephone (619) 532–3403.

Dated: November 27, 1996.

D.E. Koenig,

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 96–30721 Filed 12–2–96; 8:45 am]

BILLING CODE 3810–FF–M

DEPARTMENT OF ENERGY

Certification of the Radiological Condition of the Herring-Hall-Marvin Safe Company Site in Hamilton, Ohio, 1995

AGENCY: Office of Environmental Management, Department of Energy (DOE).

ACTION: Notice of Certification.

SUMMARY: DOE has completed remedial actions to decontaminate the Herring-Hall-Marvin Safe Company site in Hamilton, Ohio. Formerly, the property was found to contain quantities of residual radioactive material resulting from activities conducted by contractors for DOE's predecessors, the Manhattan Engineer District (MED) and the Atomic Energy Commission (AEC). Radiological surveys show that the property now meets applicable requirements for use without radiological restrictions, and the docket related to cleanup activities is now available.

ADDRESSES: The docket is available from:

Public Reading Room, Room 1E–190, Forrestal Building, U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585

Public Document Room, Oak Ridge Operations Office, U.S. Department of Energy, 200 Administration Road, Oak Ridge, Tennessee 37831

Lane Public Library, 300 N. Third Street, Hamilton, Ohio 45011

FOR FURTHER INFORMATION CONTACT: William E. Murphie, Acting Director, Office of Eastern Area Programs, Office of Environmental Restoration (EM–42), U.S. Department of Energy, Germantown, Maryland 20874, (301) 903–2328 Fax: (301) 903–2385.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE), Office of Eastern Area Programs, the Formerly Utilized Sites Remedial Action Program (FUSRAP) Team, has conducted remedial at the Herring-Hall-Marvin Safe Company site in Hamilton, Ohio, as part of FUSRAP. The objective of the program is to identify and remediate or otherwise control sites where residual radioactive contamination remains from activities carried out under contract to the Manhattan Engineer District/Atomic Energy Commission (MED/AEC) during the early years of the nation's atomic energy program or from commercial operations causing conditions that Congress has authorized DOE to remedy. In June 1994, the site was designated for cleanup under FUSRAP.

The Herring-Hall-Marvin Safe Company, intermittently from the 1940s to the early 1950s, machined natural (not depleted or enriched) uranium metal slugs from rolled stock under subcontract to prime MED contractors Dupont and the University of Chicago. Records indicate that two work orders were performed at the site in 1943 in support of the MED and one in 1951 for the AEC. The uranium machining was relatively small scale and appears to have been conducted during brief periods. The available records indicate that MED/AEC work performed at the site was discontinued by August 1951.

The structure is a large, roughly rectangular building (approximately 300,000 ft^2), constructed mostly of concrete. The interior is primarily an open design with few walls and a

support structure of columns and beams with cross braces. High bays are offset by rows of windows at the ceiling. Early site documents used for the original radiological survey noted that uranium was machined on lathes in the large machine room on the first floor of this section of the building. A portion of the first floor is currently occupied by Union Paper Company. The remainder of the building is unoccupied and is used for storage.

On August 29 and 30, 1988, and April 24, 1989, radiological surveys were conducted at the request of DOE and with the consent of the property owner. The results of the radiological surveys revealed no radionuclide concentrations in excess of the applicable DOE criteria for air and soil on the first floor, and no beta or gamma radiation above background could be detected. Consequently, the site was eliminated from consideration under FUSRAP.

Later interviews with individuals formerly associated with the site revealed that uranium machining operations for MED also occurred in the southeastern corner of the building in a section with three floors, accessed by a stairwell and an elevator. Uranium was machined on the third floor in a room with concrete columns. Radiological surveys performed in 1988 and 1989 did not include that area of the building because it has not been previously identified as an area where uranium operations had taken place. A third radiological survey, conducted by Oak Ridge National Laboratory in 1993, identified uranium in portions of the floor and walls of the 9,000-square-foot third floor area. Also, it was determined from historical records that MED and/or its agents exercised significant control over the fabrication process and that MED had an on-site representative during some operations. In June 1993, the property was designated for remedial action by FUSRAP. Remedial action was conducted at the site from December 1994 to March 1995.

Post-remedial action surveys have demonstrated and DOE has certified that the subject property is in compliance with DOE radiological decontamination criteria and standards. The standards are established to protect members of the general public and occupants of the properties and to ensure that future use of the properties will result in no radiological exposure above applicable health-based guidelines. Accordingly, this property is released from FUSRAP.

The certification docket will be available for review between 9:00 a.m. and 4:00 p.m., Monday through Friday (except Federal holidays) in the DOE Public Reading Room located in Room 1E–190 of the Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585. Copies of the certification docket will also be available in the DOE Public Document Room, U.S. Department of Energy, Oak Ridge Operations Office, Oak Ridge, Tennessee, 37831, and in the Lane Public Library, 300 N. Third Street, Hamilton, Ohio, 45011.

DOE, through the Oak Ridge Operations Office, Former Sites Restoration Division, has issued the following statement:

Statement of Certification: Herring-Hall-Marvin Safe Company Site in Hamilton, Ohio

DOE, Oak Ridge Operations Office, Former Sites Restoration Division, has reviewed and analyzed the radiological data obtained following remedial action at the Herring-Hall-Marvin Safe Company Site in Hamilton, Ohio. Based on analysis of all data collected, including post-remedial action surveys, DOE certifies that any residual contamination on the site falls within current guidelines for use without radiological restrictions. This certification of compliance provides assurance that reasonably foreseeable future use of the site will result in no radiological exposure above current radiological guidelines established to protect members of the general public as well as occupants of the site.

Property owned by William Burchfield, 1550 Grand Boulevard, Hamilton, Ohio 45011.

Issued in Washington, D.C., on November 25, 1996.

James M. Owendoff,

Deputy Assistant Secretary for Environmental Restoration.

[FR Doc. 96–30707 Filed 12–2–96; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. RP97–94–000]

ANR Pipeline Co.; Notice of Proposed Changes in FERC Gas Tariff

November 26, 1996.

Take notice that on November 22, 1996, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1 and Original Volume No. 2, the following tariff sheets, proposed to become effective December 1, 1996:

Second Revised Volume No. 1

Original Sheet No. 2A through 2J
First Revised Sheet No. 4
Original Sheet Nos. 4A through 4J
Fourth Revised Sheet Nos. 5 through 7
Sixteenth Revised Sheet No. 8
Eighteenth Revised Sheet No. 9
Fourth Revised Sheet Nos. 10 through 12
Fourth Revised Sheet Nos. 14 and 15
Eighteenth Revised Sheet No. 16
Sixth Revised Sheet No. 17A
Twenty-first Revised Sheet No. 18
Third Revised Sheet No. 23
Second Revised Sheet No. 33A
Third Revised Sheet No. 40
Second Revised Sheet No. 89
Second Revised Sheet No. 145
Second Revised Sheet No. 175
Third Revised Sheet No. 180
Fourth Revised Sheet No. 181
Second Revised Sheet No. 186
Third Revised Sheet No. 192

Original Volume No. 2

Title Page

ANR states that this filing is being made to implement the remaining changes to its tariffs to conform with the revisions made to Part 154 of the Commission's regulations pursuant to Order No. 582 and 582–A (''Orders''). The Orders directed pipelines to complete the revisions to their tariffs to reflect the changes by no later than December 31, 1996.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protest must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Inspection Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30678 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. OA97–12–000]

Central Vermont Public Service Corporation; Notice of Filing

November 26, 1996.

Take notice that on October 16, 1996, Central Vermont Public Service Corporation tendered for filing an amendment to its October 11, 1996 filing in the above-reference docket.

Any person desiring to be heard or to protest said filing should file a motion

to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before December 6, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30671 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. PR97–2–000]

Teco Pipeline Company; Notice of Compliance of Petition for Rate Approval

November 26, 1996.

Take notice that on October 29, 1996, Teco Pipeline Company (TECO) filed with the Federal Energy Regulatory Commission a Petition for Rate Approval Filed in Compliance With Commission Order, requesting that the Commission approve as fair and equitable under 18 CFR 284.123(b)(2) its proposed rates for transportation service rendered pursuant to Section 311 of the NGPA.

TECO seeks approval to charge cost-justified rates, not to exceed 40 cents ($0.40) per MMBtu and 18 cents ($0.18) per MMBtu, for firm and interruptible NGPA § 311(a)(2) transportation services, respectively, plus reimbursement for all applicable third party transportation and/or gathering charges plus actual fuel.

Any person desiring to be heard or to make a protest in this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedures. All motions to intervene or protest should be filed by December 11, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30673 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP93–151–000, RP94–39, RP94–127, RP94–197, RP94–309, RP94–425, RP95–89, RP95–216, RP95–368, RP95–451, RP96–85, RP96–195, RP96–297, RP97–7, RP93–148, RP95–62, RP96–73, RP94–222, RP94–202, and RP95–112]

Tennessee Gas Pipeline Company, Notice of Customer Conference

November 26, 1996.

Take notice that an informal customer conference will be convened in this proceeding on Wednesday, December 4, 1996, at 10:00 a.m., at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC, 20426, for the purpose of discussing the draft settlement of the above-referenced dockets.

Any party, as defined by 18 CFR 385.102(c), or any participant, as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Donald Williams at (202) 208–0743 or Dennis H. Melvin at (202) 208–0042.

Lois D. Cashell,

Secretary.

[FR Doc. 96–30674 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. GT97–12–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

November 26, 1996.

Take notice that on November 22, 1996, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1 and Original Volume No. 2, the following tariff sheets to become effective December 23, 1996:

Sixth Revised Volume No. 1

Title Page
Third Revised Sheet No. 1000
Third Revised Sheet Nos. 1001–1011

Original Volume No. 2

Title Page

Texas Eastern states that the purpose of this filing is to (1) delete the Index of Firm Customers from its tariff and replace it with a statement indicating that the index is available on Texas Eastern's Electronic Bulletin Board (EBB), and (2) update the title pages to reflect the correct person to whom communications regarding the tariff should be sent. Texas Eastern states that it is in compliance with the electronic filing requirements of Section 284.106(c) of the Commission's Regulations, regarding the posting of the current Index of Firm Customers on its EBB in a downloadable format each calendar quarter and submitting the electronic file to the Commission. Accordingly, pursuant to Section 154.111(a) of the Commission's Regulations, Texas Eastern is not required to provide an index of customers in its tariff.

Texas Eastern states that copies of the filing were served on firm customers of Texas Eastern and interested state commissions.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30668 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. OA96–140–000]

Tucson Electric Power Company; Notice of Informal Settlement Conference

November 26, 1996.

Take notice that an informal settlement conference will be convened in this proceeding on Friday, December 6, 1996, at 10:00 a.m., at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined

in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Betsy R. Carr (202) 208–1240 or Stan Berman (202) 208–1159.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30669 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. OA96–171–000]

The United Illuminating Company; Notice of Filing

November 26, 1996.

Take notice that on November 4, 1996, The United Illuminating Company (UI), tendered for filing proposed changes in its FERC Electric Tariff, Original Volume No. 4 (Tariff), which it filed on July 9, 1996 in Docket No. OA96–171–000. In these changes, UI proposes revisions to Schedules 1 and 3 of the Tariff.

UI requests an effective date of July 9, 1996 and has therefore requested that the Commission waive its 60-day prior notice requirement. Copies of the filing were served upon all persons listed on the official service compiled by the Secretary in Docket No. OA96–171–000, and upon Robert J. Murphy, Executive Secretary, Connecticut Department of Public Utility Control, and McCallum Enterprises I Limited Partnership.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before December 6, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30670 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. OA97–17–000]

Wisconsin Public Service Corporation; Notice of Filing

November 26, 1996.

Take notice that on October 16, 1996, Wisconsin Public Service Corporation (WPSC) tendered an informational filing applicable to its service agreement with the Oconto Electric Cooperative.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before December 6, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96–30672 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EG97–18–000, et al.]

Edison Bataan Cogeneration Corporation, et al.; Electric Rate and Corporate Regulation Filings

November 25, 1996.

Take notice that the following filings have been made with the Commission.

1. Edison Bataan Cogeneration Corporation

[Docket No. EG97–18–000]

On November 12, 1996, Edison Bataan Cogeneration Corporation (''Edison Bataan'') filed with the Federal Energy Regulatory Commission (''Commission'') an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Edison Bataan is the owner and operator of a 58 MW eligible facility located in Bataan on the island of Luzon, Republic of the Philippines.

Comment date: December 13, 1996, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Carolina Power & Light Company

[Docket No. ER96–2941–000]

Take notice that on November 8, 1996, Carolina Power & Light Company tendered for filing an amendment in the above-referenced docket.

Comment date: December 6, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Commonwealth Edison Company

[Docket No. ER97–470–000]

Take notice that on November 14, 1996, Commonwealth Edison Company (ComEd) submitted Amendment No. 3, dated September 1, 1996 to the Electric Coordination Agreement (ECA), dated December 31, 1988, between Commonwealth Edison Company (ComEd) and the Village of Winnetka, Illinois (Village). Amendment No. 3 establishes a new point of interconnection. The Village has agreed that effective September 1, 1996, the original point of interconnection, now designated the Northbrook Interconnection, will serve only as a non-firm source of supply on a capacity available basis. Amendment No. 3 also revises Service Schedule E, Local Facilities. The Commission has previously designated the ECA as ComEd's Rate Schedule FERC No. 37.

ComEd requests an effective date of September 1, 1996, and accordingly seeks waiver of the Commission's requirements. Copies of this filing were served upon the Village and the Illinois Commerce Commission.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Pennsylvania Power & Light Company

[Docket No. ER97–471–000]

Take notice that on November 14, 1996, Pennsylvania Power & Light Company (PP&L), filed a Service Agreement, dated October 30, 1996, with Atlantic Electric (Atlantic) for non-firm point-to-point transmission service under PP&L's Open Access Transmission Tariff. The Service Agreement adds Atlantic as an eligible customer under the Tariff.

PP&L requests an effective date of August 2, 1996, for the Service Agreement.

PP&L states that copies of this filing have been supplied to Atlantic and to the Pennsylvania Public Utility Commission.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Pennsylvania Power & Light Company

[Docket No. ER97–472–000]

Take notice that on November 14, 1996, Pennsylvania Power & Light Company (PP&L), tendered for filing a Capacity and Energy Sales Agreement, dated as of April 6, 1995, as supplemented between PP&L and Jersey Central Power & Light Company (JCP&L), in compliance with § 35.12 of the Regulations of the Federal Energy Regulatory Commission (FERC or the Commission), 18 CFR 35.12.

PP&L requests an effective date of June 1, 1997, for the Agreement.

PP&L states that copies of this filing have been supplied to JCP&L as well as to the Pennsylvania Public Utility Commission and the New Jersey Board of Public Utilities.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Northern Indiana Public Service Company

[Docket No. ER97–473–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Standard Transmission Service Agreement between Northern Indiana Public Service Company and Carolina Power & Light Company.

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to Carolina Power & Light Company pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. ER96–1426–000 and allowed to become effective by the Commission. *Northern Indiana Public Service Company*, 75 FERC ¶ 61,213 (1996). Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Northern Indiana Public Service

[Docket No. ER97–474–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Standard Transmission Service Agreement between Northern Indiana Public Service Company and Entergy Power Marketing Corporation.

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to Entergy Power Marketing Corporation pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. ER96–1426–000 and allowed to become effective by the Commission. *Northern Indiana Public Service Company*, 75 FERC ¶ 61,213 (1996). Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Northern Indiana Public Service Company

[Docket No. ER97–475–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and Industrial Energy Applications, Inc.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to Industrial Energy Applications, Inc. under Northern Indiana Public Service Company's Power Sales Tariff, which was accepting for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and Industrial Energy Applications, Inc. request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Northern Indiana Public Service Company

[Docket No. ER97–476–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and PacifiCorp Power Marketing, Inc.

Under the Service Agreement, Northern Indiana Public Service company agrees to provide services to PacifiCorp Marketing, Inc. under Northern Indiana Public Service Company's Power Sales Tariff, which was accepting for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and PacifiCorp Power Marketing, Inc. request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. Northern Indiana Public Service Company

[Docket No. ER97–477–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and CNG Power Services Corporation.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to CNG Power Services Corporation under Northern Indiana Public Service Company's Power Sales Tariff, which was accepting for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and CNG Power Services Corporation request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Northern Indiana Public Service Company

[Docket No. ER97–478–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and JPower, Inc.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to JPower, Inc. under Northern Indiana Public Service Company's Power Sales

Tariff, which was accepting for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and JPower, Inc. request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. Northern Indiana Public Service Company

[Docket No. ER97–479–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and VTEC Energy.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to VTEC Energy under Northern Indiana Public Service Company's Power Sales Tariff, which was accepted for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and VTEC Energy request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Northern Indiana Public Service Company

[Docket No. ER97–480–000]

Take notice that on November 14, 1996, Northern Indiana Public Service Company, tendered for filing an executed Service Agreement between Northern Indiana Public Service Company and Williams Energy Services Company.

Under the Service Agreement, Northern Indiana Public Service Company agrees to provide services to Williams Energy Services Company under Northern Indiana Public Service Company's Power Sales Tariff, which was accepting for filing by the Commission and made effective by Order dated August 17, 1995 in Docket No. ER95–1222–000. Northern Indiana Public Service Company and Williams Energy Services Company request a waiver of the Commission's sixty-day notice requirement to permit an effective date of November 15, 1996.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

Comment date: December 9, 1996, in accordance with Standard Paragraph E at the end of this notice.

14. UtiliCorp United Inc.

[Docket No. ES97–11–000]

Take notice that on November 19, 1996, UtiliCorp United Inc. (UtiliCorp) filed an application, under § 204 of the Federal Power Act, seeking authorization to implement shareholder Rights Plan. Under such Plan, the Board of Directors of UtiliCorp has authorized and declared a dividend of one Right for each share of Common Stock, of UtiliCorp outstanding at close of business on December 31, 1996. Each Right will initially represent the right to purchase one one-thousandth (1/1000) of a share of Series A Participating Cumulative Preference Stock, no par value, of UtiliCorp.

UtiliCorp also requests an exemption from the Commission's competitive bidding and negotiated placement requirements.

Comment date: December 18, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–30666 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–P

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: November 22, 1996 61 FR 59433.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: November 26, 1996 10:00 a.m.

CHANGE IN THE MEETING: The following Docket Numbers and companies have been added to the Agenda scheduled for the November 26, 1996 meeting.

Item No.—Docket No. and Company

CAE–10—OA97–23–000, Edison Sault Electric Company

CAG–9—RP95–197–000, Transcontinental Gas Pipe Line Corporation

Lois D. Cashell,

Secretary.

[FR Doc. 96–30825 Filed 11–25–96; 4:20 pm]

BILLING CODE 6717–01–M

[Docket No. CP97–92–000, et al.]

Transcontinental Gas Pipe Line Corporation, et al.; Natural Gas Certificate Filings

November 22, 1996.

Take notice that the following filings have been made with the Commission:

1. Transcontinental Gas Pipe Line Corporation

[Docket No. CP97–92–000]

Take notice that on November 12, 1996, Transcontinental Gas Pipe Line Corporation (Transco), P. O. Box 1396, Houston, Texas 77251, filed in Docket No. CP97–92–000 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing an extension and expansion of Transco's Mobile Bay Lateral including (i) authorization to construct and operate approximately 76.8 miles of 30-inch diameter pipeline extending from a proposed new platform in Main Pass Area, Block 260 to its existing Compressor Station No. 82 in Mobile County, Alabama; approximately 17.5 miles of 36-inch diameter onshore pipeline loop located immediately downstream of Station No. 82 in southern Mobile County, Alabama; a new 30,000 horsepower compressor Station No. 83 located in northern Mobile County, Alabama; and a 26,000 horsepower compression addition at Transco's existing Station No. 82; all of which facilities will provide a total of the dekatherm equivalent of 600 MMcf per day of additional service offshore [1]

[1] In referring to the ''offshore extension'' of its Mobile Bay Lateral, Transco states that approximately 73.0 miles of the extension will be located offshore and approximately 4.0 miles will

Continued

and 500 MMcf per day of additional service onshore [2], to become available in late 1998; (ii) approval of Transco's initial rates for such service to be Transco's then-current Rate schedule FT rate for Zone 4A, and (iii) approval of rolled-in rate treatment for costs associated with the Mobile Bay Lateral Extension and Expansion Project, to be made effective in Transco's first NGA Section 4 rate proceeding following the in-service date of the project, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

In order to create the firm transportation capacity under the project, Transco states that it will construct and operate the following facilities:

Offshore Facilities

- Approximately 76.8 miles of 30-inch diameter pipeline commencing at a proposed offshore platform in Main Pass Area, Block 260 to be constructed by a producer, to Transco's Station No. 82 in Mobile County, Alabama.

Onshore Facilities

- Approximately 17.5 miles of 36-inch diameter pipeline loop located immediately downstream of Station No. 82 in Mobile County, Alabama, from Mobile Bay Lateral MP 105.19 to MP 122.68;
- A new 30,000 horsepower compressor Station No. 83 located in Mobile County, Alabama at Mobile Bay Lateral MP 71.57; and
- A 26,000 horsepower compression addition at Transco's existing Station No. 82 in Mobile County, Alabama.

Third Party/Non-Jurisdictional Facilities

- A third party will construct, own and operate a 600 MMcf per day separation plant, including a slug catcher, immediately upstream of Compressor Station No. 82. The plant will be designed to remove liquids from the pipeline and deliver pipeline quality natural gas to the suction side of Compressor Station No. 82. The plant is estimated to require thirty acres of land and is planned to be located immediately to the west and adjacent to Compressor Station No. 82.

Transco states that the proposed in-service date for the project is December 1, 1998. Transco estimates that the proposed facilities will cost, in the aggregate, $171.5 million.

According to Transco, the project will create firm transportation capacity of the dekatherm equivalent of 600 MMcf per day from Main Pass Block 260 to Transco's Station No. 82 and 500 MMcf per day from Station No. 82 to Station No. 85, where Transco's Mobile Bay Lateral interconnects with its mainline in Choctaw County, Alabama. Transco states that it will make the capacity under the project available to all shippers by means of an ''open season'' planned to be held commencing November 15, 1996. It is stated that the open season will extend until December 16, 1996. Concurrent with the open season, Transco states that it intends to solicit interest in the relinquishment of firm capacity currently held by shippers on the Mobile Bay Lateral, in order to assure that the project facilities are properly sized. Transco states that it will notify the Commission of the commitments received from customers as soon as practicable after the end of the open season period, and Transco will seek to enter into firm transportation precedent agreements which reflect a minimum 15 year term. Transco states that it expects to file these executed precedent agreements within thirty days of the end of the open season period. Transco states that the firm transportation service to be rendered through this new capacity will be performed under its Rate Schedule FT and Part 284(G) of the Commission's regulations. Transco states that it will charge the project shippers the then-current Zone 4A rate under Rate Schedule FT in effect when the facilities are placed in service, plus any applicable surcharges.

Transco avers that the project shippers will have primary firm transportation rights to all delivery points located in Transco's Rate Zone 4A, enabling them to access various market points on the interstate pipeline grid, including markets at the pooling points located at Transco's Station No. 85 and the existing upstream and downstream interconnections with other pipelines on Transco's system.

Transco requests that the Commission grant rolled-in rate treatment for the costs associated with the project in Transco's first Section 4 rate proceeding to become effective after the in-service date of this project. Transco states that the presumption to roll-in the project costs applies because the rate impact on its existing customers under each firm rate schedule is less than five percent, which is the level set forth in the Commission's Statement of Policy for a presumption of rolled-in rate treatment on the pricing of new pipeline construction. Transco also states that the facilities constructed as part of the project will produce significant system-wide operational and financial benefits and will be operated on an integrated basis with its existing facilities.

To meet the proposed in-service date for the project, Transco requests that the Commission issue a preliminary determination approving all aspects of the proposal other than environmental matters by July 1, 1997, with a final determination and all appropriate certificate authorizations by February 1, 1998.

The Commission staff cannot schedule a completion date for the environmental analysis of this project, because Transco has not begun certain critical processes. Transco has not yet filed applications with the Minerals Management Service (MMS) or the U.S. Army Corps of Engineers (COE), nor has it requested a determination of consistency with the Coastal Zone Management Plan (Alabama Department of Environmental Management (ADEM)). The staff wants to coordinate its environmental analysis with the MMS, ADEM, and the COE.

Other missing material that will delay the completion of the environmental analysis include surveys for threatened or endangered species and consultation with the U.S. Fish and Wildlife Service and completion of surveys for cultural resources and consultation with the State Historic Preservation Office. These resources are of particular interest because they were of concern with respect to the construction of the original Mobile Bay Lateral.

Concerns over erosion and sedimentation plans must also be resolved as part of our environmental analysis.

Comment date: December 13, 1996, in accordance with Standard Paragraph F at the end of this notice.

2. Colorado Interstate Gas Company

[Docket No. CP97–94–000]

Take notice that on November 12, 1996, Colorado Interstate Gas Company (CIG), P.O. Box 1087, Colorado Springs, Colorado 80944, filed in Docket No. CP97–94–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to lease to Vessels Hydrocarbons, Inc. (Vessels) almost 2.22 miles of 8-inch diameter pipe located in Adams County, Colorado, under CIG's blanket certificate issued in Docket No. CP83–21–000 pursuant to Section 7 of the Natural Gas

be located onshore upstream of and connecting with Station No. 82, which is the existing terminus of the Mobile Bay Lateral.

[2] Transco states that it is sizing its onshore expansion facilities smaller than its offshore facilities based on informal indications that it will receive 100 MMcf of capacity turnback on the Mobile Bay Lateral.

Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

CIG states it has been advised by Vessels that Vessels plans to consolidate its processing activities by closing its Third Creek plant and constructing a line to move raw gas from the tailgate of the Third Creek plant to its Wattenberg plant which is almost 18.5 miles away. CIG also states the abandonment by lease to Vessels of CIG's Third Creek Lateral will prevent the construction of almost 2.22 miles of pipe and avoid the associated environmental disruption. Vessels has advised CIG that Shippers using the Wattenberg plant will have access to CIG's transmission after processing.

CIG further states that the subject facilities were certificated and operated pursuant to the certificate of public convenience and necessity issued in Docket No. CP79–284.

Comment date: January 6, 1997, in accordance with Standard Paragraph G at the end of this notice.

3. Columbia Gas Transmission Corporation

[Docket No. CP97–95–000]

Take notice that on November 13, 1996, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, SE., Charleston, West Virginia 25314–1599, filed in Docket No. CP97–95–000, pursuant to Section 7(b) of the Natural Gas Act (NGA), as amended, and Section 157.7 and 157.18 of the Commission's Regulations thereunder, an abbreviated application requesting permission and approval to abandon certain natural gas compression facilities, all as more fully set forth in the application on file with the Commission.

Columbia requests NGA Section 7(b) authorization for the abandonment of seven 500 horsepower horizontal type engine compressor units, located within the York Compressor Station, located in Medina County, Ohio.

Columbia states that in addition to the abandonment of the compressor units for which Columbia is seeking authorization, Columbia would also remove any associated equipment, appurtenances and buildings associated with these units.

Columbia further states that the York Compressor Station has been in service since 1914 to compress local field production gas and relay transmission volumes into Columbia's Line L. Columbia states that although authorization to abandon the horizontal units, originally installed between 1914 and 1928, was received in Docket No. CP80–14–000 (*Columbia Gas Transmission Corporation*, 11 FERC Paragraph 61,047 (1980); *order amending certificate*, 11 FERC Paragraph 61,214 (1980)), an increase in actual over estimated local production in the area prompted Columbia to retract its abandonment authorization.

Columbia states that in a letter dated January 21, 1982 to the Commission, Columbia advised that the horizontal units would be retained in service. It is stated that since that time, the decline in location production along with other facility upgrades in the York Production field rendered the horizontal units inactive by 1989. Columbia now requests approval to proceed with the abandonment granted by the Commission in 1980. Columbia states that the horizontal units are no longer needed and have become obsolete and their abandonment will not result in any termination of service. Therefore, Columbia submits that the proposed abandonment is required by the present and future public convenience and necessity.

Columbia states that the cost of retiring the seven horizontal compressor units is approximately $264,000, with an estimated net debit to accumulated provision for depreciation of $835,305.

Comment date: December 13, 1996, in accordance with Standard Paragraph F at the end of this notice.

4. National Fuel Gas Supply Corporation

[Docket No. CP97–101–000]

Take notice that on November 18, 1996, National Fuel Gas Supply Corporation (National), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP97–101–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate a residential sales tap under National's blanket certificate issued in Docket No. CP83–4–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Specifically, National proposes to construct and operate a sales tap for delivery of approximately 150 Mcf annually of gas to National Fuel Gas Distribution Corporation (Distribution) at an estimated cost of $1,500, for which National would be reimbursed by Distribution.

Comment date: January 6, 1997, in accordance with Standard Paragraph G at the end of this notice.

5. ANR Pipeline Company

[Docket No. CP97–103–000]

Take notice that on November 18, 1996, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243–1902, filed in Docket No. CP97–103–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to operate an existing interconnection constructed under the authorization of Section 311 of the Natural Gas Policy Act of 1978 and to construct and operate additional facilities for the delivery of natural gas to Alcan Ingot, a division of Alcan Aluminum Corporation (Alcan) in Webster County, Kentucky, under ANR's blanket certificate issued in Docket No. CP82–480–000, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

ANR proposes to operate the existing facilities, which consist of a 4-inch tap and associated piping, valves and fittings, and to construct and operate electronic measurement equipment in order to provide a transportation service for Alcan pursuant to a firm transportation rate schedule. It is stated that the existing facilities were installed in 1984 to deliver gas to Alcan on behalf of Orbit Gas Company (Orbit). It is explained that Orbit deactivated its interconnection with Alcan and that Alcan purchased the facilities downstream of ANR from Orbit.

It is stated that the facilities would be designed to deliver up to 417 Mcf of natural gas per hour. ANR estimates the cost of the facilities at $23,100, for which ANR would be fully reimbursed. It is explained that Alcan has informed ANR that it proposes to use capacity release transportation on ANR's system. It is stated that the proposal would have no adverse impact on ANR's peak day deliveries or on annual entitlements of ANR's existing customers. It is further stated that ANR has sufficient gas supply to make the deliveries and that the deliveries can be made without detriment or disadvantage to ANR's existing customers.

Comment date: January 6, 1997, in accordance with Standard Paragraph G at the end of this notice.

6. Texas Gas Transmission Corporation

[Docket No. CP97–106–000]

Take notice that on November 19, 1996, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42301, filed in Docket No. CP97–106–000 a

request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate a delivery point for Clarksdale Public Utilities (Clarksdale), in Coahoma County, Mississippi, under Texas Gas's blanket certificate issued in Docket No. CP82–407–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Texas Gas proposes to install, operate, maintain and own a dual, four-inch meter station with electronic flow measurement equipment and remote flow control equipment and related facilities on a site to be provided by Clarksdale. Texas Gas states that the proposed delivery point will be known as the Clarksdale P.U.C. Meter Station.

Texas Gas states that Clarksdale is requesting up to 16,800 MMBtu per day of interruptible natural gas transportation service for use at its Clarksdale facility for electric generation.

Texas Gas states that Clarksdale's natural gas requirements are presently supplied by Mississippi Valley Gas Company, a local distribution customer of Texas Gas, and that Clarksdale has requested that Texas Gas construct a new delivery point in Coahoma County, Mississippi to enable Clarksdale to receive natural gas transportation service directly from Texas Gas.

Texas Gas states that Clarksdale will reimburse Texas Gas in full for the cost of the facilities to be installed by Texas Gas, which cost is estimated to be $139,670.

Comment date: January 6, 1997, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. 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.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 96–30667 Filed 12–2–96; 8:45 am]

BILLING CODE 6717–01–P

Western Area Power Administration

Proposed Allocation of the Post-2000 Resource Pool—Pick-Sloan Missouri Basin Program, Eastern Division

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of clarification, response to comments and request for additional comments.

SUMMARY: The purpose of this notice is to clarify and respond to comments Western Area Power Administration (Western) received regarding the ''levelized'' method of calculating the proposed allocations for new Native American customers associated with the Post-2000 Resource Pool—Pick-Sloan Missouri Basin Program, Eastern Division (P–SMBP–ED). Western received numerous comments regarding the proposed allocation published August 30, 1996, in 61 FR 45957 (Method One) and is prepared to use an alternative method (Method Two). Western is, therefore, soliciting comments only on the use of Method One or Method Two and will base final allocations on those comments.

DATES: Written comments must be sent to the Upper Great Plains Regional Manager by certified or return receipt requested U.S. mail and received by close of business on January 6, 1997.

Western will hold a public meeting on the allocation method alternatives on December 17, 1996, in Rapid City, South Dakota at the following location: Rushmore Plaza Holiday Inn, 505 North 5th Street, Rapid City, South Dakota.

Information forum—9 a.m. (not to exceed 2 hours)

Comment forum—immediately following the information forum

ADDRESSES: All comments regarding the methodology used to calculate the proposed allocations for new Native American customers from the Post-2000 Resource Pool should be directed to the following address: Mr. Gerald C. Wegner, Regional Manager, Upper Great Plains Customer Service Region, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107–5800. All documentation developed or retained by Western for the purpose of developing the Proposed Allocation of the Post-2000 Resource Pool will be available for inspection and copying at the Upper Great Plains Customer Service Regional Office, 2900 Fourth Avenue North, Billings, Montana.

FOR FURTHER INFORMATION CONTACT: Mr. Robert J. Harris, Power Marketing Manager, Upper Great Plains Customer Service Region, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107–5800, (406) 247–7394.

SUPPLEMENTARY INFORMATION: Western, a Federal power marketing agency of the Department of Energy, published on August 30, 1996, in the Federal Register (61 FR 45957), a notice of Proposed Allocation of its Post-2000 Resource Pool to fulfill the requirements of Subpart C—Power Marketing Initiative of the Energy Planning and Management Program Final Rule, 10 CFR 905. On October 8, 1996, Western published a notice to extend the time written comments could be submitted until October 21, 1996. The Post-2000

Resource Pool Proposed Allocation of Power is Western's implementation of Subpart C—Power Marketing Initiative of the Energy Planning and Management Program Final Rule. Western published the final Post-2000 Resource Pool Allocation Procedures in the Federal Register on August 7, 1996, at 61 FR 41142.

As a result of comments received during the comment period regarding the ''levelized'' method (Method One) of calculation used in determining the proposed allocation, Western is proposing an alternative method for comment. Method One, the alternative Method Two, and a brief summary follow:

Method One: The proposed allocations of power under Method One for new Native American customers and the data these allocations were based upon are as follows:

New Native American customers	Estimated demand (kilowatts)	Average current western service		Proposed post-2000 power allocation	
		Summer (percent)	Winter (percent)	Summer (kilowatts)	Winter (kilowatts)
Blackfeet Nation	18,600	34	29	5,454	5,184
Cheyenne River Sioux	13,500	33	29	4,094	3,762
Chippewa Cree-Rocky Boy	5,000	55	44	416	643
Crow Creek	4,100	50	47	546	405
Crow	12,500	55	44	1,040	1,609
Devils Lake Sioux	7,700	22	14	3,182	3,301
Flandreau Santee Sioux	2,355	55	56	196	20
Fort Belknap Indian Community	6,200	28	22	2,190	2,162
Fort Peck Tribes	15,300	34	31	4,486	3,958
Lower Brule Sioux	3,100	33	29	940	864
Lower Sioux	3,750	0	0	2,375	2,133
Northern Cheyenne	9,400	36	37	2,568	1,868
Oglala Sioux-Pine Ridge	29,600	28	24	10,456	9,729
Omaha Tribe of Nebraska	5,100	15	14	2,464	2,186
Ponca Tribe of Nebraska	2,100	8	6	1,162	1,068
Rosebud Sioux	21,300	49	43	3,051	2,954
Santee Sioux Tribe of Nebraska	1,100	10	8	587	538
Sisseton-Wahpeton Sioux	7,500	40	38	1,749	1,415
Standing Rock Sioux	12,900	30	29	4,299	3,595
Three Affiliated Tribes	8,000	30	25	2,666	2,550
Turtle Mountain Chippewa	18,000	35	18	5,098	6,996
Upper Sioux	1,250	42	39	267	223
White Earth Indian Reservation	3,500	6	7	2,006	1,745
Winnebago Tribe of Nebraska	3,100	10	8	1,653	1,515
Yankton Sioux	5,300	25	24	2,031	1,742

The proposed allocations for new Native American customers were calculated based upon the estimated demand figures set forth in the table above. Inconsistent demand estimates were adjusted by Western.

Western calculated the proposed power allocations in the table above in such a manner as to levelize total Federal hydropower benefits to each of the Native American tribes. This results in a total Federal hydropower benefit of 63.323 percent in the summer season and 56.869 percent in the winter season to each of the tribes. To levelize the total Federal hydropower benefits, the average current percentage of Western service that each of the tribes receives through their current power supplier(s) was utilized and is as shown in the table above. For the Blackfeet Nation, Western used the weighted average of the current percentage of Western service for the remaining tribes. The Blackfeet Nation is served by Glacier Electric Cooperative, which is a total requirements customer of Bonneville Power Administration; therefore, the Blackfeet Nation does not receive Western service, but does receive the benefit of Federal hydropower. The proposed allocations to new Native American customers set forth in the table above are based on the P–SMBP–ED marketable resource available at this time. If the P–SMBP–ED marketable resource is adjusted in the future, the proposed allocations will be adjusted accordingly.

Method Two: The proposed allocations of power under Method Two for new Native American customers and the data these allocations were based upon are as follows:

New Native American customers	Estimated demand (kilowatts)	Percent of total estimated demand (percent)	Proposed post-2000 power allocation	
			Summer (kilowatts)	Winter (kilowatts)
Blackfeet Nation	18,600	8.4448	5,487	5,250
Cheyenne River Sioux	13,500	6.1293	3,983	3,810
Chippewa Cree-Rocky Boy	5,000	2.2701	1,475	1,411
Crow Creek	4,100	1.8615	1,209	1,157
Crow	12,500	5.6752	3,688	3,528
Devils Lake Sioux	7,700	3.4959	2,272	2,173
Flandreau Santee Sioux	2,355	1.0692	695	665
Fort Belknap Indian Community	6,200	2.8149	1,829	1,750
Fort Peck Tribes	15,300	6.9465	4,514	4,318

New Native American customers	Estimated demand (kilowatts)	Percent of total estimated demand (percent)	Proposed post-2000 power allocation	
			Summer (kilowatts)	Winter (kilowatts)
Lower Brule Sioux	3,100	1.4075	914	875
Lower Sioux	3,750	1.7026	1,106	1,058
Northern Cheyenne	9,400	4.2678	2,773	2,653
Oglala Sioux-Pine Ridge	29,600	13.4390	8,732	8,355
Omaha Tribe of Nebraska	5,100	2.3155	1,505	1,439
Ponca Tribe of Nebraska	2,100	0.9534	619	593
Rosebud Sioux	21,300	9.6706	6,284	6,012
Santee Sioux Tribe of Nebraska	1,100	0.4994	324	311
Sisseton-Wahpeton Sioux	7,500	3.4051	2,213	2,117
Standing Rock Sioux	12,900	5.8568	3,806	3,641
Three Affiliated Tribes	8,000	3.6322	2,360	2,258
Turtle Mountain Chippewa	18,000	8.1723	5,310	5,080
Upper Sioux	1,250	0.5675	369	353
White Earth Indian Reservation	3,500	1.5891	1,032	988
Winnebago Tribe of Nebraska	3,100	1.4075	914	875
Yankton Sioux	5,300	2.4063	1,564	1,496

Under Method Two, the proposed allocations for new Native American customers were calculated based upon the same estimated demand figures as in Method One above. The proposed allocations were derived by dividing the Native American tribes' share of the resource pool among the tribes in the same proportion as each tribe's percent of total estimated demand.

The proposed allocations to new Native American customers set forth in the table above are based on the P–SMBP–ED marketable resource available at this time. If the P–SMBP–ED marketable resource is adjusted in the future, the proposed allocations will be adjusted accordingly.

After all public comments have been thoroughly considered, Western will prepare and publish the Final Post-2000 Resource Pool Allocation in the Federal Register.

Issued at Golden, Colorado, November 21, 1996.

J.M. Shafer,

Administrator.

[FR Doc. 96–30706 Filed 12–2–96; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5658–1]

Proposed Settlement Agreement; PM–10 SIP for the State of Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement.

SUMMARY: In accordance with section 113(g) of the Clean Air Act (''Act''), as amended, 42 U.S.C. 7413(g), notice is hereby given of a proposed settlement agreement concerning litigation instituted against the Environmental Protection Agency (''EPA'') by Edward M. Ober, et al., through his counsel Davis S. Baron of the Arizona Center for Law in the Public Interest. The lawsuit concerns EPA's alleged failure to perform a nondiscretionary duty with respect to promulgating a federal implementation plan (''FIP'') controlling particulate matter (''PM–10'') emissions in the Phoenix, Arizona Planning Area.

For a period of thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement agreement. EPA or the Department of Justice may withhold or withdraw consent to the proposed settlement agreement if the comments disclose facts or circumstances that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

Copies of the settlement agreement are available from Phyllis Cochran, Air and Radiation Division (2344), Office of General Counsel, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260–7606. Written comments should be sent to Michael A. Prosper at the above address and must be submitted on or before January 2, 1997.

Dated: November 25, 1996.

Scott C. Fulton,

General Counsel.

[FR Doc. 96–30740 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–M

[FRL–5657–6]

National Advisory Council for Environmental Policy and Technology Information Impacts Committee; Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act, Public Law 92463, EPA gives notice of a two-day meeting, of the National Advisory Council for Environmental Policy and Technology (NACEPT) Information Impacts Committee (IIC). NACEPT provides advice and recommendations to the Administrator of EPA on a broad range of environmental policy issues. The IIC has been asked to review information requirements, and provide recommendations on how to effectively position information resources to support new, comprehensive and long-term Agency initiatives. This meeting is being held to provide the IIC with perspectives unique to EPA's program office and media-specific information and regulatory requirements.

DATES: The two-day public meeting will be held on Tuesday, January 21, 1997 from 9:00 am to 5:00 pm and Wednesday, January 22, 1997 from 9:00 am to 3:00 pm. The meeting will be held at the Channel Inn Hotel, 650 Water Street, SW Washington, DC 20024.

ADDRESSES: Materials, or written comments, may be transmitted to the Committee through Joe Sierra, Designated Federal Official, NACEPT/IIC, U.S. EPA, Office of Cooperative Environmental Management (1601F), 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Joseph Sierra, Designated Federal Official for the Information Impacts Committee at 202–260–5839.

Dated: November 20, 1996.

Joseph A. Sierra,

Designated Federal Official.

[FR Doc. 96–30739 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–M

[FRL–5658–2]

National Drinking Water Advisory Council; Notice of Open Meetings

Under Section 10(a)(2) of Public Law 92–423, ''The Federal Advisory Committee Act,'' notice is hereby given that a meeting of the National Drinking Water Advisory Council established under the Safe Drinking Water Act, as amended (42 U.S.C. S300f *et seq.*), will be held on December 19, 1996, from 3:00 p.m. until 6:00 p.m., in Room 1026 East Tower, U.S. Environmental Protection Agency (EPA) Headquarters, 401 M Street SW, Washington, D.C. 20460. Council members will be participating by Conference Call. The meeting is open to the public, but due to past experience, seating will be limited.

The purpose of this meeting is to provide the Council with the mini-workplans for the new working groups that will be set up to advise them on consumer confidence reports, operator certification, small systems capacity building, the Drinking Water State Revolving Fund, drinking water contaminant identification, source water protection, and possibly rule development for microbial contaminants and disinfectants/disinfection by-products. This meeting will also serve as a planning session for future Council meetings and scheduling of participation of its members on the working groups.

The meeting is open to the public. The Council encourages the hearing of outside statements and will allocate one-half hour for this purpose. Oral statements will be limited to five minutes, and it is preferred that only one person present the statement. Any outside parties interested in presenting an oral statement should petition the Council by telephone at (202) 260–2285 before December 18, 1996.

Any person who wishes to file a written statement can do so before or after a Council meeting. Written statements received prior to the meeting will be distributed to all members of the Council before any final discussion or vote is completed. Any statements received after the meeting will become part of the permanent meeting file and will be forwarded to the Council members for their information.

Members of the public that would like to attend the meeting, present an oral statement, or submit a written statement, should contact Ms. Charlene Shaw, Designated Federal Officer, National Drinking Water Advisory Council, U.S. EPA, Office of Ground Water and Drinking Water (4601), 401 M Street SW, Washington, D.C. 20460. The telephone number is Area Code (202) 260–2285 or E-Mail Shaw.Charlene@epamail.epa.gov.

Dated: November 26, 1996.

Barbara Elkus,

Acting Director, Office of Ground Water and Drinking Water.

[FR Doc. 96–30738 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–P

[OPP–340104; FRL 5572–3]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request for amendment by registrants to delete uses in certain pesticide registrations.

DATES: Unless a request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on June 2, 1997.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location for commercial courier delivery and telephone number: Room 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of FIFRA, provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the Federal Register. Thereafter, the Administrator may approve such a request.

II. Intent to Delete Uses

This notice announces receipt by the Agency of applications from registrants to delete uses in the 10 pesticide registrations listed in the following Table 1. These registrations are listed by registration number, product names, active ingredients and the specific uses deleted. Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before June 2, 1997 to discuss withdrawal of the applications for amendment. This 180-day period will also permit interested members of the public to intercede with registrants prior to the Agency approval of the deletion.

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
000334–00364	Flying Insect Killer	*d-trans*-Allethrin; 2-Methyl-4-oxo-3- (2-cyclopenten-1-Yl *d-trans*-2,2 dimethyl; (Butylcarbityl)(6-pro pylpipernoyl) ether 88% & related compounds)	Aircraft uses
000432–00041	Brittle Extract of Cube Root	Rotenone	Domestic pet uses
000432–00046	Rotenone Crystalline	Rotenone; Cube Resins other than Rotenone	Domestic pet uses
000432–00525	Powdered Cube Root	Rotenone	Domestic pet uses
002217–00383	Sevin Dust 5%		Asparagus uses
002217–00572	Gordon's Sevin Dust 5%	Carbaryl	Asparagus & poultry uses
002393–00375	Hopkins Poultry and Garden Dust	Carbaryl	Pet uses

TABLE 1. — REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
006458–00001	Cube Powder	Cube Resins other than Rotenone; Rotenone	Domestic pet uses
006458–00005	Cube Extract	Cube Resins other than Rotenone; Rotenone	Domestic pet uses
064405–00002	Redzone Bait	Boric Acid	Beetles

The following Table 2, includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Company No.	Company Name and Address
000334	Tech-Line Products, P.O. Box 24095, Milwaukee, WI 53224.
000432	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
002217	PBI/Gordon Corp., 1217 W. 12th Street, P.O. Box 4090, Kansas City, MO 64101.
002393	Platte Chemical Company, P.O. Box 667, 419 18th Street, Greeley, CO 80632.
006458	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
064405	RegWest Company, P.O. Box 2220, Greeley, CO 80632.

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: November 18, 1996.

Linda A. Travers,

Acting Director, Program Management and Support Division, Office of Pesticide Programs.

[FR Doc. 96–30744 Filed 12–2–96; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collections Being Reviewed by FCC for Extension Under Delegated Authority 5 CFR Part 1320 Authority, Comments Requested

November 25, 1996.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commissions burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

The FCC is reviewing the following information collection requirements for possible 3-year extension under delegated authority 5 CFR part 1320, authority delegated to the Commission by the Office of Management and Budget (OMB).

DATES: Written comments should be submitted on or before February 3, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Dorothy Conway, Federal Communications Commission, Room 234, 1919 M St., N.W., Washington, DC 20554 or via internet to dconway@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Dorothy Conway at 202–418–0217 or via internet at dconway@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Number: 3060–0157.

Title: Section 73.99 Presunrise Service Authorization (PSRA) and Postsunset Service Authorization (PSSA).

Form Number: None.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Number of Respondents: 200.

Estimated time per response: 0.5 hours (0.25 hours respondent/0.25 hours attorney).

Total annual burden: 50.

Needs and Uses: Section 73.99(e) requires the licensee of an AM broadcast station intending to operate with a presunrise or postsunset service authorization to submit by letter the licensee's name, call letters, location, the intended service, and a description of the method whereby any necessary power reduction will be achieved. Upon submission of this information, operation may begin without further authority. The letter is used by FCC staff to maintain complete technical information about the station to ensure that the licensee is in full compliance

with the Commission's rules and will not cause interference to other stations.

OMB Number: 3060–0474.

Title: Section 74.1263 Time of Operation.

Form Number: None.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Number of Respondents: 75.

Estimated time per response: 0.5 hours.

Total annual burden: 38.

Needs and Uses: Section 74.1263(c) requires licensees of FM translator or booster stations to notify the Commission of its intent to discontinue operations for 30 or more consecutive days. In addition, licensees must notify the Commission within 48 hours of the station's return to operation. Section 74.1263(d) requires FM translator or booster station licensees to notify the Commission of its intent to permanently discontinue operations and to forward the station license to the FCC for cancellation. The data is used by FCC staff to keep records up-to-date. These notifications inform FCC staff that frequencies are not being used for a specified amount of time and that frequencies have become available for other users.

Federal Communications Commission

William F. Caton,

Acting Secretary.

[FR Doc. 96–30703 Filed 12–2–96; 8:45 am]

BILLING CODE 6712–01–P

Notice of Public Information Collections Submitted to OMB for Review and Approval

November 25, 1996.

SUMMARY: The Federal Communications, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commissions burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before January 2, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Dorothy Conway, Federal Communications, Room 234, 1919 M St., N.W., Washington, DC 20554 or via internet to dconway@fcc.gov and Timothy Fain, OMB Desk Officer, 10236 NEOB 725 17th Street, N.W., Washington, DC 20503 or fain__t@a1.eop.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Dorothy Conway at 202–418–0217 or via internet at dconway@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: New Collection.

Title: Children's Television Programming Report.

Form No.: 398.

Type of Review: New Collection.

Respondents: Businesses or other for-profit.

Number of Respondents: 1,200 Commercial TV Licensees.

Estimated Time Per Response: 3.5–4.5 hour.

Total Annual Burden: 18,000 hours.

Needs and Uses: On 8/8/96, the Commission adopted a Report and Order in MM Docket No. 93–48 Policies and Rules Concerning Children's Television Programming. As a result of this Report and Order, the Commission has developed a new FCC Form 398 ''Children's Television Programming Report''. The FCC Form 398 will request information to identify children's educational and informational programs aired to meet their obligations under the Children's Television Act of 1990 (CTA). The form will also request information on children's educational and informational programs that stations plan to air in the next calendar quarter. This standardized form will facilitate consistency of reporting among licensees, assist in efforts by the public and the Commission to monitor compliance with the CTA, and lessen the budern on the public and Commission staff.

Federal Communications Commission

William F. Caton,

Acting Secretary.

[FR Doc. 96–30704 Filed 12–2–96; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Affordable Housing Advisory Board Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App., announcement is hereby published of the Affordable Housing Advisory Board (AHAB) meeting. The meeting is open to the public.

DATES: The Federal Deposit Insurance Corporation, Affordable Housing Advisory Board will hold its fourth quarter meeting on Tuesday, December 17, 1996 in New York, New York, from 9:00 a.m. to 12 Noon.

ADDRESSES: The meeting will be held at the following location: New York Hilton & Towers, 1335 Avenue of the Americas, Beckman Parlor, Second Floor, New York, New York 10019.

FOR FURTHER INFORMATION CONTACT: Danita M.C. Walker, Committee Management Officer, Federal Deposit Insurance Corporation, 801 17th Street, NW, Room 736, Washington, D.C. 20429, (202) 416–4086.

SUPPLEMENTARY INFORMATION: The Board consists of the Secretary of Housing and Urban Development (HUD) or delegate; the Chairperson of the Board of Directors of the FDIC, or delegate; the Chairperson of the Oversight Board, or delegate; four persons appointed by the General Deputy Assistant Secretary of HUD who represent the interests of individuals and organizations involved in using the affordable housing programs, and two former members of the Resolution Trust Corporations Regional Advisory Boards. The AHAB's original charter was issued March 9, 1994, and recharter was issued on February 26, 1996.

Agendas

An agenda will be available at the meeting. At the general session, the Board will (1) Report on FDIC downsizing and the affect on the Affordable Housing Program, (2) Discuss the status report on Monitoring & Compliance and (3) Report on Board

options, meeting schedule and Work Program for 1997. The AHAB will develop recommendations at the conclusion of the Board meeting. The AHAB's chairperson or its Delegated Federal Officer may authorize a member or members of the public to address the AHAB during the public forum portion of the session.

Statements

Interested persons may submit, in writing, data, information or views on the issues pending before the Affordable Housing Advisory Board prior to or at the general session of the meeting. Seating for the public is available on a first-come first-served basis.

Dated: November 26, 1996.

Danita M.C. Walker,

Committee Management Officer, Federal Deposit Insurance Corporation.

[FR Doc. 96–30656 Filed 12–2–96; 8:45 am]

BILLING CODE 6714–01–M

Notice of Agency Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 11:13 a.m. on Tuesday, November 26, 1996, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following matters:

Matters relating to the Corporation's corporate and supervisory activities

Matters relating to an administrative enforcement proceeding.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr, seconded by Director Joseph H. Neely (Appointive), concurred in by Director Nicolas P. Retsinas (Director, Office of Thrift Supervision), Ms. Judith Walter, acting in the place and stead of Director Eugene A. Ludwig (Comptroller of the Currency), and Chairman Ricki Helfer, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

Dated: November 26, 1996.

Federal Deposit Insurance Corporation

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 96–30907 Filed 11–29–96; 2:30 pm]

BILLING CODE 6714–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Revocations

The Federal Maritime Commission hereby gives notice that the following freight forwarder licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, effective on the corresponding revocation dates shown below:

License number: 978
Name: Elco Freight International, Inc.
Address: 420 West Merrick Road, Valley Stream, NY 11580
Date revoked: October 23, 1996
Reason: Failed to maintain a valid surety bond.

License number: 2138
Name: Greystone International, Inc. d/b/a American Exporters Forwarding International
Address: 840 Hinckley Road, Suite 143, Burlingame, CA 94010
Date revoked: November 1, 1996
Reason: Failed to maintain a valid surety bond.

License number: 2149
Name: International Consolidators and Freight Forwarders, Inc.
Address: 16284 S.W. 74th Street, Miami, FL 33193
Date revoked: October 17, 1996
Reason: Failed to maintain a valid surety bond.

License number: 3331
Name: Ransar International, Inc.
Address: 6 Colonial Drive, Smithtown, NY 11787
Date revoked: November 7, 1996
Reason: Surrendered license voluntarily.

License number: 515
Name: Silvey Shipping Co., Inc.
Address: Building 75, Suite 200, North Hanger Road, Jamaica, NY 11430
Date revoked: October 25, 1996
Reason: Failed to maintain a valid surety bond.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 96–30686 Filed 12–2–96; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 17, 1996.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Berthoud Bancorp Employee Stock Ownership Plan, Berthoud, Colorado to acquire at least 50 percent of the voting shares of Berthoud Bancorp, Inc., Berthoud, Colorado, and thereby indirectly acquire Berthoud National Bank, Berthoud, Colorado.

Board of Governors of the Federal Reserve System, November 26, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–30696 Filed 12-2-96; 8:45 am]

BILLING CODE 6210-01-F

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 17, 1996.

A. Federal Reserve Bank of New York (Christopher J. McCurdy, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. Bayerische Vereinsbank AG, Munich, Germany; to engage *de novo* through its subsidiary, VB Risk Management Products, Inc., New York, New York in intermediating in the international swap markets by acting as an originator and principal in interest rate swap and currency swap transactions; in acting as an originator and principal with respect to certain interest rate and currency risk-management products such as caps, floors and collars, as well as options on swaps, caps, floors and collars (''swap derivative products''); in acting as a broker or agent with respect to the foregoing transactions or instruments; and in acting as an advisor to institutional customers regarding financial strategies involving interest rate and currency swaps and swap derivative products; *Swiss Bank Corporation*, 81 Fed. Res. Bull. 185 (1995); *The Long-Term Credit Bank of Japan*, 79 Fed. Res. Bull. 345 (1993); *The Sumitomo Bank, Limited,* 75 Fed. Res. Bull. 582 (1989).

Board of Governors of the Federal Reserve System, November 26, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–30695 Filed 12-2-96; 8:45 am]

BILLING CODE 6210-01-F

[Docket No. R–0941]

Federal Reserve Bank Services; Notice

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board has approved a private sector adjustment factor (PSAF) for 1997 of $101.5 million, as well as the fee schedules for Federal Reserve priced services and electronic connections. These actions were taken in accordance with the requirements of the Monetary Control Act of 1980, which requires that, over the long run, fees for Federal Reserve priced services be established on the basis of all direct and indirect costs, including the PSAF.

DATES: The PSAF and the fee schedules become effective on January 2, 1997.

FOR FURTHER INFORMATION CONTACT: For questions regarding the private sector adjustment factor: Elizabeth Tacik, Accountant, (202/452–2303), Division of Reserve Bank Operations and Payment Systems; for questions regarding the fee schedules: Julius Weyman, Financial Services Analyst, Check Payments, (202/452- 5223), Scott Knudson, Senior Financial Services Analyst, ACH Payments, (202/452–3959), Darrell Mak, Financial Services Analyst, Funds Transfer and Book-Entry Securities Services, (202/452–3223), Anne Paulin, Senior Information Technology Analyst (electronic connections), (202/452–2560), Michael Bermudez, Financial Services Analyst, Noncash Collection Service, (202/452–2216), or Kate Connor, Senior Financial Services Analyst, Special Cash Services, (202/452–3917), Division of Reserve Bank Operations and Payment Systems. For users of Telecommunications Device for the Deaf (TDD) *only,* please contact Dorothea Thompson (202/452–3544).

Copies of the 1997 fee schedules for the check, automated clearing house (ACH), funds transfer and net settlement, book-entry securities, noncash collection, and special cash services, as well as electronic connections to Reserve Banks, are available from the Reserve Banks.

SUPPLEMENTARY INFORMATION:

I. Private Sector Adjustment Factor

A. Overview

The Board has approved a 1997 PSAF for Federal Reserve priced services of $101.5 million. This amount represents an increase of $15.7 million or 18.3 percent from the PSAF of $85.8 million targeted for 1996.

As required by the Monetary Control Act (12 U.S.C. 248a), the Federal Reserve's fee schedule for priced services includes ''taxes that would have been paid and the return on capital that would have been provided had the services been furnished by a private business firm.'' These imputed costs are based on data developed in part from a model comprised of the nation's 50 largest (in asset size) bank holding companies (BHCs).

The methodology first entails determining the value of Federal Reserve assets that will be used in producing priced services during the coming year. Short-term assets are assumed to be financed by short-term liabilities; long-term assets are assumed to be financed by a combination of long-term debt and equity derived from the BHC model.

Imputed capital costs are determined by applying related interest rates and rates of return on equity (ROE) derived from the bank holding company model. The rates drawn from the BHC model are based on consolidated financial data for the 50 largest BHCs in each of the

last five years. Because short-term debt, by definition, matures within one year, only data for the most recent year are used for computing the short-term debt rate.

The PSAF comprises capital costs, imputed taxes, expenses of the Board of Governors related to priced services, and an imputed FDIC insurance assessment on clearing balances held with the Federal Reserve to settle transactions.

B. Asset Base

The estimated value of Federal Reserve assets to be used in providing priced services in 1997 is reflected in Table A–1. Table A–2 shows that the assets assumed to be financed through debt and equity are projected to total $623.5 million. As shown in Table A–3, this represents a net decrease of $13.8 million or 2.2 percent from 1996. This decrease results from lower priced asset base levels at the Federal Reserve Automation Services (FRAS), slightly offset by an increase in the Reserve Banks' priced asset base due to building projects in three districts and increased long-term prepayments.

C. Cost of Capital, Taxes, and Other Imputed Costs

Table A–3 shows the financing and tax rates as well as the other required PSAF recoveries proposed for 1997 and compares the 1997 rates with the rates used for developing the PSAF for 1996. The pre-tax return on equity rate increased from 14.2 percent in 1996 to 19.1 percent for 1997. The increase is a result of stronger 1995 BHC financial performance included in the 1997 BHC model, which replaces the 1990 BHC financial performance in the 1996 BHC model.

The decrease in the FDIC insurance assessment from $2.2 million in 1996 to $2.0 million in 1997, as shown in Table A–3, is attributable to the impact of the new lower rate for deposit insurance. The FDIC rate for adequately capitalized institutions of $0.04 on every $100 in clearing balances was reduced to $0.03 in January 1996.

D. Capital Adequacy

As shown on Table A–4, the amount of capital imputed for the proposed 1997 PSAF totals 32.6 percent of risk-weighted assets and 4.1 percent of total assets. While the capital to risk-weighted asset ratio is well in excess of the 8 percent capital guideline for adequately capitalized state member banks and BHCs, the Federal Reserve is treated as an adequately capitalized bank for FDIC assessment purposes based on its capital to total asset ratio.

II. Priced Services

A. Overview

Over the period 1986 through 1995, the Reserve Banks recovered 100.1 percent of their total costs of providing priced services, including special project costs that were budgeted for recovery and targeted after-tax profit, i.e., ROE.[1] [2] Because the revenue from the Reserve Banks' priced services recovers imputed costs that are not actually incurred, the Federal Reserve's provision of priced services has consistently had a positive effect on the level of earnings transferred by the Federal Reserve to the Treasury. Over the past 10 years, priced services revenue has exceeded operating costs by more than $872 million. This net revenue contributes to the amount transferred to the Treasury. Table 1 summarizes the cost and revenue performance for priced services since 1986.

During 1994 and 1995, the Reserve Banks did not fully recover their targeted ROE due primarily to declining check volumes resulting from the new same-day settlement rule. In response to declining volumes, the Reserve Banks adjusted the resources devoted to the check service and increased prices selectively. In 1996, the Reserve Banks estimate that priced services revenue will yield an after-tax net income of $55.6 million, compared with a targeted return on equity of $36.6 million. The 1996 recovery rate is estimated to be 102.4 percent of the costs of providing priced services, including imputed expenses, automation consolidation special project costs budgeted for recovery, and targeted ROE.[3] Approximately $26.8 million in automation consolidation special project costs will be recovered in 1996, leaving $30.8 million in accumulated costs to be financed and recovered in future years.[4]

The variation from the Reserve Banks' original budget is attributable to two factors. First, volumes have been higher than expected in the funds transfer, book-entry securities transfer, and noncash collection services, resulting in higher net revenue. Second, costs have been lower than budgeted in the funds transfer and automated clearing house (ACH) services, largely due to efficiency gains from automation consolidation.[5]

In 1997, the Reserve Banks project to recover 100.5 percent of total expenses, including special project costs and targeted ROE. The proposed 1997 fees for priced services will yield a projected net income of $49.8 million for the year, compared with a targeted ROE of $45.8 million. Approximately $27.7 million of automation consolidation special project expenses will be recovered, leaving an accumulated balance of special project costs of $22.0 million to be recovered in future years. The Reserve Banks have indicated that the most significant risk associated with the proposed fee schedules is the uncertainty of 1997 volume estimates given the current competitive environment and the effects of interstate branch banking.

Overall, prices across all services are projected to decline by approximately

[1] The Monetary Control Act requires that, over the long run, the Federal Reserve set fees for priced services to recover all direct and indirect costs of providing the services plus imputed costs, such as taxes that would have been paid and the return on capital that would have been earned had the services been provided by a private business firm. The targeted ROE is the budgeted after-tax profit that the Federal Reserve would have earned, as required by law, had it been a private business firm. The targeted ROE is derived from the BHC model based on consolidated financial data for each of the last five years.

[2] Certain offsets to costs and certain costs are treated differently in the *pro forma* income statement for Federal Reserve priced services that is published in the Board's *Annual Report* than they are for purposes of setting fees. For example, offsets to costs associated with the transition to and retroactive application of the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 87 (SFAS 87), pension accounting, and SFAS 106, other post-retirement employee benefits accounting, have not been considered in setting fees for priced services. Under the procedures used to prepare the *pro forma* income statement, the Reserve Banks recovered 100.7 percent of the expenses incurred in providing priced services, including targeted ROE, from 1986 through 1995.

[3] Through August 1996, the Reserve Banks recovered 103.2 percent of total priced services expenses, including automation consolidation special project costs and targeted ROE.

[4] Under an existing Board policy, the Reserve Banks may defer and finance development costs if the development costs would have a material effect on unit costs, provided that a conservative time period is set for full cost recovery and a financing factor is applied to the deferred portion of development costs. The 1996 and 1997 financing rates are 12.0 and 15.1 percent, respectively, which are the weighted-average imputed costs of the Federal Reserve's long-term debt and equity. This methodology is similar to the approach a private firm would use in financing such costs. Starting in 1992, the Reserve Banks deferred and financed special project costs for automation consolidation that were associated with employee retention and severance and excess mainframe computer capacity. Each priced service is expected to recover fully its portion of these deferred expenses and accumulated finance charges within five years after that service has completed its transition to the consolidated automation environment. Most services have been able to recover these expenses more quickly than the five-year deadline.

[5] The Reserve Banks have substantially completed the transfer of mainframe computer operations to the System's consolidated data centers, managed by the Federal Reserve Automation Services (FRAS) and also have completed significant milestones in the centralization of certain key software applications, such as ACH, Fedwire funds transfers, and the Integrated Accounting System.

3.4 percent in 1997, reflecting increases in paper-based check product prices and selected electronic access fees, price reductions for ACH, Fedwire funds transfers, and selected electronic check products, and stable prices for the book-entry securities transfer and noncash collection services.[6]

TABLE 1.[7]—PRO FORMA COST AND REVENUE PERFORMANCE[a]

[$ millions]

Year	1 Revenue[b]	2 Operating costs & imputed expenses[c]	3 Special project costs recovered[d]	4 Total expense [2+3]	5 Net income ROE [1–4]	6 Target ROE[e]	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred & financed[f]
1986	627.7	571.6	0.0	571.6	56.1	27.3	104.8	0.0
1987	649.7	598.2	0.0	598.2	51.5	29.3	103.5	0.0
1988	667.7	641.1	3.2	644.3	23.4	32.7	98.6	0.0
1989	718.6	692.1	4.6	696.7	21.9	32.9	98.5	0.0
1990	746.5	698.1	2.8	700.9	45.6	33.6	101.6	0.0
1991	750.2	710.0	1.6	711.6	38.6	32.5	100.8	0.0
1992	760.8	731.0	11.2	742.2	18.6	26.0	99.0	1.6
1993	774.5	722.4	27.1	749.5	25.0	24.9	100.0	12.5
1994	767.2	748.3	8.8	757.1	10.1	34.6	96.9	33.9
1995	765.2	724.0	19.8	743.8	21.4	31.5	98.7	36.3
1996 (Est)	810.4	728.0	26.8	754.8	55.6	36.6	102.4	30.8
1997 (Bud)	813.9	736.4	27.7	764.1	49.8	45.8	100.5	22.0

[a] The revenues and expenses for 1986 through 1993 include the definitive securities safekeeping service, which was discontinued in 1993. The table includes revised revenue and expense data for 1992 and 1993.

[b] Beginning in 1987, net income on clearing balances is included in revenue.

[c] Imputed expenses include interest on debt, taxes, FDIC insurance premiums, and the cost of float. Credits for prepaid pension costs under SFAS 87 and the charges for post-retirement benefits in accordance with SFAS 106 are included beginning in 1993.

[d] Special project costs include research and development expenses for evaluating a different computer processing platform for electronic payments from 1988 through 1990, check image project costs from 1988 through 1993, and automation consolidation costs from 1992 through 1997.

[e] Targeted ROE is based on the ROE included in the private sector adjustment factor and has been adjusted for taxes, which are included in column 2. Targeted ROE has not been adjusted to reflect automation consolidation special project costs deferred and financed.

[f] Totals are cumulative and include financing costs.

B. *Check*—Table 2 presents the actual 1995, estimated 1996, and projected 1997 cost recovery performance for the check service.

TABLE 2.—CHECK PRO FORMA COST AND REVENUE PERFORMANCE

($ millions)

Year	1 Revenue	2 Operating costs and imputed expenses	3 Special project costs recovered	4 Total expense [2+3]	5 Net income (ROE) [1–4]	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred and financed
1995	574.0	558.9	5.3	564.2	9.8	24.0	97.6	12.4
1996 (Est)	605.1	569.7	6.5	576.2	28.9	28.0	100.1	10.4
1997 (Bud)	616.7	572.9	7.5	580.4	36.3	35.3	100.2	7.4

1. 1995 Performance

The check service recovered 97.6 percent of total expenses in 1995, including targeted ROE. The volume of checks collected decreased 5.3 percent from 1994 levels, as volume losses associated with bank consolidations and the implementation of the same-day settlement regulation continued. In 1995, however, volume losses were less substantial than the double-digit losses that accompanied the introduction of the same-day settlement regulation in 1994. Return item volume increased 3.8 percent in 1995 compared to 1994 levels.

2. 1996 Performance

Through August 1996, the check service recovered 101.2 percent of total expenses, including automation consolidation special projects costs budgeted for recovery and targeted ROE. The Reserve Banks estimate that they will recover 100.1 percent of their costs for the full year, compared with the targeted 1996 recovery rate of 100.0 percent. Check collection volumes appear to be stabilizing compared to the relatively significant volume losses in 1994 and 1995. The Reserve Banks now project that the volume of checks collected during 1996 will decline by 0.4 percent from 1995 levels, reflecting a 1.6 percent increase in processed volume and a 9.1 percent decrease in

[6] This estimate is based on a chained Fisher Ideal price index. This index was not adjusted for quality changes in Federal Reserve priced services. Because the index was not adjusted for quality and due to data deficiencies in certain electronic services, the index may overstate the price effects of paper-based services. Generally, processing costs (and hence prices) have risen in services that are paper-based, such as check collection, but have declined in those services that are mostly electronic, such as ACH, funds transfer, and check payor bank services.

[7] Calculations on this table and subsequent *pro forma* cost and revenue tables may be affected by rounding.

fine sort volume. Return item volume is estimated to increase by 2.9 percent.

3. 1997 Issues

The total number of interbank checks will likely continue to decline as banks merge when interstate branch banking becomes effective nationwide in June 1997 and as banks continue to consolidate their payment processing operations. In addition, other service providers in the interbank check processing market are expected to compete aggressively for check collection and returned check volume. The Reserve Banks project modest volume increases in 1997 despite the challenges posed by this environment. Total forward check collection volume is expected to increase by 0.7 percent in 1997, reflecting a projected increase of 1.9 percent in processed volume and a decrease of 5.5 percent in fine sort volume. Returned check volume is expected to increase 0.4 percent.

The Reserve Banks continue to take steps to improve the efficiency of their check processing operations. For example, on October 15, the Federal Reserve Bank of New York closed its Regional Check Processing Center in Jericho, New York, and consolidated those operations at its East Rutherford (New Jersey) Operations Center. In addition, the New York Bank is centralizing the processing of adjustments at its Utica, New York, Regional Check Processing Center. In addition, on October 27, the System's Interdistrict Transportation Service (ITS) moved one of its five airport hubs from Teterboro, New Jersey, to Philadelphia, Pennsylvania. This move allows for improvements in deposit deadlines and funds availability for many depositors.

The Reserve Banks will continue to promote electronic check products that are designed to increase operating efficiency and improve the speed of the check collection system. For example, Reserve Banks are expanding the range of deposit products that use electronic cash letters (ECL). The expanded use of these deposit products is expected to improve the efficiency of the Reserve Banks' operations and may ultimately contribute to efficiencies in paying banks' operations by reducing rejects and minimizing adjustments.

The Reserve Banks also are expanding their image-enhanced check products, which have the potential to increase the use of electronic check presentment and to reduce the risks associated with it. At present, 19 Reserve Bank offices offer image-enhanced products; in 1997, 34 Reserve Bank offices plan to offer these products.

Total check service operating costs plus imputed expenses are projected to increase by $3.2 million, or 0.6 percent above estimated 1996 expenses.

4. 1997 Fees

The Reserve Banks are continuing the steps taken over the last several years to set check fees to reflect more accurately the fixed and variable costs associated with providing check services. The 1997 fees and product offerings are intended to encourage the use of electronics and to improve the efficiency of the check collection mechanism. Table 3 summarizes key check service fees.

TABLE 3.—SELECTED CHECK FEES

Products	1996 price ranges	1997 price ranges
Items:	(per item)	(per item)
Forward processed:		
City	$0.003 to 0.080	$0.003 to 0.080.
RCPC	$0.003 to 0.079	$0.004 to 0.090.
Fine sort:		
City	$0.003 to 0.012	$0.003 to 0.012.
RCPC	$0.002 to 0.017	$0.003 to 0.017.
Qualified return items:		
City	$0.100 to 1.110	$0.160 to 1.110.
RCPC	$0.120 to 1.560	$0.017 to 1.560.
Raw return items:		
City	$0.580 to 4.000	$0.580 to 4.000.
RCPC	$0.900 to 4.000	$0.650 to 4.000.
Cash letters:	(per cash letter)	(per cash letter)
Forward processed	$1.500 to 9.000	$1.500 to 9.000.
Forward fine-sort package	$2.500 to 11.000	$2.500 to 13.000.
Return items: raw and qualified	$1.500 to 8.000	$1.500 to 7.000.
Payor bank services:	Min Per item	Min Per item
MICR information	$5–$30 $0.001–0.0050	$5–$30 $0.001–0.0050.
Electronic presentment	$3–$14 $0.001–0.0045	$3–$14 $0.001–0.0045.
Truncation	$3–$25 $0.010–0.0170	$3–$25 $0.010–0.0170.

Overall, 1997 fees for forward collection products will increase by about 1.8 percent on a volume-weighted basis, compared with January 1996 prices. For returned check products, the increase is 2.6 percent. The most significant increases are in fine sort fees, which are increasing by 7.8 percent.

Fees for electronic check services will decline or remain stable. These fees include per-item fees for the Reserve Banks' electronic check presentment and payor bank information products as well as for ECL products. On average, the fees assessed for deposits made with a matching ECL file will result in per-item charges that are $0.002 less than the same deposit received without an accompanying ECL file. This price differential reflects the potential efficiencies from processing checks in conjunction with ECL data. Payor bank services revenue is expected to increase by 13.9 percent, primarily due to more widespread acceptance of electronic check presentment and image-enhanced check products.

For the first time since 1993, the Reserve Banks will change some ITS fees. For 1997, ITS fees will increase about 11 percent on a volume-weighted basis. The price changes are designed to reflect more accurately the cost of servicing certain low-volume and remote routes. Fees for 12 percent of the routes, representing 47 percent of the check volume carried on ITS, will remain unchanged. The Reserve Banks are investigating, for possible implementation during 1997, alternative fee structures for the ITS.

The Reserve Banks project that the check service will recover 100.2 percent of total costs in 1997, including targeted ROE and $7.5 million in automation consolidation special project costs. Approximately $7.4 million in accumulated automation consolidation special project costs will be deferred and financed for recovery in future years.

The Reserve Banks continue to take steps to control costs, and their volume projections for 1997 are relatively conservative. It is difficult, however, to project the effect of interstate branch banking on the Reserve Banks' check service. The Board believes that steps could be taken during 1997 to reduce operating costs if volume projections were not realized. The Board approved the proposed 1997 check service fees, including ITS fees, and the deposit deadlines.

C. Automated Clearing House (ACH)

Table 4 presents the actual 1995, estimated 1996, and projected 1997 cost recovery performance for the commercial ACH service.

TABLE 4.—ACH PRO FORMA COST AND REVENUE PERFORMANCE

[$ millions]

Year	1 Revenue	2 Operating costs & imputed expenses	3 Special project costs recovered	4 Total expense [2+3]	5 Net income (ROE) [1–4]	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 special project costs deferred & financed
1995	75.6	66.6	4.0	70.6	5.0	3.1	102.6	21.3
1996 (Est)	79.8	63.6	9.2	72.8	7.0	3.6	104.5	16.7
1997 (Bud)	75.4	59.9	11.1	71.0	4.3	4.0	100.5	10.8

1. 1995 Performance

Revenues from the ACH service recovered 102.6 percent of total expenses, including automation consolidation special project costs and targeted ROE, during 1995. The overrecovery was due primarily to higher-than-expected growth in commercial ACH volume. Commercial volume increased 17.8 percent, compared to a projected growth rate of 12.9 percent. As a result, total ACH revenue was 6.7 percent above target.

2. 1996 Performance

Through August 1996, the ACH service recovered 104.6 percent of total expenses, including automation consolidation special project costs budgeted for recovery and targeted ROE. The Reserve Banks estimate that they will recover 104.5 percent of their costs for the full year, compared with the targeted 1996 recovery rate of 100.0 percent. This overrecovery is attributable primarily to lower-than-expected data processing costs resulting from the efficiencies realized with the new Fed ACH application software. The conversion to Fed ACH began in late 1995 and was completed in August 1996.

On October 1, the Reserve Banks implemented a number of changes to their ACH fees and products, which were approved under delegated authority by the Director of the Board's Division of Reserve Bank Operations and Payment Systems. The changes included combining the interregional and intraregional fee into one basic fee of $0.01 per item, representing a 16.7 percent reduction from the former $0.012 interregional fee; reducing the presort deposit fee by 10 percent to 0.9 cent from 1.0 cent; and eliminating the interregional and presort deposit deadlines, as well as one local deposit deadline. The reduction in fees is expected to result in substantial savings to the banking industry, and the changes in the deadlines will provide originators of ACH transactions an additional one to one and one-half hours of processing time.

Through August, commercial ACH volume has increased 16.1 percent over the 1995 level. For the full year, the Reserve Banks expect commercial volume to increase 15.2 percent, compared to the 17.5 percent increase originally projected. The revised projection reflects the effect of consolidation in the banking industry and some increased use of private-sector processors.

3. 1997 Issues

1997 will be the first full year that all Reserve Banks operate in the Fed ACH environment. The projected reduction in ACH operating costs reflects the expected cost savings that should be realized from centralized processing. Beginning in January 1997, several new features will be made available to depository institutions, including additional file delivery options and automated trace and research request capabilities. The projected volume growth rate of 18.5 percent is very aggressive in light of 1996 volume estimates. The Reserve Banks believe, however, that Federal Reserve and industry marketing efforts will spur commercial ACH volume growth. Moreover, the recent requirement that most federal government payments be made electronically by January 1999 may indirectly increase commercial ACH volume.[8]

4. 1997 Fees

The new Fed ACH processing environment is expected to enable the Federal Reserve to realize significant operating efficiencies. The Board has approved several fee reductions effective January 1997. These changes support the System's strategic direction of moving from a paper-based to an electronic payments system and recognize the technological and operational changes implemented during the past year.

TABLE 5

Fee category	Current fee	Proposed 1997 fee
Premium surcharge	$0.01	$0.005
Addenda fee	0.004	0.003
Discrete/commingled file fee.	10.00	Eliminate.

As Table 5 indicates, the Reserve Banks will reduce the premium surcharge by 50 percent on items deposited after 8:00 p.m. Eastern Time. Reducing the premium cycle surcharge recognizes the improvements made in the Federal Reserve's processing of ACH transactions that reduce operational and

[8] The Debt Collection Improvement Act of 1996 mandates the use of electronic funds transfers for federal government payments to recipients who become eligible after July 26, 1996. The Act also mandates that all federal government payments, with limited exceptions, be made electronically after January 1, 1999.

float risk. The Reserve Banks will continue to review originating institutions' deposit patterns to determine whether the current premium deposit deadline can be extended. In addition, the Reserve Banks will reduce the fee for addenda records by $0.001, or 25 percent. The reduction in the addenda record fee is intended to promote the use of electronic payments for financial electronic data interchange applications. Finally, the Reserve Banks will eliminate the monthly discrete/commingled file receipt fee. The discrete/commingled file fee, which is charged to receiving points that receive multiple files segregated by routing number, is being eliminated because of the new delivery features that are available in Fed ACH.

In addition to the above changes, the Reserve Banks plan to propose a new fee schedule during 1997 that fully reflects the efficiencies of the Fed ACH processing environment.

To determine the nature and extent of the expected efficiencies, the Reserve Banks are studying their processing costs in the new environment. It is anticipated that, under delegated authority, the Director of the Board's Division of Reserve Bank Operations and Payment Systems will be requested to approve a new ACH fee schedule by mid-1997.

The Reserve Banks project that the ACH service will recover 100.5 percent of its 1997 costs, including $11.1 million in automation consolidation special project costs and targeted ROE. Approximately $10.8 million in automation consolidation special project costs will continue to be deferred and financed for recovery in future years.

D. Funds Transfer and Net Settlement

Table 6 presents the actual 1995, estimated 1996, and projected 1997 cost recovery performance for the funds transfer and net settlement service.

TABLE 6.—FUNDS TRANSFER AND NET SETTLEMENT PRO FORMA COST AND REVENUE PERFORMANCE

[$ millions]

Year	1 Revenue	2 Operating costs & imputed expenses	3 Special project costs recovered	4 Total expense [2+3]	5 Net Income (ROE) [1−4]	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred & financed
1995	90.6	74.1	9.7	83.8	6.8	3.4	103.8	0.0
1996 (Est)	97.3	69.6	9.3	78.8	18.5	3.8	117.7	0.3
1997 (Bud)	95.2	80.2	7.4	87.6	7.6	5.1	102.7	0.0

1. 1995 Performance

For 1995, the funds transfer and net settlement service recovered 103.8 percent of total expenses, including automation consolidation special project costs and targeted ROE. Basic funds transfer origination volume increased 5.6 percent over the 1994 level, resulting in higher revenues.

2. 1996 Performance

Through August 1996, the funds transfer and net settlement service recovered 117.9 percent of total expenses, including automation consolidation special project costs budgeted for recovery and targeted ROE. For full-year 1996, the Reserve Banks estimate that the funds transfer service will recover 117.7 percent of total expenses, compared to a targeted recovery rate of 106.0 percent. This difference is attributable to both lower-than-anticipated costs and higher-than-anticipated revenue. The Reserve Banks estimate that operating costs will be lower than the original budget estimates due to lower-than-budgeted allocations of local and national data communications costs. In addition, the Reserve Banks are beginning to realize the efficiencies from processing funds transfers in a centralized software environment.

Total revenue is estimated to be $6.4 million (or 7.1 percent) over the original budget, due to higher-than-expected on-line funds transfer volume. Basic origination volume growth is estimated to be 8.3 percent in 1996 compared to original budget projections of 2.1 percent. The higher volume has been attributed to sharply increased mutual fund activity, aggressive marketing of cash management services by depository institutions to their customers, and, to a lesser extent, increased mortgage activity and securities-related settlement payments (the latter due to the market's move to a T+3 settlement cycle and same-day funds settlement on securities trades).

3. 1997 Issues

The Reserve Banks expect funds transfer origination volume to increase 5.3 percent over 1996 estimated levels. This projected growth rate is lower than the 1996 estimated growth rate but slightly above the ten-year historical average annual growth rate of 5.0 percent. Uncertainties in achieving the projected volume growth include the effects of increased bank mergers and consolidations as interstate branch banking takes effect in 1997 and the level of mutual fund and cash management activity in 1997.

Operating costs also are anticipated to increase in 1997 due primarily to two changes to the Reserve Banks' cost accounting methodology that become effective in 1997.[9] Partially offsetting this increase is a projected decline in data processing costs due to the conversion of the New York Reserve Bank's funds transfer application to the consolidated FRAS environment in spring 1997.

4. 1997 Fees

Despite projected increased costs in 1997, the benefits of automation consolidation combined with strong volume growth will enable the Reserve Banks to reduce the basic funds transfer fee by 10 percent from $0.50 to $0.45. All other funds transfer and net settlement fees will remain unchanged. The Reserve Banks project that revenues will recover 102.7 percent of total funds transfer expenses, including targeted ROE and all allocated automation consolidation special project costs.

E. Book-Entry Securities[10]

Table 7 presents the actual 1995, estimated 1996, and projected 1997 cost

[9] The Reserve Banks have modified their methodology for allocating FRAS data processing and data communications (DP/DC) costs to provide more incentives for the efficient use of DP/DC resources, and for allocating certain joint overhead costs to recognize that these costs are not closely related to particular services. These cost accounting changes are consistent with general industry practices.

[10] Includes Purchase and Sale Activity.

recovery performance for the book-entry securities service.[11]

TABLE 7.—BOOK-ENTRY SECURITIES PRO FORMA COST AND REVENUE PERFORMANCE

[$ millions]

Year	1 Revenue	2 Operating costs & imputed expenses	3 Special project costs recovered	4 Total expense	5 Net income (ROE)	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred & financed
1995	15.9	14.6	0.9	15.5	0.4	0.7	97.8	2.4
1996 (Est)	16.9	14.3	1.7	16.0	0.9	0.8	100.7	3.2
1997 (Bud)	16.7	14.4	1.5	15.8	0.9	0.9	100.1	3.8

1. 1995 Performance

The book-entry securities service recovered 97.8 percent of total expenses in 1995, including automation consolidation special project costs budgeted for recovery and targeted ROE. Origination volume declined 0.3 percent from the 1994 level, compared to a budgeted increase of 3.1 percent. Total costs were over budget due to higher-than-expected data communication costs as a result of increased circuit expenses and lower-than-expected savings from reductions in local data processing operations.

2. 1996 Performance

Through August 1996, the book-entry securities service recovered 100.6 percent of total expenses, including automation consolidation special project costs and targeted ROE. For the full-year 1996, the Reserve Banks estimate that revenues will recover 100.7 percent of total costs compared to a budgeted recovery rate of 100.0 percent. Total revenue is expected to be $1.1 million higher than budget due primarily to higher-than-anticipated growth in on-line origination volume. Volume in 1996 is estimated to grow 9.7 percent, compared to a budgeted decline of 0.4 percent. This unexpected growth partially reflects the one-time movement of securities associated with mergers and higher-than-expected mortgage-backed securities activity.

3. 1997 Issues

The Reserve Banks expect book-entry securities transfer origination volume to decline 1.3 percent in 1997 from the 1996 estimated level. Participants Trust Company (PTC) expects to expand its mortgage-backed securities business by mid-1997 to include Fedwire-eligible securities issued by the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association. In addition, Reserve Banks may face potential volume reductions resulting from bank mergers and consolidations as interstate branch banking takes effect in 1997. The Board believes that there is some risk in achieving the volume levels projected by the Reserve Banks because of uncertainties regarding the extent to which Reserve Banks' mortgage-backed securities transfer volume will move to PTC's new service.

4. 1997 Fees

The Reserve Banks will maintain 1997 book-entry securities fees at the 1996 level. The Reserve Banks project that the book-entry securities service will recover 100.1 percent of costs, including targeted ROE and $1.5 million in automation consolidation special project costs.

F. Electronic Connections

The Reserve Banks charge fees for the electronic connections used by depository institutions to access priced services and allocate the cost and revenue associated with electronic access to the various priced services. The Reserve Banks will retain the current monthly fees for electronic access for all connection types in 1997 without modification but increase the fees for installation and training.

Currently, the Reserve Banks assess an installation and training fee of $300 for new Fedline customers and a $300 fee for the installation of new computer-interface connections. These fees have not changed since 1986. The current fees assessed for customer training and installation do not reflect fully the costs of these activities, particularly for computer-interface customers.

In 1997, the Reserve Banks will charge separate fees for installation and training activities. Compared to the current combined installation and training fee of $300, the Reserve Banks will assess a fee of $150 for the training of new Fedline customers and a fee of $300 for Fedline installations; the $150 fee for retraining is unchanged. In addition, the Reserve Banks will increase the one-time computer-interface installation fee from $300 to $800.

G. Noncash Collection

Table 8 presents the actual 1995, estimated 1996, and projected 1997 cost recovery performance for the noncash collection service.

[11] The Reserve Banks provide securities transfer services for securities issued by the U.S. Treasury, federal government agencies, government sponsored enterprises, and certain international institutions. The priced component of this service, reflected in this memorandum, consists of the revenues, expenses, and volumes associated with the transfer of all non-Treasury securities. For Treasury securities, the Reserve Banks act as fiscal agents and the Treasury Department assesses fees for those transfer services.

TABLE 8.—NONCASH COLLECTION PRO FORMA COST AND REVENUE PERFORMANCE

[$ millions]

Year	1 Revenue	2 Operating costs & imputed expenses	3 Special project costs recovered	4 Total expense [2+3]	5 Net income (ROE) [1–4]	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred & financed
1995	4.0	4.5	0.0	4.5	(0.5)	0.2	84.7	0.3
1996 (Est)	5.6	5.2	0.0	5.2	0.4	0.2	103.0	0.3
1997 (Bud)	4.5	3.8	0.3	4.1	0.3	0.2	102.8	0.0

1. 1995 Performance

The noncash collection service recovered 84.7 percent of total expenses, including targeted ROE, in 1995. Volume increased 23.2 percent compared to an original budgeted growth rate of 16.6 percent. The cost recovery shortfall was attributed to transition costs associated with consolidation of the Federal Reserve's noncash collection service at two processing sites—the Cleveland Reserve Bank and the Jacksonville Branch of the Federal Reserve Bank of Atlanta.

2. 1996 Performance

Through August 1996, the noncash collection service recovered 103.3 percent of total expenses, including targeted ROE. For the year, Reserve Banks now estimate that the noncash collection service will recover 103.0 percent of total expenses, including targeted ROE, compared with the targeted full-year recovery rate of 100.0 percent. Noncash collection volume is expected to continue its long-term contraction.[12] The Reserve Banks estimate that 1996 volume will be less than 24 percent of the peak volume processed in 1985. Due to this declining demand, most national providers have withdrawn from providing noncash collection services. As a result, the Reserve Banks estimate that volume will increase 31.8 percent in 1996, compared to the budgeted increase of 22.5 percent. The combined effect of higher than budgeted volume, fee increases, and cost containment efforts account for the better-than-anticipated cost recovery.

3. 1997 Issues

The Depository Trust Company (DTC) has recently entered the noncash collection business. The Reserve Banks believe that DTC's entrance into this service will not materially affect the Reserve Banks' 1997 noncash volume, since DTC's noncash collection service is limited to its participants. For 1997, the Reserve Banks project a 19.6 percent volume decline from the 1996 estimated volume.

4. 1997 Fees

The current fees will be retained in 1997. At these fee levels, the Reserve Banks project a cost recovery of 102.8 percent for 1997.

H. Special Cash Services

Priced special cash services represent a very small portion (approximately 2 percent) of overall cash services provided by the Reserve Banks to depository institutions. Special cash services include cash transportation, coin wrapping, nonstandard packaging of currency orders and deposits, and nonstandard frequency of access to cash services.

Table 9 presents the actual 1995, estimated 1996, and projected 1997 cost recovery performance for special cash services.

TABLE 9.—CASH PRO FORMA COST AND REVENUE PERFORMANCE

[$ millions]

Year	1 Revenue	2 Operating costs & imputed expenses	3 Special project costs recovered	4 Total expense [2+3]	5 Net income (ROE) [1–4]	6 Target ROE	7 Recovery rate after target ROE (percent) [1/(4+6)]	8 Special project costs deferred & financed
1995	5.2	5.2	0.0	5.2	0.0	0.1	97.7	0.0
1996 (Est)	5.7	5.7	0.0	5.7	0.0	0.2	96.9	0.0
1997 (Bud)	5.5	5.2	0.0	5.2	0.4	0.3	102.1	0.0

1. 1995 Performance

The special cash services recovered 97.7 percent of total expenses, including targeted ROE, in 1995.

2. 1996 Performance

Through August 1996, the special cash services recovered 98.1 percent of total expenses, including targeted ROE. For full-year 1996, the Reserve Banks estimate that special cash services will recover 96.9 percent of total expenses, compared to a targeted recovery rate of 102.2 percent. Costs were higher than budgeted and priced volumes were lower than budgeted in certain offices.

In March 1996, the Director of the Board's Division of Reserve Bank Operations and Payment Systems, under delegated authority from the Board, approved a proposal from the Federal Reserve Bank of San Francisco to charge fees for access to cash services beyond the basic service level.[13] Estimated

[12] The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) imposed a tax disadvantage to the holding of bearer securities, which has resulted in the virtual elimination of new issues. Following the enactment of TEFRA, many bearer municipal securities were ''immobilized'' in depositories, such as DTC, further reducing the demand for noncash collection services.

[13] In April 1996, the Board approved a new cash access policy for the Federal Reserve Banks that becomes effective on May 1, 1998. The policy provides for a base level of free currency access to all depository institutions, but restricts the number of offices served and the frequency of access. Depository institutions that meet minimum volume

revenues are lower than budgeted for 1996 because of lower-than-anticipated volume levels in the San Francisco District.

3. 1997 Fees

For 1997, the Reserve Banks project that special cash services will recover 102.1 percent of costs, including targeted ROE. Several Reserve Banks will increase fees for wrapped coin.

III. Competitive Impact Analysis

All operational and legal changes considered by the Board that have a substantial effect on payment system participants are subject to the competitive impact analysis described in the March 1990 policy statement ''The Federal Reserve in the Payments System.'' In this analysis, the Board assesses whether the proposed change would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints or due to a dominant market position of the Federal Reserve deriving from such legal differences.

The Board believes that the recommended price and service level changes will not have a direct and material adverse effect on the ability of other service providers to compete with the Reserve Banks in providing similar services. The 1997 fees proposed by the Reserve Banks result in a projected return on equity that meets the targeted return on equity, based on the 50 bank holding company model. Over the long term, the Reserve Banks have recovered their total costs of providing priced services, including imputed costs and targeted return on equity. Other service providers have pricing flexibility that is equal to, or greater than, that used by the Reserve Banks.

TABLE A–1—COMPARISON OF PRO FORMA BALANCE SHEETS FOR FEDERAL RESERVE PRICED SERVICES

[Millions of dollars—average for year]

	1997	1996
Short-term assets:		
Imputed reserve requirement on clearing balances	$545.7	409.6
Investment in marketable securities	4,911.3	3,686.7
Receivables[1]	64.3	64.4
Materials and supplies[1]	11.6	8.6
Suspense & Difference[1]	0.0	0.0
Prepaid expenses[1]	14.6	13.9
Items in process of collection	2,548.2	2,413.2
Total short-term assets	8,095.7	6,596.4
Long-term assets:		
Premises[1 2]	348.0	346.4
Furniture and equipment[1]	167.0	189.4
Leasehold improvements and long-term prepayments[1]	18.0	14.6
Capital leases	0.7	2.3
Total long-term assets	533.7	552.7
Total assets	8,629.4	7,149.1
Short-term liabilities:		
Clearing balances and balances arising from early credit of uncollected items	5,457.0	4,096.3
Deferred credit items	2,548.2	2,413.2
Short-term debt[3]	90.5	86.8
Total short-term liabilities	8,095.7	6,596.3
Long-term liabilities:		
Obligations under capital leases	0.7	2.3
Long-term debt[3]	180.5	182.7
Total long-term liabilities	181.2	185.0
Total liabilities	8,276.9	6,781.3
Equity[3]	352.5	367.8
Total liabilities and equity	8,629.4	7,149.1

[1] Financed through PSAF; other assets are self-financing.
[2] Includes allocations of Board of Governors' assets to priced services of $0.5 million for 1997 and $0.5 million for 1996.
[3] Imputed figures represent the source of financing for certain priced services assets.
Note: Details may not add to totals due to rounding.

thresholds will be able to obtain more frequent free access. Additional access, beyond the free level, will be priced.

[1] The Dockets Management Branch used the letter ''G'' to refer to the Government exhibits by the participants.

Table A–2—Derivation of the 1997 PSAF

[Millions of dollars]

A. Assets to be Financed: [1]	
Short-term	$90.5
Long-term [2]	533.0
Total	$623.5
B. Weighted Average Cost:	
1. Capital Structure: [3]	
Short-term Debt	14.5%
Long-term Debt	28.9%
Equity	56.5%
2. Financing Rates/Costs: [3]	
Short-term Debt	5.2%
Long-term Debt	7.1%
Pre-tax Equity [4]	19.1%
3. Elements of Capital Costs:	
Short-term Debt	$90.5×5.2%=$4.7
Long-term Debt	180.5×7.1%=12.8
Equity	352.5×19.1%=67.5
Total	85.0
C. Other Required PSAF Recoveries:	
Sales Taxes	$11.6
Federal Deposit Insurance Assessment	2.0
Board of Governors Expenses	2.9
Total	$16.5
D. Total PSAF Recoveries	$101.5
As a percent of capital	16.3%
As a percent of expenses [5]	16.6%

[1] Priced service asset base is based on the direct determination of assets method.
[2] Consists of total long-term assets, including the priced portion of FRAS assets, less self financing capital leases.
[3] All short-term assets are assumed to be financed by short-term debt. Of the total long-term assets, 33 percent are assumed to be financed by long-term debt and 67 percent by equity.
[4] The pre-tax rate of return on equity is based on the average after-tax rate of return on equity, adjusted by the effective tax rate to yield the pre-tax rate of return on equity for each bank holding company for each year. These data are then averaged over five years to yield the pre-tax return on equity for use in the PSAF.
[5] Systemwide 1997 budgeted priced service expenses less shipping are $613.1 million.

TABLE A–3.—COMPARISON BETWEEN 1997 AND 1996 PSAF COMPONENTS

	1997	1996
A. Assets to be Financed (millions of dollars):		
Short-term	$90.5	$86.9
Long-term	533.0	550.4
Total	$623.5	$637.3
B. Cost of Capital:		
Short-term Debt Rate	5.2%	3.9%
Long-term Debt Rate	7.1%	7.6%
Pre-tax Return on Equity	19.1%	14.2%
Weighted Average Long-term Cost of Capital	15.1%	12.0%
C. Tax Rate	32.1%	29.9%
D. Capital Structure:		
Short-term Debt	14.5%	13.6%
Long-term Debt	29.0%	28.7%
Equity	56.5%	57.7%
E. Other Required PSAF Recoveries (millions of dollars):		
Sales Taxes	$11.6	$11.3
Federal Deposit Insurance Assessment	2.0	2.2
Board of Governors Expenses	2.9	2.8
F. Total PSAF:		
Required Recovery	$101.5	$85.8
As Percent of Capital	16.3%	13.5%
As Percent of Expenses	16.6%	14.1%

TABLE A–4.—COMPUTATION OF CAPITAL ADEQUACY FOR FEDERAL RESERVE PRICED SERVICES

[Millions of dollars]

	Assets	Risk weight	Weighted assets
Imputed reserve requirement on clearing balances	$545.7	0.0	$0.0
Investment in marketable securities	4,911.3	0.0	0.0
Receivables	64.3	0.2	12.9
Materials and supplies	11.6	1.0	11.6

TABLE A–4.—COMPUTATION OF CAPITAL ADEQUACY FOR FEDERAL RESERVE PRICED SERVICES—Continued

[Millions of dollars]

	Assets	Risk weight	Weighted assets
Suspense & Difference	0.0	0.2	0.0
Prepaid expenses	14.6	1.0	14.6
Items in process of collection	2,548.2	0.2	509.6
Premises	348.0	1.0	348.0
Furniture and equipment	167.0	1.0	167.0
Leases & long-term prepayments	18.7	1.0	18.7
Total	$8,629.5	.....	1,082.4
Imputed Equity for 1996	$352.5	.....	.....
Capital to Risk-Weighted Assets (percent)	32.6	.....	.....
Capital to Total Assets (percent)	4.1	.....	.....

By order of the Board of Governors of the Federal Reserve System.

Dated: November 26, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–30705 Filed 12–2–96; 8:45 am]

BILLING CODE 6210–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Monday, December 9, 1996.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: November 29, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–30934 Filed 11–29–96; 4:03 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Case Plan, Sections 422, 471(a)(16), 475(1) and 475(5)(A) of the Social Security Act Child Care and Development Block Grant Reporting Requirements.

OMB No.: 0980–0140.

Description: Under section 471(a)(16) of title IV–E of the Social Security Act, in order for a State to be eligible for payments they must have an approved State plan which provides for the development of a case plan (as defined in section 475(1)) for each child receiving foster care maintenance payments and provides a case review system which meets the requirements in section 475(5)(B). Through these requirements the State also complies with title IV–B, section 422(b)(9) (as of 4/1/96) which assures certain protection for children in foster care.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case plan	445,000	1	4	1,780,000

Estimated Total Annual Burden Hours: 1,780,000.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 25, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–30657 Filed 12–2–96; 8:45 am]

BILLING CODE 4184–01–M

Submission for OMB Review; Comment Request

Title: Family Preservation and Family Support (FP/FS) Service Implementation Study—Community Level Data Collection.

OMB No.: New request.

Description: The Omnibus Budget Reconciliation Act of 1993 (OBRA 93) established title IV–B, subpart 2 of the Social Security Act (42 U.S.C. 62–628) to provide funds to states for the development of family preservation and family support programs and services. Subpart 2, Section 435 of OBRA 93 requires the Secretary of HHS to evaluate the effectiveness of programs carried out under the legislation. This data collection is being conducted to help meet this requirement and to implement reauthorization of the legislation in 1999.

Data collection will ask local child welfare agencies and other community service providers and agencies involved in planning and implementation of title IV–B subpart 2 to provide information on the programs and services funded, populations targeted, reform efforts initiated, and the coordination of new or expanded programs with the child welfare system and other existing providers. Both qualitative and quantitative analyses will be completed to highlight the process states employ to implement the legislation, coordinate with other funding sources, develop new programs, and improve service delivery systems. The analysis of this information will be used to provide feedback to ACF necessary to determine the need for future policy guidance and refine the nature and scope of technical assistance. The information will also provide direct feedback to states and communities concerning successful implementation strategies.

Respondents: State, Local or Tribal Govt., and Not-for-profit institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Welfare	20	1	1.5	30
Family Preservation	20	1	1.0	20
Family Support	60	1	1.5	90
FP/FS Coordinator	20	1	1.5	30
Oversight Committee/Board Member	60	1	1.0	60

Estimated Total Annual Burden Hours: 230.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 27, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–30774 Filed 12–2–96; 8:45 am]

BILLING CODE 4184–01–M

Senior Executive Service; Performance Review Board Members

Title 5, U.S. Code, Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board members be published in the Federal Register.

The following persons will serve on the Performance Review Board or Panels which oversee the evaluation of performance appraisals of Senior Executive Service members of the Administration for Children and Families:

Diann Dawson

Robert C. Harris

Laurence J. Love

Madeline Mocko

Carol W. Williams

Dated: November 25, 1996.

Olivia A. Golden,

Acting Assistant Secretary for Children and Families.

[FR Doc. 96–30658 Filed 12–2–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0326]

New Monographs and Revisions of Certain Food Chemicals Codex Monographs; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on pending changes to certain Food Chemicals Codex monographs in the fourth edition and on specifications for proposed new monographs. Specifications consisting of new monographs for certain substances used as food ingredients and additions, revisions, and corrections to current monographs are being prepared by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee). This material will be presented in the next publication of the Food Chemicals Codex (the first supplement to the fourth edition), scheduled for publication in late summer 1997.

DATES: Written comments by February 18, 1997. (The committee advises that comments received after this date may not be considered for the first

supplement to the fourth edition. Comments received too late for consideration for the first supplement will be considered for later supplements.)

ADDRESSES: Submit written comments and supporting data and documentation to the NAS/IOM Committee on Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the new monographs and proposed revisions to current monographs may be obtained upon written request from NAS (address above) or from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests for copies should specify the monographs desired by name. New and revised monographs may also be obtained through the Internet at http://www2.nas.edu/codex.

FOR FURTHER INFORMATION CONTACT:

Fatima N. Johnson, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or

Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS–247), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

SUPPLEMENTARY INFORMATION: By contract with NAS/IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the Federal Register. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the Federal Register of May 31, 1995 (60 FR 28413) , FDA last announced that the committee was considering an additional monograph and a number of monograph revisions for inclusion in the fourth edition of the Food Chemicals Codex. The fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in March 1996. It is now available for sale from NAP (1–800–624–6242; 202–334–3313; FAX 202–334–2451; Internet http://www.nap.edu) 2101 Constitution Ave. NW., Lockbox 285, Washington, DC 20055.

FDA now gives notice that the committee is soliciting comments and information on additional proposed new monographs and proposed changes to certain current monographs. These new monographs and changes will be published in the first supplement to the fourth edition of the Food Chemicals Codex, which is scheduled for publication in late summer, 1997. Copies of the proposed new monographs and revisions to current monographs may be obtained upon written request from NAS at the address listed above or through the internet at http://www2.nas.edu/codex.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs or monograph revisions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the Federal Register.

The committee invites comments and suggestions by all interested parties on specifications to be included in the proposed new monographs (12) and revisions of current monographs (22) that follow:

I. Proposed New Monographs

Beta-Cyclodextrin
Calcium Lignosulfonate
Dimethyl Dicarbonate
Glyceryl Palmitostearate
4-Hexylresorcinol
Sodium Lignosulfonate
Sucrose Fatty Acid Esters
Sugar Beet Fiber
Reduced Lactose Whey
Reduced Minerals Whey
Whey Protein Concentrate
Autolyzed Yeast

II. Current Monographs to Which the Committee Proposes to Make Revisions

Aspartame (delete transmittance test)
Calcium Phosphate, Dibasic (decrease lead limit)
Calcium Phosphate, Monobasic (decrease lead limit)
Calcium Phosphate, Tribasic (decrease lead limit)
Calcium Silicate (revise fluoride test)
Carbon Dioxide (combine nitric oxide and nitrogen dioxide limits, and revise test)
Dextrin (add sulfur dioxide test)
Dioctyl Sodium Sulfosuccinate (revise identification test)
Enzyme-Modified Fats (modify enzyme-modified milkfat monograph)
L-Glutamic Acid (revise identification test B)
Konjac Flour (revise identification test B)
Magnesium Phosphate, Dibasic (decrease loss on ignition limits)
Niacin (revise identification tests)
Niacinamide (revise identification tests, assay)
Pectins (revise identification tests)
Potassium Phosphate, Dibasic (decrease lead limit)
Potassium Phosphate, Monobasic (decrease lead limit)
Sodium Acid Pyrophosphate (revise assay limit)
Sodium Carboxymethylcellulose (change primary name to *Cellulose Gel*)
Sodium Tripolyphosphate (reduce lead limit)
Spice Oleoresins (add oleoresin rosemary)
Whey

Interested persons may, on or before February 18, 1997, submit to NAS written comments regarding the monographs listed in this notice. Timely submission will ensure that comments are considered for the first supplement to the Fourth Edition of the Food Chemicals Codex. Comments received after this date may not be considered for the first supplement, but will be considered for subsequent supplements. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs listed in this notice are to be submitted to NAS (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this Federal Register notice. NAS will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 14, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–30727 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 84N–0168]

Cyclospasmol®; Final Decision on Proposed Withdrawal of Approval of New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Commissioner of Food and Drugs (the Commissioner) is issuing his Final Decision on the proposal to withdraw approval of the new drug application (NDA) for the human drug product Cyclospasmol® (cyclandelate) (NDA 11–544). This drug is labeled for use in two indications: specifically, as a treatment for intermittent claudication caused by arteriosclerosis obliterans and as a treatment for cognitive dysfunction in patients suffering from senile dementia of the multiinfarct or Alzheimer's type. The Commissioner has determined that Cyclospasmol® has not been shown to be effective for such uses, and the Commissioner hereby withdraws approval for this drug. The Commissioner's Decision sustains the Initial Decision of the Administrative Law Judge (ALJ), who found that Cyclospasmol® had not been shown by sufficient evidence of adequate and well-controlled studies to be effective for its intended uses.

EFFECTIVE DATE: January 2, 1997.

ADDRESSES: The transcript of the hearing, evidence submitted, and all other documents cited in this decision may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Drive, rm. 1–23, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The purpose of this proceeding has been to determine whether FDA should withdraw approval of the NDA for the human drug product Cyclospasmol® (cyclandelate). This drug is being offered for use in two indications, specifically: (1) As a treatment for intermittent claudication caused by arteriosclerosis obliterans (AHP Exceptions at 14; AHP Post-Hearing Brief at (1), and (2) as a treatment for cognitive dysfunction in patients suffering from senile dementia of the multiinfarct or Alzheimer's type. (AHP Exceptions at 111; AHP Post-Hearing Brief at 1.)

Under § 12.130 (21 CFR 12.130), the Commissioner makes the following decision adjudicating the significant issues raised by the parties following the administrative hearing. The effect of this decision is that this drug may no longer be marketed in the United States.

Because the Commissioner's discussion of the issues is necessarily detailed, an outline of this discussion is being given for the reader's convenience:

I. The Commissioner's Final Decision

A. Background

Cyclospasmol® is a drug consisting of 200 milligrams (mg) of cyclandelate. (G–33.2 at 7.)[1] The NDA for Cyclospasmol® (NDA 11–544) was approved at a time when the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et. seq.*) (the act) required only proof of safety. In 1962, the act was amended by the Drug Amendments Act of 1962 (Pub. L. 87–781) to provide that drugs could no longer be approved unless both safety and efficacy had been proved.

The act, as amended, also required FDA to evaluate drugs approved before 1962 to determine whether such drugs were effective and to withdraw approval for any NDA where ''substantial evidence'' of the drug's effectiveness was lacking. (Section 505(e)(3) of the act (21 U.S.C. 355(e)(3)).) FDA's review of these pre-1962 drugs for effectiveness is known as the Drug Efficacy Study Implementation (DESI) program. The act placed the burden of coming forward with evidence of effectiveness on the manufacturer of the drug. (*Weinberger* v. *Hynson, Westcott and Dunning,* 412 U.S. 609, 617 (1973), citing 21 U.S.C. 355(e)(3).)

The Commissioner announced in a notice published in the Federal Register of July 20, 1971 (36 FR 13347), that he had evaluated a report received from the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group pertaining to certain peripheral vasodilators for oral use, including Cyclospasmol® Capsules and Tablets. Under the NAS/NRC report, the Commissioner classified Cyclospasmol® as possibly effective for its labeled indications, except for those claims specifically found in the notice to lack substantial evidence of effectiveness.

In a notice published in the Federal Register of December 14, 1972 (37 FR 26623), the FDA announced that it would permit Cyclospasmol® capsules and tablets, as well as other peripheral vasodilators, to remain on the market beyond the time limits prescribed for implementation of the DESI program. In a subsequent notice published in the Federal Register of July 11, 1973 (38 FR 18477), FDA required that by September 10, 1973, persons interested in conducting clinical studies to determine the effectiveness of peripheral vasodilators to submit protocols and provide the agency with notice of the date when such studies were expected to begin.

On June 20, 1978, the manufacturer of Cyclospasmol®, Ives Laboratories, a wholly owned subsidiary of American Home Products (hereinafter referred to as ''AHP''), submitted to FDA's Bureau of Drugs (currently the Center for Drug Evaluation and Research (hereinafter referred to as ''the Center''), a status report of five completed studies for peripheral vascular disease and five completed studies for cerebral vascular disease studies. These studies were reviewed by the Center and found not to provide substantial evidence of adequate and well-controlled studies indicating the effectiveness of Cyclospasmol® for its labeled indications. In two subsequent notices published in the Federal Register of May 25, 1979 (44 FR 30436; 44 FR 30443), FDA proposed to withdraw approval for Cyclospasmol®'s NDA and offered an opportunity for a hearing on the proposed withdrawal. Ives Laboratories (hereinafter referred to as ''AHP'') was also given until May 26, 1980, to complete any studies which were still in progress.

On June 25, 1979, AHP filed a request for a hearing, and this request was granted by the Commissioner on October 18, 1984 (49 FR 40972). Under

[1] The Dockets Management Branch used the letter ''G'' to refer to the Government exhibits by the participants.

21 CFR 12.45, both the Center and AHP filed notices of participation. A prehearing conference was held on January 15, 1985. Following the submission of written testimony and documentary evidence, a hearing was held before ALJ Daniel J. Davidson beginning on June 18, 1985, and ending on June 27, 1985.

Subsequently, on September 25, 1986, Judge Davidson issued his decision, in which he found that the efficacy of Cyclospasmol® had not been proved by substantial evidence of adequate and well-controlled clinical trials, and concluded that the approval of NDA 11–544 should be withdrawn. Both AHP and the Center filed exceptions to various points in Judge Davidson's decision and appealed to the Commissioner, under 21 CFR 12.125.

B. The Legal Standard

I am issuing this Final Decision under § 12.130. In taking this action, I have all the powers I would have had in making the Initial Decision. (§ 12.130(a); see also Commissioner's Decision on Polychlorinated Biphenyls (49 FR 21514 at 21519, May 22, 1984).) Further, under § 5.10 (21 CFR 5.10(a)(1)), I have been delegated the authority by the Secretary of the Department of Health and Human Services ''to determine, after giving full consideration to all of the evidence that has been submitted, including expert opinions, if the (evidence) meet(s) the regulatory criteria and show(s) effectiveness.'' (*Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147, 154 (3d Cir. 1986).)

In the present case, I have fully reviewed the complete administrative record, including: (1) The transcript of the hearing that was held before the ALJ from June 18, to June 27, 1985; (2) the written testimony and documentary evidence submitted by AHP and the Center before, during, and after the Hearing; (3) the exceptions which AHP and the Center filed to the ALJ's Decision; and (4) all briefs filed by AHP and the Center pursuant to this matter. My Decision is based upon a full review of the facts and arguments that appear in the record, and my independent conclusions are based upon that review.

AHP first argues that the ALJ's decision did not meet the minimum standard required by the Administrative Procedure Act and by FDA regulations pertaining to initial decisions following formal adjudicatory proceedings. (AHP Exceptions at 3, citing 5 U.S.C. 557(c) and 21 CFR 12.120(b).) In support of its argument, AHP cites the Administrative Procedure Act for the requirement that all initial decisions shall include a statement of ''findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record * * *.'' (AHP Exceptions at 3, quoting 5 U.S.C. 557(c).) AHP also cites FDA regulations requiring that initial decisions contain findings of fact based upon relevant, material and reliable evidence in the record and also contain ''(a) discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant'' with ''(c)itations to the record supporting the findings and conclusions * * *.'' (AHP Exceptions at 3, quoting 21 CFR 12.120(b).)

AHP argues that the ALJ did not state how he arrived at his findings of fact. (AHP Exceptions at 8.) Ignoring the bulk of the ALJ's decision, AHP refers to the concluding section of the ALJ's decision, which is appropriately entitled ''Conclusions,'' to argue that the ALJ simply announced his findings in one sentence decrees. (AHP Exceptions at 9, citing the ALJ's Initial Decision (I.D.) at 23.)

An identical issue was addressed in the Commissioner's Decision on Lutrexin, wherein the Commissioner stated:

> (The manufacturer) implies that the findings and order are deficient because the numbered findings of fact at the end of the narrative do not contain the evidentiary details that (the manufacturer) feels would justify the judge's ruling. Those details, however, are fully set out in the judge's narrative explanation. Stating, discussing, and resolving factual issues in narrative form rather than in numbered paragraphs is a commonly used format that has been specifically recognized as fulfilling the Administrative Procedure Act requirement of a ''statement of * * * findings and conclusions * * * on all the material issues of fact, law, or discretion. 5 U.S.C. 557(c). *Gilbertville Trucking Co.* v. *United States*, 196 F. Supp. 351 (D. Mass. 1961); *State Corporation Comm.* v. *United States*, 184 F. Supp. 691 (D. Kan. 1959). ''An agency which issues opinions in narrative and expository form may continue to do so without making separate findings of fact and conclusions of law.'' Attorney General's Memorandum on the Administrative Procedure Act 86 (1947). So too may an Administrative Law Judge.

(Commissioner's Decision on Lutrexin, 41 FR 14406 at 14410, April 5, 1976.)

I have reviewed the ALJ's decision in the present matter, and I find that it comports with the previously cited requirements of the Administrative Procedure Act and FDA regulations. As in the Commissioner's decision regarding Lutrexin, I find that the ALJ fully set out the reasons for his decision in the narrative explanation section of the Initial Decision. Therefore, I find no merit in AHP's argument.

AHP further argues that the ALJ erred in concluding that at least two adequate and well-controlled studies are necessary to establish efficacy. (AHP Exceptions at 2 n.1; I.D. at 8.) As with AHP's previous objection, this issue, too, has been settled in previous Commissioner's decisions. In the Commissioner's Decision on Oral Proteolytic Enzymes (OPE), it was held that, except in certain limited cases, a minimum of two adequate and well-controlled studies are required. (Commissioner's Decision on OPE, slip op. at 23, FDA Docket No. 75N–0139 (FDA May 30, 1985), aff'd sub nom. on other grounds *Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147 (3d Cir. 1986).) This requirement arises from the statutory language of the act at 21 U.S.C. 355(d), which mandates the submission of a plural number of adequate and well-controlled investigations. (Commissioner's Decision on OPE, slip op. at 23; Commissioner's Decision on Deprol (58 FR 50929 at 50936, September 29, 1993).)

FDA has permitted exceptions to the requirement for at least two adequate and well-controlled studies in limited circumstances, including: (1) When the disease is very rare and it is extremely difficult to obtain enough subjects for two studies, (2) when the disease process is expensive to study experimentally, (3) when the study conducted is very large and multicentered, and (4) when the disease is rapidly fatal and there is no alternative therapy. (Commissioner's Decision on OPE, slip op. at 24; Commissioner's Decision on Deprol, 58 FR 50929 at 50936.) AHP does not argue that any of these exceptions apply to the present case, nor do I find these exceptions to be applicable. Therefore, I find no merit in AHP's objections to the ALJ's ruling that at least two adequate and well-controlled studies are necessary to demonstrate the efficacy of Cyclospasmol®.

Finally, AHP argues that many sections of the ALJ's Decision paraphrase, or contain recitations of, portions of the post-hearing briefs filed by the Center and AHP. AHP states that, as a result, ''(t)he substantive statements made by the ALJ raise questions as to the ALJ's understanding of the issues.'' (AHP Exceptions at 12.) AHP has not cited, however, any authority which indicates that it is impermissible for an ALJ to paraphrase or recite in his decision statements from the post-hearing briefs. After reviewing the ALJ's Decision, I find that the ALJ fully set out the reasons for the conclusions he reached. Additionally, I find that AHP's claim that ''(t)he ALJ's Decision fails to

meet the requirements of the APA or of FDA's regulations'' (id.) because the ALJ paraphrased or reproduced language which was submitted in the post-hearing briefs is without merit.

Moreover, I have fully reviewed the administrative record, and, as discussed above, have reached independent conclusions from the evidence presented to the agency and to the ALJ. For the following reasons, I find that there is a lack of substantial evidence that Cyclospasmol will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling, and I therefore affirm the Initial Decision of the ALJ.

C. *The Intermittent Claudication Indication*

The labeling for Cyclospasmol previously described its first indication as being for an ''adjunctive therapy in intermittent claudication; arteriosclerosis obliterans; thrombophlebitis (to control associated vasospasm and muscular ischemia); nocturnal leg cramps; (and) Raynaud's phenomenon.'' (G–33.2 at 7; see also A–89 at 2–4; G–57 at 2–4.) However, AHP has modified this proposed indication to limit it to treatment of intermittent claudication caused by arteriosclerosis obliterans. (See AHP Post-Hearing Brief at 1; AHP Exceptions at 14.)

Peripheral vascular disease is a generic name given to diseases that affect the arteries, veins, and lymphatics in the arms and legs. (Coffman, G–58 at 1; Vyden, G–59 at 3.) The most common peripheral vascular disease is arteriosclerosis obliterans, in which a buildup of cholesterol and fatty acids accumulates in the lining of the arteries of the legs. This condition results in a narrowing of the lumens of these vessels, with consequent decreased blood flow to the muscles. (Coffman, G–58 at 2; Vyden, G–59 at 3.)

The first indication for which Cyclospasmol is labeled is as a treatment for intermittent claudication caused by arteriosclerosis obliterans. (AHP Exceptions at 14; AHP Post-Hearing Brief at 1.) Arteriosclerosis obliterans can cause intermittent claudication, which is pain, cramps, fatigue, or weakness in the legs during exercise. (Coffman, G–58 at 1–2.) A patient with intermittent claudication experiences exercise-induced pain in the calf or thigh muscles caused by a lack of oxygen in the blood being supplied to the leg muscles after walking a certain distance. (Reich, Tr. Vol. V at 17; Vyden, G–59 at 3.) Typically, pain is relieved within 1 to 3 minutes after resting. (Reich, Tr. Vol. V at 17; see also Coffman, G–58 at 2 (Dr. Coffman testified that relief should come within 5 to 10 minutes).) If relief takes longer to come, then the problem is not likely to be intermittent claudication. (Reich, Tr. Vol. V at 17.)

AHP submitted two studies—the MDS–96 (Reich) study and the five-center study—in support of the indication for intermittent claudication. Each of these studies will be discussed in turn.

1. The MDS–96 (Reich) Study

The MDS–96 study, also referred to as the Reich study, was conducted by Dr. Theobald Reich as a 12-week, crossover study of 39 patients with arterial insufficiency. The stated purpose of the study was ''(t)o determine the effect of cyclandelate (Cyclospasmol®), in comparison with a placebo, on the clinical course and certain vasomotor reflexes in patients with peripheral vascular disease.'' (G–25.2 at 163.) Each patient was in the study for 12 weeks, assigned to either 6 weeks on the test drug followed by 6 weeks on the placebo, or vice versa. (G–9.1 at 2.) Patients included in the study were to have a diagnosis of peripheral vascular disease, including one or more of the following symptoms: Intermittent claudication, rest pain, cold extremities, or peripheral cyanosis. (G–25.2 at 163.)

The evaluation of the subjects included skin temperature, skin color, pulse, distance walked prior to claudication, and severity of pain at rest. (G–25.2 at 164.) Additionally, skin temperature of the toes and foot, reactive hyperemia time, blanching time on elevation, and rubor time on dependence was also to be measured. (G–25.2 at 164.) The protocol further stated that vasomotor reflexes of the leg and calf blood flow were to be measured at the beginning of the study and at 2-week intervals during the study by means of venous occlusion plethysmography with a mercury-in-rubber strain gauge. (G–25.2 at 164.) Blood flow was to be measured at rest in the recumbent position, and after exercise on a foot pedal ergometer. (G–25.2 at 164.)

Exercise on a foot pedal ergometer was performed by a patient in a supine position, with the patient using his or her foot to repeatedly raise a weight attached to the foot ergometer pedal. (Reich, A–112 at 29; Denton, A–121 at 3–4.) Exercise on the foot pedal ergometer was to be continued until claudication or, if pain did not appear, was to be discontinued after 500 plantar flexions of the foot. (G–25.2 at 164.)

Thirty-nine patients were entered into the study. (Reich, A–112 at 13.) While all 39 patients completed the study, only 32 were found to be suitable for inclusion in the statistical analysis. (G–9.1 at 252.) Seven patients were excluded from analysis for failure to take the required dose during a 2-week interval. (G–9.1 at 252.) The results of the analysis reported a statistically significant difference in favor of Cyclospasmol® on the mean number of foot pounds of work that could be performed on the foot pedal ergometer. (Reich, A–110 at 10.)

The ALJ concluded that the Reich study was not an adequate and well-controlled investigation because: (1) The protocol failed to clearly identify the condition to be studied, (2) patient selection was marred by the lack of an objective test to determine the presence of the disease, and (3) reliance on the foot pedal ergometer to measure patient improvement in walking ability was not shown to be proper. (I.D. at 23.)

a. *Objective of the study*. The ''objective'' section of the Reich study protocol read in its entirety, ''To determine the effect of cyclandelate, in comparison with a placebo, on the clinical course and certain vasomotor reflexes by objective measurement in patients with peripheral vascular disease.'' (G–25.2 at 163.) The ALJ, after reviewing the arguments by both AHP and the Center (see I.D. at 12), ruled, ''Because the objective of the Reich study was to determine the effect of the drug on certain vasomotor reflexes, it failed to clearly identify and isolate the condition to be studied.'' (I.D. at 55.) AHP raises several issues regarding this ruling.

First, AHP argues that the ALJ erred in restricting himself to a reading of the section of the protocol entitled ''Objective'' when the ALJ determined the study's objective. (AHP Exceptions at 25.) AHP argues that under FDA regulations, AHP was not required to have a separate section in its protocol for the objective, and that it was acceptable if the objective of a study could be ascertained from a reading of the complete study protocol. (AHP Exceptions at 26.) AHP also questions what the ALJ meant by finding that the Reich protocol ''failed to clearly identify the condition to be studied.'' (AHP Exceptions at 28, quoting I.D. at 23.) AHP further asks how the ALJ concluded that the sole objective of the Reich study was to determine the effect of the drug on ''certain vasomotor reflexes.'' (AHP Exceptions at 28, quoting I.D. at 55.)

The Center counters by arguing that the vagueness of the objective for the Reich study lies in the absence of a clear statement in the protocol identifying

intermittent claudication as the focus of the study. (Center Response to AHP Exceptions at 7–11.) The Center points to the fact that intermittent claudication was only one of a number of symptoms in the patient selection criteria, and that patients were not required to have intermittent claudication in order to enter the study. (Center Response to AHP Exceptions at 8.) In sum, the Center is arguing that although AHP is now submitting the Reich study as proof of Cyclospasmol®'s efficacy in treating intermittent claudication, the Reich study's protocol was vague in identifying this as the objective of the study. I find the Center's arguments to have merit.

For a study to be considered adequate and well-controlled, FDA regulations require the study to contain ''a clear statement of the objectives of the investigation.'' (§ 314.126(b)(1) (21 CFR 314.126(b)(1)); see also Commissioner's Decision on Cothyrobal (42 FR 28602 at 28613, June 3, 1977).) The reason for requiring a clear statement of objective was aptly summarized by Dr. Marvin Schneiderman, a statistician and one of the witnesses for the Center, who testified, ''Having a vague objective means that you have a free hand to examine any kind of data and decide after the fact what data are important to report in relation to this kind of objective.'' (Schneiderman, G–65 at 5.)

Turning first to that section of the protocol entitled ''Objective,'' I note that the Reich study set out its focus in general terms as being on ''the clinical course and certain vasomotor reflexes * * * in patients with peripheral vascular disease.'' (G–25.2 at 163.) In another section of the protocol, entitled ''Number and Kind of Subjects,'' the protocol stated that it was anticipated that the underlying diagnosis for the patients would be ''atherosclerosis of the arterial vessels of the extremities.'' (G–25.2 at 163.) As described in this section, patients admitted to the study were required to have ''one or more of the following symptoms: intermittent claudication, rest pain, cold extremities, or peripheral cyanosis.'' (G–25.2 at 163.)

While AHP is correct in stating that FDA regulations do not require a section entitled ''objective'' in the protocol, nevertheless, I am not persuaded by AHP's argument because I find the objective of the Reich study to be vague even after having read the entire protocol. As is evident from reading the entire protocol, intermittent claudication was not a necessary requirement for inclusion in the study. I find that the protocol does not clearly identify intermittent claudication as the intended object of the study. A clear statement of objectives is required by the regulations. (§ 314.126(b)(1).) Not finding the objective to be clear in the protocol, I therefore find no error in the ALJ's decision on this point.

Next, AHP argues that the ALJ failed to read the ''Objective'' section of the protocol correctly. (AHP Exceptions at 27.) AHP argues that in the ALJ's opinion, the ALJ incorrectly quoted from the ''Objective'' section of the MDS–96 protocol.

As previously discussed, the ALJ wrote in his opinion that he had found that the objective of the Reich study was ''to determine the effect of cyclandelate on certain vasom(otor) reflexes in patients with peripheral vascular disease as compared to those patients on placebo.'' (I.D. at 12–13.) The verbatim statement of objective in the protocol read, ''To determine the effect of cyclandelate, in comparison with a placebo, on the clinical course and certain vasomotor reflexes by objective measurement in patients with peripheral vascular disease.'' (G–25.2 at 163.) In the ALJ's ruling, the ALJ left out the phrases ''on the clinical course'' and ''by objective measurement,'' which AHP argues contributed to the ALJ's assertedly erroneous conclusion regarding the objective. I find AHP's argument to be without merit. With or without the phrases in question, the identification of the study's objective fails because the purpose of the study is not clear from a reading of the protocol.

AHP also takes exception to the ALJ's decision on the grounds that the ALJ did not expressly state how much weight he gave to the testimony of AHP's witnesses who testified in support of the objective contained in AHP's protocol. (AHP Exceptions at 28.) AHP offers no legal authority as a basis for asserting that the ALJ must expressly assign a weight to the testimony of witnesses, and I find this argument to be without merit. The ALJ is not required to make findings on all the evidence when the findings he has made support his decision. (See *Immigration and Naturalization Serv.* v. *Bagamasbad*, 429 U.S. 24, 25 (1976); *Deep South Broadcasting Co.* v. *FCC*, 278 F.2d 264, 266 (D.C. Cir. 1960); *Community & Johnson Corp.* v. *United States*, 156 F. Supp. 440, 443 (D.N.J. 1957).) If the ALJ identified at least one conclusive deficiency in each of the studies proffered, the ALJ's decision must be upheld. (*American Cyanamid Co.* v. *FDA*, 606 F.2d 1307, 1314 & n.53 (D.C. Cir. 1979); *SmithKline Corp.* v. *FDA*, 587 F.2d 1107, 1120–21 (D.C. Cir. 1978); *Masti-Kure Products, Inc.* v. *Califano*, 587 F.2d 1099, 1104 (D.C. Cir. 1978); *Cooper Laboratories, Inc.* v. *FDA*, 501 F.2d 772, 779–81 (D.C. Cir. 1974).) Also, the ALJ is not required to accept the opinion of expert witnesses, as such testimony is only as strong as the studies on which it is based. (*Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147, 154 (3d Cir. 1986); Commissioner's Decision on OPE, slip op. at 22, citing *Upjohn Co.* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); Commissioner's Decision on Deprol, 58 FR 50929 at 50930.) For these reasons, I find no error in the ALJ's decision on this matter.

AHP also argues that the objective of the MDS–96 protocol is indistinguishable from another protocol which AHP identifies as an ''FDA/Industry protocol.'' (AHP Exceptions at 32–33.) AHP, citing exhibit G–6, argues that document is a protocol drafted by the pharmaceutical industry in conjunction with FDA, and that the protocol used in the MDS–96 study is comparable. (AHP Exceptions at 32–33.) The Center argues that AHP is incorrectly characterizing this document as an ''FDA/Industry protocol,'' and the Center further argues that the document is actually a protocol from another study, the MDS–176 study, performed by Dr. Reich as part of the multicenter Five-center study, the second study submitted by AHP in support of the intermittent claudication indication for Cyclospasmol®. (Center Response to AHP Exceptions at 15.) I find that the Center is correct in its argument.

I therefore conclude that the ALJ was correct in finding that the MDS–96 study did not clearly state its objectives.

b. *Test for presence of the disease.* The ALJ ruled that patient selection in the MDS–96 study was marred because the study lacked an objective test to determine the presence of intermittent claudication. (I.D. at 23, 55.) AHP argues that the ALJ did not express his views as to what he concluded were the shortcomings of evaluating patients for intermittent claudication on the basis of a personal history and a physical examination, the latter which included the palpation of pulses. (AHP Exceptions at 38.) In a related argument, AHP charges that the ALJ did not give his rationale for concluding that some type of objective instrumentation should have been used to make the diagnosis of intermittent claudication. (AHP Exceptions at 40.) I disagree with AHP's characterization of the ALJ's opinion.

It must be noted that the Reich study's protocol did not require the patients to have intermittent claudication as a condition of entering the study. Rather, under the protocol, patients included in the Reich study were to have a diagnosis of peripheral vascular disease, with one or more of the following symptoms:

Intermittent claudication, rest pain, cold extremities, or peripheral cyanosis. (G–25.2 at 163.) Intermittent claudication was mentioned only as one symptom among a number of symptoms of peripheral vascular disease which patients entering the study could have.

I further note that while ''claudication'' was marked on most patient forms as a symptom reported by the patient, intermittent claudication was not listed in the physician's diagnosis for most patients. In fact, only one patient had intermittent claudication marked as a diagnosis. (G–29.1 at 16.) Most other patients had a diagnosis of arteriosclerosis obliterans.

However, even assuming for the moment that intermittent claudication was the physician's diagnosis, my review of the patients' forms nevertheless reveals a number of instances where it is not at all clear that the patient in fact had intermittent claudication. For example, rest pain is an indication that the patient has a condition other than intermittent claudication. (See Reich, Tr. Vol. V at 17, 58 (speaking generally about intermittent claudication).) Dr. Scheiner, an AHP witness, testified that patients with rest pain were excluded from the study (Scheiner, Tr. Vol. V at 14), but this does not appear to be the case. A review of the records reveals that at least four patients had ''rest pain'' checked as a symptom on their case records (G–29.1 at 21, 34, 46, 82), and a fifth patient had a question mark entered into the box for rest pain on the case record. (G–29.1 at 65.) A sixth patient had night cramps in calves listed as a symptom (G–29.1 at 5), which is also distinct from intermittent claudication.

Additionally, another patient was diagnosed as having Raynaud's syndrome, and not intermittent claudication. (G–29.1 at 21.) Also, two patients accepted into the study, Patient Nos. 39 and 62, had ulceration marked as a symptom (G–29.1 at 42; G–29.1 at 75), which in itself can be a cause of pain and which was a basis for exclusion under the protocol. (G–25.2 at 163.) While one of these two patients with ulcerations, Patient No. 39, was excluded at the completion of the study for failure to follow the medication regimen, I note that the existence of this patient's leg ulcerations was not discussed. (G–29.1 at 4.) The other patient with reported leg ulcerations, Patient No. 62, remained in the study.

The problem with the patient histories for the Reich study is that these histories are not well documented. The patient histories do not provide sufficient information to support the diagnosis of intermittent claudication. For example, as previously discussed, although several patients complained of rest pain, these patients were included. Dr. Reich testified that these patients ''may have pains at night, and this is certainly rest pain of sorts but it is not ischemic neuritic rest pain.'' (Reich, Tr. Vol. V at 58.) However, there is nothing in the patient records which reveals how this diagnosis was made. The patient records do not elaborate on the type of rest pain which the patients experienced, and so this aspect of the study cannot be reviewed.

Regarding the necessity in a clinical study for documentation supporting a diagnosis, Dr. Lipicky, a witness for the Center, testified:

> The protocol did not specify the diagnostic aspects of the disease. Ordinarily, if one is doing a specific hypothesis testing protocol, the diagnostic criteria would be explicitly laid out. * * * * Such specificity was lacking from the protocol under question. From an overall point of view, *the inclusion of patients was entirely dependent upon the clinical judgment and the clinical opinion of the investigator. No documentation of the validity of that opinion was made available.* This is not acceptable.

(Lipicky, G–61 at 6 (emphasis added).)

I find that the reliability of the diagnosis of intermittent claudication for the patients in the Reich study was properly called into question, and that the ALJ was correct when he ruled that ''(t)he method of patient selection failed to limit entry into the study to patients with intermittent claudication. This could easily have been rectified with the use of an objective test to determine the presence of the condition under review.'' (I.D. at 55.)

Additionally, further tests were needed to confirm the diagnosis of intermittent claudication because there are other conditions which may present as intermittent claudication arising from arteriosclerosis obliterans, but in actuality be another disease or condition. Regarding this point, Dr. John Vyden, a witness for the Center, testified:

> Over half of the patients that I have seen in my professional career, which amounts to thousands of patients sent to me for investigation of intermittent claudication, do not in fact have intermittent claudication. *The commonest cause of full leg pain is, in fact, degenerative joint disease of the (lumbar) spine and sciatic nerve radiation.*

(Vyden, G–59 at 7 (emphasis added).)

Specifically with regard to the Reich study, Dr. Vyden testified:

> A major problem with this study is that there is no evidence that these people really suffered from intermittent claudication. By this I mean that they should have been tested by the technique named oscillometry to insure that, in fact, they did have narrowing of the arteries in the legs. The feeling of pulses is not an adequate substitute because it is misleading. One must actually examine by oscillometry the status of the arteries in the thighs and legs to see whether in fact there is arterial disease in the person or not.

(Vyden, G–59 at 6–7.)

AHP argues that Dr. Vyden's testimony should not be credited because oscillometry, the type of instrument which was identified by Dr. Vyden as an objective measure of intermittent claudication, is an outmoded technique. AHP's arguments do not change my ruling.

Firstly, AHP's argument fails to address the main point of Dr. Vyden's testimony, i.e., that a common cause of full leg pain is degenerative joint disease of the lumbar spine and sciatic nerve radiation. This is a possible confounding factor to the Reich study.

Secondly, Dr. Reichle, a witness for AHP who criticized oscillometry as outmoded, conceded that he, too, had used oscillometry as recently as 1 year before the Reich study was conducted. (Tr. Vol. II at 14.) While oscillometry may have been eclipsed by newer technology, such as the Doppler, I note that this does not diminish Dr. Vyden's main point, i.e., that an objective test was needed to confirm a suspected diagnosis of intermittent claudication.

FDA regulations require adequate assurance that patients have the disease or condition being studied. (§ 314.126(b)(3).) As was ruled in the Commissioner's Decision regarding the drug Cothyrobal, ''Clearly, a study * * * must be conducted in patients who have one of the labeled indications if that study is to be used a proof of effectiveness for those indications.'' (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28610.) Therefore, I find no error in the ALJ's ruling on this basis.

AHP next argues that the ALJ did not consider Dr. Reich's testimony in which he stated that he had tested the MDS–96 study patients with a Doppler instrument even though that was not required by the protocol. (AHP Exceptions at 39–40; Reich, Tr. Vol. V at 61–62.) On this point, Dr. Reich testified:

> Every patient had a Doppler study in the MDS- 96 study, every single one of them. * * * As a matter of fact, you know, in the '70s when this was being done, in the early '70s, the Doppler was just being introduced for this sort of a measurement. I was using the Doppler for at least ten years earlier than that. In the '70s they were coming out with commercial instruments. Now, blood pressure—you know, measuring ankle blood

pressure was just being introduced in clinical medicine and, as I say, the cheap Doppler instruments—the low cost Doppler instruments were being made available and I was doing this just out of curiosity to see how my numbers would stack up with other people's. You know, there was no big clinical mass of data to evaluate the significance of it but I have Doppler measurements on all of my patients, probably going back about 16—

(Question from the Center's Attorney): Did you report the Doppler measurements?

(Answer from Dr. Reich): *No, the protocol didn't call for it—not the protocol but the report sheet didn't have a thing but I have it in my own records.*

(Reich, Tr. Vol. V at 61–62 (emphasis added).)

As is clear from Dr. Reich's testimony, no written reports were submitted to the Center to show what values were obtained with the Doppler and what criteria were used to determine whether the patients had intermittent claudication. FDA regulations require that the report of a study ''provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.'' (§ 314.126(a).) I find that the mere fact that Dr. Reich obtained some Doppler measurements for patients in the study to be of no moment if those measurements were never recorded in the study results, nor submitted to the Center for review, nor were in evidence before the ALJ for his consideration. For this reason, I find no error in the ALJ's decision on this matter.

AHP further argues that the ALJ erred when he considered Dr. Travis V. Winsor's testimony regarding a previous, similar study that Dr. Winsor conducted in 1972. (AHP Exceptions at 41–43.) Specifically, Dr. Winsor testified that in 1972 he conducted a study which required, in addition to the clinical estimation of the patient's condition at baseline, an objective evaluation of the pulse volume by segmental plethysmogram obtained at one wrist and both ankles. (Winsor, Tr. Vol. III at 105.) A segmental plethysmogram was not performed in the MDS–96 study. The ALJ found that the implication was that the MDS–96 study protocol was deficient in not requiring some form of objective evaluation. (I.D. at 15.) AHP challenges this conclusion.

I find no error in the ALJ's reliance on this evidence as one of the factors in his decision. Dr. Winsor's testimony regarding this matter was in evidence (Winsor, Tr. Vol. III at 105), as was a copy of the protocol for that study. (G–25.2 at 176–180.) This evidence was available for the ALJ's review, and I find that his use of it was proper.

Based on my review of the evidence, I find that the ALJ's conclusion is supported by the evidence. The ALJ's conclusion that the MDS–96 study should have included an objective test for the presence of intermittent claudication was correct. Therefore, I find no error in the ALJ's ruling.

c. *Foot pedal ergometer as an evaluative measure.* The ALJ determined that the evidence was insufficient to show that the foot pedal ergometer was a useful measure of Cyclospasmol®'s efficacy in treating intermittent claudication. (I.D. at 18–21, 56.) AHP takes several exceptions to the ALJ's ruling on this matter. (AHP Exceptions at 48–53.) (AHP also disputes the ALJ's findings with regard to the Winsor study, which was a study submitted by AHP to show the correlation between the foot pedal ergometer measurements and treadmill measurements. I will discuss the Winsor study separately in section I.C.1.d. of this document.)

First, to reiterate the specifications of the Reich protocol regarding the foot pedal ergometer, the protocol provided that blood flow was to be measured both with the patient at rest in a recumbent position, and after the patient exercised on a foot pedal ergometer. (G–25.2 at 164.) Exercise on a foot pedal ergometer was performed by the patient in a supine position, with the patient using his or her foot to repeatedly raise a weight attached to a foot pedal. (Reich, A–112 at 29; see also Denton, A–121 at 3–4.) Exercise on the foot pedal ergometer was to be continued until claudication or, if pain did not appear, was to be discontinued after 500 plantar flexions of the foot. (G–25.2 at 164.) The protocol further stated that vasomotor reflexes of the leg and calf blood flow were to be measured at the beginning of the study and at 2-week intervals during the study by means of venous occlusion plethysmography with a mercury-in-rubber strain gauge. (G–25.2 at 164.)

In AHP's first objection on this point, AHP questions ''what the ALJ's basis'' was for ruling that the foot pedal ergometer used in the Reich study was not an accurate predictor of walking ability. (AHP Exceptions at 48.) The basis for the ALJ's decision is set forth in the Initial Decision. More important, however, is the question of whether the evidence was sufficient to support AHP's claim that the foot pedal ergometer was an accurate predictor of walking ability, and it appears that this is the issue which AHP is arguing and which I will address.

In considering this issue, I have reviewed the ALJ's decision, and I find that the ALJ adequately summarized the evidence on both sides of the issue before making his ruling. (I.D. at 18–20.) This evidence included the testimony of Drs. Vyden and Lipicky, witnesses for the Center, who both testified that the foot pedal ergometer was not shown to be an accurate predictor of walking distance. (Vyden, G–59 at 9; Lipicky, Tr. Vol. IV at 60–66.) Specifically, Dr. Vyden testified:

> A foot ergometer, in my judgment, is not a satisfactory testing device (as compared to a treadmill) on whether a drug is effective in treating intermittent claudication. Now the reason for this is that, let us say we have a patient who is 150 pounds. That patient has to walk and support 150 pounds of weight when walking. It is a total bodily exercise. Now, when they are using the ergometer they are, in fact, not measuring the leg muscle when it is supporting the entire body weight. Therefore, the amount of work being done on the ergometer does not reflect whether a patient can walk further since most of their body is not being used in this exercise.

(Vyden, G–59 at 9.)

Similarly, when Dr. Lipicky was asked to comment on the use of the foot pedal ergometer as a measure of efficacy, he testified that while the foot pedal ergometer was a measure of the ability of the muscles to perform certain work, the foot pedal ergometer measurement was different from walking in that the patient using the foot pedal ergometer was not required to support the body's weight while exercising. (Lipicky, G–61 at 9.)

Witnesses for AHP expressed the view that the foot pedal ergometer was a valid indication of efficacy for Cyclospasmol ®. (Reichle, A–110 at 4–5;[2] Winsor, A–111 at 5; Reich, A–112 at 30- 31; Porter, A–109 at 7–8; Scheiner, A–122 at 2–3; Denton, A–121 at 3–4.) However, I note that none of the AHP witnesses can be said to have refuted the basic point of the testimony of the Center's witnesses, that being that work on a foot pedal ergometer is different from walking because walking entails more of the cardiovascular system, in addition to the joints and skeletal system, and requires a person to carry the weight of his or her body while exercising. I note that the testimony given by AHP's witnesses is consistent with the testimony of the Center's witnesses on this point. For example, Dr. Winsor, an AHP witness, testified as follows:

> Ergometry and treadmill testing are different in some respects. Exercising on a

[2] The Dockets Management Branch used the letter ''A'' to refer to the exhibits of Ives Laboratories, a wholly owned subsidiary of American Home Products.

treadmill increases the cardiac output and this increased cardiac output helps the circulation of blood in the leg. Exercising on an ergometer, however, does not have a significant cardiac aspect to it. The ergometer measures the ability of a set of muscles to perform work with a near constant cardiac participation, but exercising on a treadmill involves both cardiac and peripheral circulation.

(Winsor, A–111 at 5.)

Similar testimony was given by Dr. Porter, another AHP witness, who expanded on the differences between the foot pedal ergometer and the treadmill as follows:

The correlation (between the ergometer and the treadmill) will not be one-to-one for two reasons. First, the patient's ability to perform work on a treadmill will vary somewhat from day to day depending on a variety of physical and emotional factors, such as whether the patient got a good night's sleep and whether he is angry or depressed. Second, the ergometer focuses on the capacity of two muscles, the gastrocnemius and the soleus muscles, to perform work. While the treadmill involves principally the use of the gastrocnemius and soleus muscles, it also involves the use of other muscles in the body and of the patient's cardiovascular system. These other muscles and the cardiovascular system may affect a patient's conclusion as to when he feels forced to stop walking on a treadmill.

(Porter, A–110 at 8.)

I find that the difference between the testimony of the Center's witnesses and of AHP's witnesses lies in their disparate views as to whether the limits of the focus of the foot pedal ergometer was a positive factor because it isolated the work of certain muscles, or whether the foot pedal ergometer exercise was so dissimilar from the actual outcome of interest, i.e, walking ability, that the foot pedal ergometer could not be said to be a useful measure of a patient's walking ability.

The ALJ, after reviewing the evidence presented by both parties, ruled:

(T)he suitability of the ergometer as a measurement of walking ability is called into question since a treadmill is more commonly used in studies where the relevant function to be tested is walking. Thus if the ergometer is to be used as a measurement of walking ability, some basis is needed to correlate these factors.

(I.D. at 20.)

I find the ALJ's ruling to be sound. As stated previously in this section, the evidence indicates that exercise on a foot pedal ergometer is different in many respects from walking. Therefore, I find that the evidence offered by AHP, in which witnesses described their personal experiences with ergometers and expressed their own estimations that a foot pedal ergometer was an accurate measure of walking ability, was insufficient to show that the foot pedal ergometer was a useful measure of Cyclospasmol®'s efficacy in treating intermittent claudication, absent other sufficient evidence demonstrating such a correlation. (Again I note that the Winsor study, which was offered by AHP for the purposes of correlating the foot pedal ergometer with walking on a treadmill, will be discussed in a subsequent section of this decision. (See section I.C.1.d. of this document.))

AHP further argues that the ALJ did not consider the views of three AHP witnesses who testified regarding the foot pedal ergometer, Drs. Reichle, Scheiner, and Denton, and that the ALJ mischaracterized the views of three other AHP witnesses, Drs. Porter, Winsor, and Reich. (AHP Exceptions at 49.)

Regarding the testimony of Drs. Reichle, Scheiner, and Denton, I note that the ALJ is not required to make findings on all the evidence when the findings which the ALJ has made support the ALJ's decision. (See *Immigration and Naturalization Serv.* v. *Bagamasbad,* 429 U.S. at 25; *Deep South Broadcasting Co.* v. *FCC,* 278 F.2d at 266; *Community & Johnson Corp.* v. *United States,* 156 F. Supp. at 443.) Also, as has been established in prior cases, the ALJ is not required to accept the opinion of expert witnesses. (*Warner-Lambert Co.* v. *Heckler,* 787 F.2d at 154; Commissioner's Decision on OPE, slip op. at 22; Commissioner's Decision on Deprol, 58 FR 50929 at 50930.) Such testimony is only as strong as the studies upon which it is based. (Commissioner's Decision on OPE, slip op. at 22, citing *Upjohn Co.* v. *Finch,* 422 F.2d 944 (6th Cir. 1970).)

Regarding the testimony of Drs. Porter, Winsor, and Reich, AHP argues that the ALJ mischaracterized their testimony by failing to make it clear that these witnesses testified that they had used ergometry extensively and had testified without qualification that they believed the foot pedal ergometer was a reliable predicator of walking ability. (AHP Exceptions at 50.) I have reviewed the testimony of these witnesses, and I do not find that their testimony changes my ruling regarding the foot pedal ergometer used in the Reich study. As I stated previously, the testimony of AHP's witnesses is consistent with the testimony of the Center's witnesses, in which the latter testified that the foot pedal ergometer exercise was different in several key respects from the exercise of walking. Therefore, I find that the ALJ was correct in ruling that the suitability of the foot pedal ergometer as a measurement of walking ability was not established, and that a correlation between the foot pedal ergometer and walking ability needed to be demonstrated.

AHP also takes exception to the ALJ's decision on the grounds that the ALJ did not expressly state how much weight he gave to the testimony of the Center's witnesses who testified against the foot pedal ergometer as an evaluative measure. (AHP Exceptions at 51.) AHP offers no legal authority as a basis for asserting that the ALJ must expressly assign a weight to the testimony of witnesses, and I find this argument to be without merit. As I stated in a previous paragraph, the ALJ is not required to make findings on all the evidence when the findings which have been made support the decision. (See *Immigration and Naturalization Serv.* v. *Bagamasbad,* 429 U.S. at 25; *Deep South Broadcasting Co.* v. *FCC,* 278 F.2d at 266; *Community & Johnson Corp.* v. *United States,* 156 F. Supp. at 443.)

AHP further avers that the ALJ mischaracterized the Center's position on the use of the foot pedal ergometer when the ALJ wrote, ''However, the Center believes that the ergometer measurement is not an accurate predictor of walking distance since walking is a 'total bodily exercise.' '' (I.D. at 18–19, citation omitted.) I find this objection to be without merit, since the ALJ correctly quoted the testimony of Dr. Vyden, the Center's witness. (Vyden, G–59 at 9.)

For the above reasons, I conclude that the ALJ did not err in his consideration of the testimony of AHP's experts regarding the foot pedal ergometer.

d. *The Winsor study.* The Winsor study was an additional study performed by AHP for the purpose of correlating measurements taken on a foot pedal ergometer with measurements taken on a treadmill. (Winsor, A–111 at 4–6; A–124 at 31–44.) The Winsor study did not have a written protocol. The subsequent report on the study indicated that 13 patients were tested on both a foot pedal ergometer and on a treadmill. (A–124 at 31; AHP Post-Hearing Brief at 21.) It was reported that the two tests were carried out 30 minutes apart. The report stated that patients were randomized with respect to the order of the two tests. (Winsor, A–111 at 7; A–124 at 31.)

Of the 13 patients in the Winsor study, 4 patients were brought back for a second day of tests. One patient, Patient No. 2, was reported to have had the concomitant condition of arthritis in the knee, and it was further reported that at the patient's first test, arthritis affected this patient's performance. For this reason, Dr. Winsor decided that

Patient No. 2's first test results would not be used in the statistical analysis. (A–124 at 31.) Instead, this patient's second day test results on both the ergometer and the treadmill were used in the statistical analysis. (A–124 at 31.)

The other three patients who were tested twice—Patient Nos. 8, 9, and 12—were reported to have had peripheral vascular disease in both legs. For this reason, Dr. Winsor decided to retest these three patients on a second day on both the ergometer and the treadmill, using the other leg on the ergometer. (A–124 at 31.) In the subsequent statistical analysis, results for these three patients were analyzed in three ways. Initially, the first day test results of these patients were used in the analysis. (A–124 at 32.) Next, the results were reanalyzed twice more, once using these patients' lowest reported ergometer test results, and then using these patients' highest reported ergometer test results. (A–124 at 32.) As for the treadmill results, it appears that the treadmill readings taken on the same day as the corresponding ergometer results were used. (A–124 at 32; 36.)

The post-study report stated that there was a ''significant correlation'' between the treadmill distance and ergometer foot-pounds. (A–124 at 32.) The ALJ, describing the Winsor study as hastily organized and conducted, ruled that the study was not adequate to prove that the foot pedal ergometer was a useful measure of the efficacy of Cyclospasmol® for intermittent claudication. (I.D. at 56.) AHP disputes the ALJ's conclusions. (AHP Exceptions at 53–72.)

As one of its objections, AHP asks whether the ALJ gave any weight to the Center's contention that the Winsor study should be disregarded because it was not carried out under a written protocol. (AHP Exceptions at 58–59; see Center Post-Hearing Brief at 28.) While the ALJ did not expressly make a ruling on this point (see I.D. at 19), I find that the fact that the Winsor study lacked a written protocol is a matter properly considered in evaluating and weighing the Winsor study.

The Winsor study was not a study to prove efficacy, and therefore, strictly speaking, was not bound to comply with all of the requirements for an adequate and well-controlled study, such as blinding. In this respect, the Winsor study is comparable to a safety study, which similarly does not necessarily have to satisfy every requirement of an adequate and well-controlled clinical trial. (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28614; Commissioner's Decision on Deprol, 58 FR 50929 at 50942.) Nonetheless, safety studies and, by the same reasoning, supportive studies such as the Winsor study, must be adequately designed so that scientists can draw reasonable conclusions from them. (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28614.) For this reason, all of the factors that are relevant to a determination as to whether an efficacy study is adequate and well-controlled are also relevant in determining whether other supportive studies are adequate for their purposes. (Commissioner's Decision on Deprol, 58 FR 50929 at 50942 n.5.)

One of the most basic requirements for a study is a written protocol. The regulations provide that ''the protocol for the study * * * should describe the study design precisely * * *.'' (§ 314.126 (b)(2).) As is noted in the regulations, this characteristic, along with the other characteristics set forth in this section of the regulations, has been developed over a period of years and is recognized by the scientific community as an essential of an adequate and well-controlled clinical trial. (§ 314.126(a).) The written protocol should have included a summary of the proposed or actual methods of analysis and a description of the method of selection of subjects. (§ 314.126 (b)(1) to (b)(7).) The necessity for a written protocol is clear. It is a key factor in preventing bias, whether intentional or unintentional, from influencing a study's outcome. The problems created by the absence of a written protocol can be seen in the Winsor study. For example, Dr. Winsor retested one of the patients after noting an ''abnormality'' in the patient's first test results, an abnormality said to be attributed to the subject's arthritis. Dr. Winsor also tested three patients in a different manner from the rest, by testing each leg separately on the foot pedal ergometer. (I.D. at 19.) These types of variations in testing among patients raise serious questions of bias, and the questions of bias are only exacerbated by the absence of a written protocol describing the testing protocol.

Also, because of the absence of a written protocol, the basis for patient selection was not set forth in advance of the Winsor study. While the post-study report stated that all patients in the Winsor study had intermittent claudication, the report failed to describe the basis for this diagnosis. AHP argues that it was not necessary to have a written protocol describing the selection criteria since Dr. Winsor was familiar with all of the patients' conditions because he had been the patients' doctor for quite some time. (AHP Exceptions at 65.) The regulations state that the method of selecting subjects for a study should provide adequate assurance that the subjects have the disease or condition being studied. (§ 314.126(b)(3).) I do not find the undocumented, prestudy experience of Dr. Winsor with the study patients to be sufficient evidence of the patients' conditions.

AHP next challenges the ALJ's opinion on the grounds that the ALJ did not state what he understood to be Dr. Lipicky's central criticism of the Winsor study. (AHP Exceptions at 66–67.) AHP further questions whether the ALJ understood the Winsor study, the focus of this argument being whether the ALJ should have given any weight to Dr. Lipicky's testimony in which Dr. Lipicky questioned aspects of the Winsor study. (AHP Exceptions at 70–72.)

Dr. Lipicky testified at some length regarding the Winsor study. One of the aspects of Dr. Lipicky's testimony which AHP is challenging is Dr. Lipicky's review of certain graphs drawn by Dr. Wang, an AHP witness, based on the data points from the Winsor study. (AHP Exceptions at 71; AHP Post-Hearing Brief at 22–24.) As part of its post-study report, AHP submitted several graphs plotting the results of the Winsor study. (A–124 at 38–44.) Of particular focus in the present issue are two graphs plotting treadmill feet versus ergometer foot-pounds.[3] (A–124 at 42–43.) These graphs are of interest because the post-study report stated that there was ''significant correlation between treadmill distance and ergometer ft-lb.'' (A–124 at 32.)

As described in the post-study report, ''Regression of the work performed (was) carried out using linear regression with or without forcing through the origin (i.e. assume that if the ergometer work is zero, the treadmill work should also be zero).'' (A–124 at 32.) In other words, a straight-line graph was plotted which most closely fit the data points, and another straight-line graph was plotted forcing the graph through the origin of the graph. Regarding the former of these two graphs, Dr. Lipicky had testified that the graph ''says that when a patient cannot pump an ergometer that patient can walk 200 ft, which clearly is a nonsensical result. It defies common sense that that would be the case.'' (Lipicky, Tr. Vol. IV at 64.) Regarding the graph forced through the origin, Dr. Lipicky testified, ''most of the data points, (especially) the early ones, are well above that line and a couple of

[3] The other graphs plotted ergometer foot-pounds versus treadmill foot-pounds. (A–124 at 38–41.) There was also a scatter diagram plotting treadmill foot-pounds/minute versus ergometer foot-pounds/minute. (A–124 at 14.)

data points later on lie well below that line—to my eye, not a very good fit at all.'' (Lipicky, Tr. Vol. IV at 64.)

Using the same data points, Dr. Lipicky drew and offered several other possible graphs. (G–67 at 2–4.) Dr. Lipicky cited one of his graphs in particular as fitting the data points best of all. In this graph, the line began at slope, the slope then decreased and at one point flattened out for the later data points. (G–67 at 2–3.)

AHP criticizes Dr. Lipicky's testimony on several grounds. First, AHP argues that Dr. Lipicky is essentially testifying that the Winsor study was deficient because it did not yield a mathematical formula that described the relationship between the foot pedal ergometer measure and the treadmill measure. (AHP Post-Hearing Brief at 22.) AHP argues that Dr. Lipicky's testimony on this point is faulty because he did not disclose why such a mathematical formula would be useful. I disagree with AHP's position.

Dr. Lipicky testified that the issue raised by the results of the Winsor study was what is ''the explicit relationship between the two variables. Given a specific ergometer value, whatever its units, what can one predict would be the walking distance on (the) treadmill in the absence of having measured it?'' (Lipicky, Tr. Vol. IV at 124.) In considering this evidence, it must be kept in mind that the Winsor study was undertaken to supplement the MDS–96 study, since the results of the MDS–96 study were expressed in terms of foot pedal ergometer units, despite the fact that other evidence indicated that the treadmill is more commonly used. For this reason, I find that Dr. Lipicky was correct in noting that it was necessary for the Winsor study to demonstrate the value of the foot pedal ergometer to predict walking distance on a treadmill.

AHP further argues that Dr. Lipicky's testimony should not be credited because the graphs which he submitted, in particular the graph described in the above discussion as flattening-out, reflects only Dr. Lipicky's hypothesis. (AHP Post-Hearing Brief at 22–23.) AHP argues that Dr. Lipicky's testimony fails because Dr. Lipicky offered no physiological or other explanation to explain why his graph of the data points shows that a person might be able to increase his or her performance on the foot pedal ergometer without correspondingly increasing his or her performance on the treadmill. (AHP Post-Hearing Brief at 22–24.)

I find that Dr. Lipicky's testimony indicates that the data may be interpreted in more than one way. Indeed, Dr. Lipicky stated in his testimony that his graphs represented ''an alternate way of looking at the same data and that there's no way from that data to choose between those two interpretations.'' (Lipicky, Tr. Vol. IV at 65; see I.D. at 20.) As Dr. Lipicky noted, while there may be some relationship between the foot pedal ergometer and the treadmill, the crux of the matter at issue lies in defining the relationship between the two. (Lipicky, Tr. Vol. IV at 65, 124.)

Dr. Lipicky offered testimony indicating that the graphs submitted by AHP either did not fit the data results or suggested a result that did not make sense. The graphs submitted by Dr. Lipicky reflected a better fit with the data. Why the Winsor study's data came out as they did was not an issue which Dr. Lipicky was required to explain. While Dr. Lipicky, as a witness for the Center, suggested several possible other graphs, the Center does not have the burden of proof. AHP has the burden of proving the nature of the relationship, if any, between the results on the treadmill and the results on the foot pedal ergometer. The correlation between the two measures needed to be defined, and the burden of proof lay with AHP as proponent for approval of the efficacy of Cyclospasmol®. (*Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 617 (1973), citing 21 U.S.C. 355(e)(3).) Therefore, I find no merit in AHP's argument.

AHP also contends that the ALJ devoted only two sentences of his opinion to the Winsor study. (AHP Exceptions at 71.) As I previously discussed, the ALJ gave adequate reasons why he did not credit the Winsor study. Also, the ALJ devoted several pages of his opinion to a review of the Winsor study. (I.D. at 19–21, 23, 56.) I find that the evidence supports a finding that the ALJ did understand the Winsor study, and I affirm his decision with respect to it.

AHP further argues that the ALJ did not indicate how much weight he gave to the following arguments of the Center: (1) That the Winsor study should be disregarded because it was not carried out pursuant to a written protocol, (2) that the Winsor study should be disregarded because Dr. Winsor undertook the study after he had agreed to be a witness for AHP, (3) that Dr. Winsor retested 4 of the patients, and (4) that although it was reported that the patients in the study had intermittent claudication, there was no objective evidence that the 13 patients in the Winsor study had intermittent claudication. (AHP Exceptions at 58–66; see Center Post-Hearing Brief at 27–30.) There is no rule in law or regulations which requires the ALJ to explicitly assign a weight to the evidence which the ALJ considers. As I previously stated, the ALJ is not required to make findings on all the evidence when the findings which have been made by the ALJ support the decision. (See *Immigration and Naturalization Serv.* v. *Bagamasbad*, 429 U.S. at 25; *Deep South Broadcasting Co.* v. *FCC*, 278 F.2d at 266; *Community & Johnson Corp.* v. *United States*, 156 F. Supp. at 443.)

AHP further questions the ALJ's conclusions that the suitability of the foot pedal ergometer as a measure of walking ability was called into question because the treadmill is more commonly used, and that if the foot pedal ergometer was to be used, some basis was needed to correlate these two measures. (AHP Exceptions at 68–69.) I addressed this issue in section I.C.1.c. of this document, wherein I ruled that it was necessary to correlate the measures taken on the treadmill with measures taken on the foot pedal ergometer because the evidence indicated that the foot pedal ergometer exercise was different in several key respects from the exercise of walking on a treadmill.

In my judgment, the ALJ was correct in concluding that AHP did not prove that the foot pedal ergometer was useful in demonstrating Cyclospasmol's® efficacy in treating intermittent claudication. I find sufficient justification to support the ALJ's rejection of the Winsor study.

e. *Adequacy of the MDS–96 (Reich) study*. In sum, I find that the Reich study was not adequate and well-controlled. In making this determination, I have considered the aggregate effect of the protocol violations. As I previously discussed: (1) The objective of the study was vague and the protocol was not clear in identifying intermittent claudication as the focus; (2) the reliability of the diagnosis of intermittent claudication was properly called into question and an objective test for intermittent claudication should have been included in the study; and (3) the evidence did not establish that the foot pedal ergometer was a suitable measure of walking ability.

Regarding the Winsor study, I find that the ALJ properly concluded that AHP did not prove that the foot pedal ergometer was useful in demonstrating Cyclospasmol's® efficacy in treating intermittent claudication. As detailed above: (1) The Winsor study did not have a written protocol; (2) not all patients in the study were tested in the same manner; (3) the basis for patient selection was not set forth in advance of the study; and (4) the study did not

demonstrate the value of the foot pedal ergometer in predicting walking distance on the treadmill.

2. The Five-Center Study

The five-center study was, as its name indicates, a multicenter study conducted at five sites. The study's stated objective was to ''evaluate the efficacy of Cyclospasmol® versus placebo, as an adjunct to generally accepted therapy, for the amelioration of symptoms (including intermittent claudication) in the lower extremities of patients with chronic occlusive arterial disease (atherosclerosis) who have no manifestations of severe (advanced) disease * * *.'' (G–6 at 3.) Severe disease was defined in the protocol as:

> severe (advanced) chronic occlusive arterial disease as manifested by major trophic changes (e.g., atrophic shiny skin, major nail changes and/or muscle atrophy), ischemic rest pain, ulceration and/or gangrene, marked pallor or rubor with the extremity in the horizontal position. Also those in whom prior arteriography has demonstrated combined aortoiliac and femoropopliteal disease; or popliteal disease involving the trifurcation; or distal arterial (tibial) disease or arteriolar disease such as may be associated with diabetes mellitus.

(G–6 at 5–6.)

The five-center study employed a crossover design. (G–9.1 at 85.) Initially, a 6 to 8 week, single-blinded placebo washout period was used. (G–9.1 at 85.) Patients were then randomly assigned to one of two groups in a double-blinded manner. Group I received a placebo for 12 weeks and then Cyclospasmol® for 12 weeks, with no intervening washout period. Group II underwent the reverse sequence, also with no intervening washout period. (G–9.1 at 85.) One hundred and sixteen patients were enrolled in the study, with 91 completing it. (G–9.1 at 85.) Of those who completed the study, 65 patients were adjudged to be ''acceptable,'' for analysis, i.e., capable of being evaluated. (G–9.1 at 85.)

Statistical analysis of the pooled data from the five centers indicated no statistically significant difference between Cyclospasmol® and placebo. (G–9.1 at 86, 93, 142–46; AHP Exceptions at 80.) The pooled data were then reanalyzed using only the first half of the study (the initial 12 weeks) and the inclusion/exclusion decisions for each patient were reconsidered. (A–108 at 1–11.) Using one-tailed tests of significance, the reanalysis indicated a statistically significant, drug-over-placebo effect. (A–108 at 1–11; AHP Exceptions at 81.)

The ALJ ruled that the five-center study could not be considered adequate and well-controlled, in part because the reanalysis of the initial 12 weeks of the five-center study was performed only after the failure to find a positive drug effect in the initial analysis. (I.D. at 26, 30–31.) AHP has challenged the ALJ's findings on the following matters: (1) The weight to be accorded the reanalysis of data, (2) the inclusion and exclusion of patients, (3) the calculation of treadmill distances, and (4) the inconsistency of results among the five centers in the reanalysis. I address AHP's exceptions below.

a. *Reanalysis of the five-center study.* AHP takes exception to the ALJ's conclusion that no weight should be given to the reanalysis of the data from the five-center study. (AHP Exceptions at 78–88, citing I.D. at 30, 56.) As previously discussed, the five-center study was conducted using a crossover design. After statistical analysis of the study failed to demonstrate a statistically significant difference between drug and placebo (I.D. at 26; G–9.1 at 86), the data were reanalyzed as if the study had been conducted with a parallel design. (A–108 at 1–11.) To do this, the data from the second half of the study—the final 12 weeks—were dropped. (Lipicky, Tr. Vol. IV at 68.) Also, the decisions on inclusions and exclusions of all patients were reexamined. (Issues pertaining to the reexamination of exclusions will be discussed in section I.C.2.b. of this document.) AHP's reasons for electing to perform this type of reanalysis were not communicated to the Center, either orally or in writing. (Lipicky, Tr. Vol. IV at 68.) In the reanalysis, a statistically significant improvement was reported in the Cyclospasmol®-treated group over the placebo group. (A–108 at 3.)

In support of its decision to reanalyze the first 12 weeks of the data as a parallel study, AHP cites to the testimony of Dr. Nathan Mantel, a witness for AHP who was critical of crossover protocols in general. (Mantel, A–127 at 10–12.) In relevant part, Dr. Mantel testified:

> When AHP turned to me for advice with respect to the proper analysis of the five-center study, I voiced my own long-standing criticism of use of a crossover design, albeit this is a design greatly emphasized in standard statistical texts. Biological and medical realities just do not correspond to the simple mathematical model underlying use of the crossover. When a patient receives treatment A, followed in due course by treatment B, the final response observed is not a response to treatment B. Rather, it is a response to the sequence of treatments used, including all lapses of time. Another crossover design example, one not even involving any initial values, is where half the patients get treated on the right side with A, on the left side with B, these being switched for the remaining half of patients. A crossover analysis could be invalid if treatment on one side influenced the response on the other side.

(A–127 at 11.)

AHP further cites the testimony of Dr. Lipicky, a witness for the Center, who testified that crossover studies are often analyzed as parallel studies for the first half of the data, and that he himself had probably spoken in favor of such analyses. (AHP Exceptions at 81, citing Lipicky, Tr. Vol. IV at 92.) It is to be noted, however, that Dr. Lipicky clarified his position in this regard by adding that, while such reanalyses are a ''common practice,'' in his opinion it was very often not an appropriate exercise. (Lipicky, Tr. Vol. IV at 94.) On this point, Dr. Lipicky testified:

> Well, I guess if one is talking about appropriateness, I think that reanalyses are not appropriate very often—commonly done but not appropriate very often; sometimes useful if, indeed, there are particular things that one is trying to get to and if there is an analysis that one can think of doing that, indeed, was not thought of ahead of time and where the major intent of the trial is not singularly or singly dependent upon that analysis.

(Lipicky, Tr. Vol. IV at 94.)

Other testimony on this issue was offered by Dr. Schneiderman, a statistician and witness for the Center, who gave the following testimony:

> And, thus, in a cross-over experiment if a phase or a sequence effect can be shown—a carry-over effect—then it would be inappropriate, I think, to continue the analysis as if there were no carry-over effect because that's one of the conditions, essentially, from which you create a cross-over design. *The original analysis of these data did not show such a * * * carry-over effect and, therefore, quite obviously it was appropriate to have designed the experiment as it was designed and to continue to analyze it as the indication had been for the analysis.* I see no justification really for discarding the cross-over design, which people who knew the biology had designed, and, thus, discarding half the data.

(Schneiderman, Tr. Vol. VII at 5–6 (emphasis added).)

In addressing AHP's argument, I first note that it is a requirement of an adequate and well-controlled study that there be an analysis of the results of the study adequate to assess the effects of the drug. (§ 314.126(b)(7).) Additionally, because faulty analysis can introduce bias, adequate measures must be taken to minimize bias on the part of the analysts of the data. (§ 314.126(b)(5).) Also, the study's protocol should describe the study design precisely, including information on the duration of treatment periods, whether

treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. (§ 314.126(b)(2).) One of the most important reasons for requiring protocol decisions to be made in advance of the clinical investigation is to avoid bias.

As AHP acknowledged in its Post-Hearing Brief, FDA regulations provide that a sponsor may use an analytical method that is not set out in the protocol, but the sponsor should inform FDA as to how it selected that analytical method. (AHP Post-Hearing Brief at 39; § 314.126(b)(1).) AHP did not inform the Center of the reasons for switching from analyzing the entire data as a crossover study to instead analyzing the first half of the study as a parallel study. (Lipicky, Tr. Vol. IV at 68.) The testimony of Dr. Mantel fails as an explanation because Dr. Mantel's reason for objecting to crossover studies—specifically, the failure of patients to return to baseline at the time of crossover (Mantel, A–127 at 10–12)—was not identified as a problem with the five-center study. (See Schneiderman, Tr. Vol. VII at 5–6.) Moreover, AHP's reliance upon Dr. Mantel's broad indictment of all crossover studies is difficult to accept, in view of the fact that the second study submitted by AHP in support of the indication of intermittent claudication for Cyclospasmol®, the MDS–96 study, was a crossover study and was analyzed as such by AHP. (See section I.C.1. of this document.)

The reanalysis of the five-center study was more than a mere mathematical check. It was a reconsideration of the protocol after the clinical trial had been completed. While circumstances can arise that justify analyzing only the first half of a crossover study as a parallel study, such as when a sequence effect occurs, a decision to throw out half of the data cannot be made arbitrarily if a study is to be considered adequate and well-controlled. Where, as in the five-center study, a ''reanalysis'' means that: (1) Initially no statistically significant difference between the drug and the placebo was found, (2) the inclusion and exclusion decisions for each patient were reconsidered, (3) the second half of the crossover trial was dropped, and (4) the first half of the crossover data was reviewed as if the trial had been a parallel trial, then certainly the sponsor should expect that an explanation for these changes would be in order.

AHP further challenges the ALJ's decision on the grounds that the ALJ purportedly took the position that he would not consider a parallel analysis of any study that is designed to gather data on a crossover basis. (AHP Exceptions at 82–83, citing I.D. at 25.) The ALJ did not make such a broad pronouncement. The ALJ rejected AHP's reanalysis because AHP did not provide a ''good reason'' as to why AHP analyzed only the first half of the data collected. (I.D. at 30.)

AHP also argues that the ALJ ignored evidence indicating that the 1985 reanalysis was precisely the type of analysis that the Center itself would have required to establish efficacy. (AHP Exceptions at 84.) By this argument, AHP is apparently referring to the testimony of Dr. Lipicky, a Center witness, who testified that crossover studies are often analyzed as parallel studies, and that he himself had probably spoken in favor of such a procedure. (Lipicky, Tr. Vol. IV at 92.) However, as I noted above, Dr. Lipicky explained his position by adding that while such reanalyses are commonly done in clinical studies, they are very often not appropriate. I find AHP's interpretation of Dr. Lipicky's testimony as a requirement for analysis of all crossover studies as if these were parallel studies to be incorrect. Moreover, I note that another witness for the Center, Dr. Schneiderman, was clearly critical of AHP's reanalysis of this crossover study as a parallel study. (Schneiderman, Tr. Vol. VII at 5–6.) In any event, regardless of any statements by Dr. Lipicky, or any other witnesses for either party, the Commissioner is not required to accept the testimony of expert witnesses but is to make his or her own decision regarding efficacy. (*Warner-Lambert Co.* v. *Heckler,* 787 F.2d at 154; Commissioner's Decision on OPE, slip op. at 22; Commissioner's Decision on Deprol, 58 FR 50929 at 50930.)

AHP additionally argues that the ALJ erred in his understanding of Dr. Schneiderman's testimony. (AHP Exceptions at 84.) AHP alleges that Dr. Schneiderman did not indicate that the parallel analysis was inappropriate, and that the ALJ erred in using Dr. Schneiderman's testimony as part of his rationale for rejecting the reanalysis. I have reviewed Dr. Schneiderman's testimony, and I find that the ALJ was correct in his interpretation. Dr. Schneiderman's testimony could not be more clear on this point, ''I see no justification really for discarding the cross-over design, which people who knew the biology had designed, and, thus, discarding half the data.'' (Schneiderman, Tr. Vol. VII at 5–6.)

AHP further argues that the ALJ should have required the Center to support its criticism of the reanalysis by preparing its own crossover analysis using the values submitted by AHP in its reanalysis. (AHP Exceptions at 86–87.) There is no basis in law for AHP's argument. The burden of proving safety and efficacy lies with the applicant. (*Hynson,* 412 U.S. at 617; 21 U.S.C. 355(e); 21 CFR 12.87(e).) The Center, therefore, was not obligated to perform its own crossover analysis, particularly using the results as they were calculated in the reanalysis in this case.

Notwithstanding my ruling on this issue, I nevertheless note that the Center did perform an analysis using the original crossover data; in this analysis, the Center followed the protocol for the five-center study by using maximum, rather than average, treadmill measurements. (G–71 at 1–4; Lipicky, Tr. Vol. V at 74–79.) However, this exhibit was stricken on motion of AHP. (Tr. Vol. V at 6.) Additionally, I note that, as Dr. Lipicky testified, in order for the Center to perform an independent reanalysis, the Center would have to have access to the raw data, i.e., the case report forms, and these were not submitted to FDA. (Lipicky, G–61 at 19.)

AHP further contends that the ALJ erroneously concluded that AHP had given no reason for submitting a parallel study. (AHP Exceptions at 87.) AHP is misstating the ALJ's decision. The ALJ held that AHP did not provide a *sufficient* reason for its submission of a parallel analysis for a crossover study. (I.D. at 30.) I uphold the ALJ's conclusion.

AHP argues that the ALJ failed to consider the views of AHP's expert witnesses regarding peripheral vascular disease. (AHP Exceptions at 87–88.) AHP avers that its witnesses testified that the reanalysis of the five-center study demonstrated a treatment effect. (AHP Exceptions at 88, citing: Porter, A–109 at 22–25; Reichle, A–110 at 18–20; Winsor at A–111 at 15–16; Reich, A–112 at 49–51.) As is apparent from the ALJ's Initial Decision, the ALJ did consider AHP's evidence, but the ALJ was not persuaded by it.

In any case, as I stated previously (see section I.C.1.c. of this document), the Commissioner is not bound by the conclusions of expert witnesses. (*Warner-Lambert Co.* v. *Heckler,* 787 F.2d at 154; Commissioner's Decision on OPE, slip op. at 22; Commissioner's Decision on Deprol, 58 FR 50929 at 50930.) Expert opinion testimony is only as strong as the studies on which it is based. (Commissioner's Decision on OPE, slip op. at 22, citing *Upjohn* v. *Finch,* 422 F.2d 944, 955 (1970).)

Having reviewed all of the evidence, I am in agreement with the ALJ's conclusion that AHP did not provide a sufficient reason showing that it was proper to analyze only the first 12 weeks

of this 24 week study. In a study such as the five-center study, where major changes to the protocol were made but the decision to make those changes was arrived at only after the data had been analyzed without showing a statistically significant drug effect, it is not possible in the subsequent reanalysis to ''distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation.'' (§ 314.126(a)) For the above reasons, I therefore hold that AHP's reanalysis of the five-center study can not be relied upon as substantial evidence of efficacy from an adequate and well-controlled clinical trial.

b. *Inclusion/exclusion decisions.* As part of AHP's reanalysis of the five-center study, Dr. Clarence Denton and Dr. Stuart L. Scheiner reviewed the case reports for all of the 92 patients who completed the first 12 weeks of the five-center study and reconsidered the inclusion/exclusion decisions pertaining to each patient. (AHP Exceptions at 89; A–108 at 2.) In their reanalysis, Drs. Denton and Scheiner were said to have been blinded to such factors as whether a particular patient had been included in the initial analysis, whether a patient had been on drug or placebo, and as to a patient's outcome at the conclusion of the five-center study. (AHP Exceptions at 89; AHP Post-Hearing Brief at 42; Denton, Tr. Vol. VII at 10–11, 47.) However, it is not clear that Drs. Denton and Scheiner were also blinded regarding the center to which a patient had been assigned during the trial.

A total of 23 changes in the selection of patients for analysis were made between the original analysis and the reanalysis. These changes included 11 new inclusions and 11 new exclusions of patients, and one reclassification of a patient who originally had been listed as a placebo patient but upon discovery of a coding error was reclassified as a Cyclospasmol® patient. (I.D. at 27; A–108 at 11.) The ALJ determined that these decisions were made post hoc and ruled that this was another factor for which the reliability of the reanalysis can be called into question. (I.D. at 56.) AHP disputes the ALJ's conclusions. (AHP Exceptions at 88–98.)

The first objection raised by AHP on this point is to ask ''why'' the ALJ questioned the reliability of the 1985 five-center study. (AHP Exceptions at 90–91.) This is a very broad and not well-defined issue, but it appears that its gist is the argument that the ALJ did not adequately explain the basis for his ruling on this issue. (AHP Exceptions at 91.) I do not find this argument to be persuasive. The ALJ devoted several pages of his decision to a discussion of the reanalysis. (See I.D. at 26–31, 56.) In relevant part, the ALJ noted: (1) That the five-center study was originally designed, conducted, and analyzed with a crossover design, (2) that when the original analysis failed to find a statistically significant drug effect, AHP sought to rely upon the results from only one of the five centers, (3) that AHP subsequently chose instead to reanalyze the first 12 weeks of the study as if it had been a parallel study, (4) that in the reanalysis, the inclusion and exclusion decisions for every patient were reconsidered and 23 changes were made in patient selection, and (5) calculation of the treadmill baseline data was not done in strict accordance with the protocol, i.e., average values were used instead of the highest value. (I.D. at 56.) As I ruled at the outset of this Final Decision, I find that the ALJ's Initial Decision comports with the requirements of the Administrative Procedure Act and FDA regulations, and that the ALJ fully set out the reasons for his decision in the narrative explanation section of his decision. (See section I.B. of this document.) Therefore, I find no merit in AHP's argument.

AHP also challenges the ALJ's statement that the reanalysis should be given a ''higher degree of scrutiny'' than the initial analysis. (AHP Exceptions at 92–93.) As the ALJ stated in his opinion, ''(A) higher degree of scrutiny is warranted here not because the reanalysis was termed as such but because the reanalysis was undertaken in response to the initial lack of a statistically significant difference between the drug and placebo.'' (I.D. at 26.) The ALJ's statement was appropriate, and I find no error in it.

AHP further argues that the ALJ misunderstood AHP's response to Dr. Lipicky's ''accusations of manipulation.'' (AHP Exceptions at 93.) The portion of Dr. Lipicky's testimony to which AHP refers reads as follows regarding the reanalysis:

> The first analysis showed that different investigators had different results. If I had to search for a means of turning a negative trial positive, I would retrospectively search for reasons to exclude patients studied by investigators who did not produce results favoring drug over placebo and include patients studied by investigators who did favor drug over placebo. Remarkably, the reanalysis, in addition to restricting attention to only ½ of the entire time of the study, excluded 7 patients from the Batson study, 3 patients from the Raines study (both Batson and Raines having not favored drug over placebo) and included 4 patients from the Reich study (Reich having favored drug over placebo). Yet other inclusions and exclusions resulted in a total of 20 patients (almost 25% of the patients analyzed) to be declared now analyzable whereas previously being declared non-analyzable.

(Lipicky, G–61 at 18.)

AHP argues that Dr. Lipicky's testimony was refuted in AHP's Post-Hearing Brief, wherein AHP had argued that ''(a)n examination of the difference between the initial analysis and the reanalysis show that AHP's inclusion/exclusion decisions in the reanalysis *contradict(ed)* Dr. Lipicky's manipulation theory with respect to *four* of the centers; only the Reich center was consistent with Dr. Lipicky's theory * * *.'' (AHP Post-Hearing Brief at 42 (emphasis in original).) The ALJ's finding regarding this aspect of the reanalysis, with which AHP takes issue, reads as follows:

> In addition, AHP claims the Center's allegation is incorrect with respect to four of the centers since patients were added, not subtracted to the Raines center and excluded from the Batson-Hollier and Abbott centers with no changes to the String center. Only the Reich center showed a positive drug effect and had four patients added to it.

(I.D. at 26–27.)

AHP now argues that in its Post-Hearing Brief, it had refuted Dr. Lipicky's assertions in their entirety, and that the ALJ was in error in finding that AHP had argued that the Center's allegation was incorrect with respect to four of the five centers. (AHP Exceptions at 93.) I find this argument to be clearly without merit. As the previously quoted excerpt from AHP's Post-Hearing Brief plainly shows, AHP did say that it found that Dr. Lipicky's testimony was correct with regard to the Reich center, just as the ALJ had ruled. (AHP Post-Hearing Brief at 42.) I find no indication that the ALJ misunderstood AHP's response to Dr. Lipicky's testimony, and, therefore, I find no merit in AHP's argument.

AHP also argues that the ALJ was in error in stating that the Reich Center was the only one of the five centers to show a ''positive drug effect.'' (AHP Exceptions at 94.) In this statement, the ALJ was referring to the initial analysis of the five-center study, in which only the Reich Center showed a statistically significant drug effect. (See I.D. at 26–27; G–9.1 at 85.) The ALJ also noted that when the reanalysis was performed, four patients were added to the Reich Center. (I.D. at 27.) The ALJ's statements were correct, and I find no error in them.

AHP further challenges the ALJ's decision by asking what the ALJ's rationale was for ruling that two patients who had been included in the initial analysis—Patient Nos. 15 and 16

from the Batson-Hollier center—were improperly excluded from the reanalysis. (AHP Exceptions at 94–98, citing I.D. at 28.) This issue refers to the setting of a baseline treadmill measurement for patients under a section of the protocol that has been termed the ''salvage'' provision. (AHP Exceptions at 95.) (Other issues related to the salvage provision are discussed below in section I.C.2.c. of this document.)

Basically, the salvage provision was a contingency that required a fairly stable treadmill measurement for the baseline for a patient's entry into the study. Each patient entered into the five-center study was enrolled in a 6 to 8 week, pretreatment washout period during which all patients were given a placebo. (G–6 at 9.) A set of two treadmill tests were performed each time a treadmill reading was required by the study. (G–6 at 10.) To establish a patient's baseline value on the treadmill, the maximum value recorded on the last visit of the pretreatment period was to be used as the baseline. (G–6 at 10, 21.) The protocol also provided that if the maximum values recorded on the last two consecutive, pretreatment visits differed from one another by more than 20 percent of the value of the larger of these two readings, then up to two additional sets of treadmill tests at weekly intervals could be made. (G–6 at 10–11.) Only the last two consecutive set of tests would be considered for qualification of the patient into the study. If agreement within 20 percent failed to be found after four visits, the patient was to be dropped from the study. (G–6 at 11.)

In the initial analysis, Patient Nos. 15 and 16 from the Batson-Hollier center were said to have entered the study under the salvage provision, i.e., these patients required additional pretreatment visits and treadmill tests to establish an acceptable baseline. (AHP Exceptions at 95.) While these patients were included in the initial analysis, these patients were excluded from the reanalysis. (AHP Exceptions at 95.) Regarding this change in inclusion/exclusion decisions, the ALJ wrote, ''AHP cannot exclude these patients after the initial analysis failed to demonstrate a positive drug effect. There is no reason why AHP could not have identified this problem area sooner.'' (I.D. at 28.)

I am in agreement with the ALJ's ruling on the exclusion of these two patients. As I said before, inclusion/exclusion decisions made after randomization may affect the initial randomization and assignment of subjects in such a way as to bias the results. (Commissioner's Decision on OPE, slip op. at 238–39; Commissioner's Decision on Deprol, 58 FR 50929 at 50939 and 50940.) In the present case, the issue of bias has been raised all the more strongly because the exclusions also involved a change in the protocol and subsequent reanalysis after the initial analysis failed to find statistical significance. I find AHP's exclusion of these patients effectively to be a change in the entry criteria made after the data were collected, analyzed, and failed to show statistically significant results. The ALJ was right to question it. Therefore, I uphold the ALJ's rejection of the inclusion/exclusion decision regarding these two patients in the reanalysis.

AHP further argues that the ALJ misunderstood AHP's evidence regarding the exclusion of Patient Nos. 15 and 16 from the Batson-Hollier center. (AHP Exceptions at 98.) On this point, AHP takes issue with the following statement by the ALJ: ''This (exclusion of patients who would have qualified for entry in the study by means of the 'salvage provision'), according to AHP, explains why the patient population at the Batson-Hollier Center was different than that of the other centers.'' (I.D. at 28; see AHP Exceptions at 98.) I have reviewed the record, and I find that the ALJ's opinion accurately summarizes the statements made by AHP in its Post-Hearing Brief, particularly this language from that brief: ''The patient population studied at the one center (the Batson center) was, as a consequence (of the salvage provision), different from the patient population studied in the other four centers.'' (AHP Post-Hearing Brief at 52.) Therefore, I find no merit in AHP's argument.

I am in agreement with the ALJ's determination that the inclusion/exclusion decisions called the reliability of the reanalysis into question. An adequate and well-controlled study must ensure that adequate measures are taken to minimize bias on the part of the analysts. (§ 314.126(b)(5)) Exclusion decisions made after randomization may affect the initial randomization and the assignment of subjects in such a way as to bias the results. (Commissioner's Decision on OPE, slip op. at 238–39; Commissioner's Decision on Deprol, 58 FR 50929 at 50939–40.) Under the facts in the present case, it is not possible in the reanalysis to distinguish the effect of a drug from other influences, such as biased observation. (See § 314.126(a).) Therefore, for the reasons previously discussed I reject AHP's exceptions.

c. *Calculation of treadmill distances.* As previously indicated, each patient entered into the five-center study was enrolled in a 6 to 8 week, pretreatment washout period during which all patients were given a placebo. (G–6 at 9.) As provided under the protocol, a set of two treadmill tests were to be performed each time a treadmill reading was required by the study. (G–6 at 10.) To establish the baseline value for a patient on the treadmill, the maximum value recorded on the last visit of the pretreatment period was to be used as the baseline. (G–6 at 10, 21.) The protocol also stipulated that if the maximum values recorded on the last two consecutive pretreatment visits differed from one another by more than 20 percent of the larger of these two values, then, under a section of the protocol referred to as the ''salvage provision'' (AHP Exceptions at 95), up to two additional sets of treadmill tests at weekly intervals could be made. (G–6 at 10–11.) Only the last two consecutive sets of tests would be considered for qualification of the patient into the study. If agreement within 20 percent failed to be found after four visits, the patient was to be dropped from the study. (G–6 at 11.) The protocol contained a comparable requirement for the measurement of treadmill values throughout the study, in that ''*(t)he test resulting in the longer claudication time (was to) be used for calculating the maximum distance walked*.'' (G–6 at 21 (emphasis in original).)

The report of the initial analysis for the five center study stated that ''the baseline measurement used was the maximum of the two values from the last visit'' of the pretreatment period. (G–9.1 at 90.) However, it is not clear that, in fact, the maximum values were used for all five of the centers, for in a separate report on the MDS–176 (Reich) center it was stated that the baseline measurement was ''the *average* of the last two visits of the single blind pre-medication placebo phase'' (G–9.1 at 180 (emphasis added)), rather than the maximum value as provided in the protocol. Moreover, in the reanalysis, AHP calculated the baseline values for each patient by averaging the two treadmill measurements from the pretreatment results rather than by using the maximum value, as per the protocol. (Lipicky, Tr. Vol. IV at 70; see also A–108 at 2–11; AHP Exceptions at 100.)

In his Initial Decision, the ALJ found, ''AHP also did not calculate all the treadmill data in strict accordance with the instruction of the protocol.'' (I.D. at 56.) AHP takes exceptions to the ALJ's findings on this point. (AHP Exceptions at 98.) AHP first avers that no witness

for the Center criticized the 1985 five-center study analysis on the basis of the manner in which the baseline treadmill values for patients were calculated, and that the issue was raised for the first time by the Center in its brief. (AHP Exceptions at 101.) However, my review of the hearing transcript reveals that Dr. Lipicky, a witness for the Center, testified, ''(E)ven though the protocol clearly stated that the analysis was to be based upon the longest walking distance measured at any of the visits, AHP chose to use mean values of the two treadmill walking times that were measured at each visit.'' (Lipicky, Tr. Vol. IV at 70.) The calculation of treadmill values was identified as a protocol violation by the Center at the hearing, and so AHP's assertions to the contrary are simply incorrect.

AHP next argues that the Center, in preparing its own analysis of the data, computed baseline and final treadmill measurement by averaging the measurements from the study. (AHP Exceptions at 102–03.) In support of its argument, AHP cites to the testimony of Dr. Lipicky, a witness for the Center, who relied upon an exhibit identified as G–70 in his testimony on this point. (See Lipicky, Tr. Vol. IV at 74–82, 97–104.)

The record indicates that the Center performed at least eight different analyses in its review of the five-center study, with exhibit G–70 being one of the Center's analyses. (Lipicky, Tr. Vol. IV at 75.) Dr. Lipicky testified that in Exhibit G–70, the Center looked at the data in the same way as did AHP in its reanalysis. (Lipicky, Tr. Vol. IV at 76.) Baseline walking distances were computed by averaging a given patient's test measurements at the third and fourth visits. (Lipicky, Tr. Vol. IV at 98.) However, I note that Exhibit G–70 was stricken from evidence by the ALJ on motion of AHP. (Tr. Vol. V at 6.) Therefore, I find any issues pertaining to Dr. Lipicky's testimony regarding this evidence to be moot.

AHP also asks if the ALJ considered whether the study results would have been any different if maximum values had been used rather than average values. (AHP Exceptions at 103.) The ALJ is not required to perform such calculations. More importantly, the fact is that AHP's calculation of the treadmill values using average values was yet one more protocol violation in a study with other protocol violations.

AHP raises the additional argument that the ALJ rejected the five-center study solely on the basis of AHP's use of average treadmill values instead of the maximum values required by the protocol. (AHP Exceptions at 103.) This is a misstatement of the ALJ's opinion. The ALJ rejected the reanalysis because AHP ''provided no good reason'' for analyzing only the first half of the data from this study. (I.D. at 30) Therefore, I find AHP's argument to have no merit.

d. *Variability among centers.* AHP next objects to the ALJ's ruling that the results of the various centers within the five-center study are so inconsistent as to make any finding of a significant drug effect questionable. (AHP Exceptions at 105, citing I.D. at 31.) In its arguments, AHP raises the broad questions of when it is appropriate to ''break open'' a multicenter study and review the results of individual centers, and what it is that the ALJ should examine in such a review. (AHP Exceptions at 107–08.)

By statutory mandate, FDA is charged with reviewing all DESI drugs for efficacy and to withdraw approval for any NDA where ''substantial evidence'' of the drug's effectiveness is lacking (21 U.S.C. 355(e)(3)). Among the considerations to be weighed in the FDA's review are the validity of the methodology used in a particular study, and the determination of whether substantial evidence of efficacy has been proved. (*Warner-Lambert,* 787 F.2d at 153.)

To this end, a thorough review of the studies submitted by a manufacturer to the FDA as proof of a drug's efficacy is always appropriate. All aspects of the data are proper subjects for review. When the study is a multicenter trial, the methodology and data from each participating center may be evaluated and reviewed. I therefore find that the ALJ did not err when he ''broke open'' the multicenter trial and reviewed the outcome at each of the centers.

AHP next argues that the ALJ ignored the pooled results of the five-center study. (AHP Exceptions at 107.) I find that the ALJ did weigh the pooled data but that he concluded that the data failed to meet the requirements of an adequate and well-controlled study. (See generally Commissioner's Decision on Phenformin Hydrochloride (44 FR 20967 at 20970, April 6, 1979) (Commissioner ruled that ALJ did not disregard specified evidence but instead was found to have considered the overall evidence.))

AHP next challenges the ALJ's finding that ''the results of the five-center study are so inconsistent as to make a significant drug effect questionable.'' (AHP Exceptions at 105, quoting I.D. at 31.) I find that the ALJ's ruling is supported by the evidence. Regarding the reanalysis, Dr. Schneiderman, a witness for the Center, testified that there were substantial differences among the five centers in the study. (Schneiderman, Tr. Vol. VII at 8.) On this point, Dr. Schneiderman testified:

> Oh, I think there's a substantial difference among the institutions that tested the patients. One institution shows substantial improvements in the average among the patients, much of that improvement being contributed by one patient who was in one of the inclusions—included once and excluded once—thereby, the selection criteria become of considerable importance in that one institution.
>
> In the four other institutions, two of them show some minor effects for the drug, slightly better than placebo; two of them show some minor effects for placebo, slightly better than the drug. So it seems to me there was a substantial difference among the institutions.

(Schneiderman, Tr. Vol. VII at 8.)

Additionally, another Center witness, Dr. Lipicky, testified that results of the various investigators differed to an extent that made the pooled data difficult to accept as accurate. (Lipicky, G–61 at 19.) Dr. Lipicky reported that two of the five centers found the placebo to be numerically superior to Cyclospasmol®, and that it was the Reich Center which found the largest numerical difference between drug and placebo. Dr. Lipicky further testified, ''Within the study, replication is poor and this remains a major problem. In fact at one point in time AHP used this argument to argue the results of the multicenter study could not be pooled.'' (Lipicky, G–61 at 19.)

e. *Adequacy of the five-center study.* In sum, I find that the five-center study was not adequate and well-controlled. In making this determination, I have considered the aggregate effect of the protocol violations. As I previously discussed: (1) AHP's reanalysis of the five-center study cannot be relied upon as substantial evidence of efficacy from an adequate and well-controlled clinical trial; (2) reconsideration of the inclusion/exclusion decisions called into question the reliability of the reanalysis; (3) calculation of treadmill distances were not performed according to the protocol; and (4) the evidence indicated that results of the various centers differed to an extent that made the pooled data difficult to accept as accurate.

D. *The Senile Dementia Disease Indication*

The labeling for Cyclospasmol® originally identified ''selected cases of ischemic cerebral-vascular disease,'' as being one of Cyclospasmol®'s indications. (G–33.2 at 7; see also A–89 at 4–6; G–57 at 4–7.) However, AHP has modified this proposed labeled indication to that of treatment for cognitive dysfunction in patients

suffering from senile dementia of the multiinfarct or Alzheimer's type. (See AHP Post-Hearing Brief at 1; AHP Exceptions at 111.)

Senile dementia is a clinical term used to describe a series of conditions in which elderly individuals have memory loss and cognitive impairment. (Thal, G–63 at 3.) There are various etiologies which can result in the clinical syndrome of senile dementia. (Thal, G–63 at 3.) Multiinfarcts and Alzheimer's disease are two such etiologies. Other diseases and conditions which can cause dementia include psychiatric problems masquerading as dementia, metabolic disorders, such as hyperthyroidism or Vitamin B–12 deficiency, diseases of the central nervous system, and systemic illnesses that affect the function of the central nervous system, such as diseases of the heart, lungs, liver, kidneys, endocrine and hematologic organ systems. (Thal, G–63 at 3; Leber, G–64 at 5.)

Cognitive dysfunction is a symptom of senile dementia. (Zung, Tr. Vol. III at 43.) Cognitive dysfunction can include a lack of mental alertness, confusion, inattentiveness, memory problems, and disorientation. (Goodman, A–123 at 4; Klerman, A–118 at 6.) Emotional or motivational disturbances are also sometimes associated with cognitive dysfunction. (Klerman, A–118 at 7.)

AHP submitted two studies in support of the dementia indication—the Rao study and the Yesavage study. Each study will be reviewed in turn.

1. The Rao Study

The Rao study was a placebo-controlled, parallel group study conducted from December 1975 through June 1976 at Oak Forest Hospital, Illinois, by Drs. Dodda B. Rao, Emile L. Georgiev, P.D. Paul, and A.B. Guzman. (I.D. at 32.) The stated objective of the study was ''to evaluate the efficacy of Cyclospasmol® in alleviating symptoms of senescence commonly associated with cerebral vascular insufficiency.'' (G–28.8 at 314.)

Patients in the drug group were given 1,600 mg of Cyclospasmol® per day for 12 weeks, while patients in the control group received a placebo. (G–28.8 at 314.) Seventy patients were enrolled in the study. However, nine patients dropped out and three patients were later excluded from the statistical analysis, leaving 58 patients whose results were included in the final analysis. (I.D. at 32.)

Patients in the Rao study were rated by using the Sandoz Clinical Assessment—Geriatric (SCAG), and the Nurses Observation Scale—Inpatient Evaluation (NOSIE). (G–14.2 at 242–43.) Also, a global evaluation of each patient's clinical improvement was made at final visit. (G–14.2 at 243–44.)

With the SCAG measurement, a physician rated each patient based on a list of 19 items, or symptoms, associated with dementia. (G–3.1 at 97.) These items included attributes such as ''confusion,'' ''bothersomeness,'' ''appetite,'' and ''anxiety.'' (G–3.1 at 98.) Each Item in the SCAG was rated on a scale from 1 to 7, with 1 indicating that the symptom was ''not present,'' and 7 indicating that the symptom was ''severe.'' (G–3.1 at 97; see, e.g., G–14.2 at 6–8.)

Eighteen of the SCAG items were then grouped into five factors for patient rating. (G–3.1 at 97; see also G–11.1 at 69–71 (Dr. Yesavage discussing SCAG in the Yesavage study).) The five factors for the SCAG included: (1) Cognitive dysfunction, (2) interpersonal relationships, (3) affect, (4) apathy, and (5) somatic dysfunction. The 19th item, a physician's overall assessment of the patient, was rated separately and was not grouped into a factor. (G–3.1 at 97; see also G–11.1 at 70 n.7 (Dr. Yesavage discussing SCAG in the Yesavage study).)

The NOSIE rated the frequency of 30 specific behaviors, employing a scale from ''1'' for ''never,'' to ''5'' for ''always.'' (See, e.g., G–14.2 at 10.) Among the rated behaviors were such items as ''is sloppy,'' ''sleeps, unless directed into activity,'' and ''has trouble remembering.'' (See, e.g., G–14.2 at 10.)

For the final, global evaluation, the patient's physician rated the patient's overall clinical condition during the study as being either ''worsened,'' ''unchanged,'' ''minimal improvement,'' ''moderate improvement,'' or ''marked improvement.'' (See, e.g., 14.2 at 25.)

Regarding the SCAG ratings, Dr. Rao reported a statistically significant change from baseline in favor of Cyclospasmol® on four of the five SCAG Factors, but not on the separate SCAG Item 19. (G–3.1 at 97–98.)

As for the NOSIE results, the Rao study grouped the 30 items on the NOSIE into 5 factors, identified as: (1) Social competence, (2) social interest, (3) personal neatness, (4) irritability, and (5) retardation. (G–3.1 at 98.) The specific grouping into factors was not discussed in the report on the Rao study. (See G–3.1 at 96–99.) However, it was reported that for three of the five NOSIE factors, the test and control arms were not comparable at baseline. (G–3.1 at 98.) For the remaining two NOSIE factors, which were found to have been comparable at baseline, it was reported that statistical significance was not shown for Cyclospasmol®. (G–3.1 at 98.)

As for the physicians' global evaluations, Dr. Rao reported a statistically significant difference in favor of Cyclospasmol®. (G–3.1 at 98, 99.)

The ALJ ruled that the Rao study cannot be considered an adequate and well-controlled study because he found that the study was conducted ''so poorly that the results cannot be relied on with any degree of certainty.'' (I.D. at 42.) Both AHP and the Center raise objections pertaining to rulings made by the ALJ regarding the Rao study.

a. *Admissibility of the reanalysis.* AHP argues that the ALJ erred in refusing to admit AHP's reanalysis of the Rao study into evidence. (AHP Exceptions at 117–21; I.D. at 9.) In denying the admission of the reanalysis into evidence, the ALJ ruled that the reanalysis was not timely filed as required under FDA regulations. (I.D. at 9; ALJ Order of 5/29/85, Exhibit Vol. 89; § 12.85 (21 CFR 12.85.)) The ALJ further ruled that AHP failed to demonstrate, as was required per the regulations, that AHP could not have submitted the reanalysis sooner, and that the value of the reanalysis to the evidentiary record would justify potential delay resulting from the document's late submission. (I.D. at 9; see § 12.85(c).)

The circumstances preceding the submission of the reanalysis are not in dispute. Following the publication in the Federal Register on May 25, 1979, of a Notice of an Opportunity for a Hearing regarding Cyclospasmol® (44 FR 30443), AHP made a request for a hearing and submitted in support of Cyclospasmol®'s efficacy a four page article published by Dr. Dodda B. Rao discussing this study. (Center Exceptions at 34.) Subsequently, FDA asked AHP for the Rao study's case report forms, but AHP advised FDA that only 3 of the 58 forms could be located. (Center's Narrative, G–57 at 5.) In July of 1984, representatives of FDA visited Oak Forest Hospital and were able to locate and review the hospital records for 56 of the 58 subjects in the Rao study. (Center Exceptions at 35, citing Center's Allegations of Fact Nos. 58–62; Center's Narrative, G–57 at 5.)

In October of 1984, the Center filed its Narrative Statement in which the Center criticized the Rao study for failing to exclude certain patients who had been given concomitant medications during the study and for other violations of the protocol's exclusionary requirements. (Center Exceptions at 35; see Center's Narrative, G–57 at 1–8.) On December 17, 1984, AHP filed with the administrative record copies of AHP's

documentary data and other information relied upon, as required under FDA regulations. (§ 12.85.) The reanalysis of the Rao study was not included with AHP's prehearing submission.

On May 6, 1985, a reanalysis of the Rao study was submitted as an attachment to the deposition testimony of Mr. Danny Chaing. (A–125, Attachment E.) In this reanalysis, AHP excluded 14 patients from the analysis because of concomitant medication violations or concomitant diseases and conditions. (AHP Exceptions at 118.) The results of the reanalysis, using 44 patients of the 58 patients originally analyzed, were reported as showing statistical significance in favor of Cyclospasmol®. (AHP Exceptions at 119.)

The Center moved to strike the reanalysis on the grounds that it was a late submission and that there was no justification for its delayed filing. (Center Motion to Strike 5/13/85, Exhibit Vol. 88 at p. 12–13.) The Center argued that the reanalysis should have been submitted to the FDA in either the NDA for Cyclospasmol® or in the prehearing submissions required under FDA regulations. (§ 12.85.)

FDA regulations require that within 60 days of the publication of the notice of hearing, each participant in the hearing shall submit to the docket all data and information relied upon. (§ 12.85(b).) The regulations further provide that such submissions may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement ''was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.'' (§ 12.85(c).)

If written evidence is not submitted as required under the regulations, the ALJ may exclude the evidence as inadmissible. (§ 12.94 (21 CFR 12.94(c)(1)(iii)).) Under the regulations, the ALJ in the present case excluded the Rao reanalysis, inasmuch as the submission was neither timely filed, nor was a motion to supplement AHP's submissions made offering an explanation for the lateness of the submission.

In support of its submission, AHP argues that the reanalysis was ''highly relevant,'' and that the reanalysis was the appropriate response to the Center's criticisms of the Rao study. (AHP Exceptions at 120.) AHP also argues that the ALJ's ruling prevented AHP from demonstrating that even if certain patients were excluded from the statistical analysis, the Rao study still resulted in a statistically significant result. (AHP Exceptions at 121.) I find that these arguments merely beg the question and do not address the fact that AHP made no attempt to offer a motion with explanation to the ALJ to supplement AHP's submissions for the Rao study, as stipulated in the regulations. (§§ 12.85(c) and 12.94(c)(1)(iii).) (By contrast, I note that AHP made such a motion, which was granted by the ALJ, to supplement its submissions in connection with the five-center study. (See I.D. at 8–9.))

The reanalysis submitted by AHP entailed a reconsideration of the exclusionary decisions made regarding the study subjects and a recalculation of statistical significance. As was ruled in the Commissioner's Decision on the drug Cothyrobal, ''(I)t is not the function of a hearing to consider new evidence, i.e., evidence that was not available to the agency at the time it initially denied the NDA.'' (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28616, June 3, 1977), aff'd *Edison Pharmaceutical Co.* v. *FDA*, 600 F.2d 831 (1979); see also *Warner-Lambert,* 787 F.2d at 162 (ALJ has ''the power to make reasonable, nonarbitrary decision regarding the admission or exclusion of evidence for procedural reasons.'').)

Similar decisions pertaining to administrative hearings before other Federal agencies have been affirmed by the courts. For example, in *Michigan Consolidated Gas Co.* v. *Federal Energy Regulatory Comm'n*, 883 F.2d 117, 124–25 (D.C. Cir. 1989), the circuit court ruled, ''When a party is on reasonable notice as to the dates and times for hearings and for filings in an administrative proceeding, we are hard pressed to hold that the administering agency acted arbitrarily or capriciously in denying admission of materials untimely filed.'' (See also *Irving Bank Corp.* v. *Board of Governors of Fed. Reserve System*, 845 F.2d 1035, 1039 n.5 (1988) (Board of Governors of Federal Reserve System had discretion over extent to which it was required to consider late-submitted evidence); *Pittsburgh & Lake Erie R.R. Co.* v. *Interstate Commerce Comm'n*, 796 F.2d 1534, 1544–45 (D.C. Cir. 1986) (Carrier challenging cancellation of several joint rates was not entitled to admission of certain rebuttal evidence which the carrier submitted at a stage in the administrative proceedings when the opposing party would not have had an opportunity to respond.))

In challenging an evidentiary ruling such as this, the objecting party has the burden to make a ''strong showing'' that the ALJ abused his or her discretion. (*Warner-Lambert,* 787 F.2d at 162.) I do not find that AHP has made the necessary strong showing that such an abuse of discretion occurred on the part of the ALJ. Therefore, I find that the ALJ did not err in granting the Center's motion to strike the reanalysis.

b. *Labeling and patient selection.* AHP next argues that the ALJ erred in concluding that the Rao study was not adequate and well-controlled because the claimed indications for Cyclospasmol® went beyond those of the patient group which was originally said to have been studied. (AHP Exceptions at 121; I.D. at 34, 42, 56.) The ALJ had noted that while AHP was now seeking to label Cyclospasmol® for indications in patients with dementia resulting from both Alzheimer's disease and from multiinfarcts, Dr. Rao, in his published account of the study, stated that he had excluded patients with ''a history of Alzheimer's disease.'' (I.D. at 56; G–3.1 at 97.)

As stated in the protocol, the objective of the Rao study was ''to evaluate the efficacy of Cyclospasmol® in alleviating symptoms of senescence commonly associated with cerebral vascular insufficiency.'' (G–28.8 at 314.) The protocol also required, among other things, that patients ''whose symptoms of senescence occurred prior to age fifty'' be excluded. (G–28.8 at 314.)

Dr. Rao, in his subsequently published article, indicated that the focus of the study was the treatment of cerebrovascular insufficiency. (G–3.1 at 96.) Dr. Rao noted ''that in the past vasodilators have too often been prescribed indiscriminately, without proper selection of patients.'' (G–3.1 at 97.) Dr. Rao then went on to describe the patient population for his study as follows:

> Sixty geriatric patients (men and women aged 65 or older) were selected initially for the study. We excluded those with a history of Alzheimer's disease; stroke; psychiatric illness; traumatic, neoplastic or infective brain damage; and other relevant disorders. We attempted to identify patients with clearly evident symptoms of senility, but excluded those who were so severely debilitated as to make the possibility of significant improvement unlikely.

(G–3.1 at 97.)

Notwithstanding Dr. Rao's article reporting that he had excluded patients with Alzheimer's disease, AHP argues that Dr. Rao's exclusions did not prevent the study population from including patients with dementia due to Alzheimer's disease. (AHP Exceptions at 123.) AHP argues that the definition of Alzheimer's disease has changed since the time of Dr. Rao's article. AHP argues that in the mid-1970's, when Dr. Rao conducted this study and published his

article, Alzheimer's disease was defined as dementia in a relatively young patient population, i.e., patients under age 65. Dr. Rao, when he purported to be excluding Alzheimer's patients from his study, excluded only dementia patients under age 65. This definition for Alzheimer's disease is today outmoded. (AHP Exceptions at 122; Zung, Tr. Vol. III at 15–16.) AHP argues that today the definition of Alzheimer's disease includes patients over the age of 65, which would include patients in the age group represented in the Rao study.

Citing the change in the definition of Alzheimer's disease, AHP also argues that despite Dr. Rao's claim of excluding Alzheimer's disease patients from the study, Dr. Rao could not possibly have excluded patients with Alzheimer's disease because the only way to differentiate conclusively between multiinfarct dementia and Alzheimer's disease is by an autopsy. (AHP Exceptions at 123, citing Denton, Tr. Vol. VII at 14; Yesavage, Tr. Vol. IV at 27; Yesavage, A–115 at 7.) AHP argues that the patient population represented in the Rao study was the same as would currently be identified as suffering from either multiinfarct dementia or Alzheimer's disease. (AHP Exceptions at 123.) AHP concludes by arguing that Dr. Rao's exclusions did not prevent the Rao study population from including patients with both multiinfarct dementia and dementia due to Alzheimer's disease, notwithstanding Dr. Rao's contrary intention. (AHP Exceptions at 123.) AHP cites to the testimony of three witnesses in support of its position. (AHP Exceptions at 123.)

The first of the witnesses cited by AHP is Dr. Lowell I. Goodman, a witness for AHP, who testified generally about the population suffering from dementia. Dr. Goodman stated, ''Almost certainly subsequent epidemiological studies and further research into this population have revealed that approximately two-thirds of such patients, diagnosed as having senile dementia, were of the Alzheimer type and approximately a third were either multiinfarct dementia or a mixture of the two.'' (Goodman, Tr. Vol. V at 82.)

AHP also cited to the testimony of Dr. Gerald L. Klerman, also an AHP witness, who testified:

> Our current thinking is that cerebral arteriosclerosis plays relatively little role in most cases of senile dementia and that they are either of the Alzheimer's type or what is called multi-infarct dementia. The Rao and the Yesavage study by current standards would be primarily cases with Alzheimer's disorder and some with a mixture of previous strokes.

(Klerman, Tr. Vol. III at 69.)

The third witness cited by AHP is Dr. Leon J. Thal, a witness for the Center. I have reviewed Dr. Thal's testimony, however, and I do not find it to support the point being advanced by AHP. When Dr. Thal was asked whether it was likely that the patient population chosen under the Rao protocol, i.e., patients having ''symptoms of senescence commonly associated with cerebral vascular insufficiency,'' would today be the same as a population consisting of Alzheimer's patients and multiinfarcts dementia patients, Dr. Thal responded in the negative. Contrary to the position which AHP is arguing, Dr. Thal testified, ''No, that's not correct because, in addition to multi-infarct dementia and Alzheimer's disease, there are many other causes of dementia. The patients in the Rao study were not systematically examined for other causes of dementia.'' (Thal, Tr. Vol. VI at 38.) Dr. Thal went on to add that even if Alzheimer's disease patients and multiinfarct patients were counted as one group, still it was likely that approximately 20 percent of the patients included in the Rao study had other causes of dementia. (Thal, Tr. Vol. VI at 38.)

FDA regulations require that ''(t)he method of selection of subjects provides adequate assurance that they have the disease or condition being studied * * *.'' (§ 314.126(b)(3).) Towards this end, the Commissioner's Decision on Mysteclin, relying upon this section of the regulations, stated:

> It is essential, therefore, that the most accurate diagnostic techniques available be used in order to provide as much assurance as possible that the results are credible. See Lutrexin; Withdrawal of Approval of New Drug Application, 41 Fed. Reg. 14406, 14419 (1976). Because patients often are treated on the basis of preliminary diagnoses that suggest, without confirmation, a disease's etiology, the diagnostic criteria used by physicians when treating patients are not always applicable in the context of a drug investigation.

(Commissioner's Decision on Mysteclin, slip op. at 36–37, FDA Docket No. 82N–0153 (FDA February 8, 1988) (some citations omitted), opinion denying review sub nom. *E.R. Squibb & Sons, Inc.*, v. *Bowen*, 870 F.2d 678 (D.C. Cir. 1989) (hereinafter cited as Commissioner's Decision on Mysteclin).)

Leaving aside the question of Dr. Rao's intent, I turn instead to the evidence that Alzheimer's and/or multiinfarct patients were included in the Rao study, and that patients with other causes of dementia were excluded. The evidence argued by AHP basically consists of the facts that: (1) The patients in the study exhibited dementia, and (2) the patients were in the typical age group for patients having Alzheimer's or multiinfarct.

I find that evidence about dementia in general in the geriatric population, such as that evidence offered by Drs. Goodman and Klerman, does not provide adequate assurance that the subjects of the Rao study had Alzheimer's disease. As Dr. Thal, the third witness cited by AHP, testified, dementia can be caused by various conditions or diseases. (Thal, Tr. Vol. VI at 38.) Included among these other diseases or conditions are hypothyroidism, vitamin B_{12} deficiency, hydrocephalus, psychiatric problems (pseudodementia), chronic alcoholism, Parkinson's disease, severe diabetes, neurological disease, infection in the central nervous system, and brain tumors. (Zung, Tr. Vol. III at 17–18; 23–24, 32, 50; Goodman, Tr. Vol. V at 82–83; Goodman, A–123 at 23.) Despite this fact, the evidence does not show that the patients in the Rao study were examined for other causes of dementia. (Thal, Tr. Vol. VI at 38.)

AHP argues that it did perform a physical examination to screen for other neurological causes of dementia. (AHP Post- Hearing Brief at 88; see Goodman, A–123 at 21–23; Goodman, Tr. Vol. V at 82–83; Zung, A–117 at 30.) This examination was said to consist of an evaluation of each patient's gait, muscle strength, balance, deep-tendon reflexes, level of consciousness, attention and understanding, cooperation and intelligence, and visual, auditory and other special senses. (Goodman, A–123 at 21.) However, none of the results of these tests were in evidence, nor were the results available for review by the Center. In the absence of evidence of the results of such tests, AHP's argument that it did perform certain diagnostic tests is not persuasive and has no probative value. (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28608 (Where a particular condition can be caused by many factors, evidence must be provided regarding diagnostic criteria and the confirmatory laboratory tests.))

AHP further argues that, because most of the patients entered into the study had been under the close supervision of the study's physicians for years and were familiar to the physicians before the study began, further diagnostic testing was not necessary to screen for other causes of dementia. (AHP Post-Hearing Brief at 88; see Klerman. A–118 at 28–29; Goodman, A–123 at 21–23; Goodman, Tr. Vol. V at 82–83; Zung, A–117 at 30.) I am not persuaded by this argument. By statutory mandate, a

drug's efficacy must be proved by substantial evidence from adequate and well-controlled clinical trials. (21 U.S.C. 355(d).) It is established that the burden of proving the adequacy of a study is on the proponent for the drug. (*Hynson*, 412 U.S. at 617, citing 21 U.S.C. 355(e)(3).) Under agency regulations, the method of selecting subjects for a study must provide adequate assurance that the subjects have the disease or condition being studied. (§ 314.126(3).) In the Rao study, I do not find the undocumented, prestudy experience of the physicians with the study patients to be acceptable as substantial evidence of the patients' conditions.

As for the change in the definition of Alzheimer's disease, I find this equally unpersuasive as a basis for supporting an indication for Alzheimer's disease. As I previously stated, general observations about the geriatric, senile population at large do not provide adequate assurance that the subjects of the Rao study had Alzheimer's disease.

Moreover, as AHP concedes, Alzheimer's disease and multiinfarct dementia are distinct diseases with different etiologies. AHP argues that etiology does not matter because AHP does not have to prove the mechanism of action for Cyclospasmol®. While it is true that the regulations do not require proof of mechanism of action, this is beside the point now at issue. The issue is diagnosis of the disease, not mechanism of action for the drug. In an adequate and well-controlled study, it is not acceptable to group persons having similar symptoms but distinct diseases together into one study without identifying which patient has which disease (as was done in the Rao study). If this practice were permitted, it would be impossible to assess a drug's effectiveness on a particular disease. (Cf. Commissioner's Decision on Lutrexin, 41 FR 14406 at 14422 (In a study of premature labor, results were incapable of scientific interpretation because patients with different conditions were evaluated together without distinguishing between the conditions.); see also Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28608 (Where a particular condition can be caused by many factors, evidence must be provided regarding diagnostic criteria and the confirmatory laboratory tests.))

Difficulty in diagnosis is not a justification for a less than adequate and well-controlled study. (Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28608.) While Alzheimer's disease may not be positively diagnosed until an autopsy is performed, evidence indicated that it was possible to make a differential diagnosis on the basis of patient history by ruling out other causes of dementia. On this point, Dr. William Zung, a witness for AHP, testified that in order to make a differential diagnosis, one must consider the history of the patient. Dr. Zung testified that with Alzheimer's disease, ''the signs and symptoms are progressive. They are of a slow onset.'' (Zung, Tr. Vol. III at 14.) However, for multiinfarct dementia, Dr. Zung testified, ''the symptomatology would come on fairly rapidly * * *.'' (Zung, Tr. Vol. III at 14.) Dr. Zung further testified:

> (Y)ou can tell a differential diagnosis between senile dementia of the Alzheimer type and the multi-infarct because patients who have multi-infarct dementia have focal signs. That is to say, specifically where that part of the brain has been affected by lack of the oxygen and by death of the cells, say, if it's in the motor part of the brain, then that patient would have a decrease in their motor function.

(Zung, Tr. Vol. III at 15.)

I find that for an adequate and well-controlled study, merely selecting an elderly population which has dementia is not sufficient to assure that the study will demonstrate the effectiveness of a drug for patients with Alzheimer's disease. While the ''gold standard'' for diagnosing Alzheimer's disease lies in autopsies, nonetheless, there was evidence indicating that antemortem diagnosis can be made by the process of eliminating other possible causes of dementia. Identification of dementia caused by other conditions must be made and patients with other causes for their dementia excluded from the study. Alternatively, if patients with other causes of dementia, such as multiinfarct dementia, are to be included, then all patients' diagnoses should be identified.[4]

As was ruled in the Commissioner's Decision on Lutrexin, ''The evidence made clear that although existing diagnostic techniques do not permit certainty in the matter, they do allow physicians to make a valid judgment * * *. That the judgment will sometimes prove to be incorrect does not mean that diagnosis * * * is impossible, only that it is inherently uncertain.'' (41 FR 14406 at 14414.) Similarly, in the Commissioner's Decision on Cothyrobal, it was ruled that where a disease or condition can be caused by many factors, a study must give the patients' diagnoses and must also provide sufficient information to substantiate the diagnoses, notwithstanding the fact that a particular disease may be difficult to diagnose. (42 FR 28602 at 28608.)

While AHP argues that difficulties in making a diagnosis are what prevented the Rao study from distinguishing Alzheimer's patients from others, the fact remains that the Rao study was neither looking for nor attempting to identify Alzheimer's patients as that disease is currently defined, i.e., including patients with an onset of dementia over the age of 50. Rather, the Rao study primarily used an age cut off to identify Alzheimer's patients under the old definition. To retrospectively identify Alzheimer's patients under the current definition for Alzheimer's disease would require adequate information in the patient records which could be used to support the diagnoses. This information is not available in the Rao study records.

As was stated in the Commissioner's Decision on Lutrexin, ''(T)he law is clear that the applicant must provide substantial evidence of a drug's effectiveness under its labeled conditions of use, not those under which an investigator chooses to test it.'' (41 FR 14406 at 14419). Therefore, for all of the aforementioned reasons, I find that the Rao study was not adequate and well-controlled in that it failed to show that Cyclospasmol® was tested in Alzheimer's patients.

c. *Concomitant diseases and conditions.* AHP further argues that the ALJ erred in ruling that the Rao study was not adequate and well-controlled because the ALJ found that patients with strokes, histories of alcoholism, severe diabetes, and Parkinson's disease were admitted to the study, although these patients were to have been excluded under the protocol. (AHP Exceptions 125–26, citing I.D. at 42, 56.) In all, the Center identified 18 patients with concomitant diseases or conditions, including 3 patients with multiple conditions, whom they claim should have been excluded. (Center Exceptions at 5–6; Center Post-Hearing Brief at 53–62, & Attachment A.)

AHP concedes that protocol violations occurred, but argues that inclusion of most of these patients resulted in mere technical violations of the protocol and did not confound the results of the study. (AHP Exceptions at 126–28.) AHP further states that the Rao protocol was overly rigid, and that it was a question of medical judgment and expertise as to whether these protocol violations affected the study results. (AHP Post-Hearing Brief at 90, 93.)

The stated objective of the Rao study was ''to evaluate the efficacy of Cyclospasmol®'' in alleviating symptoms of senescence commonly

[4] I note that this was done in the Yesavage study. (See Yesavage, Tr. Vol. IV at 27.)

associated with cerebral vascular insufficiency.'' (G–28.8 at 314.) Towards this end, the protocol provided for the exclusion of patients with dementia caused by other conditions. In relevant part, the protocol's exclusionary criteria read as follows:

> Patients exhibiting any one of the following will be excluded from the study:
> 1. Those with a history of CVA (cerebral vascular accident, i.e., stroke (See A–121 at 28)).
> 2. Those who, upon physical examination, demonstrate neurological evidence of a past CVA.
> * * * * *
> 8. Those with severe diabetes mellitus which requires insuli(n) therapy, or with evidence of glycosuria on urinalysis or who exhibit complication of diabetes.
> * * * * *
> 10. Those with any other severe disease: e.g. significant hematologic disorders; history of malignant disease within one (1) year; recent (4 months) major surgical procedure; pulmonary embolism within one (1) year; severe chronic infection; severe renal, hepatic or neurological disorder, except the one being studied herein * * *.
> * * * * *
> 12. Those whose symptoms of senescence occurred prior to age fifty (50).
> 13. Those with a history of alcohol or other drug abuse, except that patients with a history of alcoholism prior to age 45, with no recurrence after that age, may be entered if the investigator feels that the patient's alcoholism did not contribute to his present symptoms.
> 14. Those with a history of major psychiatric illness.

(G–28.8 at 315–16.)

Relying upon the protocol, the Center identifies numerous patients whom it contends were admitted in violation of the exclusion provisions. I will address each type of alleged violation in turn.

i. *Strokes.* The Center first specifies seven patients, identified as Numbers 3, 12, 15, 21, 31, 45 and 64, as having histories of strokes and therefore subject to exclusion. (Mohs, G–62 at 8–9; Thal, G–63 at 6; Leber, G–64 at 10–15; Leber, G–64, Attachment B at 2; Denton, A–121 at 25, 27–28, 74, 76, 77, 79, 83, 85; Denton Tr. Vol. VII at 16–17; G–14.6 at 351.)

AHP concedes that Patient Nos. 12 and 64 should be excluded (AHP Post-Hearing Brief at 91; Denton, A–121 at 28), but argues against excluding the other five patients, on the grounds that the protocol was overly rigid because it excluded patients whose strokes occurred 2 to 3 years prior to the start of the Rao study. (AHP Post-Hearing Brief at 93.)

In support of its position that these stroke patients need not be excluded, AHP cites to the testimony of Dr. Clarence Denton, a witness for AHP, who testified as follows:

> Generally, there is no need to exclude patients on the basis of a stroke which occurred more than two to three years prior to the onset of the study. Strokes which occurred shortly before the onset of the study should be excluded, however, because the natural recovery process which occurs soon after a stroke is suffered could make it appear that a drug (or placebo) was having a favorable action. Ordinarily, normal recovery from a stroke would occur within six months to one year of the occurrence of the stroke. From a practical standpoint, therefore, it is perfectly reasonable to include patients whose strokes occurred many years prior to the onset of the study, as long as dementia is still present.

(Denton, A–121 at 26.)

It is beyond cavil that patients having a history of strokes were to be excluded under the protocol. Inclusion of these patients was a clear protocol violation. The question now is what effect do these protocol violations have on the validity of the study.

I begin my review of these protocol violations by noting that some protocol violations may be inadvertent or unavoidable on the part of those conducting the study, such as occurs with the failure of a study subject to follow the study's drug regimen. However, other protocol violations may reflect a lack of attention to the requirements of the protocol by those conducting the study. (Commissioner's Decision on Benylin, 44 FR 51512 at 51531 (The inclusion of subjects who did not meet the entrance criteria of the study ''suggests inattention to detail'' and can ''be considered in deciding whether the study was adequate and well-controlled.'').) Failure to follow inclusion/exclusion criteria, such as occurred in the Rao study, can be an indication of such inattention to the details of a study's protocol.

Even violations which by themselves may not warrant rejection of a study can be considered in the aggregate in determining whether a study is adequate and well-controlled. (Commissioner's Decision on Benylin, 44 FR 51512 at 51531.) Evidence of any protocol violation, even if inadvertent or unavoidable, is relevant to the issue of whether the study is adequate and well-controlled. Therefore, I rule that inclusion of the seven stroke patients, both the two patients whom AHP concedes should be excluded and the five whom AHP disputes, properly can be considered as protocol violations and weighed in the review of the Rao study.

ii. *Alcoholism.* The Center further argues that five subjects—Patient Nos. 16, 22, 32, 54, and 63—should have been excluded because they were suffering from alcoholism. (Mohs, G–62 at 9; Thal G–63 at 6; Leber, G–64 at 10–12; Denton, A–121 at 28–29, 42, 77, 79, 84, 85; Denton, Tr. Vol. VII at 22–24; A–126 at 17–20, 22–25.)

AHP makes an argument only against the exclusion of Patient No. 16. (AHP Post-Hearing Brief at 93; AHP Exceptions at 129.) AHP cites to the testimony of Dr. Denton, who testified that Patient No. 16 had consumed no alcohol for 3½ years before the start of the study, and that the initial psychiatric consultation diagnosed both cerebral arteriosclerosis and chronic alcoholism. (Denton, A–121 at 28–29.) Because of the diagnosis of cerebral arteriosclerosis, Dr. Denton suggested that it is unlikely that alcoholism is the primary cause of the dementia in Patient No. 16. (*Id.* at 29.)

Although in the practice of medicine it is expected that a physician may be called upon to treat patients with concomitant illnesses, in clinical drug trials it is necessary to exclude patients with any concomitant conditions that may confound the results of the study. Aside from the fact that Dr. Denton offers no facts to support his position regarding Patient No. 16, I conclude that, at the very least, alcoholism was a confounding factor with this patient. It is clear that Patient No. 16 should have been excluded, as should the other four patients (Nos. 22, 32, 54, and 63) who also had alcoholism.

iii. *Severe diabetes.* The Center next argues that three subjects—Patient Nos. 23, 29, and 32—had severe diabetes, a basis for exclusion under the protocol. (Mohs, G–62 at 9; Thal, G–63 at 6; Leber, G–64 at 13; Denton, A–121 at 32, 80; A–126 at 21.)

AHP takes issue with only the exclusion of Patient No. 32. (AHP Post-Hearing Brief at 92; AHP Exceptions at 130.) AHP argues that it was not necessary to exclude Patient No. 32 because this patient's diabetes was not severe enough to be insulin dependent. (AHP Exceptions at 130; Denton, A–121 at 32.) I find AHP's arguments with regard to this patient to be moot, since AHP has already conceded that Patient No. 32 should be excluded for alcoholism. (See section I.D.1.c.(2). of this document.)

iv. *Severe diseases, Parkinson's disease, psychiatric illness, and other diseases.* The Center argues that three other patients—Nos. 20, 31 and 59—had severe, chronic infections, which was a basis for exclusion under the protocol. (Center Post-Hearing Brief at 56–57; see G–28.8 at 315–16.) The Center first argues that Patient No. 20 should have been excluded because this patient had active pulmonary tuberculosis. (Center

Exceptions at 7–8, citing Mohs, G–62 at 9; Leber, G–64 at 11–12.) Regarding Patient No. 20, Dr. Leber, a Center witness, testified that ''(a)dequate treatment of his condition rather than treatment with Cyclospasmol® may easily have accounted for the patient's 3.0 improvement on Item 19 of the SCAG.'' (Leber, G–64 at 15.)

AHP argues that the diagnosis of severe pulmonary tuberculosis was incorrect for Patient No. 20, and cites to the testimony of Dr. Denton, an AHP witness, who undertook a post-study review of records for the Rao study. (AHP Reply to Center Exceptions at B–6, citing Denton, Tr. Vol. VII at 28–33; AHP Post-Hearing Brief at 91.) In his testimony, Dr. Denton agreed that the patient records showed that Patient No. 20 was treated with anti-tuberculous drugs (see G–14.6 at 77), and further agreed that the records reflect that this patient was diagnosed during the study as having pulmonary tuberculosis with chronic brain syndrome (see G–14.6 at 53, 55), but nevertheless disputes the diagnosis. Dr. Denton based his challenge to the diagnosis on the absence in the patient records of the actual X-ray report and the absence of the sputum examination. (Denton, Tr. Vol. VII at 30.)

I am not persuaded by Dr. Denton's testimony on this point. I find that there is sufficient evidence in Patient No. 20's records to support a conclusion that this patient did have severe pulmonary tuberculosis. There are several notations in this patients' records which state that this patient had pulmonary tuberculosis. (See, e.g., G–14.6 at 53, 55.) Under the protocol, this patient appropriately should have been excluded.

The Center also argues that Patient Nos. 31 and 59 should have been excluded because these patients had severe, chronic infections. (Center Post-Hearing Brief at Attachment A, citing Thal, G–63 at 6.) However, the Center does not identify the types of chronic infections which these two patients were said to have had. I reviewed the extant patient records, but these records were not always legible and I was unable to determine what type of infections these patients had. Therefore, in absence of more specific evidence, I rule that Patient Nos. 31 and 59 should not be excluded.

The Center further argues that two subjects, Patient Nos. 56 and 63, had Parkinson's disease. (Thal, G–63 at 6–7; Leber, G–64 at 14.) AHP concedes that both of these patients should be excluded, and I accept AHP's concession on this matter. (AHP Exceptions at 130; Denton, A–121 at 29, 35, 84–85.)

The Center also argues that Patient No. 9 should have been excluded because this patient had a major psychiatric illness, i.e., hysterical personality. (Leber, G–64 at Attachment B, p.2.) AHP similarly concedes that this patient should have been excluded, and I also accept this concession. (Denton, A–121 at 33, 75.)

The Center next argues that Patient No. 32 had grand mal epilepsy and should have been excluded for this reason. (G–14.7 at 9; A–126 at 21; Denton, Tr. Vol. VII at 20–21.) I need not reach the merits of this argument because AHP has already conceded that Patient No. 32 should be excluded for alcoholism. (See section I.D.1.c.(2). of this document.)

d. *Concomitant Medications.* AHP further argues that the ALJ erred in ruling that the widespread administration of concomitant medications precluded any meaningful analysis of the effects of Cyclospasmol® in the Rao study. (AHP Exceptions at 132, citing I.D. at 37, 42, 56.) In support of its argument, AHP cites to a previous Commissioner's Decision pertaining to the human drug, Oral Proteolytic Enzymes (OPE), in which it was ruled that a study may be used to demonstrate efficacy ''if the identity, quantity, strength, frequency, and length of administration of the concomitant medication is known and if the confounding effect of the concomitant medication has been analyzed so that the effect of the test drug can be determined.'' (Commissioner's Decision on OPE, slip op. at 52–53 (footnote omitted).) AHP argues that under the OPE decision, the ALJ failed to analyze sufficiently whether the concomitant medications had any effect on the study results.

In the Commissioner's OPE decision, it was noted that ''(t)he uncontrolled use of concomitant medication violates several of the most basic scientific principles governing clinical investigations.'' (Commissioner's Decision on OPE, slip op. at 47.) Three such scientific principles, all of which have been incorporated into FDA regulations, were cited by the Commissioner's Decision on OPE.

The first of these principles, as articulated in the regulations, requires that ''(t)he method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as * * * use of drugs or therapy other than the test drug.'' (§ 314.126(b)(4) (At the time of the Commissioner's Decision on OPE, the citation for the comparable regulation was 21 CFR 314.111(a)(5)(ii)(a)(2)(iii)).) The objective of this requirement is to limit, before the study has begun, the extraneous factors which could be responsible for a difference between groups. (Commissioner's Decision on OPE, slip op. at 47–48.) If the assignment of patients is biased, this can skew the study's results.

The second relevant principle, also incorporated into agency regulations, is a requirement that ''(t)he study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect.'' (§ 314.126(b)(2) (The comparable numbered section of the regulations at the time of the Commissioner's Decision on OPE was § 314.111(a)(5)(ii)(a)(4)).) The use of concomitant medication can make it impossible to state with accuracy whether the results of a study were due to the test drug under study or were due to the use of concomitant medication. (Commissioner's Decision on OPE, slip op. at 48–50.)

Thirdly, the Commissioner's Decision on OPE ruled that concomitant medication use must be sufficiently documented so that a scientific evaluation of the use of concomitant medication can be done. (Commissioner's Decision on OPE, slip op. at 50–53.) If a study lacks sufficient documentation of concomitant medication use, the study cannot be considered as part of the basis for approval of effectiveness claims. (Id.) This requirement is expressed in the regulatory requirement that the report of a study ''provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.'' (§ 314.126(a) (The comparable numbered section of the regulations at the time of the Commissioner's Decision on OPE was 21 CFR 314.200(d)(2)).)

Regarding the review of concomitant medication, I note that the Commissioner's Decision on OPE further states that the use of concomitant medication must be considered as ''a fatal flaw'' in the absence of detailed records which would permit evaluation of the effect of the concomitant medication on the results of the study. (Commissioner's Decision on OPE, slip op. at 52.) The burden is on the proponent of the drug to supply detailed records demonstrating the effects of the concomitant medication on the results of the study. (Commissioner's Decision on OPE, slip op. at 134, 144, 203–04.)

As for the Rao study, I have reviewed the ALJ's decision, and I find that the ALJ considered each instance of concomitant medication use. (See I.D. at A–1 to A–5.) Contrary to AHP's claim, the ALJ did not base his decision solely upon the number of patients who were given concomitant medication. As was observed in the Commissioner's OPE decision, ''the use of more than one concomitant medication increases the difficulty of the evaluation of the (study drug's) effect.'' (Commissioner's Decision on OPE, slip op. at 56 (footnote omitted).) While the number of patients given concomitant medication was one factor which properly was considered by the ALJ (Commissioner's Decision on OPE, slip op. at 57), a review of the ALJ's complete decision reveals that the ALJ also considered the identity, quantity, strength, frequency, and length of administration of the various concomitant medications. (See I.D. at A–1 to A–5.) The ALJ took the cited portion of the Commissioner's Decision on OPE into consideration when the ALJ ruled that the concomitant medications ''were so numerous and so pervasive in the Rao study as to preclude any meaningful analysis of the test drug.'' (I.D. at 37.)

AHP also made arguments regarding the individual patients' concomitant drug use. (AHP Post-Hearing Brief at 96–99.) The Center, based upon a review of the hospital records, identified 16 different concomitant medications used by 21 patients in the Rao study,[5] including Patient No. 1 (Valium, Compazine), Patient No. 2 (Mellaril), Patient No. 6 (Valium), Patient No. 9 (Haldol, Benadryl), Patient No. 10 (Valium), Patient No. 14 (Valium), Patient No. 17 (Valium, Mellaril), Patient No. 22 (Mellaril), Patient No. 23 (Seconal), Patient No. 24 (Aldomet), Patient No. 28 (Hydergine), Patient No. 29 (Mellaril, Insulin, Doxepin), Patient No. 32 (Phenobarbital, Dilantin), Patient No. 36 (Haldol, Seconal, Meprobamate), Patient No. 42 (Seconal), Patient No. 43 (Seconal, Peritrate), Patient No. 45 (Mellaril, Peritrate), Patient No. 51 (Mellaril), Patient No. 56 (Valium, Sinemet), Patient No. 57 (Compazine), and Patient No. 68 (Thorazine). The Center argued that the confounding effect of the concomitant medications used by these patients made the Rao study results unreliable. (Center Post-Hearing Brief at 65.)

I note, however, that of these 21 patients, AHP has already conceded that 9 patients (Patient Nos. 9, 22, 23, 29, 32, 36, 43, 56, 68) should be excluded for violations of the inclusion/exclusion criteria. (See section I.D.1.c. of this document.) Additionally, Dr. Denton, a witness for AHP, conceded that Patient No. 36 should be excluded because this patient was taking the concomitant medication, Seconal, a psychoactive drug, and Haldol, a major tranquilizer, at the time of final evaluation. (Denton, A–121 at 81–82.) Remaining after these nine conceded exclusions are 12 patients who received 7 different drugs, including Patient No. 1 (Valium, Compazine), Patient No. 2 (Mellaril), Patient No. 6 (Valium), Patient No. 10 (Valium), Patient No. 14 (Valium), Patient No. 17 (Valium, Mellaril), Patient No. 24 (Aldomet), Patient No. 28 (Hydergine), Patient No. 42 (Seconal), Patient No. 45 (Mellaril, Peritrate), Patient No. 51 (Mellaril), and Patient No. 57 (Compazine). I will address the issues concerning these remaining, contested exclusions.

However, before I address the specific records for each patient, I will make some general observations regarding all the patient records in evidence from the Rao study. First, it must be noted that the contents and status of the patient records in evidence is not consistent from patient to patient. Most records appear to contain only excerpts from the original records. Some records include numerous pages from the physician order sheets, medication records, nursing care record sheets, and patient progress notes. (See, e.g., Patient No. 24, G–14.6 at 175–209.) Other patient records contain only a single page. (See, e.g., Patient No. 18, G–14.6 at 30.) Then again, other records contain a few pages of various sections from the original patient records. (See, e.g., Patient No. 2, G–14.5 at 51–62.)

In addition to the difficulty presented by the inconsistent content of the patient records, another problem is legibility of records. In some instances, although records are in evidence, portions of those records are printed so faintly as to be illegible. (See, e.g, Patient No. 1, G–14.5 at 32, 34, 39, 41; Patient No. 42, G–14. 7 at 245–264; Patient No. 45, G–14.7 at 320.)

Another problem I have found with the records in evidence is the difficulty in identifying the dates on which the patient was evaluated during the study. The protocol provided that ''(e)ach patient will be observed four (4) times. These observations will be made at the initial evaluation and at weeks 4, 8, 12.'' (G- 14.2 at 241.) The dates of these evaluations are important to a review of concomitant medication use because the protocol also provided that ''no major tranquilizer should be administered within the four (4) days immediately proceeding (sic) any evaluation.'' (G–14.2 at 243.)

In reviewing the patient records, I noted that, despite the requirements of the protocol, in a number of patient records the dates on which the patient received the study drug and the dates of the patient evaluations are not consistent with the specifications of the protocol. For example, in the physician order sheets and in the medication records for Patient No. 1, evidence indicates that this patient began to receive the study drug on December 17, 1975, and continued to receive this drug until March 19, 1976. (G–14.5 at 13–16, 21, 23, 25, 27.) However, other documents in evidence indicate that this patient was initially evaluated on January 14, 1976, 1 month after the patient began to receive the study drug. (G–14.5 at 10.) Additional documents in evidence also point to a delayed evaluation occurring in January. For example, one document lists a date of February 25, 1976, and states, ''Mental Status: Second evaluation during the fourth week.'' (G–14.5 at 9.) Another document lists the date of May 11, 1976, as the date of the third evaluation. (G–14.5 at 8.)

It is difficult to fathom why the initial evaluation would have occurred a month after the study had begun, but the dates in the records of a number of other patients clearly support this conclusion. (See also Patient No. 6, G–14.5 at 153, 154; Patient No. 17, G–14.6 at 14, 18.) I further noted that this 1 month difference in dates is not found consistently in all patient records. (See, e.g., Patient No. 57, G–14.8 at 132, 135 (initial evaluation and start of study drug occurred on same date.)) Of course, an initial evaluation that occurred 1 month after the start of the study drug would be a protocol violation and would not be the proper procedures for an adequate and well-controlled study. An initial evaluation of the patient should be taken before the patient has been randomized in the study.

I also noted that while most patient records in evidence contained a page from a psychological evaluation which was captioned at the top ''Final Evaluation,'' I found that the date of this evaluation in many instances appeared to be from the middle of the study, often closer to week 8 than to the actual time of final evaluation at week 12. (See, e.g.,

[5] The Center also argues that Patient No. 2 in the Rao study should be excluded because this patient had been given Elavil, which was a violation of the protocol. The Center further argues that Patient No. 24 had received Serax, and Patient No. 34 had received Phenergan in violation of the protocol. However, my review of the records reveals that it was Patient Nos. 2, 24, and 34 in the Yesavage study, not the Rao study, who had taken these drugs. Accordingly, these issues will be addressed in the discussion of the Yesavage study.

Patient No. 25, G–14.6 at 210–213; Patient No. 26, G–14.6 at 234–237.) However, not all patient records follow this pattern. In some cases, the date on the ''Final Evaluation'' document does appear to have occurred 12 weeks after the patient started on the study drug. (See, e.g., Patient No. 45, G–14.7 at 310, 312.) Therefore, I did not find the date on the document entitled ''Final Evaluation'' to be a reliable means of establishing the dates of the patients' final evaluations in many instances.

Also, I have found several records in which the physician order sheets or medication records indicate that the patient had been receiving the test drug for a month before the recorded date of the patient's initial evaluation. (See, e.g., Patient No. 1, G–14.5 at 10, 13; Patient No. 3, G–14.5 at 68, 73; Patient No. 26, G–14.6 at 235, 239.)

Nevertheless, despite these flaws I have given the patient records full consideration. These records were closely scrutinized for pertinent dates and schedules of relevant medication use. However, AHP, as sponsor of these studies, bears the responsibility of providing adequate records for review. For this reason, any failure of the records to document concomitant medication use can be weighed against finding the Rao study adequate. (Commissioner's Decision on OPE, slip op. at 50–53.) With this as background, I turn now to the specifics of each use of concomitant medication now at issue.

The Rao protocol's requirements regarding concomitant medications were as follows:

> No vasodilating agents, psychoactive drugs, narcotics, reserpine derivatives or steroids other than estrogen will be permitted during the study, except for an h.s. (*hora somni,* i.e., at bedtime) hypnotic, which may be either Noludar or chloral hydrate, or an occasional dose of a major tranquilizer (phenothiazines, haloperidol, etc.) deemed necessary for the patient's welfare. However, any patient who receives more than sixteen (16) doses of a major tranquilizer during the entire course of the study, or more than three (3) doses in any one week, will be dropped from the study. Also, no major tranquilizer should be administered during the four (4) days immediately proceeding (sic) any evaluation. Other routine drugs (e.g. digitalis, diuretics, oral hypoglycemics, non-narcotic analgesics, antibiotics, etc.) required by the patient may be administered, but every effort should be made to maintain a consistent dosage schedule. Patients who have been receiving agents not permitted during the study should have them discontinued 21 days prior to entry.

(G–28.8 at 318.)

Regarding the use of concomitant medication, the Center first argues that Patient No. 1 should be excluded because this patient received both Valium and Compazine during the course of the study. (Center Post-Hearing Brief at 64 and Attachment B; G–14.5 at 20–28; Thal, G–63 at 7.) Valium, a benzodiazepine, is a psychoactive drug, given to reduce anxiety; this drug can cause drowsiness, and affect attention and alertness. (Leber, G–64 at 14; Zung, Tr. Vol. III at 38; Denton, Tr. Vol. VII at 25–26.) Compazine, also a psychoactive drug, may impair mental and physical abilities. (Denton, Tr. Vol. VII at 39.)

The frequency of administration of Valium given to Patient No. 1 is particularly troubling. According to the testimony of Dr. Denton, this patient was given 23 doses of Valium during the study. (Denton, A–121 at 72; see also G–14.5 at 20–28; I.D. at A–1.) Specifically, this patient received Valium 11 times between December 18 to December 23, 1975, 5 times between January 24 to January 31, 1976, 8 times between February 14 to February 22, 1976, and 4 times between March 2 to March 5, 1976. (Denton, A–121 at 72; I.D. at A–2; G–14.5 at 13–49.) In addition, at least 5 doses of Valium were given during the prestudy washout period. (I.D. at A–2; G–14.5 at 13–28.) Moreover, the time of administration of the Valium is not always clearly indicated in the record. This is a clear violation of the protocol, which provided that no psychoactive drugs, except for a bedtime dose of Noludar or chloral hydrate, were permitted. (G–28.8 at 318.) Accordingly, I am in agreement with the ALJ in finding that this is no mere technical violation of the protocol, and that Patient No. 1 should be excluded.

The Center also argues that Patient No. 6 should be excluded for receiving Valium during the study. (Center Post-Hearing Brief at 64 & Attachment B.) The ALJ ruled that this patient should have been excluded because medication records appeared to indicate that this patient had received Valium throughout the course of the study. (I.D. at A–1.) The ALJ cited to the fact that the copy of the medication records in evidence shows a line drawn across all dates in the chart entry for Valium. (I.D. at A–1, citing G–14.5 at 154.) AHP challenges the ALJ's interpretation of the medication records, arguing that the referenced markings on Patient No. 6's chart do not support a finding that the patient was given Valium on those days. (AHP Post-Hearing Brief at 97.)

I have reviewed the cited portion of the medication records for Patient No. 6, and I find that the medication chart in question does show an arrow drawn across all dates in the chart. (G–14.5 at 154.) There are also notations in the margins next to this Valium entry which read, ''Start 12/31,'' ''Valium 10 mg. 'IM' daily,'' ''q 8°,'' and ''Stop 3/19,'' or it may be ''Stop 5/19,'' the writing is not clear. (G–14.5 at 154.) However, my interpretation of this entry is that this particular chart was begun on December 31, and the arrow across the chart was intended to delete the earlier days in the month of December, and was not meant to reflect dosages on those earlier dates. Therefore, I find that the ALJ was in error in his interpretation of this particular chart.

Notwithstanding my ruling with regard to the previously mentioned chart, I find that other records in evidence do support a finding that Patient No. 6 was receiving regular doses of Valium at later dates throughout the study. Aside from the aforementioned chart entries, there are several other chart entries which state that 10 mg of Valium was to be given intramuscularly every 8 hours, commencing on December 31, 1975, and running through March 9, 1976. (G–14.5 at 154, 155, 156, 157.) During this same time, Patient No. 6 was receiving the study drug. (G–14.5 at 154, 155, 156, 157.) The extent of Valium administration was a clear violation of the protocol's general prohibition on the use of psychoactive drugs except for bedtime doses of Noludar or chloral hydrate. (G–28.8 at 318.) Therefore, I affirm the ALJ's ruling in excluding Patient No. 6.

As for Patient No. 17, the physician order sheet states that Patient No. 17 was to receive chloral hydrate PRN (*pro re nata*, as occasion arises) during the study (G–14.6 at 19, 21), and evidence indicates that the patient received this drug on several occasions. (Mohs, G–62 at 9–10.) I note, however, that chloral hydrate at bedtime was permitted under the protocol, and I do not find this to be a basis for excluding this patient. (G–28.8 at 318.)

The Center also argues that Patient No. 17 received both Valium and Mellaril on several occasions, and that this is a basis for excluding this patient. (Center Post-Hearing Brief at Attachment B; Mohs, G–62 at 9–10.) As previously discussed, Valium is a psychoactive drug. The use of psychoactive drugs was generally prohibited except for bedtime doses of Noludar or chloral hydrate. (G–28.8 at 318.) Mellaril, on the other hand, would fall under the category of a major tranquilizer under the protocol, of which occasional doses were permitted if necessary for the patient's welfare. (G–28.8 at 318.)

I have reviewed the extant charts for Patient No. 17, and I have found that the

physician order sheets contain a notation, dated December 18, 1975, to run through February 18, 1976, which reads, ''Valium 10 mg I.M. (intramuscularly) PRN.'' (G–14.6 at 17.) Another entry in the physician order sheets, dated February 18, 1976, directed that the Valium order be continued through April 19, 1976. (G–14.6 at 20.) Entries on the nursing care records, which are illegible in sections, indicate that Patient No. 17 received 10 mg of Valium intramuscularly on at least five occasions. (G–14.6 at 23–25.) The record indicates administration of Valium on December 16 and 21, 1975, and on January 1, January 9, and January 14, 1976. It also appears from the record that this patient began receiving the study drug on December 19, 1975. (G–14.6 at 18.)

The physician order sheets further show that on December 18, 1975, orders were given for Patient No. 17 to receive 25 mg of Mellaril, an antipsychotic drug, ''t.i.d.'' (*ter in die*, three times a day), beginning during the final 2 days of the washout period. (G–14.6 at 17; see also Leber, G–64 at 11; Mohs, G–62 at 9–10.) However, another chart entry, dated December 19, 1975, ordered the Mellaril discontinued. (G–14.6 at 18.) The nursing care records do not record the administration of Mellaril.

With regard to the dates of evaluation of Patient No. 17, I note that there are significant inconsistencies in this patient's records. While the physician's order sheets indicate that Patient No. 17 was started on the study drug on December 19, 1975 (G–14.6 at 18), another document in the record indicates that this patient's initial evaluation occurred on January 19, 1976 (G–14.6 at 14), 1 month after the patient had been on the study drug. This January date for the initial evaluation is consistent with another record entry, which lists the date for the ''(s)econd evaluation during the fourth week'' as being on February 25, 1976. (G–14.6 at 13.) But in apparent contradiction to the January date, yet another record item, this one found in the patient progress notes, dated January 23, 1976, states that the patient ''is on vasodilator drug Cyclospasmol® for another month.'' (G–14.6 at 15.) This would place this patient's initial evaluation at sometime in November 1975, and final evaluation in February 1976.

These inconsistencies, along with the illegibilities and obvious incompleteness of the record (there are large gaps of at least two months duration between dates in the patient progress records), make the records of Patient No. 17 inadequate for proper review. Therefore, I find that this patient should be excluded. (Commissioner's Decision on OPE, slip op. at 50–53.)

Regarding Patient No. 24, Dr. Paul Leber, a witness for the Center, testified that there were several interruptions in treatment with Cyclospasmol® between the dates of February 18, and February 22, 1976, during the study. (Leber, G–64 at 12.) I have reviewed the physician's order sheet for this patient, and I have found that the records do show that Cyclospasmol® was discontinued on February 18, but was started again on February 22, 1976. (G–14.6 at 182, 183.) I note Patient No. 24's records indicate that this patient's initial evaluation was on January 26, 1976, and the patient's final evaluation was on May 7, 1976. (G–14.6 at 175, 177.) In view of the brevity of the interruption, and the fact that it did not occur close to the time of either the initial or the final evaluation, I do not find this a basis to exclude Patient No. 24.

Dr. Leber also testified that Patient No. 24 received Aldomet, an antihypertensive medication which can affect mood and cognition. (Leber, G–64 at 13.) Dr. Leber testified that ''the protocol (was) unclear as to whether such patients could or could not have been admitted, but discontinuation of this medication (Aldomet) might affect a patient's mental status.'' (Leber, G–64 at 13.)

In considering the administration of Aldomet to Patient No. 24, I note that the protocol provided that ''routine drugs (e.g., digitalis, diuretics, oral hypoglycemics, non-narcotic analgesics, antibiotics, etc.) required by the patient may be administered, but every effort should be made to maintain a consistent dosage schedule.'' (G–14.2 at 243.) I would place Aldomet in the category of routine drugs for the purposes of the Rao study. As for the schedule of administration of Aldomet to Patient No. 24, the physician's order sheets indicate that this patient was receiving 250 mg of Aldomet four times a day from November 14, 1975 (G–14.6 at 186), until February 16, 1976. (G–14.6 at 184.) As I previously noted, this patient's initial evaluation was on January 26, 1976, and the final evaluation was on May 7, 1976. (G–14.6 at 175, 177.) Thus, this patient was receiving Aldomet throughout the washout period and continuing through several weeks of the study.

Having considered Patient No. 24's use of Aldomet, I find that this is not a basis to exclude this patient. At the time of initial evaluation, this patient was well-established on the regimen of Aldomet, which could mean that any initial drowsiness which the patient might have experienced may have passed. As for the withdrawal of Aldomet during the study, I do not find the evidence of any negative effects on the patient to be sufficient to exclude this patient. Therefore, I uphold the ALJ's decision to include Patient No. 24 in the Rao study. (I.D. at A–2.)

The Center next argues that Patient No. 28 should be excluded for receiving Hydergine during the study. (Center Post- Hearing Brief at 64 & Attachment B.) Evidence indicates that this patient received Hydergine three times a day during the first week of the study. (Denton, A–121 at 80; Thal, G–63 at 7; G–14.6 at 261–62.) Regarding the effect of this drug, Dr. Denton testified, ''Hydergine is an agent which helps to relieve some of the cognitive aspects of dementia through an unknown mechanism of action.'' (Denton, A–121 at 39; see also Zung, Tr. Vol. III at 64.) However, Dr. Denton suggested that Patient No. 28 did not have to be excluded because Hydergine was administered during the first week of the study in December 1975, and this should not have affected the final evaluation made in March 1976. (Denton, A–121 at 40.)

I have reviewed the records in evidence for Patient No. 28, and I found that the physician order sheets indicate that this patient was receiving Hydergine for at least two months prior to the start of the Rao study. (G–14.6 at 261, 262, 265.) To the extent that Hydergine is effective, then Patient No. 28's baseline might have been higher than it would have been otherwise. The withdrawal of Hydergine could have caused a worsening in the patient's condition over the course of the 12-week study. I therefore find that the possible confounding effect of Hydergine must be considered, and that for this reason, Patient No. 28 should be excluded.

Regarding Patient No. 42, Dr. Denton testified that this patient received Seconal at bedtime during the final week of the study, from March 27 to April 2, 1976. (Denton, A–121 at 82.) As Dr. Denton acknowledged, Seconal is a psychoactive medication, and, as such, its use was generally prohibited under the protocol. (Denton, A–121 at 81 (discussing Patient No. 36); G–28.8 at 318.) Nevertheless, Dr. Denton takes the position that this is not a reason to exclude Patient No. 42, notwithstanding the fact that the medication was given at the time of final evaluation. (Denton, A–121 at 82.)

First, I note that this patient's use of Seconal does not appear to be documented in the patient records in evidence; however, I also note that

many of this patient's records are not legible. (G–14.7 at 219–264.) The question of documentation was not raised by the Center; rather, the Center's arguments are based on the violation of the concomitant medication restrictions in the protocol.

Because the averred level of use of Seconal was that of a bedtime hypnotic, I find that, while Patient No. 42's concomitant medication use violated the protocol's general prohibition on psychoactive drugs except for bedtime doses of Noludar or chloral hydrate (G–28.8 at 318), this level of use is not cause for excluding Patient No. 42. Nevertheless, I note that AHP's failure to provide documentation for the administration of Seconal can be considered as a flaw in the Rao study and can be weighed in evaluating the adequacy of this study. (Commissioner's Decision on OPE, slip op. at slip op. at 52–53.) Additionally, the fact of this protocol violation can also be considered in evaluating this study.

Regarding Patient No. 45, evidence indicated that this patient received 20 mg of Peritrate, a vasodilator, twice a day during the study, from March 23 to March 31, 1976. (G–14.7 at 314; Denton, A–121 at 39, 82–83; Mohs, G–62 at 11.) Patient No. 45's records do not indicate the date of initial evaluation, but, from an entry on the physician's order sheet, it appears that this patient had been receiving the study drug since January 5, 1976. (G–14.7 at 312.) Another entry in this patient's progress notes states that, as of March 7, 1976, this patient had been on Cyclospasmol® for 2 months, which would be consistent with an initial date of January 5, 1976. (G–14.7 at 318.) Final evaluation of this patient apparently was on April 8, 1976. (G–14.7 at 310.) Evidence also indicates that Patient No. 45 was receiving an unspecified level of Mellaril during the washout period. (Denton, A–121 at 83.) The Center argues that because of these concomitant medications, Patient No. 45 should be excluded. (Center's Post-Hearing Brief at 64.)

In Dr. Denton's written review of Patient No. 45, Dr. Denton wrote that Mellaril was given prior to the study, but was discontinued on December 26, 1975, about 10 days before the study drug was started. (Denton, A–121 at 83.) Regarding the Peritrate, Dr. Denton concluded that the use of this drug for a period of one week was ''irrelevant.'' (Denton, A–121 at 83.)

I have reviewed the records in evidence for Patient No. 45, but these records, which are illegible in parts, do not appear to contain the chart of administration of Mellaril. (See G–14.7 at 310–333.) While the absence of complete records can be considered a ''fatal flaw'' for the adequacy of a study (Commissioner's Decision on OPE, slip op. at 52–53), nevertheless, because the issue is the washout period, in this instance I will accept Dr. Denton's testimony regarding the administration of Mellaril. Specifically, I will accept that Mellaril was discontinued 10 days prior to the commencement of the Rao study. I find that this is probably sufficient for the purposes of including this patient in the study, although the protocol required a 21-day washout period. (See G–14.2 at 243.)

Notwithstanding my finding regarding the inclusion of Patient No. 45 despite this patient's use of Mellaril, I note both the violation of the protocol's 21-day washout period, and the incompleteness of the records regarding Patient No. 45's use of Mellaril can be considered in evaluating the adequacy of the Rao study.

As for the administration of Peritrate to Patient No. 45, I note that the administration of this vasodilating agent was a violation of specific prohibitions of the protocol against the use of vasodilating agents other than Cyclospasmol®. (G–28.8 at 318.) However, because Peritrate was not administered near the time of either the initial evaluation, on January 5, or the final evaluation, on April 8, I will accept Dr. Denton's estimation that this level of Peritrate was not a basis to exclude this patient, although I do not accept his characterization of the use of this drug as ''irrelevant.'' Therefore, I find that this patient could be included in the analysis of the Rao study. Nevertheless, this is a clear protocol violation, and the possible confounding effect of Peritrate should be weighed in reviewing the adequacy of the Rao study.

Regarding Patient No. 57, Dr. Denton testified that this patient received Compazine for 2 days during the course of the study. (Denton, A–121 at 84.) However, I have reviewed the records for this patient, and I found that the physician's order sheet indicates that Compazine, 10 mg PRN, was ordered on January 30, 1976, with the order running through February 20, 1976. (G–14.8 at 135.) A second order to discontinue the Compazine was entered on February 20, 1976. (G–14.8 at 136.) There were no medication records tracking actual administration of Compazine. I note that this patient's initial evaluation was on January 30 (G–14.8 at 132), and the patient's final evaluation was on May 11, 1976. (G–14.8 at 131.)

The Center's argument pertaining to Patient No. 57's concomitant medication use is based on Dr. Denton's testimony that this patient received Compazine twice during the study. Because this was the focus of the Center's argument, I will address my ruling to the Center's argument, rather than considering the standing order for Compazine reflected in the patient's records. On this basis, I do not find that Patient No. 57 needed to be excluded.

Notwithstanding my ruling regarding Patient No. 57's receiving Compazine, I nevertheless note that AHP's failure to provide documentation of the administration of Compazine can be considered as a flaw in the Rao study. (Commissioner's Decision on OPE, slip op. at 52–53.) While Dr. Denton testified that Compazine was only administered twice, the physician's order sheets for this patient suggest that this drug might have been administered more frequently. Because of the absence of adequate records, this patient's concomitant medication use can not be fully reviewed, and this fact can be considered in weighing the adequacy of this study.

The Center also argues that several patients were in violation of the protocol's 21-day, prestudy washout requirement. (Center Post-Hearing Brief at Attachment B.) It is alleged that a number of patients received major tranquilizers during the washout period. However, before I review the records of each of the patients which the Center cites, I note that administration of occasional doses of a major tranquilizer during the study were permitted by the protocol. (G–28.8 at 318). Because occasional doses were permitted during the study, by extension, I find that occasional administration of a major tranquilizer might be said to have been permitted during the prestudy washout period. However, I also find that the same restrictions on the level of the dose and the timing of administration, i.e., not within 4 days of an evaluation, would still apply during the washout period.

Turning now to the Center's arguments, first, the Center argues that Patient No. 2 received Mellaril during the washout period. (Denton, A–121 at 72–74.) The problem with assessing Patient No. 2's use of Mellaril is that this patient's records reveal only that Mellaril, dose unspecified, was discontinued at the same time that Cyclospasmol® was begun. (G–14.5 at 55.) The record of Mellaril use during the washout period is not included in the evidentiary record.

Dr. Leber, a witness for the Center, had testified regarding the effects of Mellaril. Dr. Leber testified that Mellaril, an anticholinergic,

antipsychotic drug, has a great potential to adversely affect cognition, learning, and memory. (Leber, Tr. Vol. I at 68–69.) Patients who are receiving Mellaril can have their cognitive performance appear worse than it actually would have been, absent Mellaril. When the patient is withdrawn from Mellaril, the patient's cognitive performance may improve due to the withdrawal of Mellaril. (Leber, Tr. Vol. I at 69.) Moreover, Mellaril is a drug with a ''very long half-life.'' (Leber, Tr. Vol. I at 70.) That is to say, it can accumulate in the body. (Leber, Tr. Vol. I at 70.)

As for the administration of Mellaril to Patient No. 2, I find this to be an apparent violation of the protocol's restriction against giving a patient a major tranquilizer within 4 days of an evaluation, in this instance the initial evaluation. (G–28.8 at 318.) I use the word ''apparent,'' since the necessary records of Mellaril use are not in evidence. However, as was held in the Commissioner's Decision on OPE, the use of concomitant medication can be considered as ''a fatal flaw'' in the absence of detailed records which would permit evaluation of the effect of the concomitant medication on the results of the study. (Commissioner's Decision on OPE, slip op. at 52–53.) Without the necessary records regarding Patient No. 2, I find that this patient should have been excluded from the Rao study.

The Center next argues that Patient No. 51 also received Mellaril during the washout period. (Center Post-Hearing Brief at Attachment B.) I have reviewed this patient's medication charts, and I have found that these records indicate that this patient received Mellaril, 25 mg four times a day, from December 4, 1975, to January 31, 1976, a time period which included the entire washout period. (G–14.8 at 40, 41.) This patient began receiving the study drug on January 30, 1976. (G–14.8 at 40; Leber, G–64 at 14.) Dr. Denton, in his review of this patient's records, wrote, ''There is no practical necessity of the 3 week washout, when the final evaluation is done 3 months after the start of the study.'' (Denton, A–121 at 83.) Dr. Denton, however, did not address himself to the fact that the initial evaluation of this patient may have been affected by the frequent and regular use of Mellaril.

The level of Mellaril used by Patient No. 51 was a violation of two provisions of the protocol. Specifically, this patient received more than three doses of a major tranquilizer in 1 week, and received a major tranquilizer within 4 days of initial evaluation. (G–28.8 at 318.) In fact, records support a finding that Mellaril was administered four times a day even on the day of initial evaluation. I find this level of Mellaril use by Patient No. 51 at the time of initial evaluation to be a basis for excluding this patient from the study.

Patient No. 10 received Valium during the washout period. (Denton, A–121 at 75.) In my review of this patient's records, I found that the physician order sheets contained a notation which read, ''Valium 5 mg at 8 PM,'' with the further notation that the medication was to start on December 11, 1975, and continue until January 19, 1976. (G–14.5 at 233.) However, a later notation indicated that Valium was discontinued on December 23, 1975, two weeks after it had been initiated. (G–14.5 at 234.) This patient had begun to receive the study drug on December 18, 1975. (G–14.5 at 233.) The administration of Valium to this patient violated the protocol's general prohibition against the use of psychoactive drugs except for bedtime use of Noludar or chloral hydrate. (G–28.8 at 318.) However, I do not find this level of use of Valium to be cause to exclude this patient. Nevertheless, I note the fact that this protocol violation can be weighed in evaluating the adequacy of the Rao study.

Patient No. 14 received Valium, 2 mg twice a day, beginning on December 15, 1975. (G–14.5 at 334; Denton, A–121 at 77.) This patient started on the study drug on December 19, 1975; Valium was discontinued on December 23, 1975. (G–14.5 at 334.) As with the previously discussed patient, the administration of Valium to Patient No. 14 violated the protocol's general prohibition against the use of psychoactive drugs except for bedtime use of Noludar or chloral hydrate. (G–28.8 at 318.) Nevertheless, I do not find this level of use of Valium to be cause to exclude this patient, but I note the fact of this protocol violation can be weighed in evaluating the adequacy of the Rao study.

Also cited by the Center for receiving medications during the washout period, in addition to the Center's claims of concomitant medication use during the study by these particular patients, were Patients No. 22 for receiving Mellaril (Leber, G–64 at 12), Patient No. 29 for receiving both Doxepin, an antidepressant, and Mellaril (Leber, G–64 at 13), and Patient No. 56 for receiving Valium (Leber, G–64 at 14) during the washout period. I need not discuss these three patients because AHP has conceded that these patients should be excluded for violations of the inclusion/exclusion criteria. (See sections I.D.1.c.2. (regarding Patient No. 22), I.D.1.c.3. (regarding Patient No. 29), and I.D.1.c.4. (regarding Patient No. 56).)

In summary, the Center had alleged concomitant medication use in violation of the protocol by 21 of the 58 patients in the Rao study. Of these 21 patients, AHP has already conceded that 9 patients (Patient Nos. 9, 22, 23, 29, 32, 36, 43, 56, 68) should be excluded for violation of the inclusion/exclusion criteria. Additionally, it was conceded by Dr. Denton, AHP's witness reviewing the Rao study, that Patient No. 36 should be excluded for the concomitant use of Seconal at the time of final evaluation.

After these conceded exclusions, there remained 12 other patients cited by the Center for concomitant medication use, but whose exclusion AHP contests. Of these patients, I have found that Patient Nos. 1, 2, 6, 17, 28, and 51 should be excluded for concomitant medication use. I further find that Patient Nos. 10, 14, 42, 45 and 57 can be included, but that for the various reasons previously discussed, the inclusion of these patients can be weighed against problems with the records for these patients, and with the fact that protocol violations were found in connection with these patients. I note that even protocol violations which individually may not warrant rejection of a study can be considered in the aggregate in determining whether a study is adequate and well-controlled. (See Commissioner's Decision on Benylin, 44 FR 51512 at 51531.) Lastly, I find that Patient No. 24 can be included.

e. Case Report Forms. AHP further makes a general challenge to the ALJ's consideration of the lack of case report forms for 55 out of the 58 patients as another factor to be weighed in reviewing the adequacy of the Rao study. (AHP Exceptions at 137–39, citing I.D. at 40, 42.) AHP argues that the case report forms were not needed because hospital records (see G–14.5; G–14.6; G–14.7; G–14.8) and computer printouts (see G–11.2) regarding most of the patients were available. (AHP Exceptions at 139.)

The Center argues that the case report forms were needed for several reasons. (Center Response to AHP Exceptions at 53; Center Post-Hearing Brief at 60–62, 65–66, 68–74.) The Center argues that for most of the patients, there are no results for the neurological examination required by the protocol, the absence of which undermines any assurances by AHP that the patients did not have a neurological cause for their senility. (Center Post-Hearing Brief at 61–62.) Additionally, there were no hospital records available for two of the

patients—Nos. 7 and 48—included in the analysis. (Center Post-Hearing Brief at 65–66.) For these reasons, it was impossible to determine whether these patients were given concomitant medications to any extent. (Center Post-Hearing Brief at 65–66.)

Regarding the computer printouts, the Center argues that these documents are inadequate because they do not contain necessary information such as the results of the physical examination, the neurological examination, and the laboratory tests. (Center Post-Hearing Brief at 70–72.) Moreover, the Center argues that computer printouts are not an adequate supplement because the printouts do not record any of the subjects' medical histories, concomitant medication use, the SCAG evaluations for ten of the placebo patients, nor the identities of investigators who made each patient's SCAG evaluation. (*Id.* at 70–73.)

Dr. Mohs, a witness for the Center, explained the reasons for needing the case report forms as follows:

> (I)t makes it very difficult to evaluate the study when the original data forms are not available. It is difficult to determine how well the records were kept and whether or not there were errors made in taking the data from the original case report forms to the analysis system. In other words, it makes it impossible to verify whether the protocol was followed and whether the results, which were eventually reported in the published article, accurately reflect the data that were collected.

(Mohs, G–62 at 8.)

Similar testimony was given by Dr. Leber, a witness for the Center, who testified in part, ''The documentation supplied by the sponsor (makes) it impossible to determine whether or not certain requirements of the protocol were actually carried out.'' (Leber, G–64 at 16.)

The act requires that a new drug application include ''full reports of investigations'' which have been made to show whether such drug is effective in use. (21 U.S.C. 355(b)(1).) This statutory requirement was extensively discussed in the Commissioner's Decision on OPE. In that decision, it was noted that neither the statute nor agency regulations imposes a per se requirement that in every instance raw data be submitted in support of a new drug application. (Commissioner's Decision on OPE, slip op. at 66.) The Commissioner's decision on OPE went on to note that while raw data are not required in support of all NDAs, this does not mean, however, that the submission of raw data may never be required by the agency. The ''full reports'' requirement can be met without access to the raw data only when the report of the study: (1) Is published in the scientific literature, (2) is reliable, and (3) describes an adequate and well-controlled study. (Commissioner's Decision on OPE, slip op. at 67.)

Additionally, it should be noted that publication alone does not negate the necessity for raw data from a study to be supplied to the agency. Regarding published studies, the Commissioner's Decision on OPE ruled:

> (P)ublished studies can be considered reliable and can be accepted without supporting raw data *only if the reports of the studies contain details adequate to support a scientific determination that the study is an adequate and well-controlled clinical investigation*. The determination of whether the report is adequate (and raw data unneeded) is a discretionary determination made on the basis of the quality of the published data. Among the factors that determine whether a published report is sufficient are whether the protocol, the results, and the manner by which the study meets each of the requirements of (FDA regulations) are described in detail.

(Commissioner's Decision on OPE, slip op. at 70–71 (citations omitted, emphasis added).)

Turning now to the Rao study, I note that while the Rao study was published in the *Journal of the American Geriatrics Society*, the article, which was four pages in length, failed to provide any details regarding the patient selection process, and completely failed to discuss concomitant medication use, and further failed to discuss concomitant diseases or conditions which the patients had during the course of the study. (A–80 at 1–4.) The computer printouts which AHP cites are not sufficient to make up this deficit because the printouts do not contain information such as the results of the neurological examination required by the protocol, nor do the printouts identify which doctor performed which SCAG evaluation. (I.D. at 39.) The hospital records, which do not contain SCAG or NOSIE scores but which do contain information regarding concomitant medication use, are missing for two of the patients included in the analysis. (Center Post-Hearing Brief at 65.)

I find that Dr. Rao's published report fails to contain details adequate to support the scientific determination necessary to find that the Rao study is an adequate and well-controlled clinical investigation. Therefore, I find that the unavailability of the raw data was a matter properly considered by the ALJ. I conclude that the omission of the raw data can be weighed in determining whether the Rao study was adequate and well-controlled.

f. *Blinding and bias.* Regarding the matter of bias, the Center argues that Dr. Rao did not remain blinded throughout the clinical trial and for this reason was biased in his observations. (Center Post-Hearing Brief at 75; Center Response to AHP Exceptions at 53–54.) AHP argues that the evidence fails to support the Center's claims. (AHP Post-Hearing Brief at 99–104; AHP Exceptions at 142–47.) While the ALJ discussed the issues of bias and blinding in the Initial Decision, the ALJ made no ruling regarding this matter. (I.D. at 41–42, 43.)

Dr. Rao had died prior to the commencement of the administrative hearing, so there was no direct testimony from him on this point. The underlying basis for the Center's claims lies in the fact that of the 16 Cyclospasmol®-treated subjects assigned to Dr. Rao, Dr. Rao rated 10 of these subjects as ''markedly improved,'' whereas the three other investigators in the same study (Drs. Georgiev, Guzman and Paul), who together rated 16 Cyclospasmol®-treated subjects, only rated one subject as ''markedly improved.'' (Mohs, G–62 at 12–13; Thal, G–63 at 8, citing (G)-11.2 at 72–73 & (G)-14.2 at 254; Leber, G–64 at 18.) The Center argues that this disparity in ratings among the four evaluators indicates that adequate measures were not taken to minimize bias on the part of the observers and analysts of the data. (Center Response to AHP Exceptions at 53–54.)

In support of its argument on the blindness issue, the Center cites to the testimony of three of its witnesses—Drs. Leber, Thal, and Mohs. (Center Post-Hearing Brief at 75.) Each of these witnesses raised questions about the credibility of Dr. Rao's ratings as compared with that of the three other investigators in the Rao study.

On this issue, Dr. Leber, a witness for the Center, testified that there was ''a marked inconsistency between (Dr.) Rao's findings and those of his three co-investigators.'' (G–64 at 18.) Dr. Leber noted that of the 32 patients collectively assigned to the four investigators in the Cyclospasmol® arm, 12 of the 13 patients reported to have shown the largest improvements from baseline on SCAG Item 19 were in Dr. Rao's group. (G–64 at 18.) Additionally, Dr. Leber testified that on the physician's final global evaluation of each patient, a ''marked improvement,'' the highest level of improvement, was reported by all investigators for 11 of the 32 patients in the Cyclospasmol® arm, with 10 of these 11 ''marked improvements'' being reported by Dr. Rao. (G–64 at 18.) Dr.

Leber added that the hospital records often failed to support the marked improvements which Dr. Rao reported. (G–64 at 20.) Dr. Leber expressed the view that ''at best, Dr. Rao's use of the SCAG represents a sort of 'grade inflation.' That is, patients who have either had only trivial or minimal changes are rated as having very large improvements.'' (G–64 at 20.)

Dr. Leber also cited numerous specific examples of patient evaluations which he found to be questionable. (G–64 at 20–22.) Among the patients cited by Dr. Leber were Patient Nos. 15, 17, 20, 29, and 63. All of these patients were reported by Dr. Rao to have had a 3.0 change on SCAG Item 19, yet the clinical psychologist reports for the Rao study indicated that these patients worsened during the study. (G–64 at 20–22.) Other patients, including Patient Nos. 16, 22, 24, 52, and 56 were also reported by Dr. Rao to have had an improvement in their SCAG scores by 3.0 points, and, in one instance, a 4.0 improvement, yet the clinical psychologist evaluation reported no change in these patients or, in the case of the patient with the reported 4.0 change, minimal improvement. (Leber, G–64 at 21–22.)

Dr. Thal, another witness for the Center, similarly expressed the view that there were a number of items that suggested a ''credibility gap'' in the Rao study. (Thal, G–63 at 8.) On this point, Dr. Thal testified:

> First, although 4 different investigators rated the patients, only Dr. Rao found a large number of markedly improved patients. * * * The second problem is that Dr. Rao's global improvement evaluation of marked improvement in the 10 patients is not substantiated by other observers (including NOSIE scores, clinical psychology notes, nursing notes, and doctors' progress notes.) Overall, the discrepancies noted raise questions about the credibility of the data.

(Thal, G–63 at 8.)

Regarding this issue, Dr. Richard C. Mohs similarly testified:

> Since (Dr. Rao) evaluated only 16 patients in this group (the Cyclospasmol® arm) Dr. Rao rated 62% of his Cyclospasmol® patients as markedly improved while the other three physicians together only rated 1 of 16 patients as markedly improved (6%). This is very unlikely to have occurred by chance and suggests that Dr. Rao may not have been blind to the drug conditions of the patients.

(Mohs, G–62 at 13.)

I have reviewed the evidence cited by the Center in support of its argument, but I do not find the evidence sufficient to support the serious charge that Dr. Rao became unblinded during the clinical trial and failed to report becoming unblinded. While the evidence does seem to indicate a sort of ''grade inflation'' on Dr. Rao's part, as was suggested by Dr. Leber in his testimony, nevertheless the evidence is inconclusive regarding the question of Dr. Rao's blinding. There is no evidence which I find which is dispositive of the Center's claim of unblinding by Dr. Rao. Moreover, there is no evidence which indicates that Dr. Rao's patients were randomized between placebo and Cyclospasmol® arms in a way different from that of the patients in other investigators' groups, which might have revealed the patient's status to Dr. Rao. I find that while the disparity in ratings among the investigators was an issue properly raised by the Center, nevertheless I find the evidence ambiguous and not sufficient to support the Center's claim. Therefore, I rule in favor of AHP on the issues of blinding and bias.

g. *Adequacy of the Rao study.* In sum, I find that the Rao study was not adequate and well-controlled. In making this determination, I have considered the aggregate effect of the protocol violations. As I previously discussed: (1) The study failed to show that patients were examined for other causes of dementia, and therefore the study did not adequately show that Alzheimer's disease patients were included in the study; (2) patients with concomitant diseases and conditions, including strokes, histories of alcoholism, severe diabetes, Parkinson's disease, and other serious diseases were admitted to the study, although these patients were to have been excluded under the protocol; and (3) the widespread administration of concomitant medications precluded any meaningful analysis of the effects of Cyclospasmol® in the study. Also, I find that Dr. Rao's published report failed to contain details adequate to support the scientific determination that the Rao study is an adequate and well-controlled clinical investigation; the unavailability of the raw data was a matter properly considered by the ALJ, and the omission of the raw data can be weighed in determining whether the Rao study was adequate and well-controlled. I further find that the ALJ did not err in refusing to admit AHP's reanalysis of the Rao study, since the reanalysis was not timely filed and AHP did not make a motion justifying the potential delay resulting from the document's late submission. I did rule in favor of AHP on the issue of the blinding and bias of Dr. Rao. However, the favorable ruling on this issue is not enough to counteract the aggregate effect of the other deficiencies of the Rao study.

2. The Yesavage Study

The Yesavage study was originally planned as a multicenter study combining the results of three investigators at three different sites. However, the results of one of these investigators were dropped at the request of FDA because of certain questions about that portion of the study. (I.D. at 43; see also G–10.2 at 1–2.) The results of the second investigator were not submitted by AHP, for reasons which are disputed by the Center but which are not at issue in this appeal. (I.D. at 43- 44.) In any case, only the results of Dr. Yesavage's group were submitted as proof of efficacy for Cyclospasmol®. Hereinafter, the results of Dr. Yesavage's group will be referred to as the Yesavage study.

The Yesavage study was a placebo-controlled, parallel group study with the stated objective of evaluating ''the efficacy of Cyclospasmol® compared to placebo in improving symptoms usually associated with impaired brain function in the elderly, whether due to cerebral arterial disease or diffuse cellular dysfunction.'' (G–9.2 at 32.) Twenty-eight patients were enrolled at the start of the study. (I.D. at 43, citing G–9.2 at 32; G–11.1 at 10, 17.)

Under the protocol, patients selected for the Yesavage study were to be ''residing in a retirement, intermediate care facility, convalescent, nursing or other home for the aged and who exhibit mild to moderate deterioration of brain function as manifested by their behavior or symptoms * * *.'' (G–9.2 at 32.) Accordingly, the patients selected for the study were drawn from one of three nursing homes and from an intermediate care facility (Lincoln Glen Manor, Empress Convalescent Hospital, Skyline Convalescent Hospital, or Lincoln Glen Intermediate Care Facility). (I.D. at 43, citing Yesavage, Tr. IV at 43–44.) However, a few patients lived at home with relatives. (I.D. at 43, 46; Yesavage, Tr. Vol. IV at 43–44.)

Subjects in the study were assessed on the basis of 28 outcome measures. These measures included the Nurses Observation Scale—Inpatient Evaluation (NOSIE), which, in contrast to the NOSIE in the Rao study, was used to give a single measure for each patient, the Hamilton Depression Scale, the Buschke Memory Test (BMT), the physician's clinical global impression score, and the 24 measures—5 factors plus 19 items—on the Sandoz Clinical Assessment—Geriatric (SCAG). (G–9.2 at 45.)

At time of final analysis, the results of 23 of the 28 patients in the study were analyzed on the basis of measurements

taken at Weeks 3, 6, 9, and 12. (I.D. at 43, citing G–64 at 24; see also G–11.1 at 17.) However, additional and variable numbers of patients were excluded from the final analysis for which the patients' baselines were compared with their outcomes at Week 16, which was the final week of the study. (G–11.1 at 20–37.) For the SCAG rating, 20 patients, including 12 Cyclospasmol® and 8 placebo patients, were used. (G–11.1 at 29–31.) For the BMT, the results of 17 patients, including 10 Cyclospasmol® and 7 placebo patients, were analyzed. (G–11.1 at 32.) For the Clinical Global Impression, the measures of 22 patients, of which 13 were Cyclospasmol® patients and 9 were placebo patients, were used. (G–11.1 at 33.) For the NOSIE scale, 15 patients, including 10 Cyclospasmol® and 5 placebo patients, were used. (G–11.1 at 34–36.) For the Hamilton Depression Scale, 21 patients, including 13 Cyclospasmol® and 8 placebo patients, were analyzed. (G–11.1 at 37.) AHP's reasons for analyzing different numbers of patients for each outcome measure were not discussed in the final analysis of the Yesavage study. (See G–11.1 at 5- 45.)

Based upon the results of the 20 patients whose outcomes were included in the final analysis of the SCAG Factors, AHP reported a statistically significant difference in favor of Cyclospasmol® on SCAG Factor 1 (''cognitive dysfunction''), and SCAG Item 19 (''overall impression of patient functional capacity''). (G–11.1 at 19–20, 29, 78; Thal, G–63 at 16–17; Chaing, Tr. Vol. I at 52–53; Overall, A–116 at 6.)

The ALJ ruled that the Yesavage study cannot be considered an adequate and well-controlled study, in part, because: (1) Patients who did not meet the entrance criteria were included in the study, (2) concomitant medication use confounded the study, and (3) clinical significance was not demonstrated. AHP and the Center make the following arguments challenging the ALJ's decision.

a. *Selection of patients.*—(i) *Parkinson's Disease.* AHP first argues that the ALJ erred in ruling that two of the patients in the study—Patient Nos. 34 and 37—had Parkinson's disease and should have been excluded. (AHP Exceptions at 149, citing I.D. at 53, 57.) AHP argues that this ruling is an error because the protocol for the Yesavage study did not exclude patients with Parkinson's disease. (AHP Exceptions at 149.)

The Center argues that these two patients should properly be excluded because Parkinson's disease itself causes dementia, which could confound the results of the study. (Center Response to AHP Exceptions at 55–57.) The Center additionally argues that Parkinson's disease is a type of organic brain syndrome (Denton, Tr. Vol. VII at 38), and that patients with organic brain syndrome were to have been excluded under the Yesavage protocol's exclusionary criteria. (Center Response to AHP Exceptions at 56 n.26, citing G–9.2 at 34.)

Whether the inclusion or exclusion of a particular patient is consistent with the protocol is one factor which can be considered in reviewing a study, for it goes towards proving whether the study was adequate and well-controlled. However, conformance to a study's protocol is not an ironclad guarantee that the study will be found to be adequate and well-controlled.

The burden of designing and conducting an adequate and well-controlled study lies with the proponent of the drug. (Commissioner's Decision on Mysteclin, slip op. at 11; see generally § 314.126.) Protocols can be found to be inadequate. If a protocol is flawed, it does not matter if the protocol was perfectly adhered to in its execution. (Cf. Commissioner's Decision on Cothyrobal, 42 FR 28602 at 28604 and 28606 (Study found not to be adequate and well-controlled because design of study did not include test arms for all components of a combination drug.).) Moreover, FDA cannot be estopped in its review of safety and effectiveness issues. (*United States* v. *Articles of Drug * * * Hormonin*, 498 F. Supp. 424, 437 (D.N.J. 1980), aff'd 672 F.2d 904 (3d Cir. 1981).)

Turning now to the evidence regarding the Yesavage study, the record shows that Dr. Leon Thal, a witness for the Center, testified that Parkinson's disease can cause dementia. (Thal, G–63 at 12.) Specifically, Dr. Thal testified, ''Patients with Parkinson's disease do have dementia, however, the dementia may not be secondary to Alzheimer's disease but due to a dementia associated with Parkinson's disease which has a different pathological basis.'' (Thal, G–63 at 12.)

FDA regulations require that a protocol for an adequate and well-controlled study have a ''method of selection of subjects (that) provides adequate assurance that they have the disease or condition being studied * * *.'' (§ 314.126(b)(3).) In the Commissioner's Decision on Lutrexin it was ruled, under an earlier edition of the regulations, that it is necessary to use ''the most accurate diagnostic techniques available'' to assure that patients who do not have the condition under study are identified and excluded from the study; the failure to do so ''undermin(es) the validity of the results.'' (41 FR 14406 at 14419.)

Having reviewed the Yesavage study, I find that the ALJ was correct in ruling that Parkinson's disease, though not specifically excluded by the protocol, would make it more difficult to characterize the improvement of a demented patient. (I.D. at 45.) I conclude that because dementia caused by Parkinson's disease is not a labeled indication for Cyclospasmol®, Patient Nos. 34 and 37, who had Parkinson's disease, should have been excluded from the study to prevent confounding of the study's results.

The record also supports a finding that Patient No. 18 had Parkinson's disease. Patient No. 18's case record states that this patient had ''Parkinsonian tremor.'' (G–12.4 at 108.) Additionally, testimony indicates that this patient received the drug, Sinemet, during the study. Sinemet is used in the treatment of Parkinson's disease. (Denton, A–121 at 54.)

While the ALJ noted that the evidence indicated that Patient No. 18 had Parkinson's disease, the ALJ declined to rule that this patient should have been excluded for having Parkinson's disease because the Center failed to make this argument. (I.D. at B–2.) In view of the ALJ's ruling on this matter, I, too, will refrain from ruling that Patient No. 18 should be excluded despite the evidence of Parkinson's disease. Nevertheless, I rule that AHP's failure to address this patient's apparent concurrent condition can be considered in the weighing of the Yesavage study.

ii. *Outpatients.* AHP further argues that the ALJ erred in ruling that three other patients—Patients Nos. 14, 16, and 18—should have been excluded from the study because these patients lived at home with their families, rather than in a nursing home as required by the protocol. (AHP Exceptions at 152, citing I.D. at 46.) AHP argues that the inclusion of these patients represented mere technical violations of the protocol, and that these patients need not have been excluded.

The relevant section of the Yesavage study protocol provided that subjects for the study shall be ''(p)atients who are residing in a retirement, intermediate care facility, convalescent, nursing home or other home for the aged * * *.'' (G–9.2 at 32.) While the purpose for this requirement is not stated in the protocol, the ALJ, after hearing all the evidence, concluded that the purpose of this requirement was to assure that patients were taking the study medication as directed, and to assure that the use of concomitant medication would be monitored. (I.D. at

46; AHP Exceptions at 152; see generally Porter, Tr. Vol. IV at 43–46.) The ALJ's conclusions on this point are not in dispute.

While the ALJ made a ruling regarding three of the study subjects, I note that testimony from Dr. Clarence Denton, an AHP witness, indicates that five patients—Patient Nos. 14, 15, 16, 17, and 18—were outpatients. (Denton, A–121 at 48.) However, the evidence in the record does not include the case reports for Patient Nos. 15 and 17. Perhaps for this reason, the ALJ mentions only Patient Nos. 14, 16, and 18 in his decision. (See I.D. at 46.) However, I conclude that the testimonial evidence of Dr. Denton is a sufficient basis for reviewing the status of all five of the outpatients.

Dr. Yesavage testified that the patients who lived at home were seen by Dr. William Garcia in the latter's private office, although Dr. Yesavage was listed on the case report forms as the patients' doctor. (Yesavage, Tr. Vol. IV at 43, 46.) Dr. Yesavage testified that Dr. Garcia was not required by the protocol to record concomitant medications into the case report forms. (Yesavage, Tr. Vol. IV at 45.) For nursing home patients, concomitant medications were noted on the patient order sheets; regarding outpatients, Dr. Yesavage testified that he ''presume(d)'' that Dr. Garcia made notes in his private files regarding concomitant medications for the outpatients. (Yesavage, Tr. Vol. IV at 44–46.)

The responsibility of recording all subjects' concomitant medications, including that of the outpatients, onto the case report forms was given to Mr. Michael Adey, Dr. Yesavage's assistant. (Yesavage, Tr. Vol. IV at 45–46.) For the nursing home patients, it was Mr. Adey's responsibility to review the order sheets, identify concomitant medications, and record these into the case report forms. (Yesavage, Tr. Vol. IV at 47.) For the outpatients, Mr. Adey was similarly to review the medical records from Dr. Garcia, identify concomitant medications, and record this information into the case report forms. (Yesavage, Tr. Vol. IV. at 48.)

The Center argues that the outpatients should properly be excluded because there is no evidence to show that the families of the outpatients kept careful records of any concomitant medications given at home, nor does the evidence show that Mr. Adey recorded in the case report forms concomitant medications given at home. (Center Response to AHP Exceptions at 59.) Additionally, the Center argues that there is no evidence that the outpatients' families kept careful records regarding the administration of the test drug. (Center Response to AHP Exceptions at 59.)

FDA regulations require that a study use a design ''that permits a valid comparison with a control to provide a quantitative assessment of drug effect.'' (§ 314.126(b)(2).) The regulations also require that ''(t)he method of assigning patients to treatment and control groups minimize bias and * * * assure comparability of the groups with respect to pertinent variables such as * * * use of drugs or therapy other than the test drug.'' (§ 314.126(b)(4).) Monitoring a patient's medications during the course of a study is an important factor in the design of an adequate and well-controlled study and is necessary for a valid comparison between a test article and a control. (See generally Commissioner's Decision on OPE, slip op. at 47–53.)

While restricting the Yesavage study to patients who were in a nursing home and under constant medical supervision is one way to monitor concomitant medications, this restriction is not perforce required to monitor concomitant medications. Although the evidence indicated that there were problems with recording of concomitant medications [6] and with concomitant medication use (the latter of which will be discussed in section I.D.2.d. of this document), these problems do not appear to be unique to the outpatients in the Yesavage study. For these reasons, I will accept AHP's argument that the inclusion of outpatients was a technical violation of the protocol and was not grounds by itself to exclude these patients.

Nevertheless, as I previously noted, even protocol violations which by themselves may not warrant rejection of a study can be considered in the aggregate in determining whether a study is adequate and well-controlled. (See Commissioner's Decision on Benylin, 44 FR 51512 at 51531.) Failure to follow inclusion/exclusion criteria can be an indication of an inattention to detail and can be considered in deciding whether the study was adequate and well-controlled.

Therefore, I find with respect to the Yesavage study that the inclusion of outpatients in violation of the study's protocol may be considered in evaluating the adequacy of the Yesavage study.

b. *Distribution of patients with strokes.* Unlike the Rao study's protocol, which planned to exclude patients with strokes, the Yesavage study's protocol did not propose to exclude stroke patients. This difference between the two studies' protocols was not an issue at the administrative hearing.

AHP argues that the ALJ erred in holding that seven patients in the Yesavage study had medical histories indicating strokes, and that these patients should have been proportionately distributed between the drug and placebo groups. (AHP Exceptions at 154, citing I.D. at 53, 57.) The Center, citing to the testimony of Dr. Thal, argues that AHP's failure to identify patients with stroke histories and to see that such patients were proportionately assigned between the Cyclospasmol® and the placebo groups meant that the two groups cannot be found to be comparable. (Center Response to AHP Exceptions at 60–61.) I find the Center's argument to have merit.

Turning first to the testimony of Dr. Thal, a witness for the Center, this witness testified:

> There are some problems with the protocol in that the protocol does not attempt to separate out patients who have Alzheimer's disease from those who had multiple strokes. *A problem with lumping together two groups of patients is that if they are unequally distributed, the treatment effect seen may be due to an effect on the treatment on one disorder and not the other.* For example, if a large number of patients with multiple strokes are in the treatment group, the effect of the drug would then be licensed for the treatment of both patients with multi-infarct dementia and Alzheimer's disease when in fact the drug may be totally non-effective in patients with Alzheimer's disease. In reviewing the case report forms for these patients, I found (7) patients with a history or an examination compatible with stroke (patients 9, 25, 28, 29, 33, 34, 35). If these patients are removed from the statistical analysis, it is perfectly possible that all statistical significance would be lost in the remaining patients.

(Thal, G–63 at 11 (emphasis added).)

I have reviewed the records for all patients in this study, and I have found that Dr. Thal was correct with regard to six of the seven patients which Dr. Thal identified as having histories of strokes. I was unable to verify the diagnosis of a stroke with regard to Patient No. 25, as there are no records in evidence for this patient. However, regarding the remaining six patients, the records support Dr. Thal's testimony. Patient No. 9's records show a clinical diagnosis of a stroke, specifically a cerebral

[6] Dr. Yesavage testified that his research assistant may not have included all sleeping medications in the case report records of concomitant medications. (Yesavage, Tr. Vol. IV at 42.) Dr. Yesavage explained that his research assistant was permitted to ''use some judgment'' in deciding which medications to include on the case report forms because it was not felt that it was important to include all concomitant medications regardless of their indications. (Yesavage, Tr. Vol. IV at 42.)

vascular accident with left hemiplegia. (G–12.2 at 106, 109.) Patient No. 28's records show a diagnosis of a stroke. (G–12.6 at 309, 312–13.) Patient No. 29's records show a diagnosis of a stroke, specifically a cerebral vascular accident with right hemiplegia. (G–12.7 at 4, 7–8.) Patient No. 33's records show a diagnosis of a stroke, specifically a cerebral vascular accident with left hemiplegia. (G–12.7 at 107, 110–11.) Patient No. 34's records show a diagnosis of a stroke with left hemiparesis. (G–12.7 at 210, 215–16.) Patient No. 35's records indicate a diagnosis of stroke. (G–12.8 at 9.) Additionally, Patient No. 7's records indicate a diagnosis of a stroke (G–12.2 at 5), although this patient was not identified by the Center in its brief as a stroke patient.

What the records do not reveal, either in the patient records or in the analysis of the Yesavage study, is to which group (Cyclospasmol® or placebo) these, or indeed any, of the patients were assigned. (See G–12.1 through 12.8; G–11.1.) While AHP faults the ALJ's decision for failing to make a finding as to how the stroke patients were distributed, AHP offers no information in this regard. (AHP Exceptions at 155.)

Based upon the evidence in the record, it cannot be ascertained whether both arms of the clinical trial included stroke patients. For this reason, I find that, strictly speaking, proportional distribution of stroke patients is not the crux of this issue; rather, it is the failure to show that stroke patients were included in both the Cyclospasmol® arm and the placebo arm of the clinical trial.

As I previously ruled (see section I.D.1.b. of this document), in an adequate and well-controlled study, it is not acceptable to group persons having similar symptoms but distinct diseases together into one study without identifying which patient has which disease, otherwise, as in the Yesavage study, it will be impossible to assess a drug's effectiveness on a particular disease. (Cf. Commissioner's Decision on Lutrexin, 41 FR 14406 at 14422 (In a study of premature labor, results were ruled incapable of scientific interpretation because women with different conditions were evaluated together.)) It is, of course, essential to show that a drug is tested on the population for which it is labeled. As was ruled in the Commissioner's Decision on Cothyrobal, ''Clearly, a study * * * must be conducted in patients who have one of the labeled indications if that study is to be used as proof of effectiveness for those indications.'' (42 FR 28602 at 28610.) Similarly, in the Commissioner's Decision on Lutrexin, it was ruled, ''(T)he law is clear that the applicant must provide substantial evidence of a drug's effectiveness under its labeled conditions of use, not those under which an investigator chooses to test it.'' (41 FR 14406 at 14419.)

The Center cites to the regulation requiring that the method of assigning subjects must assure comparability of the groups with respect to pertinent variables, including severity and duration of disease. (Center Response to AHP Exceptions, citing § 314.126(b)(4); see also Commissioner's Decision on Lutrexin, 41 FR 14406 at 14414.) Necessarily, the group assignments must be comparable with respect to the disease itself. I therefore find that the failure to show that stroke patients were included in both the drug and the placebo arms of the clinical trial can be considered as a flaw in the Yesavage study, and can be weighed in determining if the study was adequate and well-controlled.

c. *Baseline comparability.* AHP next argues that the ALJ erred in finding that the lack of comparability between the drug and placebo groups at baseline for the Buschke Memory Test (BMT) weighed against finding the Yesavage study adequate and well-controlled. (AHP Exceptions at 156–57, citing I.D. at 48, 53, 57.) The average BMT score at baseline for the Cyclospasmol® group was ''7.2'' out of a possible score of ''15.0,'' but was ''3.6'' for the placebo group, a difference between the two groups which was statistically significant. (Schneiderman, G–65 at 10; Thal, G–63 at 13.)

AHP argues that the BMT measured only a narrow parameter of cognitive functioning, and that the results of other tests at baseline should have been weighed more heavily. Specifically, AHP cites to the baseline measures for SCAG Factor 1 (''cognitive dysfunction''), SCAG Item 3 (''impaired recent memory''), SCAG Item 19 (''overall impression of patient functional capacity''), the Hamilton Depression Scale, and the NOSIE, which were comparable at baseline for the drug and placebo groups. (AHP Exceptions at 158; I.D. at 48.)

The Center concedes that the BMT measures a narrower parameter of cognitive dysfunction, specifically, recent memory dysfunction, but argues that impaired recent memory is the core of cognitive dysfunction and is, therefore, a critical parameter. (Center Post-Hearing Brief at 86, citing Thal, Vol. VI at 45.) The Center further argues that the BMT's baseline values carry more weight than the SCAG's baseline values because the BMT is an objective, quantitative test of recent memory dysfunction. (Center Response to AHP Exceptions at 63.) By contrast, the SCAG is a subjective, observer-rated test. (Center Post-Hearing Brief at 86.) The Center argues that for this reason, the BMT is more telling of baseline comparability between the two study groups. The Center further argues that the lack of baseline comparability on the BMT rendered the Yesavage study not adequate and well-controlled. (Center Reply to AHP Exceptions at 63.)

Before discussing the merits of this issue, the relevant parameters of the SCAG and the BMT need to be described. The SCAG required the physician to rate the patient from a list of 19 Items. Each Item in the SCAG was rated on a scale from ''1'' to ''7,'' with ''1'' indicating that the symptom was ''not present,'' and ''7'' indicating that the symptom was ''severe.'' (G–3.1 at 97; see, e.g., G–14.2 at 6–8.) Eighteen of these Items were then grouped into five Factors for rating the patient. (G–11.1 at 70.) The 19th Item, the Physician's Overall Assessment of the patient, was rated separately. (G–11.1 at 70 n.7.) The Factor upon which AHP now relies, Factor 1, Cognitive Dysfunction, was defined as including the following Items: (1) Confusion, (2) impaired mental alertness, (3) impaired recent memory, and (4) disorientation. (G–11.1 at 70–71, 75.)

The BMT, on the other hand, was described by Dr. Yesavage, an AHP witness, as ''a memory performance test in which subjects are required to remember and repeat words from a stimulus list of 15 objects.'' (G–11.1 at 21.)

Regarding the differences between the SCAG and the BMT, Dr. Thal, a Center witness, testified:

> The SCAG is a subjective measure based on an interviewer rating scale. The rating scale is such that it is neither objective nor as accurate as the type of data that one would generate on the Buschke memory test. Additionally, and more importantly, the SCAG measures many factors other than memory such as sociability, mood, etc. Only a small number of the SCAG items deal directly with memory.

(Thal, G–63 at 14.)

The main disagreement between AHP's witnesses and the Center's witnesses lies in which test the witnesses think should be given more weight. Dr. Thal testified that he would recommend relying upon the BMT as an indicator as to whether the two populations were similar, especially for indications of cognitive dysfunction or memory problems. (Thal, G–63 at 14.) By contrast, Dr. Klerman, an AHP

witness, testified that he would give greater weight to the SCAG. (Klerman, Tr. Vol. III at 87.)

Under FDA regulations, for a clinical trial to be considered adequate and well-controlled, assignment of patients must be accomplished by a method that minimizes bias and ''assur(es) comparability of the groups with respect to pertinent variables such as * * * severity of disease * * *.'' (§ 314.126(4).) With regard to the Yesavage study, short-term memory loss is one of the characteristics of senile dementia. Therefore, the severity of the impairment of recent memory functioning is a pertinent variable in the evaluation of senile dementia.

While SCAG Item 3 includes impaired recent memory as a characteristic to be evaluated, SCAG Item 3 is, nevertheless, a subjective measure. The BMT quantifies the severity of the recent memory impairment through an objective test of short-term memory. As such, the BMT is an indicator of the severity of this aspect of senile dementia. A statistically significant difference between the treatment and the placebo groups on this measure, with the placebo group being worse, does indicate a lack of comparability between the treatment and placebo groups on one of the hallmarks of senile dementia.

Therefore, I find that the statistically significant difference between the two groups at baseline was a proper consideration to be weighed in determining whether the Yesavage study was adequate and well-controlled.

d. *Concomitant medications.* The law regarding concomitant medications was discussed in a previous section of this decision, and I will not repeat it here. (See section I.D.1.d. of this document.)

The Yesavage study protocol contains an extensive section pertaining to concomitant medications, which in full reads:

> Treatment with vasodilating, anti-convulsive, psychoactive, or narcotic agents, ergot or reserpine derivatives or steroids (other than estrogen) will not be allowed during this study. The patient may have chloral hydrate as a hypnotic. Occasional doses of thioridazine or diazepam may be used if deemed necessary; however, no more than 16 doses of one of these agents may be taken per study and there should be no more than three doses in any week. Other medication, which is considered necessary for the patient's welfare and which will not interfere with the study medication, may be continued at the discretion of the investigator, but no new drug, other than those previously stated, should be started during the course of this study, except that medication required for an acute purpose which would not disqualify the patient (e.g., an analgesic, an antibiotic, etc.). If the investigator feels it is necessary to start or change a *chronic* medication during the course of the study, he will contact the Ives Medical Monitor to determine whether the patient may continue in the program. However, if during the course of the study the investigator feels it is necessary to start the patient on digoxin and/or diuretic therapy because of congestive heart failure he may do so, without consulting the Ives Medical Monitor, unless the severity of the congestive heart failure interferes with the administration of the study drugs or creates a major change in the patient's mental state. In either of the latter situations, the patient should be dropped from the study.
>
> Administration of *all* concomitant medication must be reported on the case report form, supplied by the sponsor, including the name of the drug, dose, reason for use and date started.

(G–9.2 at 34–35 (emphasis in original).)

Regarding concomitant medications, the Center identified 12 patients who received 11 different concomitant medications with possible confounding effects. The patients identified by the Center and the medications which these patients were said to have taken included Patient No. 2 (Aldomet, Inderal, Elavil), Patient No. 5 (Inderal, Valium), Patient No. 7 (Inderal), Patient No. 9 (Dalmane), Patient No. 16 (Sinemet), Patient No. 18 (Sinemet), Patient No. 21 (Mellaril), Patient No. 24 (Inderal, Serax), Patient No. 33 (Elavil), Patient No. 34 (Benadryl, Phenergan), Patient No. 35 (Haldol), and Patient No. 37 (Elavil, Sinemet). (See Center Post-Hearing Brief at Attachment D.) The ALJ also identified a 12th concomitant medication, Librium, which was given to Patient No. 16, who received 10 mg of this drug. (I.D. at B–2; Denton, A–121 at 52.) AHP does not concede that any of these patients should be excluded. (AHP Post-Hearing Brief at 108; AHP Exceptions at 163.) The concomitant medication use of each of these patients will be discussed in turn.

Patient No. 2, who was in the Cyclospasmol® group, received three concomitant drugs during the study, specifically Aldomet, Inderal, and Elavil. (I.D. at B–1.) Regarding Aldomet, an antihypertensive drug, Patient No. 2 received 250 mg of this drug three times a day throughout the study. (G–12.1 at 11, 29, 42, 57, 60, 63, 70.) Aldomet can affect mood and cognition. (Leber, G–64 at 13.)

Additionally, according to the testimony of Dr. Denton, a witness for AHP, Patient No. 2 received 40 mg of Inderal twice a day throughout the study. (Denton, A–121 at 52–53.) This patient's case records do not document the administration of Inderal to this patient. (See G–12.1 at 4–105.) Regarding Inderal, Dr. Denton testified that Inderal in ''a large dose, perhaps more than 80 mg/day, might make patients confused or depressed.'' (Denton, A–121 at 53.) Other possible side effects of Inderal include disorientation, short term memory loss, clouded sensorium, and decreased performance on neuropsychometric tests. (Denton, Tr. Vol. VII at 34–35.) As for the effect of Inderal on Patient No. 2, Dr. Denton testified that he believed the dosage to be ''too small to influence cognitive functioning in any manner.'' (Denton, A–121 at 53.)

The administration of Elavil to Patient No. 2 deserves particular attention because of the frequency of this drug's administration. Elavil is a psychoactive drug used in the treatment of depression. (Zung, Tr. Vol. III at 51.) While the case records in evidence for Patient No. 2 do not record the administration of Elavil, the testimony of Dr. Denton, a witness for AHP, indicates that Patient No. 2 received 25 mg of Elavil at night before sleep, but that this medication was stopped during the last 7 weeks of the study. (Denton, A–121 at 52.) Since patients were in the Yesavage study for 19 weeks—3 weeks of prestudy washout followed by 16 weeks in the clinical trial (G–9.2 at 32)—this would mean that Patient No. 2 was receiving Elavil nightly for the first 12 weeks of the 19 week study.

Despite Patient No. 2's extended use of a psychoactive drug, Dr. Denton testified that he did not believe that this patient should have been excluded. (Denton A–121 at 52.) Dr. Denton testified that, while a ''strict interpretation of the protocol might have eliminated'' Patient No. 2 for the concomitant Elavil use, Dr. Denton nonetheless concluded that this patient need not be excluded because the administration of Elavil was stopped during the last two evaluations, ''the crucial ones from an efficacy standpoint.'' (Denton, A–121 at 52.)

In considering this evidence, the ALJ was not persuaded by Dr. Denton's explanation for failing to exclude Patient No. 2. The ALJ found that the question remained as to whether Elavil use during the beginning of the study could have caused a SCAG score that was worse than it would have been without the drug. (I.D. at B–1.) When the Elavil administration was ceased during the final two evaluations, this alone may have caused any improvement in this Patient's SCAG score. (I.D. at B–1.) I agree with the ALJ's analysis of this issue, and I conclude that the concomitant medication use of Elavil by Patient No. 2 was grounds to exclude this patient.

For the next patient, Patient No. 5, a Cyclospasmol® patient, the case records indicate that this patient received Valium (diazepam) ''occasionally for nervousness,'' and Inderal ''q.i.d.'' (*quater in die,* four times a day). (G–12.1 at 212; Denton, A–121 at 51, 53–54.) The case records for this patient do not reveal the dosage for these drugs, nor is there a contemporaneous medication record tracking the days or times at which either of these medications were administered. (See G–12.1 at 206–308.)

Regarding the administration of Inderal, Patient No. 5's case records do not indicate the dose given, but Dr. Denton testified that this patient received 10 mg of Inderal four times a day. (Denton, A–121 at 53.) As was previously stated, Dr. Denton also testified that Inderal in ''a large dose, perhaps more than 80 mg/day, might make patients confused or depressed.'' (Denton, A–121 at 53.) Other possible side effects include disorientation, short term memory loss, clouded sensorium, and decreased performance on neuropsychometric tests. (Denton, Tr. Vol. VII at 34–35.)

As for the administration of Valium to Patient No. 5, Dr. Denton's testified as follows:

> The hospital records reveal that the Valium was ordered on a prn (*pro re nata,* as occasion arises) basis, which suggest that it was used infrequently, and her referring physician told me by telephone that it was used 0–2 times per week. There were no medication sheets on this patient's record.

(Denton, A–121 at 51–52.)

It should be emphasized that Dr. Denton's estimation of the ''infrequency'' of the administration of Valium to Patient No. 5 is only speculation, in view of the fact that there were no medication records for Dr. Denton's review, nor is there evidence that this patient's referring physician based his or her statements on any such medication records.

I further note that even if Dr. Denton is correct in estimating the administration of Valium to Patient No. 5 to be as much as 2 times per week during the 19 week study, that amount of Valium—as much as 38 doses during the study—is a clear violation of the protocol, which specifies, ''Occasional doses of thioridazine (Mellaril) or diazepam (Valium) may be used if deemed necessary; however, no more than 16 doses of one of these agents may be taken per study * * * .'' (G–9.2 at 34.)

The absence of detailed records tracking the administration of Valium and Inderal to Patient No. 5 makes it impossible to fully evaluate the effect of these concomitant medications. The inadequate records are a ''fatal flaw'' which can weighed against finding the Yesavage study to be adequate and well-controlled. (Commissioner's Decision on OPE, slip op. at 52.)

Patient No. 16, an outpatient and a Cyclospasmol® subject, received 10 mg of Librium, a benzodiazepine, ''only rarely,'' according to the testimony offered by Dr. Denton. (A–121 at 52.) However, Dr. Denton gave no specific information regarding the dosage, or dates and times of administration of Librium, and the records in evidence for Patient No. 16 contain no information at all pertaining to this patient's use of Librium. (G–12.4 at 1–100.) The administration of Librium could have had a confounding effect on the results of this study, and the absence of medication records is, as with the previous patient, a ''fatal flaw'' that can be weighed against finding the Yesavage study adequate and well-controlled. (Commissioner's Decision on OPE, slip op. at 52.)

Regarding Patient No. 18, a Cyclospasmol® subject, Dr. Denton testified that this patient had been given Sinemet (carbidopa/levodopa), a drug used in the treatment of Parkinson's disease, between the ratings taken at weeks 7 and 8. (Denton, A–121 at 50, 54–55.) The final rating was taken at week nine. (See G–12.4 at 190–201.) Dr. Denton acknowledged that Sinemet can have a ''positive effect on cognition.'' (Denton, A–121 at 54; see generally Leber, G–64 at 14 (Sinemet use in Rao study).) Nevertheless, Dr. Denton testified that he believed that if Sinemet had any effect on Patient No. 18, it was only to make this patient worse. (Denton, A–121 at 54.) Dr. Denton based his conclusion on the SCAG scores for Patient No. 18. (Denton, A–121 at 54.) Dr. Denton stated that at baseline this patient's SCAG score was 49, and that at visit 7 the score had improved to 43 (a lower score being a better score), but that at visit 9 the score was again 49. (Denton, A–121 at 54.)

I find Dr. Denton's proffered explanation that Sinemet made Patient No. 18's SCAG score worse to be based on mere speculation. Aside from the fact that Dr. Denton's explanation was inconsistent with his other testimony, in which he testified that Sinemet can have a positive effect on cognition, I note that another possible explanation not addressed by Dr. Denton is that Patient No. 18's SCAG score might have deteriorated even further had it not been for the Sinemet. Additionally, as Dr. Zung, a witness for AHP, testified, there are instances where patients with Parkinson's disease have a period of remission or spontaneous improvement with the disease, which could have a confounding effect on the results of a study. (Zung, Tr. Vol. III at 23.) However, these explanations, too, are speculative.

I note also that, as with the previously discussed Yesavage patients, the records in evidence pertaining to Patient No. 18 contain no information regarding this patient's concomitant medications. (G–12.4 at 101–201.) Once again, I state that the absence of such records is a fact which can be weighed against finding the study to be adequate and well-controlled. (Commissioner's Decision on OPE, slip op. at 52.)

Patient No. 24, a Cyclospasmol® subject, received both Inderal and Serax. Dr. Denton testified that this patient received 20 mg of Inderal three times a day, subsequently reduced to 20 mg, twice a day. (Denton, A–121 at 53.) Dr. Denton did not specify when this change in dosing schedule was made. However, this patient's clinical records contain a notation that this patient was on Inderal 20 mg, twice a day, as of the first visit, which was on January 10, 1982, and the patient continued this medication throughout the study. (G–12.6 at 12, 28, 41, 56, 59, 62, 71, 78, 87, 94.) As previously discussed, Inderal can cause side effects such as confusion and depression (Denton, A–121 at 53), disorientation, short term memory loss, clouded sensorium, and decreased performance on neuropsychometric tests. (Denton, Tr. Vol. VII at 34–35.)

As for the administration of Serax, a benzodiazepine, to Patient No. 24, Dr. Denton testified that 10 mg of Serax was given to Patient No. 24 at bedtime as a sedative. (Denton, A–121 at 52.) This patient's clinical records contain no mention of this medication or the frequency and dosages given. (G–12.6 at 2–104.) This level of administration of a benzodiazepine certainly violates the intent of the protocol's concomitant medication restriction, which permits ''(o)ccasional doses of thioridazine or diazepam,'' but no more than 16 doses per study per patient, and no more than 3 doses per week. (G–9.2 at 34.) For this reason, Patient No. 24 should have been excluded. Additionally, the absence of written records tracking the strength, frequency, and length of administration of this drug can be weighed against finding the Yesavage study to be adequate and well-controlled. (OPE, slip op. at 52–53.)

Patient No. 34 and Patient No. 37 both had Parkinson's disease. (G–12.7 at 210 (Patient No. 34); G–12.8 at 109, 113 (Patient No. 37); Mohs, G–62 at 16; Thal, G–63 at 12.) Patient No. 34, a Cyclospasmol® subject, received 25 mg of Benadryl twice a day. (G–12.7 at 217; Mohs, G–62 at 16; Thal, G–63 at 12.)

Benadryl is a drug which has indications for use for patients with Parkinson's disease. (Zung, Tr. Vol. III at 52; see also G–12.7 at 217.) The side effects of Benadryl can include diminished mental alertness, sedation, sleepiness, dizziness, and confusion. (Zung, Tr. Vol. III at 52.) Phenergan, an antiemetic, was also given to this patient. (Denton, A–121 at 52.)

Patient No. 37, also a Cyclospasmol® subject, received Sinemet 25/100 (25 mg carbidopa/100 mg levodopa) every four hours to control symptoms of Parkinson's disease. (Mohs, G–62 at 16; Thal, G–63 at 12; Denton, A–121 at 54.) This patient also received 25 mg of Elavil twice a day. (G–12.8 at 114.) The frequency of administration of Elavil, a psychoactive drug (Zung, Tr. Vol. III at 51), warranted the exclusion of Patient No. 37.

Additionally, as I ruled in a previous discussion, both Patient 34 and Patient 37 should have been excluded because of their concomitant Parkinson's disease. (See section I.D.2.a. of this document.) Moreover, I rule that the concomitant medication use by these patients can be weighed against finding the Yesavage study to be adequate and well-controlled because the effect of the concomitant drugs may have confounded the results now attributed to Cyclospasmol®.

Patient No. 7, a placebo patient, received Inderal twice a day during the study. (G–12.2 at 7.) The case records for this patient do not record the dose for this drug. However, Dr. Denton testified that Patient No. 7 received 10 mg of Inderal twice a day. (Denton, A–121 at 53.) Inderal can affect cognition. While this level of Inderal use may not itself be reason to exclude this patient, nevertheless, the possible confounding effect of this drug's side effects can be taken into consideration. Additionally, the failure of the case records to document Patient No. 7's concomitant medication use can be considered in evaluating the Yesavage study. (Commissioner's Decision on OPE, slip op. at 52–53.)

Regarding Patient No. 9, a placebo patient, Dr. Denton testified that orders were given for this patient to receive 15 mg of Dalmane at bedtime ''PRN.'' Dr. Denton conceded that Dalmane, a benzodiazepine, ''might be considered a contraindicated medication.'' (Denton, A–121 at 56.) However, Dr. Denton testified that Patient No. 9 was only given Dalmane once during the study—on September 14, 1981—and for this reason Dr. Denton did not believe this medication confounded the study. (Denton, A–121 at 56.) The final evaluation of this patient occurred on September 17, 1981.

The clinical documents in evidence contain no record of Patient No. 9 being administered Dalmane. (G–12.2 at 104–205.) A single administration of a benzodiazepine would not appear to be confounding to this study. Nonetheless, the actual administration of Dalmane is not corroborated in this patient's case records. The failure of the case records to document the actual administration of Dalmane can be weighed against finding the Yesavage study to be adequate and well-controlled. (OPE, slip op. at 52–53.)

Patient No. 21, also a placebo patient, received 25 mg of Mellaril (thioridazine hydrochloride) twice a day throughout the study. (Denton, A–121 at 55–56.) This patient's clinical records now in evidence contain no record of Patient No. 21 having received Mellaril. (G–12.5 at 105–208.) Mellaril can affect cognitive performance and cause a patient to perform worse on cognitive tests than he or she might have but for the Mellaril. (Leber, Tr. Vol. I at 69.) Administration of Mellaril at this frequency was clearly a violation of the protocol, which restricted thioridazine to occasional doses. (G–9.2 at 34.) This patient should have been excluded.

Regarding Patient No. 33, the Center had argued that this patient should have been excluded on the basis that this patient received the concomitant medication of Elavil during the study. (Center Post-Hearing Brief at 81 & Attachment D.) This patient's records do not reveal whether this patient was a placebo patient or a Cyclospasmol® patient, and Patient No. 33's medication use was not discussed by Dr. Denton in his testimony.

Regarding Patient No. 33's concomitant medication use, a notation in this patient's records of the prestudy evaluation indicates that this patient had received 25 mg of Elavil twice a day from January 4, 1979, through May 18, 1982. There are no medication records in evidence but, based upon this notation in the prestudy evaluation, it appears that the administration of Elavil was reported to have been stopped 2 weeks before Patient No. 33 was accepted into the Yesavage study. (G–12.7 at 112.)

Other patient records in evidence indicate that this patient's first visit during the study occurred on August 2, 1982. (G–12.7 at 128.) According to the protocol, at the first visit the patient was to enter into a single-blind washout period. (G–9.2 at 36, 38.) This washout period was to last until the patient's second visit, at which point the patient entered the double-blind medication phase of the study. (G–9.2 at 168.) A further notation in this patient's records from this patient's second evaluation, which occurred on August 24, 1982, states, ''Elavil still discontinued for length of study.'' (G–12.7 at 143.)

Although daily medication records are not in evidence for Patient No. 33, I nevertheless rule, based upon the records which are in evidence, that Patient No. 33 properly was included in the study. Based upon the evidence, it does not appear that this patient was receiving the concomitant medication of Elavil during the study.

Patient No. 35, a placebo patient, received Haldol during the study. (Denton, A–121 at 56.) This patient's clinical documents in evidence contain no record of this patient's receiving this medication. (G–12.8 at 104–205.) Nonetheless, Dr. Denton testified that Patient No. 35 received a single, 1 mg dose of Haldol, 9½ weeks before final evaluation. (Denton, A–121 at 56.) However, Dr. Denton's testimony appears inconsistent on this point, because he also testified that Patient No. 35 received Haldol ''b.i.d.,'' that is, *bis in die*, or twice a day.

Additionally, I note that Patient No. 35's clinical records indicate that this patient received 10 mg of Isordil, a vasodilator, four times a day throughout the study. (G–12.8 at 11, 40, 56, 59, 62, 71, 78, 87, 94.) This could have caused a confounding effect. Neither the Center nor AHP address this part of the patient's record, nor does the ALJ discuss the apparent concomitant Isordil use. Although there is sufficient evidence for me to conclude that Isordil was administered concomitantly, I will, in view of the fact that no party addressed this issue, instead weigh this evidence as a deficiency in the clinical records for the Yesavage study. (Commissioner's Decision on OPE, slip op. at 52–53.)

To summarize, a pervasive problem with the Yesavage study is the failure to adequately document concomitant medication use. In many instances, the case records do not even mention the concomitant medication at issue. In other instances, the medication is listed but the dosage is not, nor is the schedule of administration for the drug.

The use of concomitant medications is an important matter. Uncontrolled use of concomitant medications defeats the scientific value of a study. (Commissioner's Decision on OPE, slip op. at 204.) Vague or incomplete records of concomitant medications are ''fatal flaws'' which weigh heavily against finding a study adequate and well-controlled. (*Id*. at 53.) Also, the number of various concomitant medications

increases the difficulty of evaluating Cyclospasmol®'s effect. (*Id*. at 56.) Additionally, the proportionately large number of patients receiving concomitant medications—12 out of 23 patients in the final analysis—weighs against finding the Yesavage study adequate and well-controlled. (*Id*. at 57.)

I conclude by ruling that, based upon both the patient case records and testimonial evidence, Patient Nos. 2, 24, 37, and 21 should have been excluded for concomitant medication use. Regarding Patient Nos. 5, 16, and 35, their concomitant medication use could not be properly evaluated because of incomplete case records. The testimony offered by Dr. Denton regarding Patient Nos. 5, 16, and 35 was vague and was not sufficient to evaluate these subjects. This absence of documentation of concomitant medication use can be weighed against finding the Yesavage study to be adequate and well-controlled.

As for Patient Nos. 7 and 9, assuming for the purposes of this discussion that Dr. Denton's testimony completely and accurately described these patients' concomitant medication use, then these two patients were possibly properly included. However, the medication regimens for Patient Nos. 7 and 9 were not corroborated in their case records, which weighs against finding the Yesavage study to be adequate and well-controlled.

Regarding Patient Nos. 34 and 37, I previously ruled that these patients should have been excluded for Parkinson's disease. I note that I have additionally found that Patient No. 37 should have been excluded for concomitant medication use.

As for Patient No. 18, if concomitant medication use alone is considered, and, assuming that Dr. Denton's testimony completely and accurately describes this patient's concomitant medication use, then this patient may properly have been included. However, the failure of the case records to document this patient's concomitant medication use weighs against finding the Yesavage study to be adequate and well-controlled. Furthermore, I previously found that Patient No. 18's case records seem to indicate that this patient had Parkinson's disease. AHP's failure to address this patient's apparent concurrent Parkinson's disease can be weighed against finding the Yesavage study to be adequate and well-controlled.

Regarding Patient No. 33, it appears from the records in evidence that this patient was not receiving the concomitant medication of Elavil during the study.

Overall, I find that the uncontrolled use of concomitant medication and the poor documentation of concomitant medication use weighs against finding the Yesavage study to be adequate and well-controlled.

e. *Small sample size.* AHP argues that the ALJ erred in ruling that in view of the small sample size in the Yesavage study—12 Cyclospasmol® patients and 8 placebo patients at week 16—it was ''inappropriate to generalize the results.'' (AHP Exceptions at 166, quoting I.D. at 57.) On this point, the ALJ also had noted that earlier in the study, at week 12 when 14 Cyclospasmol® patients and 9 placebo patients were tested, there was no statistically significant drug effect. (I.D. at 52.) However, at week 16, when three patients had been dropped from the study, statistical significance was reported. (I.D. at 52, citing Thal, G–63 at 17.) While the ALJ found that there had been no showing that the dropping of the three patients resulted in statistical significance, the ALJ nevertheless observed, ''The problem with such a small sample size is that the omission of one or two patients can change the results rather dramatically.'' (I.D. at 52.) AHP objects to the ALJ's opinion on these points.

In support of its argument, AHP cites the testimony of Dr. Mantel, a statistician and witness for AHP, who, in connection with his testimony pertaining to the MDS–96 study, testified as follows regarding small studies:

> As to Dr. Reich's comment that ''most often a larger sample provides more convincing conclusions than a small one,'' Dr. Reich is correct. If I wished to have my study provide more convincing conclusions, I would conduct a larger study employing a larger sample. But once a study is completed that argument is no longer relevant. A significant result from a small study is, nevertheless, a significant result. And a significant result from a small study would betoken an important effect. Large studies would very likely yield statistical significance if the true effect were important. But with a very large study even a minor treatment effect would lead to a statistically significant outcome. It is recognized that the hypothesis of absolutely no treatment effect is almost never exactly true—thus, statistical significance could reflect large study size yet only a very minor treatment effect. * * * As indicated above, statistical significance despite limited study size would betoken an important treatment effect.

(Mantel, A–127 at 7–8.)

AHP also cites the testimony of two other of its witnesses, Mr. Danny S. Chaing and Dr. John E. Overall, who testified regarding statistical power and sample size in the Yesavage study. On this matter, Mr. Chaing testified, ''(The) Yesavage sample is large enough to produce reliable and generalizable conclusions * * *. (T)here's no single minimum required sample size.'' (Chaing, Tr. Vol. I at 22–23.) Dr. Overall testified, ''There's no merit in the criticism that a sample is too small from an appropriately designed and conducted study which has produced statistically significant results.'' (Overall, Tr. Vol. II at 55.)

AHP further argues that if a small study yields a result that is statistically significant, this suggests that the drug effect is ''large'' because ''the variability of human response would make it unlikely that statistical significance would be achieved in a small study if the drug effect were small.'' (AHP Exceptions at 167.) The Center counters that AHP is confusing the size of the drug effect with the variability inherent in a small sample. (Center Response to AHP Exceptions at 69.) The Center further argues that in a small study, regardless of the size of the drug effect, the results from only one or two subjects can completely alter the study's results. (Center Response to AHP Exceptions at 69.) I find the Center's arguments to have merit.

Small samples have larger standard errors, i.e., the uncertainty in the results encompasses a greater range of values by which the mean of the population may vary. The size of the standard error from a study is a measure of the degree to which the study's results reflect the true value which would have been found in the population-at-large having the disease or condition. In studies based on small samples, results may differ greatly from one study to the next because the results of only a few subjects can greatly affect the outcome of the study.

While a small sample study can indicate a statistically significant result, I note that the problem with a small sample is that its larger standard error can make it difficult to identify, with a useful degree of precision, the true value or result which would be found in the larger population having the disease or condition under study. This concern was expressed in the testimony of Dr. Thal, a witness for the Center, who testified, ''(A)s the number of patients in a study decreases, the chance variation or the variability introduced by a single one or two patients grows.'' (Thal, Tr. Vol. VI at 48–49.)

Because of the larger standard error with a small sample, the results from a study conducted on a small sample may not reflect the true value which would have been obtained from the population-at-large having the disease

or condition under study. Evidence of effectiveness can be drawn from small samples, but for the evidence to be reliable the sample needs to be carefully selected beforehand. The sample must be representative of the larger population having the disease or condition under study.

The problems of generalizing results from a small study were also at issue in the Commissioner's Decision on OPE, which stated:

> (A) statistically significant result, when based on a sample size of only five subjects, does introduce the strong likelihood that the subjects were not representative of the larger population from which the sample was drawn, and that there may be an inadvertent lack of comparability in the test and control groups, contrary to the requirements of (the regulations).

(Commissioner's Decision on OPE, slip op. at 117; cf. Commissioner's Decision on Lutrexin, 41 FR 14406 at 14419 (In a study with a total of 32 patients, the small size of the sample was identified as a factor which ''aggravated'' the problems arising from the unreliability of the diagnostic criteria used in the study.))

For the above discussed reasons, I therefore find that the ALJ was correct in observing that the omission of one or two patients can change the results of a small sample study (I.D. at 52), and was correct in questioning whether it was appropriate to generalize the results of the Yesavage study. (I.D. at 57.)

As for AHP's argument that a statistically significant result in a small sample indicates that the drug effect is ''large,'' I find this statement to be inaccurate and misleading. (See AHP Exceptions at 167, citing Mantel, A–127 at 7–8.) AHP seems to be implying that a statistically significant result in a small study necessarily means that the test drug had a significant clinical effect. This implication is incorrect.

Statistical significance is not the same as clinical significance. (Commissioner's Decision on Benylin, 44 FR 51512 at 51521.) Statistical significance is an expression of the probability that an observed difference between the mean outcome of the test drug group and the mean outcome of the control drug group occurred by chance. (Commissioner's Decision on Benylin, 44 FR 51512 at 51520.) A clinically significant effect, however, is an expression of the degree of benefit which was observed in the study's patients and which may be expected in future patients. (Commissioner's Decision on Benylin, 44 FR 51512 at 51520.)

As has been noted in previous Commissioner's decisions, it is possible to achieve a statistically significant difference between treatment and control groups in a clinical trial, yet the test drug may be found not to have had a clinically significant effect, i.e., the effect on the patient is not beneficial either in degree or type of effect. (Commissioner's Decision on Lutrexin, 41 FR 14406 at 14419; Commissioner's Decision on Benylin, 44 FR 51512 at 51520 and 51521; Commissioner's Decision on Mysteclin, slip op. at 24–29.) Estimates of clinical significance take into consideration other matters beyond a finding of statistical significance, such as identifying which parameters were said to have shown statistical significance and deciding whether those parameters are important in a clinical setting. These considerations are further discussed in the next section of this decision. (See section I.D.2.f. of this document.)

Therefore, for the foregoing reasons, I find that the ALJ was correct in considering the small sample size as a factor to be considered in reviewing the results of the Yesavage study.

f. *Clinical significance.* AHP next argues that the ALJ erred in finding that the improvement on SCAG Factor 1 was not clinically significant. (AHP Exceptions at 169, citing I.D. at 54, 57.) As was previously described (see section I.D.2.c. of this document), SCAG Factor 1, ''cognitive dysfunction,'' included the following four items: (1) Confusion, (2) impaired mental alertness, (3) impaired recent memory, and (4) disorientation. (G–11.1 at 70.) AHP argues that the outcome on SCAG Factor 1 was clinically significant because dementia is a progressive disease, and that any small improvement would be important to both the patient and the physician. (AHP Exceptions at 170.)

The ALJ's finding was based on the testimony of two witnesses for the Center, Drs. Mohs and Thal. These witnesses both testified that the absolute magnitude of change from baseline for SCAG Factor 1 was very small, approximately 1.9 change on a scale on which patients in the study had been shown to have a baseline value of 14.1. (Mohs, G–62 at 18; Thal, G–63 at 15–16.) Drs. Mohs and Thal testified that this degree of change—a 14 percent improvement on one SCAG Factor—would not be evident to most observers. (Mohs, G–62 at 18; Thal, G–63 at 15–16.) It should be noted that the lowest/best score on SCAG Factor 1 would be a 4; the highest/worst score would be a 28. (See, e.g., G–12.1 at 38.) This would mean that from a baseline score of 14.1, the score on SCAG Factor 1 had lowered/improved to approximately 12.2.

On the other hand, three witnesses for AHP—Drs. Overall, Zung and Klerman—testified that because dementia has no known cure and because this disease is a progressive one, a 14 percent improvement on one SCAG factor is, in their opinions, clinically significant. (Overall, Tr. Vol. II at 49; Zung, Tr. Vol. III at 7; Klerman, Tr. Vol. III at 70–71.) Based on the testimony of these witnesses, AHP essentially is arguing that any statistically significant result on any one of the several tests used in the Yesavage study is necessarily clinically significant because there is no known cure for dementia. I do not find this argument to be persuasive.

In the United States Supreme Court decision of *United States* v. *Rutherford*, 442 U.S. 544 (1979), the Court recognized that the statutory requirement of proof of effectiveness necessarily required a showing of some clinical benefit to the patient. In relevant part, the Court stated, ''(I)n the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claim of prolonged life, improved physical condition, or reduced pain.'' (442 U.S. at 555.) Consistent with the *Rutherford* decision, the United States Court of Appeals for the Third Circuit has ruled that it is within the purview of the FDA to decide whether a drug has clinical significance. (*Warner-Lambert*, 787 F.2d at 154–56; see also Commissioner's Decision on Mysteclin, slip op. at 24.)

To reiterate some of the discussion of the previous section (see section I.D.2.e. of this document) regarding the difference between statistical and clinical significance, a drug can have a statistically significant effect without having a clinically significant effect. Statistical significance is an expression of the probability that an observed difference between the test drug and the control drug occurred by chance. Clinical significance, on the other hand, is an evaluation of whether the test drug offers a therapeutic benefit to the patient. (Commissioner's Decision on Mysteclin, slip op. at 25; Commissioner's Decision on Benylin, 44 FR 51512 at 51520 and 51521; Commissioner's Decision on Lutrexin, 41 FR 14406 at 14419.) Proof of statistical significance is insufficient without proof of clinical significance. (Commissioner's Decision on OPE, slip op. at 60–62.) As the Court in *Warner-Lambert* noted:

> The fact that the drug, not chance, can be assumed to have contributed to (the finding of statistical significance for) the factor measured does not necessarily establish that patients will receive a benefit from the drug.

The Commissioner has consistently required a showing of some benefit as an element of the statutory requirement of effectiveness.

(Warner-Lambert, 787 F.2d at 155 (citation omitted).)

Turning now back to the evidence at hand, AHP's argument in favor of finding clinical effectiveness for Cyclospasmol® was expressed in the testimony of Dr. Zung, an AHP witness, who testified as follows:

I would say that first of all, we are dealing with an illness, which is the dementias, where we know that there has been no drug available for the treatment of this disease so that there has been no improvement whatsoever on any drug that's known. So here we're talking about an illness with progressive deterioration so, therefore, in fact any treatment that would either arrest the development of the illness or in fact improve the illness would definitely be significant. Factor 1 of the SCAG then, in fact, is specific to measure the cognitive dysfunction that's associated with the dementia and that, of course, has been the indication for which the drug has been studied.

(Zung, Tr. Vol. III at 7–8.)

In contradistinction to Dr. Zung's testimony, the testimony offered by Dr. Mohs, a witness for the Center, was as follows:

The absolute magnitude of change was very small for the cognitive factor in the SCAG, approximately 1.9 on a scale that had a baseline value of 14.1. This change would not be evident to most observers. Also, there was no corroboration even as a trend on the other measures, such as, the NOSIE, the Buschke memory test or the clinical global evaluation. Finally, there is a discrepancy between the overall item, item 19 on the SCAG, and (the) clinical global item completed by the investigator at the end of the study. The overall item on the SCAG did tend to show an improvement for the Cyclospasmol® group, whereas the clinical global item completed at the end of the study did not show any significant effect and these items presumably should be highly cor(r)elated. Because the effect claimed is so small, not corroborated by other tests, and in fact inconsistent with tests that measure the same effect, I do not find the results to be clinically significant.

(Mohs, G–62 at 18.)

Similar testimony was offered by Dr. Thal, another witness for the Center, who testified with reference to Cyclospasmol®, ''If the drug fails to show a clinically significant improvement on any global or clinical evaluation scale and fails to make a meaningful difference in the way a (patient) lives his or her life, one must seriously question whether that drug should be marketed for a specific indication.'' (Thal, G–63 at 16.)

Having reviewed the evidence, I do not find AHP's argument to be persuasive. There is no indication that the results on SCAG Factor 1 will translate into a clinically meaningful reversal or slowing of the progress of dementia. Moreover, AHP's witnesses failed to address the fact that the statistically significant result on SCAG Factor 1 stands alone and is not corroborated by the other measures.

I further note that when a comparable argument was advanced by the manufacturer in the Commissioner's Decision on Lutrexin, that decision ruled that, notwithstanding the fact that there may be no alternatives for the proposed indication for the drug under review, the act nonetheless requires that the effectiveness of a drug be demonstrated by substantial evidence. The Commissioner's Decision went on to note that this requirement does not result in depriving patients of the only known effective drug therapy for a proposed indication because, absent scientifically reliable evidence, that particular drug is not proven to be effective for that indication. (Commissioner's Decision on Lutrexin, 41 FR 14406 at 14411.)

For these reasons, I do not find that AHP has fulfilled the requirement of proving clinical significance.

g. *Multiple tests.* In the Yesavage study, 28 outcome measures were statistically analyzed, including the Nurses Observation Scale—Inpatient Evaluation (NOSIE) score, the Hamilton Depression Scale, the BMT, the clinical global impression score, and the 24 measures—5 factors plus 19 items—on the Sandoz Clinical Assessment—Geriatric (SCAG) measure. (G–9.2 at 45.) Each of these measures was also assessed for six time periods during the study, including at baseline and at weeks 3, 6, 9, 12, and 16. (G–11.1 at 29–37.) Of these 28 outcome measures, 2 measures—SCAG Factor 1 (''cognitive dysfunction'') and SCAG Item 19 (''overall impression of patient functional capacity'')—showed statistical significance in favor of the Cyclospasmol® group, based upon the results of the 20 patients whose outcomes were included in the final analysis of the SCAG. (G–11.1 at 19–20, 29, 78; Thal, G–63 at 16–17; Chaing, Tr. Vol. I at 52–53; Overall, A–116 at 6.)

AHP argues that the results of SCAG Factor 1 are ''the most relevant and important indicator'' of the efficacy of Cyclospasmol® for senile dementia.[7] (AHP Post-Hearing Brief at 116.) However, the ALJ ruled that because the number of tests and outcome measures for each patient in the Yesavage study were so numerous, it was ''difficult to draw definitive conclusions from the fact that statistical significance was found on one factor (SCAG Factor 1).'' (AHP Exceptions at 172, quoting I.D. at 54.) AHP argues that this was error, and AHP further argues that the fact that multiple outcome measures were used does not lessen the strength of its SCAG Factor 1 finding, nor the SCAG Item 19 finding, which was also reported to have been statistically significant. (AHP Post-Hearing Brief at 117.) AHP additionally argues that because the various outcome measures were specified in the protocol, the multiple statistical analyses were not performed to generate a post hoc hypothesis. (AHP Post-Hearing Brief at 116.)

The Center argues that the ALJ was correct in his ruling, and also argues that the statistically significant results on SCAG Factor 1 and SCAG Item 19 may be due to the multiple statistical tests employed. (Center Post-Hearing Brief at 90–92; see also Mohs, G–62 at 17; Thal G–63 at 16.) The Center argues that cognitive dysfunction is only one aspect of senile dementia, and that senile dementia has many manifestations besides that of cognitive impairment, such as impairments in social functioning, orientation, personality, and the ability to speak (aphasia). (Center Post-Hearing Brief at 91, citing Zung, Tr. Vol. III at 43–44.) The Center points to the fact that AHP did not specify cognitive impairment, either on SCAG Factor 1 or SCAG Item 19, as the parameter of interest in advance of the study. (Center Response to AHP Exceptions at 73.) In support of its argument, the Center quotes from the Yesavage study's protocol as stating more generally that the purpose of the study was to evaluate Cyclospasmol® ''in improving symptoms usually associated with brain function.'' (Center Post-Hearing Brief at 90–91, quoting G–9.2 at 32.)

The Center also cites to the testimony of Dr. Zung, a witness for AHP. (Center Response to AHP Exceptions at 72–73.) When Dr. Zung was asked how corrections for multiple comparisons are performed, he replied that there are two methods for making such corrections. The first is to specify in advance, before the statistical analysis is performed, the parameter of interest. The second method is to employ a statistical correction for the number of multiple comparisons which were made. (Zung, Tr. Vol. III at 62–63.) The Center argues that such corrections should have been

[7] I note that there was a difference between SCAG Factor 1 in the Yesavage study, and SCAG Factor 1 in the Rao study. In the Yesavage study, SCAG Factor 1 was called ''Cognitive Dysfunction,'' and it was comprised of SCAG Items 1 through 4. In the Rao study, SCAG Factor 1 was called ''Mental Dysfunction,'' and it was comprised of SCAG Items 1 through 4 and Item 8. (Chaing, Tr. Vol. I at 47.)

made in the Yesavage study. I find the Center's arguments to have merit.

A comparable issue was adjudicated in the Commissioner's Decision on Mysteclin. Therein, it was ruled, ''(E)ven if the subgroups and multiple endpoints had been identified in the protocol, * * * some downward adjustments in the p values should have been made to correct for the analyses of multiple subgroups and endpoints.'' (Commissioner's Decision on Mysteclin, slip op. at 43; see also Commissioner's Decision on Deprol, 58 FR 50929 at 50933.) Similarly, in the Commissioner's Decision on Deprol, it was noted that, ''if enough pair-wise comparisons are made, some comparisons will be 'statistically significant' by chance alone.'' (Commissioner's Decision on Deprol, 58 FR 50929 at 50933.) When multiple comparisons are made, corrections in the p values are needed to maintain the correct Type I error rate because the likelihood of a Type I error increases with the number of individual comparisons. (Commissioner's Decision on Deprol, 58 FR 50929 at 50933.) In other words, as one great author more expressively observed, ''Fortune brings in some boats that are not steered.'' (Shakespeare, *Cymbeline*, IV, iii, 46.)

For these reasons, I find that in weighing the adequacy of the Yesavage study, it is proper to consider the fact that numerous statistical analyses were employed, and to consider that the particular outcome of interest was not specified in advance, nor were adjustments to the p value made. Accordingly, I find no error in the ALJ's ruling on this point.

h. *Adequacy of the Yesavage study*. In sum, I find that the Yesavage study was not adequate and well-controlled. In making this determination, I have considered the aggregate effect of the protocol violations. I base my ruling upon these findings: (1) That the selection of patients for the study was flawed by the inclusion of patients with the concomitant condition of Parkinson's disease, and by the inclusion of outpatients, who were to be excluded under the protocol; (2) that the failure to show that stroke patients were included in both the drug and the placebo arms of the clinical trial can be considered as a flaw in the study; (3) that the fact that a statistically significant difference between test and control groups existed on the BMT was a proper consideration; (4) that the uncontrolled use of concomitant medication and the poor documentation of concomitant medication use weighs against finding the Yesavage study to be adequate and well-controlled; (5) that the small sample size was a proper factor to be considered in reviewing the results of the study, and can be weighed against the adequacy of the study; (6) that the improvement of patients on SCAG Factor 1 was not clinically significant; and (7) that the fact that numerous statistical analyses were employed and that the particular outcome of interest was not specified in advance, nor were adjustments to the p value made, can be weighed against the adequacy of the study.

II. Conclusion and Order

The foregoing opinion in its entirety constitutes my findings of fact and conclusions of law. Based on the foregoing discussion, findings, and conclusions, I affirm the ALJ's Initial Decision in all respects, except where specifically stated otherwise. I find that there is a lack of substantial evidence that Cyclospasmol® will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, under 21 U.S.C. 355(e)(3), the NDA for Cyclospasmol® must be withdrawn. I further find that, by reason of the lack of substantial evidence of its effectiveness, Cyclospasmol® is a ''new drug'' within the meaning of 21 U.S.C. 321(p).

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(e), and under authority delegated to me by the Secretary (§ 5.10(a)(1)), the new drug application for Cyclospasmol® and all amendments and supplements thereto, are hereby withdrawn, effective January 2, 1997.

Dated: November 12, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–30648 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–01–P

[Docket No. 96D–0334]

Procedures for Issuance of and Review and Response to Materials Submitted in Response to Clinical Hold for Investigational New Drug (IND) Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two documents entitled ''Centerwide Policy on Issuance of and Response to Clinical Hold Letters for Investigational New Drug Applications'' (OD–R–8–96, Center for Biologics Evaluation and Research (CBER)) and ''IND Process and Review Procedures'' (MAPP 6030.1, Center for Drug Evaluation and Research (CDER)). The documents specify the procedures for the issuance of and review and response to material submitted in response to a notice of clinical hold. It is intended that these documents will clarify the agency's policy in regard to responses to clinical holds. The documents are made available as part of the agency's commitment to review and respond to data submitted in response to a clinical hold within 30 days of receiving the submission, as stated in the November 1995, Presidential National Performance Review report entitled ''Reinventing the Regulation of Drugs Made from Biotechnology.''

ADDRESSES:

CBER Information: For additional copies of the documents submit written requests to the Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or FAX by calling the CBER FAX Information System at 1–888–CBER FAX, or 301–827–3844. Persons with access to the Internet may obtain the document using FTP, the World Wide Web (WWW), or bounce-back e-mail. For FTP access, connect to CBER at ''ftp://ftp.fda.gov/CBER/''. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. For bounce-back e-mail send a message to ''INDHOLD@a1.cber.fda.gov''.

CDER Information: For additional copies of the documents contact the Drug Information Branch (HFD–210), Division of Communications Management, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1012. The form may also be obtained by calling the CDER FAX–ON–DEMAND System at 1–800–342–2722, or 1–301–827–0577. An electronic version of the documents is also available via Internet using FTP, Gopher, or the World Wide Web (WWW). For FTP, connect to the CDER anonymous FTP server at cdvs2.cder.fda.gov and change to the ''guidance'' directory. For Gopher, connect to the CDER Gopher server at

gopher.cder.fda.gov and select the ''Industry Guidance'' menu option. For WWW, connect to the FDA home page at http://www.fda.gov.

Submit written comments on the documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Corporations should submit two copies of any comments and individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Copies of the documents and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074, or

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852–1420, 301–594–5417.

SUPPLEMENTARY INFORMATION: The President's November 1995 report, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' outlined changes to the biologics regulations designed to reduce the burden of FDA regulations on industry without reducing public health protection. One of the recommended modifications was to have investigational new drug (IND) reviewers respond within 30 days whether newly submitted information supports the initiation or continuation of a human investigation that the agency has put on clinical hold.

Companies or individuals that intend to study IND's or biologics in humans generally are required first to submit an IND application to the agency. They may proceed with the study 30 days after the agency receives the application unless FDA puts the study on clinical hold (§ 312.42 (21 CFR 312.42).) Section 312.42(a) describes a clinical hold as an ''order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation.'' Section 312.42(d) states that the hold may be relayed to the sponsor by telephone or other rapid means of communication and that FDA will provide a written explanation of the basis of the hold to the sponsor no more than 30 days following the hold. Though § 312.42(d) allows for communication of the reasons for a hold within 30 days following the placement of the hold, both CBER and CDER provide this notification in even shorter timeframes, consistent with the procedures set forth in the CBER and CDER documents. Thus, a researcher or company that intends to begin testing a biologic or new drug in humans, may not begin or continue the study until FDA releases the clinical hold. Removal of the hold may be relayed by telephone or other rapid means of communication unless FDA notified the sponsor in writing that once a correction or modification was made they could proceed as outlined in § 312.42(e).

In the past, FDA had no internal operating procedures regarding how much time it may take to evaluate data submitted by the sponsor in response to the clinical hold. FDA is committed to promptly reviewing and responding to data submitted in response to a clinical hold and to do so within 30 days of receiving the submission. FDA believes that the 30-day period meets the needs of sponsors, will prevent delays during review of data, and will prevent unnecessary delays in the start or continuation of clinical studies. These procedures are contained in CBER's Policy and Procedure Guide, OD–R–8–96, ''Centerwide Policy on Issuance of and Response to Clinical Hold Letters for Investigational New Drug Applications,'' dated August 20, 1996, and in CDER's Manual of Policies and Procedures, MAPP 6030.1, ''IND Process and Review Procedures,'' dated June 20, 1996.

Although these documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public, they do represent the agency's current thinking on time periods for the review and response to materials submitted in response to clinical hold for IND's.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the procedure documents. FDA will review the comments received and, if appropriate, consider preparing revised documents based upon that review. Corporations should submit two copies of any comments and individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Copies of the documents and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–30770 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Voluntary Customer Surveys of ''Partners'' of the Health Resources and Services Administration—NEW

In response to Executive Order 12862, Setting Customer Service Standards, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its ''partners'' to assess strengths and weaknesses in program services. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers. Partner surveys to be conducted by HRSA might include, for example, surveys of grantees to determine satisfaction with the technical assistance, or surveys of providers who receive training from HRSA grantees to measure satisfaction with the training experience. Results of

these surveys will be used to plan and redirect resources and efforts as needed to improve service. A generic approval will be requested from OMB to conduct partner surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred methodologies. An estimate of annual burden is shown below.

Type of survey	Number of respondents	Responses per respondent	Average burden/response (hours)	Total hours of burden
In-class evaluations	40,000	1	0.05	2,000
Mail/telephone surveys	6,000	1	0.25	1,500
Focus groups	100	1	1.5	150
Total	46,100	1	0.08	3,650

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 26, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–30725 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–15–P

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS) announces that approximately $11,706,000 in funds for fiscal year (FY) 1997 is available for the repayment of health professions educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. The IHS estimates that 250 loan repayment awards averaging $50,000 per award may be made with this funding.

Funds are required to be expended by September 30 of the fiscal year. This program is authorized by Section 108 of the Indian Health Care Improvement Act (IHCIA) as amended, 25 U.S.C. 1601 et seq. The IHS invites potential applicants to request an application for participation in the Loan Repayment Program.

DATE: Applications for the FY 1997 Loan Repayment Program will be accepted and evaluated monthly beginning January 2, 1997 and will continue each month thereafter until all funds are exhausted. Subsequent monthly deadline dates are scheduled for Friday of the second full week of each month. Notice of awards will be mailed on the last working day of each month.

Applicants selected for participation in the FY 1997 program cycle will be expected to begin their service period no later than September 30, 1997.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall *not* be acceptable as proof of timely mailing.)

Applications received after the monthly closing date will be held for consideration in the next monthly funding cycle. Applicants who do not receive funding by September 30, 1997 will be notified in writing.

FORM TO BE USED FOR APPLICATION: Applications will be accepted only if they are submitted on the form entitled ''Application for the Indian Health Service Loan Repayment Program,'' identified with the Office of Management and Budget approval number of OMB #0917–0014 (expires 11/30/99).

ADDRESS: Application materials may be obtained by calling or writing to the address below. In addition, completed applications should be returned to: IHS Loan Repayment Program, 12300 Twinbrook Parkway—Suite 100, Rockville, Maryland 20852, PH: 301/443–3396 [between 8:00 a.m. and 5:00 p.m. (EST) Monday through Friday, except Federal holidays].

FOR FURTHER INFORMATION CONTACT: Please address inquires to Mr. Charles Yepa, Chief, IHS Loan Repayment Program, Twinbrook Metro Plaza—Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland 20852, PH: 301/443–3396 [between 8:00 a.m. and 5:00 p.m. (EST) Monday through Friday, except Federal holidays].

SUPPLEMENTARY INFORMATION: Section 108 of the IHCIA as amended by Public Laws 100–713 and 102–573, authorizes the IHS Loan Repayment Program and provides in pertinent part as follows:

The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereafter referred to as the ''Loan Repayment Program'') in order to assure an adequate supply of trained health professionals necessary to maintain accreditation of, and provide health care services to Indians through, Indian health programs.

Section 4(n) of the IHCIA, as amended by the Indian Health Care Improvement Technical Corrections Act of 1996, Pub. L. 104–313, provides that:

''Health Profession'' means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, an allied health profession, or any other health profession.

For the purposes of this program, the term ''Indian health program'' is defined in Section 108(a)(2)(A), as follows:

. . . any health program or facility funded, in whole or in part, by the IHS for the benefit of American Indians and Alaska Natives and administered:

a. Directly by the service; or

b. By any Indian tribe or tribal or Indian organization pursuant to a contract under:

(1) The Indian Self-Determination Act; or

(2) Section 23 of the Act of April 30, 1908, (25 U.S.C. 47), popularly known as the Buy Indian Act; or

(3) By an urban Indian organization pursuant to Title V of this act.

Applicants may sign contractual agreements with the Secretary for 2 years. The IHS will repay all or a portion of the applicant's health professions educational loans (undergraduate and graduate) for tuition expenses and reasonable educational and living expenses in amounts up to $30,000 per year for each year of contracted service to be made in annual payments to the participant for the purpose of repaying his/her outstanding health professions educational loans. Repayment of health professions educations loans will be made to the

participant within 120 days after the participant's entry on duty has been confirmed by the IHS.

The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site determined by the Secretary. Loan repayment sites are characterized by physical, cultural, and professional isolation, and have histories of frequent staff turnover. All Indian health program sites are annually prioritized by discipline, based on need or vacancy by the Agency.

All health professionals will receive up to $30,000 per year, regardless of their length of contract. Where payments under the Loan Repayment Program result in an increase in Federal income tax liability, the IHS will pay up to 31 percent of the participant's total loan repayments to the Internal Revenue Service on the participant's behalf for all or part of the increased tax liability of the participant.

Pursuant to Section 108(b), to be eligible to participate in the Loan Repayment Program an individual must:

(1) A. be enrolled:

(i) in a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in the Loan Repayment Program. (This includes the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin islands, Guam, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); or

(ii) in an approved graduate training program in a health profession; or

B. have a degree in a health profession and a license to practice; and

(2) A. be eligible for, or hold an appointment as a Commissioned Officer in the Regular or Reserve Corps of the Public Health Service; or

B. be eligible for selection for civilian service in the Regular or Reserve Corps of the Public Health Service; or

C. meet the professional standards for civil service employment in the IHS; or

D. be employed in an Indian health program without service obligation; and

(3) submit to the Secretary an application and contract to the Loan Repayment Program; and

(4) sign and submit to the Secretary, a written contract agreeing to accept repayment of educational loans and to serve for the applicable period of obligated service in a priority site as determined by the Secretary; and

(5) sign an affidavit attesting to the fact that they have been informed of the relative merits of the U.S. Public Health Service Commissioned Corps and the Civil Service as employment options.

Upon approval of the applicant for participation in the Loan Repayment Program, the applicant will receive confirmation of his/her loan repayment award and the duty site at which he/she will serve his/her loan repayment obligation.

The IHS has identified the positions in each Indian health program for which there is a need or vacancy and ranked those positions in order of priority by developing discipline specific prioritized lists of sites. Ranking criteria for these sites include the following:

- Historically critical shortages caused by frequent staff turnover;
- Current unmatched vacancies in a Health Profession Discipline;
- Projected vacancies in a Health Profession Discipline;
- Ensuring that the staffing needs of Indian health programs administered by an Indian tribe or tribal or health organization receive consideration on an equal basis with programs that are administered directly by the Service; and
- Giving priority to vacancies in Indian health programs that have a need for health professionals to provide health care services as a result of individuals having breached Loan Repayment Program contracts entered into under this section. Consistent with this priority ranking, in determining which applications to approve and which contracts to accept, the IHS will give priority to applications made by American Indians and Alaska Natives and to individuals recruited through the efforts of Indian tribes or tribal or Indian organizations.
- With respect to priorities among the various health professions, the statute requires that of the total amount appropriated for FY 1997 for loan repayment contracts, not less than 25 percent be provided to applicants who are nurses, nurse practitioners, or nurse midwives and not less than 10 percent be provided to applicants who are mental health professionals (other than nurses, nurse practitioners, or nurse midwives). This requirement does not apply if the number of applications from these two groups, respectively, is not sufficient to meet the requirement.
- Subject to the above statutory priority for nurses and mental health practitioners, the IHS will give priority in funding among health professionals to physicians in the following priority specialties: anesthesiology, emergency room medicine, general surgery, obstetrics/gynecology, ophthalmology, orthopedic surgery, otolaryngology/otorhinolaryngol, psychiatry and radiology.

The following factors are equal in weight when applied, and are applied when all other criteria are equal and a selection must be made between applicants.

One or all of the following factors may be applicable to an applicant, and the applicant who has the most of these factors, all other criteria equal, would be selected.

- An applicant's length of current employment in the IHS, tribal or urban program.
- Availability for service earlier than other applicants (first come, first served); and
- Date the individual's application was received.

Any individual who enters this program and satisfactorily completed his or her obligated period of service may apply to extend the contract on a year-by-year basis, as determined by the IHS, at the maximum amount of up to $30,000 per year and additional 31 percent for Federal Withholding. If funds are available, the maximum amount will be funded in this manner and will not exceed the total of the individual's outstanding eligible health professions educational loans.

Any individual who owes an obligation for health professional service to the Federal Government or to a State or other entity under an agreement with such State or other entity is not eligible for the Loan Repayment Program unless such an obligation will be completely satisfied prior to the beginning of service under this program in the year that an application is made for this program.

This program is not subject to review under Executive Order 12372.

(The Catalog of Federal Domestic Assistance number is 93.164.)

Dated: November 26, 1996

Michael H. Trujillo,

Assistant Surgeon General Director.

[FR Doc. 96–30726 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–16–M

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/334–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787/800–242–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444/800–877–7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5784

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–549–8263/800–833–3984 (formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

CORNING Clinical Laboratories, 4771 Regent Blvd., Irving, TX 75063, 800–526–0947 (formerly: Damon Clinical Laboratories, Damon/MetPath)

CORNING Clinical Laboratories, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220–3610, 800–284–7515 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories)

CORNING Clinical Laboratories, 4444 Giddings Road, Auburn Hills, MI 48326, 800–444–0106/810–373–9120 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath)

CORNING Clinical Laboratories Inc., 1355 Mittel Blvd., Wood Dale, IL 60191, 630–595–3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING Clinical Laboratories, South Central Divison, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 (formerly: Metropolitan Reference Laboratories, Inc.)

CORNING Clinical Laboratory, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5000 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485/800–522–9235 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science)

CORNING Clinical Laboratories, 7470–A Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute)

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941–418–4700/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180/206–386–2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300 (formerly: Harrison & Associates Forensic Laboratories)

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051

LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927/

800–728–4064 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800–437–4986 (formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504–392–7961
Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734
MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38118, 901–795–1515/800–526–6339
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43614, 419–381–5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302–655–5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800–832–3244/612–636–7466
Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317–929–3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800–752–1835/309–671–5199
MetroLab-Legacy Laboratory Services, 235 N. Graham St., Portland, OR 97227, 503–413–4512, 800–237–7808(x4512)
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805–322–4250
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400/800–541–7891
PharmChem Laboratories, Inc., 1505–A O'Brien Dr., Menlo Park, CA 94025, 415–328–6200/800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–338–4070/800–821–3627
Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 619–279–2600/800–882–7272
Premier Analytical Laboratories, 15201 I–10 East, Suite 125, Channelview, TX 77530, 713–457–3784/800–888–4063 (formerly: Drug Labs of Texas)
Presbyterian Laboratory Services, 1851 East Third Street, Charlotte, NC 28204, 800–473–6640
Puckett Laboratory, 4200 Mamie St., Hattiesburgh, MS 39402, 601–264–3856/800–844–8378
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–727–8800/800–999–LABS
Sierra Nevada Laboratories, Inc., 888 Willow St., Reno, NV 89502, 702–334–3400
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520/800–877–2520
SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352–787–9006 (formerly: Doctors & Physicians Laboratory)
SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847–447–4379/800–447–4379 (formerly: International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800–523–0289/610–631–4600 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (formerly: SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602–438–8507
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405–272–7052
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373/800–966–2211 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)
UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800–492–0800/818–996–7300 (formerly: MetWest-BPL Toxicology Laboratory)
UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555–0551, 409–772–3197

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96–30757 Filed 12–2–96; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4086–N–80]

Office of the Assistant Secretary for Housing-Federal Housing Commissioner; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be 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.

DATES: Comments due: February 3, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451–7th Street, SW., Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Ivy Jackson, Telephone number (202) 708–4560 ext. 2333 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Good Faith Estimate, Special Information Booklet.

OMB Control Number: 2502–0265.

Description of the need for the information and the proposed use: Consumers who apply for a federally related mortgage to purchase a home are required to receive from the mortgage originator a Good Faith Estimate and a Special Information Booklet. These borrowers are entitled to a HUD–1 statement reflecting actual costs at settlement.

Agency form numbers: HUD–1.

Members of affected public: Mortgage originators are required to provide consumer who seek a purchase money mortgage the Good Faith Estimate and the Special Information Booklet. Attorneys or other settlement agents are required to provide the HUD–1 statement of settlement costs.

An estimation of the total numbers of hours needed to prepare the information collection is 875,500 number of respondents is 3,470,000 frequency response is on occasion, and the hours of response is 0.25 of an hour.

Status of the proposed information collection: Extension of a currently approval collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: November 13, 1996.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 96–30766 Filed 12–2–96; 8:45 am]

BILLING CODE 4210–27–M

[Docket No. FR–4086–N–81]

Office of the Assistant Secretary for Housing-Federal Housing Commissioner; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be 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.

DATES: Comments due: February 3, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451—7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Ivy Jackson, Telephone number (202) 708–4560 ext. 2333 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Housing and Community Development Act of 1992, Amendments to Real Estate Settlement Procedures Act (RESPA).

OMB Control Number: 2502–0491.

Description of the need for the information and the proposed use: Amendments to RESPA in the Housing and Community Development Act of 1992 added a new class of covered transactions—subordinate mortgages. A new settlement statement form HUD–1A was developed to reflect the settlement costs associated with these types of transactions.

Agency form numbers: HUD–1A.

Members of the affected public: Consumers who seek a subordinate lien mortgage are required to receive certain disclosures from the lender; including, a Good Faith Estimate and HUD–1A. A Controlled Business Disclosure is required where a settlement provider refers the consumer to an affiliate.

An estimation of the total numbers of hours needed to prepare the information collection is 528,025, the number of respondents is 1,508,500, frequency of response is on occasion and the hours of response is 0.35 of an hour. Status of the proposed information collection: Extension of a previously approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: November 13, 1996.

Nicolas, P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 96–30767 Filed 12–2–96; 8:45 am]

BILLING CODE 4210–27–M

[Docket No. FR–4185–N–01]

Office of Administration; Notice of 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 emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: The due date for comments is: December 10, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr. HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, HUD Notice, Site-Based Waiting Lists.

Title VI of the Civil Rights Act of 1964 prohibits discrimination on the ground of race, color, national origin, religion of sex in any program or activity receiving Federal financial assistance. HUD has implemented Title VI through regulations at 24 CFR Part 1. HUD has existing authority under 24 CFR 1.4(b)(2)(iii), to make exceptions from the community-wide waiting list regulation that are consistent with the purpose of the regulation and Title VI to prohibit discrimination in the assignment of low-income families to public housing units. HUD's policy on implementation of exceptions under the community-wide waiting list regulation is included in the attached draft Notice.

The Department has submitted the proposal for the collection of information to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Department has requested emergency clearance of the collection of information, as described below, with approval being sought by December 9, 1996:

(1) Title of the information collection proposal: PHA's Plan for Exception Request—Site-Based Waiting Lists

(2) Summary of the collection of information: Each PHA may request an exception to establish site-based waiting lists by submitting its plan and the rationale for it to the local HUD office. The plan must include all of the PHA's general occupancy developments and/or all of the PHA's mixed-population and elderly-designated developments. The request must also include: accurate statistics for the Metropolitan Statistical Area (MSA) and the PHA's jurisdiction; each development's name, number, occupancy type and number of units, date site was developed, racial composition by bedroom size and waiting list composition. For the Section 8 program: the number of certificates and vouchers currently in use by race and bedroom size; and the length and composition of the waiting list by race and bedroom size. PHAs must provide current and proposed public housing tenant selection and assignment procedures along with any Consent Decrees, Voluntary Compliance Agreements, or other documentation related to current occupancy problems along with measures being taken to correct such problems.

(3) Description of the need for the information and its proposed use: HUD needs the information to assure statutory and regulatory compliance. The information will be used to approve the PHA's plan for exception to establish site-based waiting lists.

(4) Description of the likely respondents, and proposed frequency of response to the collection of information: State, Local Governments will request exceptions on occasion.

(5) Estimate of the total reporting burden that will result from the collection of information:

Reporting Burden:
Number of respondents: 52
(@ 72 hours per response)
Total Estimated Burden Hours: 3,744

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: November 26, 1996.

David S. Cristy,

Director, IRM Policy and Management Division.

[FR Doc. 96–30768 Filed 12–2–96; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–330–1010–00]

Notice of Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The Bureau of Land Management's Ukiah Resource Advisory Council will hold a business meeting and field tour Thursday and Friday, Jan. 9 and 10, 1997, at the BLM's Arcata Resource Area Office, 1695 Heindon Rd., Arcata, California. The meeting is open to the public. The Jan. 9 meeting begins at 10 a.m. Agenda items include an update on BLM's development of standards for healthy rangelands and guidelines for livestock grazing, a discussion about recreation fees on public lands facilities, updates from the Arcata, Clear Lake and Redding Resource Areas, and a discussion of issues for future council consideration.

A public comment period is set for 1 p.m. Depending on the number of persons wishing to speak, a time limit could be imposed.

On Jan. 10, the council will convene at 8 a.m. at the Arcata Resource Area Office, then depart for a tour of public lands at the Somoa Dunes. The tour is open to the public, but participants must provide their own transportation.

Summary minutes of the meeting will be available for public review 30 days following the meeting at the Arcata Resource Area Office during regular business hours.

FOR ADDITIONAL INFORMATION CONTACT: Lynda J. Roush, Area Manager, Arcata Resource Area, (707) 825–2300.

Lynda J. Roush,

Arcata Resource Area Manager.

[FR Doc. 96–30736 Filed 12–2–96; 8:45 am]

BILLING CODE 4310–40–P

[OR–100–6321–01; GP7–0033 Case File #OR–51858]

SUBJECT: Notice of Intent, Plan Amendment.

AGENCY: Prineville District, Central Oregon Resource Area, Interior.

ACTION: Notice of realty action, Notice of exchange proposal.

SUMMARY: In accordance with 43 CFR 1610.2 and 1610.3 and 43 CFR 2200, notice is given that the Bureau of Land Management in the State of Oregon, Vale District, Baker Resource Area, intends to analyze a potential amendment to the Baker R.A. Resource Management Plan (RMP). The potential amendment will involve adjustment of land tenure designations. Currently the Baker RMP designates only two land tenure adjustment categories. The potential amendment would reclassify those areas with special designations into a ''retention only'' zone, thus adding an additional category. If necessary, the purpose of the plan amendment would be to make available for exchange certain lands located in Baker, Umatilla, Union, and Morrow Counties in Northeastern Oregon and would facilitate exchange proposals that involve the Prineville District BLM, Baker R.A., numerous private property holders, and a third party facilitator.

Subject to valid existing rights, most of the public lands referred to herein have been segregated from appropriation under the public land laws and mineral laws for a period of five years, beginning May 24, 1996. A complete list of specific lands segregated will be available in the same locations as the other elements of the supporting record, as noted elsewhere in this notice.

DATES: A two purpose public comment period is provided at this time. Publication of this Notice in the Federal Register starts the 45 day comment period necessary to meet public notification requirements for both the Notice of Intent to prepare to prepare plan amendments, an EIS and the Notice of Realty Action.

ADDRESSES:

Bureau of Land Management, Vale District, Baker R.A., P.O. Box 987, Baker City, OR, 97.
Prinville District, Central Oregon Resource Area, P.O. Box 550, Prineville, OR 97754.

FOR FURTHER INFORMATION CONTACT: Ron Lane, Central Oregon, R.A. Realty Specialist, (541) 416–6752 and Dorothy Mason, Baker R.A., Staff Supervisor, (541) 523–1256.

SUPPLEMENTARY INFORMATION: The Prineville District's Two Rivers (1986) and John Day (1985, 1995) Resource Management Plans and the Vale District's Baker (1989, 1992) Resource Management Plan (RMPs) currently provide general management guidelines for land tenure adjustments as well as overall land resource use allocations and resource protection or enhancement. Although it is anticipated that the final decisions for land exchanges considered through this analysis will be in full conformance with the applicable RMPs, it is possible that portions of some actions under some alternatives may not be in full conformance with the approved plans, as required by 43 Code of Federal Regulations (CFR), Subpart 1610.5–3, ''Conformity and Implementation''. The environmental analysis and public and interagency review process anticipated for this analysis are expected to fully comply with the Bureau's regulations for land use planning, including land use plan amendments, public involvement and coordination with other Federal agencies, State and local governments and Indian tribes, (43 CFR 1610.2, 1610.3 and 1610.5–5). This will allow the analysis to consider land tenure strategies which are inconsistent with the current direction or substantially affect other resource uses and allocations in one or more of the subject approved RMPs. Any approved decisions which amend the applicable plans will be incorporated into the plans and become part of the permanent planning record. Any refinements or clarifications of management direction, priority of disposal or use of acquired lands will be incorporated into the applicable plans and documented through published plan maintenance reports, as provided under 43 CFR 1610.5–4. Copies of the three existing approved plans (as amended) will be available in the same locations as the other elements of the supporting record, as noted elsewhere in this notice.

The decisions made through this analysis are expected to be implemented through a relatively complex series of land tenure adjustment actions over a period of several years. Although the intent is to consummate the majority of the exchanges within approximately two years of the approval of the decision(s), some residual actions or independent land exchanges which are in conformance with the analysis and decisions and associated approved RMPs may occur over a period of ten or more years. In effect, this analysis will serve both to facilitate the ongoing project as well as future actions that fall under the programmatic nature of this analysis. Future exchanges or other land transfers would be subject to appropriate environmental analyses, public and interagency reviews and would be reported in the applicable District or Resource Area periodic planning update reports which are distributed to known interested parties.

The Baker R.A. RMP proposed plan amendment and exchange proposal include public lands administered by the Baker R.A. located within the following areas.

Willamette Meridian, Baker, Morrow, Union and Umatilla Counties:

T.1N. through 6N., R.23E. through 41E.,
T.1S, through 6S., R.23E. through 42E.,
T.7S through 14S., R.36E. through 48E.

Containing approximately 45,000 acres of public land.

Public lands considered for disposal in the Central Oregon R.A. Prineville, are located within the following areas:

Willamette Meridian, Grant and Wheeler Counties:

T.7S. through 18S., R.26E. through 35E.
T.7S. through 9S., R.21E. through 25E.

Containing approximately 50,000 acres of public land.

Contingent upon approval of the amended RMP, or an approved conformance determination with the existing approved Baker RMP, the above described land within the Baker R.A. will be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976 (FLPMA), 43 U.S.C. 1716. Disposal of the public lands considered for exchange within the Central Oregon R.A. are in conformance with current Land Use Plans. These parcels are generally considered to be isolated and inefficient to manage. The total acreage considered for disposal in both the Baker and Central Oregon Resource Areas totals approximately 95,000 acres.

The Baker and Central Oregon Resource Areas have received exchange proposals from Clearwater Land Exchange for property from Pioneer Resources, the JV Ranch and other private entities, potentially affecting the public lands noted above. Some lands offered by these private landholders for this exchange are located along the North Fork of the John Day River which straddles the Grant, Morrow, and Umatilla county lines. They adjoin a second piece of land that is located west of the North Fork and includes Ditch and Cabin Creeks to the east, Wall Creek on the west and are adjacent to Forest Service administered lands to the north. Other lands considered for acquisition are located on and in the vicinity of Rudio Mountain in Grant County and along the South Fork of the John Day River. The Baker R.A. has designated the following ''target'' acquisition areas within which it would seek to acquire private lands from willing land owners: the west side of the Snake River from Homestead to Huntington (including the Lookout Mountain area), the Pedro Mountain area, the Dooley Mountain/Burnt River Canyon area and along the Powder River downstream from Thief Valley Reservoir. Additionally, any opportunity to acquire lands within or adjacent to land tenure retention zone 1 as identified in the land use plans, will also be considered for acquisition in both districts.

The parcels identified for acquisition through the exchange process are considered to contain high public values including significant forest resources, anadromous fish and wildlife habitat, substantial recreational opportunities and miles of riparian habitat. They would block up and consolidate public lands managed by the BLM, adjacent to the National Forest. Other lands offered for acquisition will be considered on the basis of the following values: key anadromous or other fisheries habitat, important wildlife habitats, wetlands and riparian values, significant cultural/historic sites eligible for National Register of Historic places, T&E/

sensitive species habitat, Unique/outstanding recreational values, provide legal public access, within or adjacent to special designated areas (ACEC, W&S Rivers), manageability and cost of administration, substantially improves manageability of existing BLM or other public land, opportunities for partnerships in management and acquisition, unique lands with ecologic, geologic, scientific or scenic values and significance in stabilizing business, social and economic conditions and/or lifestyles. Issues raised at initial scoping that will be addressed in the analysis include, but are not limited to, multiple adjacent landowners desiring acquisition of BLM disposal tract(s), adjacent landowner(s) does not wish to acquire BLM disposal tract(s), appraisal issues, tribal, values/historic use areas, county land base, water rights and agricultural lands, outright sale of public lands, resource management of acquired tracts, resource management on tracts considered for disposal, late successional forest stands/habitat, access and wildlife habitat.

Parcels will be screened by an interdisciplinary (ID) team through the environmental impact statement (EIS) process. Public parcels will be inventoried for sensitive values including special status wildlife and plants, and cultural resources. Disciplines to be represented on the ID team preparing the plan amendment and EIS include, but are not limited to: archaeology, anthropology, economics, lands and minerals, recreation, forestry, fisheries, hydrology, botanical, soils, wildlife, geology and hazardous materials.

The value of lands proposed for exchange have not yet been determined. Upon completion of final appraisal, acreage would be adjusted and/or money would be used to equalize the values. Lands will be exchanged on a value basis, based on current fair market value appraisals.

Public lands would be transferred subject to: (1) A reservation to the United States of a right-of-way for ditches canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945); and (2) all valid existing easements, leases, permits, licenses, rights-of-way or other rights, and other terms and conditions that may be identified in the EIS.

The BLM is inviting comments to be considered in the preparation of the EIS for the proposed exchange. Comments may be addressed to Dick Cosgriffe, Central Oregon Resource Area Manager, at the Prineville District Office and Gloria Brown, Baker Resource Area Manager in Baker City. Comments should be postmarked by January 17, 1997.

Public meetings have been held in John Day, Heppner, Pendleton, LaGrande and Baker City regarding this proposal. Public open houses will be held in Heppner, Pendleton, La Grande and Baker City. The need for additional meetings will be evaluated based on the level of public input as a result of public notification procedures. Any public meetings will be announced at least 15 days in advance.

Detailed information concerning the proposed exchange and plan amendment, including the EIS, will be available at a later date at BLM offices in Prineville, Baker City, John Day, and Portland. In Heppner this information will be available in the public library. When the EIS is completed in the early spring of 1997, another comment period will be provided to allow for additional public input to the exchange and associated plan amendment. This comment period will be announced in a Federal Register notice and local media. Any final decision will also be published to these same standards and applicable appeal or protest period(s) provided.

Pursuant to 7 CFR, Part 1, Subpart B, Section 1.27, all written submissions in response to this notice shall be made available for public inspection including the submitter's name, unless the submitter specifically requests confidentiality. Anonymous comments will not be accepted. All written submissions from business entities and organizations, submitted on official letterhead, in response to this notice shall be made available for public inspection in their entirety.

Dated: November 20, 1996.

James L. Hancock,

District Manager.

[FR Doc. 96–30735 Filed 12–2–96; 8:45 am]

BILLING CODE 4310–33–M

National Park Service

Notice of Availability of the final General Management Plan/ Development Concept Plan and Environmental Impact Statement for the Klondike Gold Rush National Historical Park

AGENCIES: National Park Service, Interior.

ACTION: Notice of Availability of the final General Management Plan/ Development Concept Plan and Environmental Impact Statement for the Klondike Gold Rush National Historical Park.

SUMMARY: The National Park Service announces the availability of the final General Management Plan/Development Concept Plan (GMP/DCP) and Environmental Impact Statement (EIS) for the Klondike Gold Rush National Historical Park. The final GMP/DCP and EIS describes a proposed action for the three Alaska units and one Seattle unit of the park and three alternatives (two in Seattle) to provide additional opportunities for residents and visitors to enjoy the park units while protecting the park's cultural and natural resources. A no-action alternative also is evaluated.

DATES: A Record of Decision will be made no sooner than January 2, 1997.

ADDRESSES: Copies of the statement are available on request from: Superintendent Willie Russell, Klondike Gold Rush-Seattle, 117 South Main St, Seattle WA, 98104, telephone: (206) 553–7220, FAX: (206) 553–0614 or Superintendent Clay Alderson, Klondike Gold Rush NHP, PO Box 517, Skagway, AK 99840, telephone: (907) 983–2921, FAX: (907) 983–2046.

Public reading copies of the final GMP/DCP EIS will be available for review in the following locations:

Office of Public Affairs, National Park Service, Department of the Interior, 1849 C Street, Room 3424, Washington, DC 20240, telephone: (202) 208–6843.

Alaska System Support Office, National Park Service, 2525 Gambell Street, Room 404, Anchorage, Alaska 99503–2892, telephone: (907) 257–2650.

Klondike Gold Rush National Park—Seattle, 117 South Main St, Seattle, WA 98104, telephone: (206) 553–7220.

Klondike Gold Rush National Historical Park, Second & Broadway, Skagway, AK 99840, telephone: (907) 983–2921.

Columbia Cascades Sytem Support Office & Library, NPS, 909 First Ave, 6th Floor, Seattle, WA 98104, telephone: (206) 220–4154.

SUPPLEMENTARY INFORMATION: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (Pub.L. 91-190, as amended), the National Park Service has prepared a final GMP/DCP and EIS that describes a proposed action for the three Alaska units and one Seattle unit of the park and three alternatives (two in Seattle) to provide additional opportunities for residents and visitors to enjoy the park units while protecting the park's cultural and natural resources.

The proposed action (alternative C) in Alaska includes development concept plans for Dyea and the Chilkoot Trail and would expand park management,

development, resource (cultural and natural) protection, and maintenance components to meet most, but not all, of the expected visitor-use increases and interests in the park. A Klondike History Research Center would be established, in cooperation with the city of Skagway and state of Alaska, to process, study, conserve, and store historical, ethnographic, and natural history artifacts. Part of the center's function would be to provide interpretive and educational programs, as well as the opportunity for interagency training and academic research within Skagway. Specialized historic-building restoration skills would be made available on a cost-reimbursable basis. Access to the Dyea area would be improved with a rerouted, gravel road with enhanced parking, picnic, interpretive, and trail opportunities. Selected Dyea townsite streets would be cleared and signed. Archaeological inventory, surveys, and mapping; marking the historical segments; minor trail rerouting; and increased interpretive programs would occur along the Chilkoot Trail. White Pass archaeological inventory, surveying, mapping, and marking the historic trail route would be completed; but no facilities are proposed in the unit.

In Seattle, the proposed action would lead to acquiring a permanent location for the park visitor center, park offices, and historic collections. In the interim, expanded lease space at the present location would allow park offices to move to accessible space on the third floor; and park collections would be moved to the mezzanine level of the building. The interpretive focus would shift with more emphasis toward the role of the Pacific Northwest in the gold rush. Additional interpretive information (exhibits and walking tours) would be developed within the Pioneer Square area. Interpretive exhibits, in cooperation with the city of Seattle, would be added to the waterfront area at Washington Street Landing. Contacts with the Skagway office would be expanded with staff cross training. A Friends of the Park group would be organized.

Under the No-Action Alternative (alternative A), the development of a new general management plan would not take place. Management actions would react to situations as needed. In Alaska, work toward a new crossing of Nelson Slough and beach area access would continue, and the existing park management and operations would continue. In Seattle, the basic operation would continue unchanged.

Under alternative B (minimal alternative), some actions would take place in the park units. In Alaska, the park boundary in Dyea would be marked. Work toward a new crossing of Nelson Slough and beach area access would continue. The existing road along Nelson Slough would be graveled, but remain one lane. The campground, picnic area, and ranger station would be moved to be within the park boundary; and the historic segments of the Chilkoot Trail would be marked. In Skagway interpretive programs would be slightly increased, as would the visitor center operation. Site bulletins would be developed for each restored building. There would be an increased emphasis on maintaining the restored historic buildings as that program is completed. In Seattle about 2,800 square feet of additional lease space would be acquired, and improvements would be made to storage capabilities and the mezzanine area. Collections would be moved out of the basement and minor improvements made to existing exhibits. Pioneer Square and Washington Street Landing and other appropriate waterfront location's interpretive exhibits would be developed and sited. A Friends of the Park group would be established.

Under alternative D for Alaska, park management, development, resource protection, and maintenance needs would expand to meet all of the expected visitor use increases and interests in the park well into the next century. To accommodate the additional visitor use, there would be an increase in operational activities, maintenance, interpretation, and resources management, while protecting park resources from degradation. Park facilities would be upgraded with improvements to the visitor and administrative facilities in Skagway and the development of new facilities in Dyea and along the Chilkoot Trail. The day-use education center proposed in alternative C would be expanded to provide for overnight use. This would provide visitors with additional activity options for a better understanding of park themes. Additional historic buildings would be acquired for restoration and leased for commercial activities, or retained for administrative purposes. A historical building restoration center and a Klondike History Research Center would be established in Skagway. Alternative D (Substantial Change) was not developed for the Seattle unit.

The park would work with the state of Alaska and city of Skagway to provide better access for the Dyea and Chilkoot Trail areas. The park would also initiate and maintain additional cooperation with the city of Skagway, Parks Canada, and state and federal land management agencies to assure compatible uses in areas adjacent to the park. Maximum protection of cultural and natural resources would be provided. Connections with the Brackett Wagon Road and Canadian trails would be examined.

This document is a collaborative effort between two vastly separated National Park Service system support offices and two park locations with input from the city of Skagway, state of Alaska, and international assistance from Parks Canada.

The responsible officials for a Record of Decision on the proposed action are the NPS field directors in Alaska and the Pacific West areas.

Dated: November 22, 1996.

Paul R. Anderson,

Acting Field Director, Alaska.

[FR Doc. 96–30663 Filed 12–2–96; 8:45 am]

BILLING CODE 4310–70–P

Petroglyph National Monument, Final General Management Plan/ Environmental Impact Statement

AGENCY: National Park Service, Interior.

ACTION: Notice of availability of the Final General Management Plan/ Environmental Impact Statement for Petroglyph National Monument, Albuquerque, New Mexico.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 and Public Law 101–313 (the legislation that established the monument) the National Park Service announces the availability of a Final General Management Plan/Development Concept Plan/Environmental Impact Statement (GMP/DCP/EIS) for Petroglyph National Monument.

The Final GMP/DCP/EIS has been prepared in cooperation with the City of Albuquerque, the State of New Mexico, and the Federal Aviation Administration.

The purpose of this Final GMP/DCP/EIS is to set forth the basic management philosophy of the monument and the overall approaches to resource management, visitor use, and facility development that would be implemented over the next 10–15 years.

Petroglyph National Monument, encompassing 7,244 acres, was established in June 1990 as a new unit of the National Park System to preserve the estimated 15,000 prehistoric petroglyphs and other significant natural and cultural resources that are on the west side of Albuquerque, New Mexico. The monument is the first National Park System area specifically

established to protect and interpret rock carvings and their setting.

Public input has identified issues and concerns which include management responsibilities, cultural and natural resource protection, protection of sites and values of culturally affiliated groups, and location and function of visitor and administrative facilities such as visitor center, parking areas and trail heads, a heritage education center, and a petroglyph research center. Other issues addressed in the Final GMP/DCP/EIS include interpretation, education, visitor circulation and access, public use of the monument, and boundary adjustments. There are four alternatives for the development, resource management, and visitor use of the monument. The alternatives describe different visitor experiences and different kinds and locations for facilities under a common resource management and protection approach. All alternatives have a common resource management approach because of resource management laws and policies that apply to various aspects of all National Park System areas, including cultural landscape and archaeological site values, natural resources and various other aspects of monument management. These alternatives are summarized below:

Alternative 1: The overall approach of alternative 1, the proposed action and the National Park Service's preferred alternative, would be to provide various ways for visitors of different ages and abilities to see and appreciate many of the monument's significant resources. Visitors would be directed to a visitor center/heritage education center at Boca Negra Canyon. Horseback and bicycle riding would be permitted only on elected designated mesa-top trails and at three crossing points. No horses or bicycles would be allowed in petroglyph viewing areas or archeological sites anywhere in the monument. Mesa top resources and visitor experiences would be monitored to identify adverse impacts. Impacts on cultural and natural resources, the regional economy, visitors and values held by culturally affiliated groups would be minimal or, in some cases, beneficial. New structures would impact the cultural landscape. There could be adverse impacts on values held by culturally affiliated groups from the intrusion of bicycles and horses.

Alternative 2: This alternative would preserve the greatest portion of the monument and adjacent lands in as natural a condition as possible, with the fewest intrusions from development and fewer opportunities for public access and use. Visitors would be directed to a visitor center at Lava Shadows where they would have access to selected petroglyphs. A heritage education center would be built at Boca Negra Canyon. Visitors would have more opportunities to see the petroglyphs with a greater sense of solitude than in alternative 1. More areas of the monument would be reserved for research, traditional and cultural use, and occasional guided tours than in the other alternatives. Horse and bicycle use would not be permitted in this alternative except at two escarpment crossings. Overall impacts on cultural and natural resources and values held by culturally affiliated groups would be similar to and in some cases slightly less under this alternative than under alternative 1.

Alternative 3: The overall approach would be to have easy access to the mesa-top views and the volcanoes as well as petroglyph concentrations below the escarpment. Visitors would be directed to a visitor/heritage education center at Rinconada Canyon. From the visitor center, many visitors would drive to a new 10-mile mesa-top loop road that would provide easy access to the mesa-top views and the volcanoes. Parking and trails would be developed at the volcanoes and geologic windows areas. Horse and bicycle use would be provided at three escarpment crossings. This alternative would have the greatest impact on natural resources, cultural resources and values held by culturally affiliated groups.

Alternative 4: The ''no-action'' alternative, describes the conditions that would exist at the monument without a change in current management direction or an approved management plan—providing a baseline for evaluating the changes and impacts that would occur under the three action alternatives. There would be parking areas and minor trail improvements in some areas. There would be no new visitor center. This alternative would have the fewest facilities. Horseback and bicycle riding would be permitted within the monument only where currently allowed. The interim visitor center at Las Imagines would become the primary visitor center, accommodating only a limited number of visitors. Archeological sites, petroglyphs, and the cultural landscape would continue to be adversely impacted by vandalism.

DATES: The no action period will end 30 days after the Environmental Protection Agency publishes notice that the Final GMP/DCP/EIS has been filed with the Environmental Protection Agency. After this period a Record of Decision can be issued by the National Park Service. A Record of Decision will not be issued prior to February 6, 1997.

ADDRESSES: Questions about this document should be addressed to Superintendent, Petroglyph National Monument, 6001 Unser Blvd. NW, Albuquerque, NM 87120 phone# (505) 899–0205.

SUPPLEMENTARY INFORMATION: Public reading copies of the Final GMP/DCP/EIS will be available for review at the following locations: Office of Public Affairs, National Park Service 1849 C Street, NW., Washington, DC 20240; Department of Interior Natural Resources Library, 1849 C Street NW, Washington, DC 20240; Petroglyph National Monument Las Imagines Visitor Center, 4732 Unser Blvd.,NW., Albuquerque, New Mexico; and local public libraries in Albuquerque, New Mexico.

Dated: November 25, 1996.

Vickie E. White,

Acting Superintendent, Petroglyph National Monument.

[FR Doc. 96–30655 Filed 12–2–96; 8:45 am]

BILLING CODE 4310–70–P

Maine Acadian Culture Preservation Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (PL 92–463) that the Maine Acadian Culture Preservation Commission will meet on Friday, December 20, 1996. The meeting will convene at 7:00 p.m. at *le musee et centre culturel du Mont-Carmel* on U.S. Route 1 in Lille, Aroostook County, Maine.

The Maine Acadian Culture Preservation Commission was appointed by the Secretary of the Interior pursuant to the Maine Acadian Culture Preservation Act (PL 101–543). The purpose of the Commission is to advise the National Park Service with respect to:

- The development and implementation of an interpretive program of Acadian culture in the state of Maine; and
- The selection of sites for interpretation and preservation by means of cooperative agreements.

The Agenda for this meeting is as follows:

1. Review and approval of the summary report of the meeting held October 17, 1996.
2. A talk by Dr. Barry Ancelet on the history of Acadian French in Louisiana.
3. Reports of Maine Acadian Culture Preservation Commission working groups.
4. Report of the National Park Service project staff.

5. Opportunity for public comment.

6. Proposed agenda, place, and date of the next Commission meeting.

The meeting is open to the public. Further information concerning Commission meetings may be obtained from the Superintendent, Acadia National Park. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made at least seven days prior to the meeting to: Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, ME 04609–0177; telephone (207) 288–5472.

Dated: November 25, 1996.

Len Bobinchock,

Acting Superintendent, Acadia National Park.

[FR Doc. 96–30654 Filed 12–02–96; 8:45 am]

BILLING CODE 4310–70–P

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before November 23, 1996. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013–7127. Written comments should be submitted by December 18, 1996.

Marilyn Harper,

Acting Keeper of the National Register.

ARIZONA

Maricopa County

Willo Historic District (Boundary Increase), (Historic Residential Subdivisions and Architecture in Central Phoenix MPS), Roughly bounded by Edgemont and Cambridge Rds. and 7th and 3rd Aves., Phoenix, 96001497

ARKANSAS

Pulaski County

Little Rock National Cemetery, (Civil War Era National Cemeteries MPS), 2523 Confederate Blvd., Little Rock, 96001496

CONNECTICUT

New London County

Mill Brook Bridge, Blissville Rd., jct. of Mill Brook, Lisbon, 96001498

DISTRICT OF COLUMBIA

District of Columbia State Equivalent

Woodlawn Cemetery, 4611 Benning Rd., SE, Washington, 96001499

GEORGIA

Fulton County

National NuGrape Company, 794 Ralph McGill Blvd., Atlanta, 96001502

Richmond County

Bethlehem Historic District, Roughly bounded by Wrightsboro Rd., M.L.K. Jr. Blvd., Railroad, Poplar, and Clay Sts., Augusta, 96001501

Shiloh Orphanage, 1635 15th St., Augusta, 96001500

HAWAII

Kauai County

Civilian Conservation Corps Camp in Kok'e State Park, HI 550 at Kok'e State Park Headquarters, Koke'e, 96001504

Maui County

Kalepolepo Fishpond, S. Kihei Rd., S of jct. with HI 31, Kalepolepo County Park, Kihei, 96001503

IDAHO

Ada County

Tolleth House, 134 E. State Ave., Meridian, 96001506

Fremont County

Island Park Land and Cattle Company Home Ranch, US 20, approximately 1 mi. SW of Island Park, Island Park vicinity, 96001508

Kootenai County

Harrison Commercial Historic District, Roughly bounded by N. Lake Ave., W. Harrison St., N. Coeur d'Alene., and Pine St., Harrison, 96001505

Washington Water Power Bridges, .5 mi. W of jct. of Spokane and 4th Sts., Post Falls, 96001507

NEW YORK

Monroe County

Curtis—Crumb Farm, 307 Curtis Rd., Hilton vicinity, 96001509

OHIO

Summit County

Kendall, Virginia, State Park Historic District, (Recreation and Conservation Resources of the Cuyahoga Valley) 701, 801, 1000 Truxell Rd. and 434 W. Streetsboro, Peninsula vicinity, 96001515

Butler, H. Karl, Memorial, (Recreation and Conservation Resources of the Cuyahoga Valley), Truxell Rd., SE of jct. with Peninsula Rd., Camp Manatoc, Peninsula vicinity, 96001510

Camp Manatoc Concord Lodge and Adirondacks Historic District, (Recreation and Conservation Resources of the Cuyahoga Valley), Truxell Rd., SE of jct. with Peninsula Rd., Camp Manatoc, Peninsula vicinity, 96001513

Camp Manatoc Dining Hall, (Recreation and Conservation Resources of the Cuyahoga Valley), Truxell Rd., SE of jct. with Peninsula Rd., Camp Manatoc, Peninsula vicinity, 96001511

Camp Manatoc Foresters Lodge and Kit Carson—Dan Boone Cabins Historic District, (Recreation and Conservation Resources of the Cuyahoga Valley), Truxell Rd., SE of jct. with Peninsula Rd., Camp Manatoc, Peninsula vicinity, 96001514

Camp Manatoc Legion Lodge, (Recreation and Conservation Resources of the Cuyahoga Valley), Truxell Rd., SE of jct. with Peninsula Rd., Camp Manatoc, Peninsula vicinity, 96001512

TENNESSEE

Davidson County

Nashville National Cemetery, (Civil War Era National Cemeteries), 1420 Gallatin Rd., S, Nashville, 96001516

TEXAS

Clay County

State Highway 79 Bridge at the Red River, (Historic Bridges of Texas MPS), OK 79 across the Red River at the OK-TX state line, Byers vicinity, 96001518

Fannin County

State Highway 78 Bridge at the Red River, (Historic Bridges of Texas MPS), OK 78, across the Red River at the OK-TX state line, Ravenna vicinity, 96001517

VERMONT

Addison County

Chipman's Point, Jct. of VT 73A and Chipman Point Rd., Orwell, 96001519

[FR Doc. 96–30719 Filed 12–2–96; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Investigation 332–373]

Advice on Providing Temporary Duty-Free Entry for Certain Suits and Suit-Type Jackets From Mexico

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and request for written submissions.

EFFECTIVE DATE: November 26, 1996.

SUMMARY: Following receipt on November 21, 1996, of a letter from the United States Trade Representative (USTR), the Commission instituted investigation No. 332–373, Advice on Providing Temporary Duty-Free Entry for Certain Suits and Suit-Type Jackets from Mexico, under section 332 of the Tariff Act of 1930. USTR asked that the Commission provide advice as to the probable effect of providing temporary duty-free entry under criteria similar to those of Harmonized Tariff Schedule of the United States (HTS) heading 9802.00.90 for the suits and suit-type jackets from Mexico classifiable in the HTS subheadings listed in the annex, but only where such garments contain interlining fabrics that are cut but not formed in the United States and that

otherwise meet the criteria of heading 9802.00.90. USTR requested that the Commission provide advice as to the probable effect of such action on affected segments of the U.S. textile and apparel industries, workers in these industries, and consumers of the affected goods.

As requested by USTR, the Commission expects to submit its report by January 15, 1997.

FOR FURTHER INFORMATION CONTACT: Information on general topics may be obtained from Mary Elizabeth Sweet, Office of Industries (202–205–3455) and legal aspects, from William Gearhart, Office of the General Counsel (202–205–3091). The media should contact Margaret O'Laughlin, Office of Public Affairs (202–205–1819). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202–205–1810).

Background

On December 17, 1992, the President entered into the North American Free Trade Agreement (NAFTA), approved by the Congress and implemented by Presidential Proclamation 6641 effective as of January 1, 1994. Among the provisions proclaimed to implement NAFTA obligations is heading 9802.00.90 which affords duty-free entry into the United States of apparel and other textile goods assembled in Mexico in which the textile components are made entirely from U.S.-formed-and-cut fabrics. According to USTR's letter, the impending loss of domestic supply of certain interlining fabrics has caused concern among U.S. firms that produce suits and suit-type jackets containing these interlining fabrics in production-sharing operations in Mexico and that import the finished garments under heading 9802.00.90. Because these U.S.-formed interlining fabrics will no longer be available when current inventories are exhausted, garments now imported by these U.S. firms under heading 9802.00.90 would no longer qualify for duty-free entry thereunder and would be dutiable to the extent of the value added in Mexico. Representatives of the U.S. textile and apparel industries have requested that the President authorize temporary duty-free entry for the suits and suit-type jackets from Mexico that contain imported interlining fabrics, provided that the fabrics are cut in the United States and that the garments otherwise meet the criteria of heading 9802.00.90. Section 201(b)(1)(A) of the NAFTA Implementation Act (19 U.S.C. 3331(b)(1)(A)) authorizes the President to proclaim such modifications or continuation of any duty as the President determines to be necessary or appropriate to maintain the general level of reciprocal and mutually advantageous concessions with respect to Canada or Mexico provided for by NAFTA, subject to the consultation and layover requirements of section 103(a) of the NAFTA Implementation Act (19 U.S.C. 3313(a)).

After considering the Commission's advice and all other factors specified by the NAFTA Implementation Act, the President must submit the proposed temporary tariff changes and accompanying advice and explanations to the Congress pursuant to the layover requirements of section 103 (a) of the NAFTA Implementation Act. Although USTR's letter did not identify the interlining fabrics in question, these fabrics were identified by the Committee for the Implementation of Textile Agreements (CITA) in a Federal Register notice of September 20, 1996 (61 FR 149439) in connection with similar changes to the Special Access Program for Caribbean Basin countries. According to CITA's notice, imported interlining fabrics may be used in the suit jackets and suit-type jackets entered under the Special Access Program provided they are cut in the United States and are of a type described below:

1. A chest plate, ''hymo'' piece or ''sleeve header'' of woven or weft-inserted warp knit construction of course animal hair or manmade filaments used in the manufacture of the specified garments;

2. A weft-inserted warp knit fabric that contains and exhibits properties of elasticity and resilience which render the fabric especially suitable for attachment by fusing with a thermo-plastic adhesive to the coat-front, side body or back of the specified garments; and

3. A woven fabric that contains and exhibits properties of resiliency which render the fabric especially suitable for attachment by fusing with a thermo-plastic adhesive to the coat-front, side body or back of the specified garments.

Written Submissions

The Commission has not scheduled a public hearing in connection with this investigation. However, interested parties are invited to submit written statements regarding the matters to be addressed by the Commission in its report on this investigation. Commercial or financial information that a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked ''Confidential Business Information'' at the top. All submissions requesting confidential treatment must conform with the requirements of section § 201.6 of the Commission's *Rules of Practice and Procedure* (19 C.F.R. 201.6). All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties. The Commission may include confidential business information submitted in the course of this investigation in the President and USTR. If the Commission is authorized to publish a report, the Commission will not publish confidential business information in a manner that would reveal the individual operations of the firm supplying the information. USTR has indicated that all or part of the Commission's report may be classified.

To be assured of consideration by the Commission, written statements relating to the investigation should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on December 16, 1996. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 200–205–2000.

Issued: November 26, 1996.

By order of the Commission.

Donna R. Koehnke,

Secretary.

Annex

Men's, boys', women's, and girls' suits or suit-type jackets, of wool, fine animal hair, or manmade fibers and covered by the following HTS subheadings:

6103.11.0000
6103.12.1000
6103.12.2000
6103.19.1000
6103.19.1500
6103.19.9040
6103.19.9050
6103.21.0020
6103.23.0007
6103.23.0037
6103.29.1015
6103.31.0000
6103.33.1000
6103.33.2000
6103.39.1000
6103.39.8020
6103.39.8030
6104.11.0000
6104.13.1000
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DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–10014, et al.]

Proposed Exemptions; Wells Fargo Bank, N.A., et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this Federal Register Notice. Comments and request for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Wells Fargo Bank, N.A. (Wells Fargo) Located in San Francisco, CA; Proposed Exemption

[Application No. D–10014]

Based on the facts and representations set forth in the application, the Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, August 10, 1990).[1]

Section I. Covered Transactions

If the exemption is granted, the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply, effective October 1, 1995, to the

[1] For purposes of this proposed exemption, reference to provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

purchase or redemption of shares by an employee benefit plan (the Plan), in certain mutual funds that are either affiliated with Wells Fargo (the Affiliated Funds) or are unaffiliated with Wells Fargo (the Third Party Funds),[2] in connection with the participation by the Plan in the Wells Fargo Portfolio Advisor Program (the Portfolio Advisor Program).

In addition, the restrictions of section 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (E) and (F) of the Code, shall not apply, effective October 1, 1995, to the provision, by Wells Fargo, of asset allocation services to an independent fiduciary of a participating Plan (the Independent Fiduciary) or to a participant (the Directing Participant) of a Plan covered under the provisions of section 404(c) of the Act (the Section 404(c) Plan) which may result in the selection of portfolios by the Independent Fiduciary or the Directing Participant in the Portfolio Advisor Program for the investment of Plan assets.

This proposed exemption is subject to the conditions set forth below in Section II.

Section II. General Conditions

(a) The participation by each Plan in the Portfolio Advisor Program is approved by an Independent Fiduciary or Directing Participant, in the case of a Section 404(c) Plan, and no Plan investing therein is sponsored or maintained by Wells Fargo and/or its affiliates.

(b) As to each Plan, the total fees that are paid to Wells Fargo and its affiliates constitute no more than reasonable compensation for the services provided.

(c) With the exception of distribution-related fees pursuant to Rule 12b–1 (the 12b–1 Fees) of the Investment Company Act of 1940 (the '40 Act) which are offset, no Plan pays a fee or commission by reason of the acquisition or redemption of shares in the Funds.

(d) The terms of each purchase or redemption of shares in the Funds remain at least as favorable to an investing Plan as those obtainable in an arm's length transaction with an unrelated party.

(e) Wells Fargo provides written documentation to each Plan's Independent Fiduciary or Directing Participant of its recommendations or evaluations with respect to the Affiliated Funds or the Third Party Funds based upon objective criteria.

(f) Any recommendation or evaluation made by Wells Fargo to an Independent Fiduciary or Directing Participant is implemented only at the express direction of such Independent Fiduciary or Directing Participant.

(g) The quarterly fee that is paid by a Plan to Wells Fargo and its affiliates for asset allocation and related services (the Outside Fee) rendered to such Plan under the Portfolio Advisor Program is offset by all gross investment management fees (the Advisory Fees) and administrative fees (the Administrative Fees) received from the Affiliated Funds by Wells Fargo, its affiliates, its former affiliates and unrelated parties, including all 12b–1 Fees and Administrative Fees that are paid by the Affiliated Funds to Stephens Inc. (Stephens) and all 12b–1 Fees that Wells Fargo receives from the Third Party Funds, such that the sum of the offset and the net Outside Fee (the Net Outside Fee) will always equal the Outside Fee and the selection of Affiliated or Third Party Funds will always be revenue neutral.

(h) With respect to its participation in the Portfolio Advisor Program, prior to purchasing shares in the Affiliated Funds and the Third Party Funds,

(1) Each Independent Fiduciary receives the following written or oral disclosures from Wells Fargo:

(A) A brochure describing the Portfolio Advisor Program; a Portfolio Advisor Program Account Agreement; a description of the allocation models (the Allocation Models) as discussed in Representation 1; and a reference guide/disclosure statement providing details about the Portfolio Advisor Program, the fees charged thereunder, the procedures for establishing, making additions to and withdrawing from Portfolio Advisor Program Accounts (the Accounts); and other related information.

(B) A risk tolerance and goal analysis questionnaire (the Questionnaire) as described in Representation 11.

(C) Copies of applicable prospectuses (the Prospectuses) for the Funds discussing the investment objectives of the Funds; the policies employed to achieve these objectives; the corporate affiliation existing between Wells Fargo and its affiliates; the compensation paid to such entities; disclosures relating to rebalancing and reallocating Allocation Models; and information explaining the risks attendant to investing in the Affiliated Funds or the Third Party Funds.

(D) Upon written or oral request to Wells Fargo, a Statement of Additional Information supplementing the applicable Prospectus, which describes the types of securities and other instruments in which the Funds may invest, the investment policies and strategies that the Funds may utilize, including a description of the risks.

(E) A copy of the agreement between the Plan and Wells Fargo relating to such Plan's participation in the Portfolio Advisor Program.

(F) A written recommendation of a specific Allocation Model together with a copy of the Questionnaire and response.

(G) Upon written request to Wells Fargo, a copy of its investment advisory agreement and sub-advisory agreement pertaining to the Affiliated Funds as well as its distribution agreement pertaining to the Third Party Funds.

(H) Copies of the proposed exemption and grant notice describing the exemptive relief provided herein.

(I) Written disclosures of Wells Fargo's affiliation or nonaffiliation with the parties who act as sponsors, distributors, administrators, investment advisers and sub-advisers, custodians and transfer agents of the Third Party Funds and the Affiliated Funds; and

(2) In the case of a Section 404(c) Plan,

(A) Wells Fargo provides each Directing Participant or Independent Fiduciary (for dissemination to the Directing Participant) with copies of the documents described above in paragraphs (h)(1)(A)–(I); and,

(B) In addition to the written disclosures, an explanation will be provided to the Independent Fiduciary, upon request, by a Wells Fargo Personal Financial Officer (the Personal Financial Officer) regarding the services offered under the Portfolio Advisor Program, including the operation and objectives of the Funds. Such information will be given to either the Independent Fiduciary or the Directing Participant.

(3) If accepted as an investor in the Portfolio Advisor Program, an Independent Fiduciary or Directing Participant is required to acknowledge, in writing, to Wells Fargo, prior to purchasing shares of the Funds that such Independent Fiduciary or Directing Participant has received copies of the documents described in paragraph (h)(1) of this Section II.

(4) With respect to a Title I Plan that does not permit participant-directed investments as contemplated under section 404(c) of the Act, written acknowledgement of the receipt of such documents is provided by the Independent Fiduciary (i.e., the Plan administrator, trustee, investment manager or named fiduciary, as the recordholder of shares of the Funds.) Such Independent Fiduciary will be

[2] The Affiliated Funds and the Third Party Funds are collectively referred to herein as the Funds.

required to represent in writing to Wells Fargo that such fiduciary is—

(A) Independent of Wells Fargo and its affiliates;

(B) Capable of making independent decisions regarding the investment of Plan assets;

(C) Knowledgeable with respect to the Plan in administrative matters and funding matters related thereto; and

(D) Able to make an informed decision concerning participation in the Portfolio Advisor Program.

(5) With respect to a Section 404(c) Plan or a Plan that is covered under Title II of the Act, the Directing Participant or the Independent Fiduciary is required to acknowledge, in writing, receipt of such documents and represent to Wells Fargo that such individual is—

(A) Independent of Wells Fargo and its affiliates;

(B) Knowledgeable with respect to the Plan in administrative matters and funding matters related thereto; and,

(C) Able to make an informed decision concerning participation in the Portfolio Advisor Program.

(i) Subsequent to its participation in the Portfolio Advisor Program, each Independent Fiduciary receives the following written or oral disclosures from Wells Fargo with respect to ongoing participation in the Portfolio Advisor Program:

(1) Written confirmations of each purchase or redemption transaction involving shares of an Affiliated Fund or a Third Party Fund (including transactions resulting from the realignment of assets caused by a change in the Allocation Model's investment mix and from periodic rebalancing of Account assets).

(2) Telephone quotations of such Independent Fiduciary's Plan Account balance.

(3) A periodic, but not less frequently than quarterly, statement of Account specifying the net asset value of the Plan's assets in such Account, a summary of purchase, sale and exchange activity and dividends received or reinvested and a summary of cumulative realized gains and/or losses.

(4) Semiannual and annual reports that include financial statements for the Affiliated Funds and the Third Party Funds as well as the fees paid to Wells Fargo and its affiliates.

(5) A quarterly newsletter or other report pertaining to the applicable Allocation Model which describes the Allocation Model's performance during the preceding quarter, market conditions and economic outlook and, if applicable, prospective changes in Affiliated Fund and Third Party Fund allocations for the Allocation Model and the reasons therefor.

(6) At least annually, a written or oral inquiry from Wells Fargo to ascertain whether the information provided on the Questionnaire is still accurate and to determine if such information should be updated.

(7) At least annually, a termination form (the Termination Form) as described below in Section II(l) and (m).

(j) In the case of a Section 404(c) Plan, the Independent Fiduciary will decide whether the information described in Section II(i) above is to be distributed by Wells Fargo to the Directing Participants of such Plan or whether the Independent Fiduciary will receive this information and then provide it to the Directing Participants.

(k) If authorized in writing by the Independent Fiduciary or Directing Participant, the Plan is automatically rebalanced on a periodic basis by Wells Fargo to the Allocation Model previously prescribed by the Independent Fiduciary or Directing Participant, if one or more Fund allocations deviates from the Allocation Model prescribed by the Independent Fiduciary or Directing Participant.

(l) In rebalancing a Plan,

(1) Wells Fargo is bound by the Allocation Model and is limited in the degree of change that it can make to an Allocation Model's investment mix.

(2) Wells Fargo is authorized to make changes in the mix of asset classes in a Plan Account within a range of 0–15 percent (plus or minus) for Stock and Bond Fund investments and within a range of 0–30 percent (plus or minus) for Money Market Fund investments without obtaining the prior written approval of the Independent Fiduciary or Directing Participant.

(3) Wells Fargo may not change the asset mix outside the authorized limits unless it provides the Independent Fiduciary or Directing Participant with 30 days' advance written notice of the proposed change and gives the Independent Fiduciary or Directing Participant time to elect not to have the change made.

(4) Wells Fargo may not divide a Fund sub-class unless it provides 30 days' advance written notice to the Independent Fiduciary or Directing Participant of the proposed change and gives such individual the opportunity to object to the change.

(5) Wells Fargo may not replace a Third Party Fund with an Affiliated Fund.

(m) Although an Independent Fiduciary or Directing Participant may withdraw from the Portfolio Advisor Program at any time, Wells Fargo will provide such Independent Fiduciary or Directing Participant with the Termination Form, at least annually during the first quarter of each calendar year, but in all cases where Wells Fargo changes the asset mix outside of the current Allocation Model, when a Fund sub-class is to be divided, when Wells Fargo determines that it is in the best interest of the Plan to use a Third Party Fund instead of an Affiliated Fund and whenever the Outside Fee is increased. Wells Fargo will provide such written notice to the Independent Fiduciary or Directing Participant at least 30 days prior to the implementation of the change.

(n) The instructions for the Termination Form must—

(1) State that the authorization is terminable at will by the Independent Fiduciary or Directing Participant, without penalty to such, upon receipt by Wells Fargo of written notice from the Independent Fiduciary or Directing Participant; and

(2) Explain that any of the proposed changes noted above in paragraph (m) of this Section, will go into effect if the Independent Fiduciary or Directing Participant does not elect to withdraw by the effective date.

(o) Wells Fargo maintains, for a period of six years, the records necessary to enable the persons described in paragraph (p) of this Section II to determine whether the conditions of this exemption have been met, except that—

(1) A prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Wells Fargo and/or its affiliates, the records are lost or destroyed prior to the end of the six year period; and

(2) No party in interest other than Wells Fargo shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975(a) and (b) of the Code, if the records are not maintained, or are not available for examination as required by paragraph (p) of this Section II below.

(p)(1) Except as provided in section (p)(2) of this paragraph and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to in paragraph (o) of this Section II are unconditionally available at their customary location during normal business hours by:

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service (the Service) or the Securities and Exchange Commission (the SEC);

(B) Any fiduciary of a participating Plan or any duly authorized representative of such fiduciary;

(C) Any contributing employer to any participating Plan or any duly authorized employee representative of such employer; and

(D) Any participant or beneficiary of any participating Plan, or any duly authorized representative of such participant or beneficiary.

(p)(2) None of the persons described above in paragraphs (p)(1)(B)–(p)(1)(D) of this paragraph (p) are authorized to examine the trade secrets of Wells Fargo or commercial or financial information which is privileged or confidential.

Section III. Definitions

For purposes of this proposed exemption:

(a) The term ''Wells Fargo'' means Wells Fargo Bank, N.A. and any affiliate of Wells Fargo, as defined in paragraph (b) of this Section III.

(b) An ''affiliate'' of Wells Fargo includes—

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with Wells Fargo.

(2) Any officer, director or partner in such person, and

(3) Any corporation or partnership of which such person is an officer, director or a 5 percent partner or owner.

(c) The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term ''Plan or Plans'' include Keogh plans, cash or deferred compensation plans, profit sharing plans, pension and stock bonus plans, individual retirement accounts (IRAs), salary reduction simplified employee pension plans (SARSEPs), simplified employee pension plans (SEP–IRAs) and, in the case of a Section 404(c) Plan, the individual account of a Directing Participant.

(e) The term ''Independent Fiduciary'' means a Plan fiduciary which is independent of Wells Fargo and its affiliates and is either—

(1) A Plan administrator, trustee, investment manager or named fiduciary, as the recordholder of shares of the Funds of a Section 404(c) Plan;

(2) An individual covered by a Keogh Plan which invests in shares of the Funds;

(3) An individual covered under a self-directed IRA, SEP–IRA or SARSEP which invests in shares of the Funds;

(4) An employee, officer or director of Wells Fargo and/or its affiliates covered by an IRA, a SEP–IRA or a SARSEP subject to Title I of the Act; or

(5) A Plan administrator, trustee, investment manager or named fiduciary responsible for investment decisions in the case of a Title I Plan that does not permit individual direction as contemplated by Section 404(c) of the Act.

(f) The term ''Directing Participant'' is a participant in a Plan, such as a Section 404(c) Plan, who is permitted under the terms of the Plan to direct, and who elects to so direct the investment of the assets of his or her account in such Plan.

EFFECTIVE DATE: If granted, this proposed exemption will be effective as of October 1, 1995.

Summary of Facts and Representations

Description of the Parties

1. The parties to the transactions are described as follows:

(a) *Wells Fargo,* a wholly owned subsidiary of Wells Fargo & Company, is one of the sixteenth largest commercial banks in the United States. Wells Fargo provides a full range of banking services to commercial, agribusiness, real estate and small business customers mainly in California. Its Investment Management Group manages personal trust accounts, corporate 401(k) and other qualified plans and mutual funds. Its holding company, Wells Fargo and Company, is a full-line banking firm serving institutions, government and individual investors in the United States. Wells Fargo & Company stock is publicly-traded on the New York Stock Exchange. Wells Fargo maintains its corporate headquarters in San Francisco, California.

In addition to serving as a custodian or trustee to employee benefit plans, IRAs and SEP–IRAs, Wells Fargo sponsors and serves as a mass submitter and identical adopter for master and prototype pension and profit sharing plans, including Keogh plans, cash or deferred plans, and pension and stock bonus plans. Wells Fargo sponsors prototype IRAs, SEP–IRAs and SARSEPs. With respect to the subject transactions, Wells Fargo serves as the investment adviser/manager, transfer agent, selling agent and dividend disbursing agent to certain Affiliated Funds.

(b) *Wells Fargo Securities, Inc. (WFSI),* a wholly owned broker-dealer of Wells Fargo, is a full service broker-dealer registered with the SEC and a member of the National Association of Securities Dealers. WFSI provides a full range of brokerage services to retail and private customers and is principally located in San Francisco, California.

(c) *Stephens* of Little Rock, Arkansas, is a full service broker-dealer and investment advisory firm that is unrelated to Wells Fargo and/or its affiliates. It is the clearing broker for WFSI and the sponsor and administrator for the Affiliated Funds. Stephens also serves as the principal underwriter or distributor of each Affiliated Fund's shares.

(d) *Wells Fargo Nikko Investment Advisors (WFNIA)* is a general partnership that was formerly 50 percent owned by a subsidiary of Wells Fargo and 50 percent owned by a subsidiary of The Nikko Securities Co., Ltd., an unaffiliated Japanese securities firm. WFNIA is a registered investment adviser and serves as a sub-adviser to certain of the Affiliated Funds. WFNIA maintains its principal place of business in San Francisco, California.

(e) *Wells Fargo Institutional Trust Company, N.A. (WFITC)* is a trust company that was 99.9 percent owned by WFNIA and 0.1 percent owned by Wells Fargo & Company. WFITC serves as the custodian for certain of the Affiliated Funds. WFITC maintains its principal place of business in San Francisco, California.

Pursuant to an agreement dated June 21, 1995, Wells Fargo & Company and Wells Fargo agreed to effect the sale of all of their right, title and interest in the capital stock of WFITC and the partnership interest in WFNIA, respectively, to Barclays Bank PLC, Barclays California Corporation and Barclays Bank of Canada (collectively, Barclays), all of which are unrelated to Wells Fargo & Company, Wells Fargo or any of their affiliates. After consummation of the sale, which occurred on December 29, 1995, WFITC and WFNIA became a part of BZW Global Investors, an indirect wholly owned subsidiary of Barclays Bank PLC. The new entity is located in San Francisco, California.

(f) *The Plans* are qualified plans, IRAs, SARSEPs and SEP–IRAs for which Wells Fargo acts as master or prototype plan sponsor, mass submitter sponsor and identical adopter, custodian, directed trustee or recordkeeper. None of the Plans are sponsored by Wells Fargo or its affiliates.

Description of the Affiliated Funds

2. The Affiliated Funds consist of the Stagecoach Funds, Inc. (the Stagecoach Funds) and the Overland Express Funds, Inc. (the Overland Funds), which are open-end investment companies registered under the '40 Act. The Stagecoach Funds were organized as a Maryland corporation in September 1991 and currently offer sixteen separate portfolios. The Overland Funds

were organized as a Maryland corporation in April 1987 and currently offer shares in twelve separate portfolios. Each Affiliated Fund is registered under the Securities Act of 1933, as amended (the '33 Act), and the '40 Act.

Each Affiliated Fund is designed to provide a means of investing in separate portfolios that are professionally managed by Wells Fargo or sub-advised by WFNIA. These portfolios may be sold through WFSI or Wells Fargo as selling agent on behalf of the Affiliated Funds. Shares in the Stagecoach Funds and the Overland Funds are currently being offered by Wells Fargo to Plan customers, at no load.

Overall management and supervision of each Affiliated Fund rests with such Fund's Board of Directors (the Directors). The Directors approve all significant agreements involving the appropriate Affiliated Fund and the persons and companies that furnish services. At least 40 percent of the Directors are unrelated to Wells Fargo and its affiliates, including Stephens.

Currently, fifteen Affiliated Funds are being offered to investors under the Portfolio Advisor Program. These Fund portfolios range from the Stagecoach Corporate Stock Fund to the Overland U.S. Treasury Money Market Fund. The Affiliated Funds are further divided into eight asset sub-classes which range from Growth and Income to Cash. A number of the portfolios are sub-advised by WFNIA whose sub-advisory fees are paid by Wells Fargo from its Advisory Fees.

3. Wells Fargo serves as each Affiliated Fund's investment manager pursuant to an advisory agreement entered into with such Fund. In addition, Wells Fargo serves as the transfer agent, selling agent and dividend disbursing agent of each Affiliated Fund, as custodian of certain of the Affiliated Funds and as shareholder servicing agent of the Stagecoach Funds.

For services rendered to the Affiliated Funds by Wells Fargo, its affiliates or Stephens, the underlying contracts entered thereunder must be approved by the Directors of each Affiliated Fund, including a majority of disinterested Directors. The contracts must be approved for an initial period of up to two years and then reapproved by the Directors or the shareholders of the Affiliated Funds and by the disinterested Directors, at least annually thereafter. Subject to the supervision and direction of the Directors, Wells Fargo manages the investment and reinvestment of each Affiliated Fund's assets and provides investment guidance and policy direction in connection with the objectives of the Affiliated Funds.

Each Affiliated Fund portfolio pays Wells Fargo Advisory Fees that are computed daily and paid monthly at an annual rate based on a percentage of the value of the portfolio's average daily net assets. Currently, the annualized Advisory Fees range from 0.05 percent to 0.70 percent depending upon the portfolio.

In addition to the Advisory Fees, Wells Fargo and WFTIC may receive custody, portfolio accounting, transfer agency and shareholder servicing expenses from the Affiliated Funds (i.e., the Administrative Fees) which may be waived from time to time. For some portfolios, the Administrative Fees are included in that portion of Wells Fargo's Advisory Fee that is paid to the sub-adviser. If not included in the Advisory Fee, the current fee for (a) custodial services is 0.0167 percent annually, (b) $2,000 per month plus 0.07 percent on the first $50 million, 0.045 percent on the next $50 million and 0.02 percent on the excess over $100 million for portfolio accounting services, (c) a minimum of $3,000 monthly, plus various transaction charges for transfer agency services, and (d) 0.00 percent to 0.30 percent for shareholder servicing.

4. Stephens serves as each Affiliated Fund's sponsor and administrator and as distributor of portfolio shares. In general, Stephens manages all aspects of the administration and operation of the portfolios of the Affiliated Funds. For services provided to the portfolio, Stephens receives a fee that is computed daily and paid monthly at an annual rate based on a percentage of the value of the portfolio's average net assets. As distributor, Stephens is the principal underwriter of the shares of each Affiliated Fund. Stephens enters into selling agreements with broker-dealers and other financial institutions (i.e., selling agents) which make such shares available to their customers. Stephens receives 12b–1 Fees from certain of the Affiliated Fund portfolios. These fees range from 0.05 percent of net assets annually from the Stagecoach Funds to 0.75 percent of net assets annually from certain Overland Funds. In addition, Stephens receives Administrative Fees from each Affiliated Fund portfolio ranging from 0.03 percent to 0.15 percent annually of such portfolios' net assets.

5. WFSI has entered into selling agreements with Stephens and acts as a selling agent for certain Affiliated Fund portfolios. However, with respect to Plans investing in the Affiliated Funds, WFSI will not receive a sales load or commission (in the form of a 12b–1 Fee) from Stephens.

6. WFNIA acts as the sub-adviser for certain portfolios. For services rendered, WFNIA is paid a fee that is computed daily and paid monthly at an annual rate based on a percentage of the portfolio's average daily net assets. As stated above, these sub-advisory fees are paid by Wells Fargo out of its Advisory Fees. Although WFNIA may provide investment advice to such portfolios, Wells Fargo retains final investment discretion with respect to the management of the assets of each portfolio.

7. WFTIC currently acts as the custodian of the assets of certain of the Affiliated Funds and it receives a custodian fee for such services. The amount of this expense, to the extent not included in the Advisory Fees is 0.0167 percent of the daily net assets of the applicable Affiliated Fund.

Description of the Third Party Funds

8. The Third Party Funds are open-end, diversified management investment companies registered under the '40 Act whose sponsors, administrators, distributors, investment advisers and sub-advisers are not affiliated with Wells Fargo or its affiliates. The Third Party Funds may be made available from time to time to Plans investing in the Portfolio Advisor Program.

Description of the Portfolio Advisor Program

9. The Portfolio Advisor Program is an asset allocation program that has been offered by Wells Fargo to Independent Fiduciaries of Plans since October 1, 1995. It is designed to provide small- and medium-sized Plans with access to the type of investment advice that is typically available to larger investors. The Portfolio Advisor Program is intended to provide a format for investment with the following features—a unified account statement covering all investments, automatic allocation of assets and contributions, a single asset allocation fee and no sales charges on purchases, redemptions, reinvestments or transfers between investments.[3] The minimum investment required to establish a Portfolio Advisor Program Account is $10,000.[4]

[3] Although shares in the Affiliated Funds can be marketed outside of the Portfolio Advisor Program, such shares would generally carry load fees.

[4] If an investor has already opened a Portfolio Advisor Program Account with Wells Fargo with a minimum investment of $10,000, that same investor may open a second Portfolio Advisor Program Account with Wells Fargo with a minimum investment of $2,000. An investor having other

With respect to a Section 404(c) Plan, Wells Fargo will offer the Portfolio Advisor Program to the Plan's Independent Fiduciary as an investment option for the Plan or a portion of the Plan. Alternatively, the Plan's Independent Fiduciary may decide to utilize the Portfolio Advisor Program for all of the Plan's investment needs. In either situation, Wells Fargo will afford the Independent Fiduciary the opportunity to decide whether Wells Fargo will interact directly with the Plan's Directing Participants or exclusively with the Independent Fiduciary.

Wells Fargo will provide each Independent Fiduciary contemplating investing in the Portfolio Advisor Program with a brochure describing the Program; an Account agreement; a description of the Allocation Models; and a reference guide/disclosure document providing detailed information about the Portfolio Advisor Program, the fees charged thereunder, the procedures for establishing, making additions to and withdrawing from Accounts, and other related information. In the case of a Section 404(c) Plan, this information may be provided to either the Directing Participants by Wells Fargo or to the Independent Fiduciary depending upon the arrangement such Independent Fiduciary has negotiated with Wells Fargo.[5]

10. Individual IRA, SEP–IRA and single participant Keogh plan participants contemplating investing in the Portfolio Advisor Program will open an Account with Wells Fargo. With respect to the Independent Fiduciary of a Section 404(c) Plan, Wells Fargo will ask such fiduciary to select the type of Account that is to be established. The Independent Fiduciary of a Section 404(c) Plan may open a custody Account for each individual Directing Participant or, in the alternative, establish single custody Accounts in the name of the Plan reflecting the grouping of Directing Participants by similar asset Allocation Models.[6]

11. After opening an Account, the Independent Fiduciary will obtain and complete an Account Agreement and risk tolerance and goal analysis Questionnaire (which may be in paper or electronic form). Then, the Independent Fiduciary will present the completed Account Agreement and Questionnaire to a Personal Financial Officer or other representative of Wells Fargo. The Questionnaire will be scored to determine which one of several Allocation Models is most appropriate given the financial goals, objectives and risk tolerances identified by the Independent Fiduciary in the Questionnaire.[7]

In the case of a Section 404(c) Plan, the Independent Fiduciary may elect to have Wells Fargo meet with each Directing Participant. Then, a Personal Financial Officer will provide information relating to the Portfolio Advisor Program as noted above, have each Directing Participant complete the Questionnaire, present the Directing Participant with a recommended Allocation Model and provide the Directing Participant with the relevant Prospectuses of the Funds in the Allocation Model.

Alternatively, if the Independent Fiduciary chooses to have Wells Fargo interact with it instead of the Directing Participants, the Personal Financial Officer will meet with the Independent Fiduciary and provide such fiduciary with a description of the Portfolio Advisor Program for dissemination to the Directing Participants. The Personal Financial Officer will also give the Independent Fiduciary Questionnaires for completion by the Directing Participants. Based on the results of the returned Questionnaires, Wells Fargo will then recommend to the Independent Fiduciary, the appropriate Allocation Models and provide such fiduciary with relevant Prospectuses of the Funds in the recommended Allocation Models for distribution to the Directing Participants.

12. The Allocation Models are designed to satisfy a variety of risk tolerances and investment horizons. At the outset, there will be only nine Allocation Models, some with growth-based investment objectives and others with income-based investment objectives. In the future, more Allocation Models may be added by Wells Fargo. Each Allocation Model will have three asset classes and initially, nine asset sub-classes. Table I shows the asset distribution for a sample Portfolio Advisor Program Allocation Model.

TABLE I.—PORTFOLIO ADVISOR PROGRAM SAMPLE ALLOCATION MODEL

[Moderate Medium-Term Model Allocation]

Class	Min (percent)	Norm (percent)	Max (percent)	Fund type	Asset sub-class	Min (percent)	Norm (percent)	Max (percent)
Stock Funds	45	60	75	Third party	Growth	0	15	30
				Third party	Equity International	0	5	20
				Affiliated	Growth & Income	0	15	30
				Affiliated	Equity Income	0	15	30
				Affiliated	Asset Allocation	0	10	25
Bond Funds	25	40	55	Affiliated	Total Return Bond	0	15	30
				Affiliated	Intermediate Bond	0	15	30
				Affiliated	Short-Term Bond	0	10	25
Money Market Funds	0	0	30	Affiliated	Cash	0	0	30

Note: A Third Party Fund will never be replaced by an Affiliated Fund whereas an Affiliated Fund may be replaced by a Third Party Fund. (See discussion in Representation 15 regarding extraordinary changes that are outside the accepted percentage bands.)

accounts with Wells Fargo of $10,000 or more that are not Portfolio Advisor Program Accounts will not be eligible for this lower investment minimum.

[5] The Department wishes to point out that an Independent Fiduciary has the responsibility to disseminate all information it receives to each Directing Participant investing in the Portfolio Advisor Program.

[6] If Wells Fargo establishes a single custody account in the name of a Section 404(c) Plan, it is represented that Wells Fargo will not keep track of the individual interests of the Directing Participants. Instead, the Independent Fiduciary will maintain such records or have a third party recordkeeper perform this service.

[7] Wells Fargo proposes to canvass each investor annually to ascertain whether any of the answers to the Questionnaire have changed from the previous year. If so, Wells Fargo will update the Questionnaire. However, in the event an investor wishes to change his or her Questionnaire during a quarter so that another Allocation Model is called for, that new Allocation Model will be presented to and approved by the investor and the change to the new Allocation Model will be effected immediately.

13. The Allocation Models are developed and maintained by the Wells Fargo Bank Asset Allocation Committee (the Allocation Committee) which is comprised of senior investment officers of Wells Fargo's Investment Management Group. The Allocation Committee is responsible for determining the overall asset allocation of each Allocation Model among the currently nine asset sub-class categories. The Allocation Committee integrates both quantitative and fundamental analysis to determine optimal Allocation Models that match risk and reward objectives. In this regard, the Allocation Committee does not rely upon a software program but rather examines current asset allocation strategies and determines changes based on the present financial outlook, estimates of expected returns, volatility in markets, asset class correlation, economic trends and various securities valuation measures. These criteria are provided by Wells Fargo to all Portfolio Advisor Program investors in the disclosure materials.

14. The Allocation Models may be adjusted by the Allocation Committee as changes in the economy and market conditions dictate within the permissible ranges described below in Representation 15. Such adjustments may include changing the investment mix of the Allocation Models by altering the proportion of assets invested among the asset sub-classes. However, such adjustments do not include the Allocation Committee's adding to or deleting from Funds in an Allocation Model without obtaining the written consent of the Independent Fiduciary or the Directing Participant.

In addition, the Allocation Committee is subject to certain limitations in changing the design of the Allocation Models. For example, the Allocation Committee is required to design Allocation Models that include the stock, bond and money market fund asset classes and their respective sub-classes.

15. The Independent Fiduciary or Directing Participant will authorize Wells Fargo to change the asset mix of a given Allocation Model within a 15 percent range (i.e., 15 percent above or below the normal position for the stock and bond asset sub-classes).[8] Movement within each sub-class of assets will also be authorized within a range of no more than 15 percent above or below the normal position. The Independent Fiduciary or Directing Participant will also authorize Wells Fargo to change the cash position in a given Allocation Model in a range of 0–30 percent above or below the normal position to accommodate extremes in the other two asset sub-classes.[9] Wells Fargo will make changes in the asset mix within these authorized limits without seeking further approval from the Independent Fiduciary or the Directing Participant. However, Wells Fargo will not change the asset mix outside those limits unless it provides the Independent Fiduciary or Directing Participant with 30 days' advance written notice of the proposed change[10] and gives the Independent Fiduciary or Directing Participant time to elect not to have the change made.[11]

16. Wells Fargo's Investment Review Committee (the Review Committee), which is comprised of senior Wells Fargo officers, is responsible for selecting Affiliated Funds and Third Party Funds that satisfy the asset allocations specified by the Allocation Committee for each Allocation Model. With the exception of the Growth and Equity International asset sub-classes, the Review Committee will select portfolios of the Affiliated Funds for investment. The Review Committee will always select Third Party Funds for investment to the extent an Allocation Model calls for an allocation of assets in the Equity International and Growth sub-classes. If, however, the Review Committee determines that investment in an Affiliated Fund is imprudent (e.g., the Affiliated Fund does not meet the requirements of a necessary asset sub-class), it will select a Third Party Fund in lieu of an Affiliated Fund for a particular sub-class of assets.[12] If a Third Party Fund is substituted for an Affiliated Fund, the Review Committee must thereafter use only a Third Party Fund (i.e., the same Third Party Fund or another Third Party Fund). In the applicants' view, this precaution will remove any conflicts of interest that may arise if the Review Committee is faced with the prospect of selecting an Affiliated Fund over a Third Party Fund.[13]

[8] Movement within each sub-class will apply to the total assets held in an Independent Fiduciary's or a Directing Participant's Account.

[9] For any Allocation Model, it is represented that not more than 30 percent of an investor's assets can be placed in the Money Market Funds. If the range for cash is exceeded on a rebalancing date due to market forces, then the assets will be rebalanced to achieve the targeted percentages established in the relevant Allocation Model. The rebalancing will require a redemption of shares in the Money Market Funds so that the percentage in cash will be aligned with the relevant Allocation Model percentage. In addition, a corresponding purchase of funds in the asset sub-classes that are below the targeted range will be made. (See Representation 18 for a discussion of the rebalancing of Accounts.)

[10] Changes outside these limits may take the form of an extraordinary shift (such as the movement of a large percentage of assets into cash if the Allocation Committee determines that such a move is warranted by economic conditions) or a change in the normal position for the allocation mix of a particular Allocation Model which the Allocation Committee considers necessary because of a more permanent shift in market or economic conditions. In either case, Wells Fargo will notify each Independent Fiduciary whose Plan is invested in the relevant model or Directing Participant of the change and give such Independent Fiduciary or Directing Participant time to elect not to have the change made. The change will then be made for all Independent Fiduciaries or Directing Participants who do not elect otherwise. If a change is made to the normal position for the allocation mix of a particular Allocation Model, Wells Fargo will be authorized to change the allocation of assets within a 15 percent range (30 percent in the case of cash) above or below the newly established normal position without notifying the Independent Fiduciary in advance. If, on the other hand, after first notifying the Independent Fiduciary or Directing Participant, Wells Fargo makes an extraordinary change to the asset allocation which moves it outside the authorized limit, Wells Fargo will be authorized to return the asset mix back within the authorized limit without further notice, but any other change which will result in the asset mix remaining outside the authorized limit will only be made after giving 30 days' advance written notice and allowing the Independent Fiduciary or Directing Participant the opportunity to elect not to have such change made.

[11] Assuming an Independent Fiduciary of a Section 404(c) Plan establishes a single custody Account with Wells Fargo in the name of the Plan, it is represented that if a Directing Participant does not wish to have his or her assets reallocated in accordance with Wells Fargo's recommendation, such Directing Participant may choose another Allocation Model or leave the Portfolio Advisor Program.

[12] Changes in the Affiliated Funds or Third Party Funds used to satisfy the need for investment in a particular asset sub-class will only be made after Wells Fargo has notified all of the affected Independent Fiduciaries or Directing Participants in writing and has explained that the proposed changes will go into effect if the Independent Fiduciaries or Directing Participants do not elect to withdraw by the effective date of such change. (See Representation 27.)

[13] If the Allocation Committee should later divide the asset sub-classes for an Allocation Model into one or more new sub-classes, the Review Committee will select Affiliated Fund Portfolios to satisfy the call for investment in the new sub-class unless (a) there is no Affiliated Fund Portfolio which invests in the new sub-class of assets; (b) Wells Fargo's Affiliated Fund is not performing as well as a similar Third Party Fund based upon such measurable criteria as performance, expense ratio, standard deviation and, in the case of the Bond Funds, the SEC yield; or (c) a Third Party Fund has been utilized initially for the asset sub-class that is being divided.

For example, Wells Fargo represents that ''total return'' is a recognized sub-class of the Bond Fund asset class that is set forth in Table I. Assuming the industry begins distinguishing between U.S. bonds and foreign bonds, Wells Fargo explains that it may do this for the benefit of its investors. In this regard, if an Affiliated Fund has been used as the Fund for the total return sub-class, and Wells Fargo has available two Bond Funds, each of which is appropriate for the new sub-classes, Wells Fargo explains that it will utilize these Affiliated Funds. If an Affiliated Fund is being used for the U.S. bond sub-class, but Wells Fargo does not have an appropriate Affiliated Fund for the foreign bond sub-class, it will select a Third Party Fund. Thus, when the original sub-class is serviced by an Affiliated Fund and that sub-class is divided, Wells Fargo states that it may use an Affiliated Fund, a

17. The asset allocation services provided by the Personal Financial Officer will not be binding on the Independent Fiduciary or Directing Participant. No action will be taken on the recommendation unless and until the Independent Fiduciary or Directing Participant accepts and approves in writing the particular Allocation Model and the corresponding investment mix (i.e., the investment allocation) recommended by the Personal Financial Officer. The Independent Fiduciary or Directing Participant can add or withdraw Plan assets to or from the respective Account at any time (subject to a $100 minimum redemption and purchase requirement) and can also choose a different Allocation Model if the Independent Fiduciary's or Directing Participant's investment needs and goals have changed. Moreover, Wells Fargo intends to ask Independent Fiduciaries or Directing Participants annually whether any information provided in the Questionnaire should be changed or updated.

Rebalancing and Reallocation of Plan Accounts

18. Once an Independent Fiduciary or Directing Participant has directed Wells Fargo to invest Plan assets that are held in an Account in a particular Allocation Model, Wells Fargo will invest the Account in the Affiliated Funds and/or Third Party Funds that the Allocation Committee has previously chosen to satisfy the asset allocation called for by the Allocation Model. It is anticipated that, over time, disproportionate earnings as between asset types will cause the Account's investment mix to drift out of balance with the Allocation Model originally chosen by the Independent Fiduciary or Directing Participant.

For example, the Allocation Model chosen by the Independent Fiduciary or Directing Participant may require that 60 percent of Account assets be invested in the Stock Funds and 40 percent of Account assets be invested in the Bond Funds. If the Stock Funds perform better than the Bond Funds during a particular period of time, more than 60 percent of the Account's assets will be invested in the Stock Funds by the end of the period.

To correct this imbalance, Wells Fargo will move assets among investments by buying and selling shares of the Affiliated Funds and/or Third Party Funds on the second to the last business day of each calendar quarter. For purposes of rebalancing, Wells Fargo will use the net asset values of the affected Funds as of close of business for the preceding trading day.[14] The applicants represent that the act of rebalancing Accounts will not involve any exercise of investment discretion on the part of Wells Fargo or its affiliates because the rebalancing will be confined to bringing the Account into balance with the Allocation Model chosen by the Independent Fiduciary or the Directing Participant.

Wells Fargo will also make periodic changes (or reallocations) to the asset mix of the Allocation Models and to the mix and identity of the Affiliated Funds and/or Third Party Funds that satisfy the Allocation Models. Such changes will be made to take into account changes in the economy and market conditions and will be made independently of the selection of Funds. The changes will also be confined to the percentage bands set forth above in Table I. When changes are made to the Allocation Models, Wells Fargo will automatically realign each Plan Account to make the Account's investment mix match the new investment mix of the Allocation Model selected by the Independent Fiduciary or Directing Participant.

Wells Fargo will realign the Accounts' assets by shifting assets between Affiliated Funds and Third Party Funds according to changes in the Allocation Model. This type of automatic realignment will take place only within the percentage bands that have been authorized by the Independent Fiduciary or Directing Participant. If an Allocation Model changes such that assets would be allocated outside of the authorized bands, Wells Fargo will notify the affected Independent Fiduciary or Directing Participant of the proposed change and give each individual an opportunity to elect not to permit such change.[15]

Disclosures

19. Aside from the Questionnaire described above, in order for a Plan to participate in the Portfolio Advisor Program, Wells Fargo will provide an Independent Fiduciary or Directing Participant, with the following materials and/or oral disclosures: (a) A copy of the agreement between the Plan and Wells Fargo relating to the Plan's participation in the Portfolio Advisor Program; (b) upon written request to Wells Fargo, a copy of its investment advisory agreement and sub-advisory agreement pertaining to the Affiliated Funds as well as its distribution agreement pertaining to the Third Party Funds; (c) a written recommendation of a specific Allocation Model together with a copy of the Independent Fiduciary's Questionnaire and answers; (d) a written or oral explanation of the Portfolio Advisor Program and the operation and objectives of the Allocation Models; (e) sufficient and understandable disclosure relating to rebalancing and reallocating the Allocation Models; (f) a copy of the proposed and final exemptions granting the relief requested herein; (g) written disclosures of Wells Fargo's affiliation or nonaffiliation with the parties who act as sponsors, distributors, administrators, investment advisers and sub- advisers, custodians and transfer agents of the Third Party Funds and the Affiliated Funds; and (h) in the case of a Section 404(c) Plan, to the extent requested by the Independent Fiduciary, an explanation by a Personal Financial Officer to Directing Participants in such Plan of the services offered under the Portfolio Advisor Program, the operation and objectives of the Funds and copies of the documents described in (a)–(g).

Wells Fargo will make available for inspection by the Independent Fiduciary or Directing Participant at the time of enrollment in the Portfolio Advisor Program, copies of Prospectuses of each Affiliated Fund and Third Party Fund in which a Plan's assets are invested. The Prospectuses will also be mailed to the Independent Fiduciary, or if applicable, to the Directing Participant, after the initial investment of assets under the Portfolio Advisor Program. These documents discuss the investment objectives of the Affiliated Funds and the Third Party Funds, the policies employed to achieve these objectives, the corporate affiliation existing between Wells Fargo and its

Third Party Fund or a combination of the two. If, on the other hand, a Third Party Fund is being used for the total return sub-class, Wells Fargo must utilize Third Party Funds for both the new divided sub-classes. In any event, Wells Fargo represents that it will give all investors 30 days' notice and the ability to object before any sub-class is divided.

[14] It is represented that neither Wells Fargo nor its affiliates will receive fees or commissions in connection with the rebalancing. It is also represented that the current percentage threshold for triggering rebalancing is a deviation of more than 5 percent above or below the targeted percentage for an asset sub-class.

[15] In the preceding example, if the Allocation Model were to be changed such that the new investment allocation is 55 percent in the Stock Funds and 45 percent in the Bond Funds (a 5 percent change that is within 15 percent of the normal position for that Allocation Model), Wells Fargo would then sell sufficient shares in the Stock Funds to reduce the percentage of assets invested in such fund to 55 percent and invest the proceeds in the Bond Funds. If, however, a change of more than 15 percent is proposed, Wells Fargo will first notify each Independent Fiduciary or Directing Participant affected and make changes to the Accounts of the Independent Fiduciaries or Directing Participants who did not elect otherwise.

affiliates, the compensation paid to such entities and any information explaining the risks attendant to investing in the Affiliated Funds or Third Party Funds. In addition, upon written or oral request, an Independent Fiduciary or Directing Participant will be given a Statement of Additional Information supplementing the applicable Prospectus which describes the securities and other instruments in which the Funds may invest, the investment policies and strategies that the Affiliated Funds or Third Party Funds may utilize, including a description of the risks.

20. If accepted as an investor in the Portfolio Advisor Program, the Independent Fiduciary or Directing Participant will be required to acknowledge in writing, prior to investing through the Program, that such Independent Fiduciary or Directing Participant has received copies of the aforementioned documents. With respect to a Title I Plan that does not permit participant-directed investments as contemplated under section 404(c) of the Act, written acknowledgement of the receipt of such documents is provided by the Independent Fiduciary (i.e., the Plan administrator, trustee, investment manager or named fiduciary, as the recordholder of shares of the Funds.) Such Independent Fiduciary will be required to represent in writing to Wells Fargo that such fiduciary is (a) independent of Wells Fargo and its affiliates; (b) capable of making independent decisions regarding the investment of Plan assets; (c) knowledgeable with respect to the Plan in administrative matters and funding matters related thereto; and (d) able to make an informed decision concerning participation in the Portfolio Advisor Program.

With respect to a Section 404(c) Plan or a Plan that is covered under Title II of the Act, the Directing Participant or the Independent Fiduciary is required to acknowledge, in writing, receipt of such documents and represent to Wells Fargo that such individual is (a) independent of Wells Fargo and its affiliates; (b) knowledgeable with respect to the Plan in administrative matters and funding matters related thereto; and, (c) able to make an informed decision concerning participation in the Portfolio Advisor Program.

21. On an ongoing basis, Wells Fargo will provide the Independent Fiduciary with (a) written confirmations of each purchase and redemption of shares of an Affiliated Fund or Third Party Fund (including transactions resulting from the realignment of assets caused by a change in an Allocation Model's investment mix and from periodic rebalancing of Account assets); (b) telephone quotations of such Independent Fiduciary's Account balance; (c) a periodic (but not less frequently than quarterly) statement of Account specifying the net asset value of a Plan's assets that are invested in such Account, a summary of purchase, sale and exchange activity and dividends received or reinvested and a summary of cumulative realized gains/losses; (d) semiannual and annual reports which will include financial statements for the Funds and the fees paid by the Funds to Wells Fargo and its affiliates; (e) a quarterly newspaper or other report pertaining to the applicable Allocation Model describing such Allocation Model's performance during the preceding quarter, market conditions and economic outlook and, if applicable, prospective changes in Affiliated Fund and Third Party Fund allocations for the Allocation Model and the reasons therefor; (f) a written or oral inquiry at least once annually to determine if the information provided in the Questionnaire is still accurate and to determine if such information should be updated; and (g) at least annually, a Termination Form that the Independent Fiduciary may use to withdraw from the Portfolio Advisor Program together with instructions for using such form.

With respect to a Section 404(c) Plan, the Independent Fiduciary will determine whether the aforementioned information is provided directly to the Directing Participants by Wells Fargo or whether such fiduciary will receive this information and disseminate it to the Directing Participants. If custody accounts are established in the names of the Directing Participants, such participants will receive individualized information.

Fee Structure

22. As to each investing Plan, the total fees that are paid to Wells Fargo and its affiliates will constitute no more than reasonable compensation for the services provided.[16] In this regard, for its asset allocation and related services, Wells Fargo will charge each participating Plan an annual Plan-level investment fee. The Outside Fee will be based on total assets under management which are attributable to such Plan's investment in both the Affiliated Funds and the Third Party Funds. The annualized Outside Fee will be 1.95 percent (for balances below $20,000), 1.85 percent (for balances of between $20,000 and $100,000, 1.65 percent (for balances between $100,000 and $250,000) and 1.50 percent (for balances above $250,000).[17] From time to time, Wells Fargo may reduce the Outside Fee for promotional purposes. The duration and promotional nature of such reductions will be disclosed to investors. The Outside Fee will be computed quarterly on the average daily value of assets in the Plan's Account during the quarter and will be deducted directly from the Account on a quarterly basis.

23. Wells Fargo will receive Advisory Fees from the Affiliated Funds ranging from 0.05 percent to 0.70 percent, annually, depending upon the applicable portfolio. A sub- advisory fee is paid by Wells Fargo out of its investment advisory fee to WFNIA. Wells Fargo may also receive Administrative Fees from the Affiliated Funds. As stated in Representation 3, if such fees are not included in the Advisory Fee for a portfolio, the current fee for (a) custodial services is 0.0167 percent annually, (b) $2,000 per month plus 0.07 percent on the first $50 million, 0.045 percent on the next $50 million and 0.02 percent on the excess over $100 million for portfolio accounting services, (c) a minimum of $3,000 monthly, plus various transaction charges for transfer agency services, and (d) 0.00 percent to 0.30 percent for shareholder servicing. Further, Wells Fargo may receive 12b-1 fees in the form of ''trailing'' commissions of 0.05 percent to 0.50 percent of assets invested with respect to Third Party Funds in the Portfolio Advisor Program.

24. With respect to the Affiliated Funds, Wells Fargo proposes to offset,

[16] The fact that certain transactions and fee arrangements are the subject of an administrative exemption does not relieve the fiduciaries of the Plans from the general fiduciary responsibility provisions of section 404 of the Act. Thus, the Department cautions Independent Fiduciaries of Plans investing in the Funds that they have an ongoing duty under section 404 of the Act to monitor the services provided to the Plans to assure that the services remain appropriate and that the fees paid by the Plans for such services are reasonable in relation to the value of the services provided. In considering whether to enter into the arrangement for the provision of asset allocation services, the Department emphasizes that it expects the Independent Fiduciary to fully understand that the selection or addition of Third Party Funds may result in a Plan paying a larger overall aggregate fee for the package of services than if the fiduciary had selected Affiliated Funds.

[17] In the case of a Section 404(c) Plan, the computation of the Outside Fee will be based on the average daily value of all of the assets in the Accounts of Directing Participants who invest in the Portfolio Advisor Program. In other words, the Outside Fee is based on the aggregate asset value of the Plan's asset and not on the value of each Directing Participant's Account in the Portfolio Advisor Program. The result is that all Directing Participants in a Section 404(c) Plan will be subject to the same Outside Fee as well as the breakpoints.

quarterly, against its Outside Fee, (a) all Advisory Fees and Administrative Fees that are paid by the Affiliated Funds to Wells Fargo, its affiliated sub-advisers, its former affiliates, WFNIA and WFITC, and to other unrelated parties and (b) all 12b-1 Fees and Administrative Fees that are paid to Stephens.[18] As stated in Representation 3, the annualized Advisory Fees currently range from 0.05 percent to 0.70 percent of the portfolio's average daily net assets. As stated in Representation 4, the annualized 12b-1 Fees that are paid to Stephens range from 0.05 to 0.75 percent of the net assets of the Affiliated Funds. In addition, the annualized Administrative Fees that are paid to Stephens range from 0.03 percent to 0.15 percent of the portfolio's net assets. With respect to the Third Party Funds, Wells Fargo proposes to offset quarterly, against the Outside Fee, all 12b-1 Fees that it receives. As stated in Representation 23, these fees currently range from 0.05 percent to 0.50 percent annually of net assets invested.

All such Fees described above will be offset in accordance with the crediting mechanism that is described in Prohibited Transaction Exemption (PTE) 77–4 (42 FR 18732, April 8, 1977). After the offset, Wells Fargo will be paid a Net Outside Fee that may be deducted from Plan Accounts. The Net Outside Fee, together with the Advisory Fees, the Administrative Fees and 12b- 1 Fees will equal the Outside Fee prior to any offset. Wells Fargo believes that the offset will eliminate any potential conflicts of interest that may exist as a result of the fact that the investment in certain Funds would generate higher overall fees to Wells Fargo and its affiliates. In addition, by insuring that the sum of the offset and the Net Outside Fee always equals the Outside Fee, Wells Fargo believes that the selection of Affiliated or Third Party Funds will be revenue-neutral.

Table II illustrates the revenue-neutral result of the offset arrangement. As Table II shows, if a Plan with an Account balance of $10,000 is invested in a Portfolio in which 50 percent or $5,000 is invested, respectively, in an Affiliated Fund and a Third Party Fund, the Plan will be subject to an Outside Fee of $195 or 1.95 percent of assets invested.

TABLE II.—EXAMPLE OF REVENUE-NEUTRAL FEE OFFSET

Fund type	Percentage of assets allocated to fund (percent)	Amount invested in fund	Offset (advisory, administrative, 12b-1 fees)		Net outside fee	Outside fee (1.95%)
			Percent	Amount		
Third Party	0.50	5,000	0.25	12.50	85.00	97.50
Affiliated	0.50	5,000	0.80	40.00	57.50	97.50
Total	100.00	10,000	N/A	52.50	142.50	195.00

25. At the end of each quarter, Wells Fargo will calculate the percentage of gross revenues that it has received during the quarter in the form of Advisory Fees, Administrative Fees and 12b-1 Fees from the applicable Affiliated Fund or Third Party Fund. Such percentage will also include all 12b-1 Fees and Administrative Fees that are paid to Stephens. These figures will be calculated as a percentage of the average daily net asset value of assets in the appropriate Fund. The weighted average of such revenues (the Offset Percentage) will then be calculated for each Allocation Model. This will yield the amount of Advisory Fees, Administrative Fees and 12b-1 Fees that are received. This amount will be expressed as a percentage of the average daily net value of Account assets. Wells Fargo proposes to reduce the Outside Fee for the quarter for each Plan by subtracting from the Outside Fee the Offset Percentage for the Allocation Model in which Plan assets were invested during the quarter. Only after the Offset Percentage has been subtracted will Wells Fargo deduct the Outside Fee from the Plan Account in the Portfolio Advisor Program.

26. Table III shows the calculation of the Offset Percentage for a sample Allocation Model. In this example, gross revenues for Wells Fargo, its affiliates and where applicable, Stephens, as between the Affiliated Funds and the Third Party Funds vary from 0.25 percent to 1.09 percent of the daily net asset value (annualized), depending on which Affiliated Fund or Third Party Fund is selected. The weighted average of these revenues for the entire Allocation Model is 0.83 percent (annualized), which is subtracted from the 1.95 percent Outside Fee, thereby leaving a net Outside Fee of 1.12 percent (annualized) for the quarter.

TABLE III.—EXAMPLE OF FEE OFFSET ON SAMPLE ALLOCATION MODEL

Fund type	Sub-class	Total revenues* (percent)		Percentage of assets allocated to fund		Weighted fee percentage
Third Party	Growth	0.50	×	15.00	=	7.50
Third Party	Equity Intn'tl.	0.25	×	5.00	=	1.25
Affiliated	Growth & Income	1.09	×	10.00	=	10.90
Affiliated	Equity Income	1.09	×	15.00	=	16.35
Affiliated	Asset Allocation	0.80	×	10.00	=	8.00
Affiliated	Total Return	1.03	×	15.00	=	15.45
Affiliated	Intermediate	0.75	×	15.00	=	11.25

[18] The Department notes that if the Advisory Fee that is offset includes a fee that is paid by Wells Fargo to an unrelated sub- adviser, no additional offsetting will be required with respect to that portion of the fee that is actually paid by Wells Fargo to such sub-adviser.

TABLE III.—EXAMPLE OF FEE OFFSET ON SAMPLE ALLOCATION MODEL—Continued

Fund type	Sub-class	Total revenues* (percent)		Percentage of assets allocated to fund		Weighted fee percentage
Affiliated	Short-Term	0.80	×	10.00	=	8.00
Affiliated	Cash	0.75	×	5.00	=	3.75
Total				100.00		82.45
Outside Fee				1.95		
Weighted Average of Wells Fargo Revenues (82.45 ÷ 100).				0.83		
Net Account Fee (Annual)—Would be Calculated Quarterly.				1.12		

*For the Affiliated Funds, total revenues include all fees that are paid to Wells Fargo, its affiliated sub-advisers, its former affiliates, Stephens and to other unrelated parties. For the Third Party Funds, total revenues include 12b-1 Fees. Any other fees that Wells Fargo may receive from the Third Party Funds are paid from the 12b-1 Fees.

Use of the Termination Form

27. Although an Independent Fiduciary or Directing Participant may withdraw from the Portfolio Advisor Program at any time, Wells Fargo will provide each such individual with a Termination Form, at least annually, but in all cases where Wells Fargo changes the asset mix outside of the current Allocation Model, when Wells Fargo proposes to divide a Fund sub-class, when Wells Fargo determines that it is in the best interest of the Plan to use a Third Party Fund instead of an Affiliated Fund and whenever the Outside Fee is increased. Wells Fargo will provide such written notice to the Independent Fiduciary or Directing Participant at least 30 days prior to the implementation of the change. The written notification will include the Termination Form that the Independent Fiduciary or Directing Participant may use to withdraw from the Portfolio Advisor Program. The Termination Form will be accompanied by instructions on its use. The instructions will expressly (a) provide that the authorization is terminable at will and without penalty, upon receipt by Wells Fargo of written notice from the Independent Fiduciary or Directing Participant; and (b) explain that the proposed change will go into effect if the Independent Fiduciary or Directing Participant does not elect to withdraw by the effective date.

28. In summary, it is represented that the transactions have satisfied or will satisfy the statutory criteria for an exemption under section 408(a) of the Act because:

(a) The investment of a Plan's assets in the Portfolio Advisor Program has been or will be made by a Plan fiduciary or Directing Participant who is independent of Wells Fargo and its affiliates such that the Independent Fiduciary or Directing Participant will maintain complete discretion with respect to participating in the Portfolio Advisor Program.

(b) No Plan has paid or will pay a fee or commission by reason of the acquisition, redemption, reinvestment or transfer of shares in the Funds.

(c) As to each Plan, the total fees that are paid to Wells Fargo and its affiliates have constituted or will constitute no more than reasonable compensation for the services provided.

(d) Prior to investing in the Portfolio Advisor Program, each Independent Fiduciary or Directing Participant have received or will receive offering materials and disclosures from Wells Fargo which set forth all material facts concerning the purpose, fees, structure, operation, Account rebalancing, risks and participation in such program.

(e) Wells Fargo has provided or will provide written documentation to an Independent Fiduciary or Directing Participant of its recommendations or evaluations based upon objective criteria.

(f) The quarterly Outside Fee that is paid by a Plan to Wells Fargo for asset allocation and related services rendered to such Plan under the Portfolio Advisor Program will be offset by (i) all Advisory Fees (including sub-advisory fees) and Administrative Fees received from the Affiliated Funds by Wells Fargo, its affiliates, its former affiliates, and unrelated parties, (ii) all 12b-1 Fees and Administrative Fees that are paid by the Affiliated Funds to Stephens and (iii) all 12b-1 Fees Wells Fargo receives from the Third Party Funds, such that the sum of the offset and the Net Outside Fee will always equal the Outside Fee and the selection of Affiliated or Third Party Funds will always be revenue neutral.

(g) Although Wells Fargo will have discretion to change the investment mix of an Allocation Model, it has been and will be bound by the financial goals and risk tolerances that the model represents and it will be limited in the degree of change that it can make to an Allocation Model's investment mix.

(h) Any authorizations made by an Independent Fiduciary or Directing Participant with respect to increases in the Outside Fee, changes in the asset mix outside an Allocation Model, the division of a Fund sub-class, or the substitution of a Third Party Fund for an Affiliated Fund, have been and will be terminable at will and without penalty to the Plan, upon receipt by Wells Fargo of written notice of termination from the Independent Fiduciary or the Directing Participant.

(i) Each Independent Fiduciary or Directing Participant has received and will receive ongoing disclosures from Wells Fargo regarding the continued participation in the Portfolio Advisor Program.

(j) All dealings between the Plans, the Funds and Wells Fargo have been and will remain on a basis which is at least as favorable to the Plans as such dealings are with other shareholders of the Funds.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Cassemco, Inc. Retirement Plan and Trust Agreement Located in Cookeville, Tennessee; Proposed Exemption

[Application No. D–10350]

The Department is considering granting an exemption under the authority of section 408(a) of the Act

and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale (the Sale) by the Plan of certain securities (the Securities) to Cassemco, Inc. the sponsoring employer (the Employer) and party in interest with respect to the Plan; provided (1) the Sale is a one-time transaction for cash, (2) the Plan pays no commissions nor incurs any expenses in connection with the proposed Sale, and (3) the Plan receives as consideration for the Sale no less than the fair market value of the Securities as of the date of the Sale.

Summary or Facts and Representations

1. The Employer, a Tennessee corporation organized October 19, 1978, is in the business of manufacturing protective sporting goods equipment for sporting-goods dealers and supplying packaging materials for ammunition to military prime contractors.

Mrs. Barbara Nipper Tetreault is the sole owner of the Employer, succeeding her late husband in 1991, when also she became the trustee and fiduciary of the Plan.

The Plan is a defined benefit pension plan with approximately $137,921.50 in total assets and 31 participants, as of September 3, 1996. The Employer, because of financial problems, discontinued funding the Plan in 1991. On July 3, 1996, the Plan submitted a formal notice of termination to the Pension Benefit Guaranty Corporation, and now the Plan is prepared to distribute the accrued vested benefits of the Plan to its participants and beneficiaries.

2. The Securities, which the Plan proposes to sell to the Employer, consist of 956 shares of common stock, and 956 warrants that are exercisable at $10.50 and expire December 31, 1997. The Securities were issued to the Plan, effective December 31, 1995, by AquaPro Corporation, a Tennessee corporation, in an exchange for the limited partnership holdings of the Plan in a catfish farm, Circle Creek AquaCulture, L.P., a Tennessee limited partnership. The Plan acquired its limited partnership holdings in the Circle Creek AquaCulture, L.P. on May 1, 1989, from an unrelated party for investment purposes.

In a letter dated September 4, 1996, Mr. George S. Hastings, Jr., President of AquaPro Corporation determined that the current fair market value of the Securities held by the Plan was $7.50 for each of the 956 shares and $2.25 for each of the 956 warrants, or a total fair market value of $9,321 for all the Securities held by the Plan.

Mr. Hastings represents, that although the Securities are not currently registered or listed on a national securities exchange, several million dollars have been invested in the shares of common stock of AquaPro Corporation and acquired by outside investors, paying $7.50 per share; also, Mr. Hastings determined that the automatic conversion feature of the warrants, effective on the expiration date, December 31, 1997,[19] gave the warrants a fair market value of $2.25 per warrant.

In addition, in a letter dated November 6, 1995, Bishop Crown Investment Research, Inc. (Bishop), located in San Diego, California determined the Securities value was $7.50 per share for the common stock and the value of the warrants was $2.25 per warrant. The determination by Bishop was made for determining the exchange values when AquaPro Corporation acquired the limited partnership holdings of the Plan, effective December 31, 1995, in Circle Creek AquaCulture, L.P.

The applicant and Mr. Hastings represent that both Mr. Hastings and Bishop are unrelated and independent of the Plan and the trustee or sponsor of the Plan.

3. The applicant requests an administrative exemption from the prohibited transaction provisions of the Act to enable the Plan to sell for cash the Securities at their fair market value to the Employer. Following the proposed Sale the applicant intends to complete the termination of the Plan by distributing the accrued vested benefits to the Plan participants and beneficiaries. The applicant represents that an additional funding contribution will be made to the Plan so that on the date of distribution the Plan will pay the participants and beneficiaries all their accrued benefits due under the terms of the Plan. The applicant also represents that because of the limited trading activity of the Securities since they are not registered or listed on a national securities exchange, the Plan has not been able to sell the Securities to a non-party in interest with respect to the Plan.

The Sale is represented by the applicant to be in the best interests of the Plan and its participants and beneficiaries because the Plan will be able to distribute the accrued vested benefits and be able to terminate and avoid additional costs and expenses.

Also, the applicant represents that the rights of the participants and beneficiaries are protected by the independent determination of the fair market value of the Securities by Mr. Hastings and Bishop.

4. In summary, the applicant represents that the proposed transaction will satisfy the criteria of section 408(a) of the Act because (a) the Sale of the Securities involves a one-time transaction for cash; (b) the Plan will not incur any commission payments nor any other expenses from the Sale; (c) the Plan will be able to distribute the accrued vested benefits to Plan participants and beneficiaries and terminate; (d) the Securities have been independently appraised by the president of the issuing corporation; and (e) the Plan will receive as consideration from the Sale an amount no less than the fair market value of the Securities as of the date of the Sale.

FOR FURTHER INFORMATION CONTACT: Mr. C.E. Beaver of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

PanAgora Asset Management, Inc. (PanAgora) Located in Boston, Massachusetts; Proposed Exemption

[Application No. D–10351]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, PanAgora shall not be precluded from functioning as a ''qualified professional asset manager'' pursuant to Prohibited Transaction Exemption 84–14 (PTE 84–14, 49 FR 9494, March 13, 1984) solely because of a failure to satisfy Section I(g) of PTE 84–14, as a result of affiliation with E.F. Hutton & Company, Inc. (Hutton) and Shearson Lehman Brothers, Inc. (Shearson), formerly Shearson Lehman Hutton, Inc. (SLH).

Effective Date: This exemption, if granted, will be effective as of September 22, 1989, the date on which PanAgora was formed.

Summary of Facts and Representations

1. PanAgora is a Delaware corporation that was formed on September 22, 1989.

[19] The automatic conversion feature of the warrants provides that upon their expiration each warrant converts to 3/10 share of the common stock issued by AquaPro Corporation.

PanAgora originally was a wholly-owned subsidiary of The Boston Company, Inc. (TBC), which was in turn a subsidiary of SLH. On April 27, 1990, Nippon Life Insurance Company (NLI) obtained a 50% interest in PanAgora; the remaining 50% interest was owned 25% by SLH and 25% by TBC. On May 20, 1993, the ownership was changed so that NLI owned 50% and SLH owned 50%. On July 31, 1993, as part of the reorganization accompanying the sale of the Shearson retail brokerage business, the ownership changed to 50% NLI and 50% Lehman Brothers, Inc.[20]

PanAgora has a Board of Directors of 10 persons. Four are designated by NLI, three are designated by Lehman and three are PanAgora employees. PanAgora is a registered investment adviser under the Investment Advisers Act of 1940 (the Advisers Act). As of December 31, 1995, PanAgora managed investments of $13,486,300,000 for 98 clients, including 73 clients which are plans subject to the Act, 5 foundations, 10 governmental plans, 7 mutual funds and 3 offshore funds.

2. Shearson is a wholly-owned subsidiary of Shearson Lehman Brothers Holdings Inc. (Shearson Holdings), 100 percent of the issued and outstanding common stock of which is owned by American Express Company (AMEX). AMEX is a publicly-owned company whose stock is traded on the New York Stock Exchange. AMEX and its subsidiaries form a diversified financial and travel services company.

On January 13, 1988, over 90 percent of the stock of E.F. Hutton Group Inc. (Hutton Group), the parent company of Hutton, was tendered to SLBP Acquisition Corporation (SLBP), a wholly-owned subsidiary of Shearson Holdings, pursuant to an Agreement and Plan of Merger (Merger Agreement) dated December 2, 1987, as amended on December 28, 1987, entered into among Shearson Holdings, SLBP, and the Hutton Group. On January 21, 1988, as permitted by the terms of the Merger Agreement, SLBP assigned its right to purchase those shares so accepted to Shearson and Shearson purchased the shares. As a result of the acquisition of the Hutton Group stock, Shearson controls the Hutton Group and indirectly controls Hutton.

3. On May 2, 1985, Hutton entered a plea of guilty (the Guilty Plea) to an Information filed in the United States District Court for the Middle District of Pennsylvania. The Information charged that Hutton had violated the federal mail and wire fraud statutes in connection with its handling of certain checking accounts it maintained for the deposit of its own funds during the period from July 1, 1980 to February 16, 1982. The applicant represents that as a result of the Guilty Plea, Hutton agreed to pay, and has paid, a criminal fine of $2,000,000 plus $750,000 to defray the costs of the government investigation. Hutton further agreed to establish, and has established, a restitution program for the benefit of commercial banks that may have been damaged by its actions. None of the acts alleged in the Information, however, involved funds or securities owned by any investment advisory or brokerage clients of Hutton or any employee benefit plan for which Hutton or any affiliate is a party in interest.

4. On May 16, 1988, Hutton entered a plea of guilty (the Providence Plea) in the United States District Court for the District of Rhode Island on two counts of violating the Bank Secrecy Act and one count of conspiracy to violate that Act. The applicant represents that Hutton agreed to pay, and has paid, an aggregate fine of $1,010,000 as a result of the Providence Plea. The Information filed by the government in connection with the Providence Plea alleges that the conduct of the two brokers, formerly employed at Hutton-Providence, was in violation of the Bank Secrecy Act. The Bank Secrecy Act requires the filing of a Currency Transaction Report, under certain circumstances, if more than $10,000 in cash is deposited with a financial institution. The applicant represents that the brokers' unlawful conduct occurred primarily in the period from 1982 to 1983, and no such conduct transpired later than October 1984—more than three years before Shearson acquired its majority interest in Hutton.

5. On March 3, 1989, George Inserra, a broker employed by Shearson, pled guilty to charges of securities fraud, soliciting commissions in connection with an employee benefit plan, and filing a false income tax return. On the same date, John Inserra, also employed by Shearson as a broker, pled guilty to securities fraud conspiracy. Further, on May 1, 1989, the Department filed a complaint in the U.S. District Court for the Northern District of New York alleging that Shearson, among others, and its agents, misused assets of three New York Teamsters Funds (the Funds) to benefit themselves and others through a stock parking scheme and indirect fee arrangements with banks, and that Shearson mishandled the Funds' cash balances and manipulated stock purchases. On September 19, 1990, Shearson and the Department executed a settlement agreement (the Settlement) regarding the Department's complaint. Without admitting or denying the Department's allegations, Shearson agreed pursuant to the Settlement to make a payment to the affected Funds.

6. The applicant states that the Inserras had left the employment of Shearson in October 1985, long before the guilty pleas were entered in March 1989. The applicant further represents that although the Securities and Exchange Commission (SEC) instituted proceedings against Shearson as a result of the Inserras' activities, Shearson was not charged with any criminal offenses. Shearson settled the SEC proceedings by accepting a censure by the SEC for failure to exercise reasonable supervision of the Inserras. As part of the settlement with the SEC, Shearson agreed to institute revised policies and procedures recommended by an independent consultant to prevent the kinds of defalcations engaged in by the Inserras. The applicant represents that the independent consultant thoroughly analyzed Shearson's operations and recommended systemic changes designed to preclude the types of unsupervised actions committed by the Inserras.

7. AMEX has represented that although none of the unlawful conduct involved Hutton's investment management activities or any plans covered by the Act, the criminal activities described above could preclude each component of AMEX, as an affiliate of Hutton, from serving as a ''qualified professional asset manager'' (QPAM) pursuant to sections I(g) and V(d) of PTE 84–14. Similarly, AMEX has represented that the guilty pleas of the Inserras could preclude each component of AMEX, as an affiliate of Shearson, from serving as a QPAM, pursuant to sections I(g) and V(d) of PTE 84–14. Section I(g) of PTE 84–14 precludes a person who otherwise qualifies as a QPAM from serving as a QPAM if such person or an affiliate[21] thereof has

[20] On March 13, 1993, Shearson entered into an asset purchase agreement with Primerica Corporation and its wholly-owned subsidiary, Smith Barney, providing for the sale to Smith Barney and its designated affiliates of substantially all of the assets of the Shearson Lehman Brothers Division of Shearson and the SLB Asset Management Division of Shearson. The remaining business was renamed Lehman Brothers, Inc.

[21] For purposes of section I(g) of PTE 84–14, an ''affiliate'' of a person is defined, in relevant part, as ''any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with the person * * *'' (PTE 84–14 section V(d)). As such, under this definition, American Express and all its subsidiaries (collectively, AMEX) would be considered affiliates of Shearson and Hutton.

within the 10 years immediately preceding the transaction been either convicted or released from imprisonment as a result of certain criminal activity. PanAgora requests an exemption to enable it to function as a QPAM despite its failure to satisfy section I(g) of PTE 84–14 due to affiliation with Hutton and Shearson and the pleas entered by Hutton and the Inserras.[22]

8. The transactions covered by this proposed exemption would include the full range of transactions that can be executed by investment managers who qualify as QPAMs pursuant to PTE 84–14. The applicant represents that the requested exemption is not relevant to most transactions involving the purchase/sale of securities, securities lending, investment in short-term instruments (such as repurchase agreements and bankers' acceptances) and certain residential mortgage pools, since each such transaction is covered by other class exemptions. However, the applicant represents that the requested exemption, to enable access to the exemptive relief afforded by PTE 84–14, is needed for PanAgora to engage in various transactions involving investments in real estate, mortgages, and commodities, between plans over which PanAgora has investment discretion and parties in interest with respect to such plans.

9. AMEX has represented that various measures have been taken by Hutton and Shearson, since the Hutton pleas and the Inserra pleas, to ensure that conduct such as that involved in such pleas will not recur. Among the steps taken to prevent such conduct in the future are the following:

(A) Hutton has acted to recompense its depository banks for any harm which may have been caused by the illegal acts involved in the Guilty Plea and the Providence Plea.

(B) Hutton initiated changes in its organizational structure and management practices: Realignment and centralization of financial operations, computerized enhancement of Hutton's headquarters to monitor activity at the branch and regional levels, and instruction of all employees on the procedural revisions.

(C) Hutton adopted recommendations made by former Judge Griffin Bell, U.S. Court of Appeals for the Fifth Circuit,[23] who was retained to conduct an independent inquiry into the cash management practices to which Hutton pled guilty. The changes made pursuant to Judge Bell's recommendation include restructuring of the financing, financial control, operations and general counsel functions, establishment of an independent audit committee with full access to Hutton's chief executive officer and board of directors, and development of a corporate code of ethics, supplemented by educational and monitoring programs, in conjunction with the Ethics Resource Center in Washington, D.C.

(D) In late December 1987, following the announcement of Shearson's merger with Hutton Group, Shearson retained outside counsel to investigate and advise with respect to Hutton's compliance with the Bank Secrecy Act. The investigation revealed certain unreported currency transactions at Hutton branch offices prior to Shearson's acquisition of Hutton. AMEX has represented that the United States Attorney for the Southern District of New York completed its inquiry into possible legal violations at Hutton branch offices and indicated it will take no further action.

(E) In connection with Shearson's application to the SEC for an exemption from the provisions of section 9(a) of the Investment Company Act of 1940, Shearson agreed to retain independent auditors: (i) To confirm that the Shearson currency reporting procedures are in place in each former Hutton branch office; (ii) to review the currency reporting procedures to determine whether they are reasonably designed to ensure compliance with the Bank Secrecy Act and whether changes are needed to ensure ongoing compliance; and (iii) to report the results of the review to Shearson. AMEX has represented that upon completion of the auditor's review, Shearson submitted the report and recommendations to the SEC, together with a report by Shearson setting forth the action proposed for implementation of the recommendations. AMEX stated that such proposed action has been taken.

(F) As of February 8, 1988, as part of the consolidation of the Hutton branch offices into the Shearson branch office system, each Hutton branch adopted the same internal procedures for processing currency transactions as those followed by Shearson. AMEX has represented that such procedures prevent the kind of irregularities involved in the Providence Plea. AMEX stated that as additional safeguards, the Shearson procedures forbid all Shearson employees from taking possession of currency for a customer, escorting a customer to a financial institution to convert currency, and/or advising a customer as to how to ''structure'' a transaction with a financial institution in order to avoid reporting requirements under the Currency Transaction Reporting Act.

(G) Although the SEC instituted proceedings against Shearson as a result of the Inserras' activities, Shearson was not charged with any criminal offense, and Shearson expeditiously settled the SEC proceedings by accepting a censure by the SEC for failure to reasonably supervise the Inserras and the branch manager overseeing the Inserras. As part of the settlement, Shearson committed to institute revised policies and procedures recommended by an independent consultant and designed to prevent the kinds of defalcations engaged in by the Inserras.

10. The applicant asserts that failure to grant the requested exemption will prohibit employee benefit plans for which PanAgora acts as investment manager from engaging in transactions with parties in interest that would otherwise be permitted under PTE 84–14, and will cause the plans to forego attractive investment opportunities. The applicant notes that it would be deprived of its abilities to offer and render the full panoply of specialized investment advisory services demanded by employee benefit plans covered by the Act. The applicant represents that neither of the Hutton pleas involved PanAgora in any way, and thus do not impair the abilities of PanAgora to serve as independent investment manager.

With respect to the conduct and pleas of the Inserras, AMEX has pointed out that the Inserras were not employees of Shearson at the time they pled guilty to the charges against them, and Shearson was never charged with any criminal offense in connection with their activities. The applicant represents that the ability of PanAgora or any other AMEX affiliate to act as a QPAM has not been affected by the activities of the Inserras, which were neither authorized nor condoned by Shearson or any other AMEX affiliate.

11. In summary the applicant represents that the proposed exemption satisfies the criteria of section 408(a) of the Act for the following reasons: (A) Hutton's criminal activity occurred prior to acquisition by Shearson, and the activities of the Inserras did not involve any criminal charges against Shearson; (B) Both Hutton and Shearson have undertaken substantial reforms

[22] In Prohibited Transaction Exemption 94–34 (PTE 94–34, 59 FR 19247, April 22, 1994), AMEX obtained the relief proposed herein for itself and its wholly owned subsidiaries, including Lehman Brothers, Inc., the successor to SLH. Although PanAgora was then a subsidiary of AMEX, PTE 94–34 provided no relief for PanAgora because it was not a wholly owned subsidiary.

[23] Judge Bell has also served as Attorney General of the United States.

and put in place procedures designed to prevent any recurrence of the criminal activity; (C) PanAgora will be able to engage in a broader variety of investment services on behalf of employee benefit plans which demand such services; (D) The ability of PanAgora to act as QPAM has not been impaired by criminal acts that were neither authorized nor condoned by Shearson or any other AMEX affiliate; and (E) The other conditions of PTE 84–14, combined with the procedures adopted by Hutton and Shearson, afford ample protection of the interests of participants and beneficiaries of employee benefit plans.

FOR FURTHER INFORMATION CONTACT: Gary Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

SouthTrust Securities, Inc. (ST) Located in Birmingham, Alabama; Proposed Exemption

[Application No. D–10376]

I. Transactions

A. Effective October 25, 1996, the restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan when the sponsor, servicer, trustee or insurer of a trust, the underwriter of the certificates representing an interest in the trust, or an obligor is a party in interest with respect to such plan;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.A. (1) or (2).

Notwithstanding the foregoing, section I.A. does not provide an exemption from the restrictions of sections 406(a)(1)(E), 406(a)(2) and 407 for the acquisition or holding of a certificate on behalf of an Excluded Plan by any person who has discretionary authority or renders investment advice with respect to the assets of that Excluded Plan.[24]

B. Effective October 25, 1996, the restrictions of sections 406(b)(1) and 406(b)(2) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1)(E) of the Code shall not apply to:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and a plan when the person who has discretionary authority or renders investment advice with respect to the investment of plan assets in the certificates is (a) an obligor with respect to 5 percent or less of the fair market value of obligations or receivables contained in the trust, or (b) an affiliate of a person described in (a); if:

(i) The plan is not an Excluded Plan;

(ii) Solely in the case of an acquisition of certificates in connection with the initial issuance of the certificates, at least 50 percent of each class of certificates in which plans have invested is acquired by persons independent of the members of the Restricted Group and at least 50 percent of the aggregate interest in the trust is acquired by persons independent of the Restricted Group;

(iii) A plan's investment in each class of certificates does not exceed 25 percent of all of the certificates of that class outstanding at the time of the acquisition; and

(iv) Immediately after the acquisition of the certificates, no more than 25 percent of the assets of a plan with respect to which the person has discretionary authority or renders investment advice are invested in certificates representing an interest in a trust containing assets sold or serviced by the same entity.[25] For purposes of this paragraph B.(1)(iv) only, an entity will not be considered to service assets contained in a trust if it is merely a subservicer of that trust;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates, provided that the conditions set forth in paragraphs B.(1) (i), (iii) and (iv) are met; and

(3) The continued holding of certificates acquired by a plan pursuant to subsection I.B. (1) or (2).

C. Effective October 25, 1996, the restrictions of sections 406(a), 406(b) and 407(a) of the Act, and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c) of the Code, shall not apply to transactions in connection with the servicing, management and operation of a trust, provided:

(1) Such transactions are carried out in accordance with the terms of a binding pooling and servicing arrangement; and

(2) The pooling and servicing agreement is provided to, or described in all material respects in the prospectus or private placement memorandum provided to, investing plans before they purchase certificates issued by the trust.[26]

Notwithstanding the foregoing, section I.C. does not provide an exemption from the restrictions of section 406(b) of the Act or from the taxes imposed by reason of section 4975(c) of the Code for the receipt of a fee by a servicer of the trust from a person other than the trustee or sponsor, unless such fee constitutes a ''qualified administrative fee'' as defined in section III.S.

D. Effective October 25, 1996, the restrictions of sections 406(a) and 407(a) of the Act, and the taxes imposed by sections 4975 (a) and (b) of the Code by reason of sections 4975(c)(1) (A) through (D) of the Code, shall not apply to any transactions to which those restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in section 3(14) (F), (G), (H) or (I) of the Act or section 4975(e)(2) (F), (G), (H) or (I) of the Code), solely because of the plan's ownership of certificates.

II. General Conditions

A. The relief provided under Part I is available only if the following conditions are met:

(1) The acquisition of certificates by a plan is on terms (including the certificate price) that are at least as favorable to the plan as they would be in an arm's-length transaction with an unrelated party;

(2) The rights and interests evidenced by the certificates are not subordinated

[24] Section I.A. provides no relief from sections 406(a)(1)(E), 406(a)(2) and 407 for any person rendering investment advice to an Excluded Plan within the meaning of section 3(21)(A)(ii) and regulation 29 CFR 2510.3–21(c).

[25] For purposes of this exemption, each plan participating in a commingled fund (such as a bank collective trust fund or insurance company pooled separate account) shall be considered to own the same proportionate undivided interest in each asset of the commingled fund as its proportionate interest in the total assets of the commingled fund as calculated on the most recent preceding valuation date of the fund.

[26] In the case of a private placement memorandum, such memorandum must contain substantially the same information that would be disclosed in a prospectus if the offering of the certificates were made in a registered public offering under the Securities Act of 1933. In the Department's view, the private placement memorandum must contain sufficient information to permit plan fiduciaries to make informed investment decisions.

to the rights and interests evidenced by other certificates of the same trust;

(3) The certificates acquired by the plan have received a rating at the time of such acquisition that is in one of the three highest generic rating categories from either Standard & Poor's Ratings Servicer (S&P's), Moody's Investors Service, Inc. (Moody's), Duff & Phelps Inc. (D & P) or Fitch Investors Service, Inc. (Fitch);

(4) The trustee is not an affiliate of any member of the Restricted Group. However, the trustee shall not be considered to be an affiliate of a servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of a pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer;

(5) The sum of all payments made to and retained by the underwriters in connection with the distribution or placement of certificates represents not more than reasonable compensation for underwriting or placing the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trust represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith; and

(6) The plan investing in such certificates is an ''accredited investor'' as defined in Rule 501(a)(1) of Regulation D of the Securities and Exchange Commission under the Securities Act of 1933.

B. Neither any underwriter, sponsor, trustee, servicer, insurer, nor any obligor, unless it or any of its affiliates has discretionary authority or renders investment advice with respect to the plan assets used by a plan to acquire certificates, shall be denied the relief provided under Part I, if the provision of subsection II.A.(6) above is not satisfied with respect to acquisition or holding by a plan of such certificates, provided that (1) such condition is disclosed in the prospectus or private placement memorandum; and (2) in the case of a private placement of certificates, the trustee obtains a representation from each initial purchaser which is a plan that it is in compliance with such condition, and obtains a covenant from each initial purchaser to the effect that, so long as such initial purchaser (or any transferee of such initial purchaser's certificates) is required to obtain from its transferee a representation regarding compliance with the Securities Act of 1933, any such transferees will be required to make a written representation regarding compliance with the condition set forth in subsection II.A.(6) above.

III. Definitions

For purposes of this exemption:

A. ''Certificate'' means:

(1) a certificate—

(a) that represents a beneficial ownership interest in the assets of a trust; and

(b) that entitles the holder to pass-through payments of principal, interest, and/or other payments made with respect to the assets of such trust; or

(2) a certificate denominated as a debt instrument—

(a) that represents an interest in a Real Estate Mortgage Investment Conduit (REMIC) within the meaning of section 860D(a) of the Internal Revenue Code of 1986; and

(b) that is issued by and is an obligation of a trust;

with respect to certificates defined in (1) and (2) above for which ST or any of its affiliates is either (i) the sole underwriter or the manager or co-manager of the underwriting syndicate, or (ii) a selling or placement agent.

For purposes of this exemption, references to ''certificates representing an interest in a trust'' include certificates denominated as debt which are issued by a trust.

B. ''Trust'' means an investment pool, the corpus of which is held in trust and consists solely of:

(1) either

(a) secured consumer receivables that bear interest or are purchased at a discount (including, but not limited to, home equity loans and obligations secured by shares issued by a cooperative housing association);

(b) secured credit instruments that bear interest or are purchased at a discount in transactions by or between business entities (including, but not limited to, qualified equipment notes secured by leases, as defined in section III.T);

(c) obligations that bear interest or are purchased at a discount and which are secured by single-family residential, multi-family residential and commercial real property (including obligations secured by leasehold interests on commercial real property);

(d) obligations that bear interest or are purchased at a discount and which are secured by motor vehicles or equipment, or qualified motor vehicle leases (as defined in section III.U);

(e) ''guaranteed governmental mortgage pool certificates,'' as defined in 29 CFR 2510.3–101(i)(2);

(f) fractional undivided interests in any of the obligations described in clauses (a)–(e) of this section B.(1); [27]

(2) property which had secured any of the obligations described in subsection B.(1);

(3) undistributed cash or temporary investments made therewith maturing no later than the next date on which distributions are to made to certificateholders; and

(4) rights of the trustee under the pooling and servicing agreement, and rights under any insurance policies, third-party guarantees, contracts of suretyship and other credit support arrangements with respect to any obligations described in subsection B.(1).

Notwithstanding the foregoing, the term ''trust'' does not include any investment pool unless: (i) the investment pool consists only of assets of the type which have been included in other investment pools, (ii) certificates evidencing interests in such other investment pools have been rated in one of the three highest generic rating categories by S&P's, Moody's, D & P, or Fitch for at least one year prior to the plan's acquisition of certificates pursuant to this exemption, and (iii) certificates evidencing interests in such other investment pools have been purchased by investors other than plans for at least one year prior to the plan's acquisition of certificates pursuant to this exemption.

C. ''Underwriter'' means:

(1) ST;

(2) any person directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with ST; or

(3) any member of an underwriting syndicate or selling group of which ST or a person described in (2) is a manager or co-manager with respect to the certificates.

D. ''Sponsor'' means the entity that organizes a trust by depositing

[27] It is the Department's view that the definition of ''trust'' contained in III.B. includes a two-tier structure under which certificates issued by the first trust, which contains a pool of receivables described above, are transferred to a second trust which issues securities that are sold to plans. However, the Department is of the further view that, since the exemption provides relief for the direct or indirect acquisition or disposition of certificates that are not subordinated, no relief would be available if the certificates held by the second trust were subordinated to the rights and interests evidenced by other certificates issued by the first trust.

obligations therein in exchange for certificates.

E. ''Master Servicer'' means the entity that is a party to the pooling and servicing agreement relating to trust assets and is fully responsible for servicing, directly or through subservicers, the assets of the trust.

F. ''Subservicer'' means an entity which, under the supervision of and on behalf of the master servicer, services loans contained in the trust, but is not a party to the pooling and servicing agreement.

G. ''Servicer'' means any entity which services loans contained in the trust, including the master servicer and any subservicer.

H. ''Trustee'' means the trustee of the trust, and in the case of certificates which are denominated as debt instruments, also means the trustee of the indenture trust.

I. ''Insurer'' means the insurer or guarantor of, or provider of other credit support for, a trust. Notwithstanding the foregoing, a person is not an insurer solely because it holds securities representing an interest in a trust which are of a class subordinated to certificates representing an interest in the same trust.

J. ''Obligor'' means any person, other than the insurer, that is obligated to make payments with respect to any obligation or receivable included in the trust. Where a trust contains qualified motor vehicle leases or qualified equipment notes secured by leases, ''obligor'' shall also include any owner of property subject to any lease included in the trust, or subject to any lease securing an obligation included in the trust.

K. ''Excluded Plan'' means any plan with respect to which any member of the Restricted Group is a ''plan sponsor'' within the meaning of section 3(16)(B) of the Act.

L. ''Restricted Group'' with respect to a class of certificates means:

(1) each underwriter;

(2) each insurer;

(3) the sponsor;

(4) the trustee;

(5) each servicer;

(6) any obligor with respect to obligations or receivables included in the trust constituting more than 5 percent of the aggregate unamortized principal balance of the assets in the trust, determined on the date of the initial issuance of certificates by the trust; or

(7) any affiliate of a person described in (1)–(6) above.

M. ''Affiliate'' of another person includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee, relative (as defined in section 3(15) of the Act), a brother, a sister, or a spouse of a brother or sister of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

N. ''Control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

O. A person will be ''independent'' of another person only if:

(1) such person is not an affiliate of that other person; and

(2) the other person, or an affiliate thereof, is not a fiduciary who has investment management authority or renders investment advice with respect to any assets of such person.

P. ''Sale'' includes the entrance into a forward delivery commitment (as defined in section Q below), provided:

(1) The terms of the forward delivery commitment (including any fee paid to the investing plan) are no less favorable to the plan than they would be in an arm's-length transaction with an unrelated party;

(2) The prospectus or private placement memorandum is provided to an investing plan prior to the time the plan enters into the forward delivery commitment; and

(3) At the time of the delivery, all conditions of this exemption applicable to sales are met.

Q. ''Forward delivery commitment'' means a contract for the purchase or sale of one or more certificates to be delivered at an agreed future settlement date. The term includes both mandatory contracts (which contemplate obligatory delivery and acceptance of the certificates) and optional contracts (which give one party the right but not the obligation to deliver certificates to, or demand delivery of certificates from, the other party).

R. ''Reasonable compensation'' has the same meaning as that term is defined in 29 CFR 2550.408c–2.

S. ''Qualified Administrative Fee'' means a fee which meets the following criteria:

(1) The fee is triggered by an act or failure to act by the obligor other than the normal timely payment of amounts owing in respect of the obligations;

(2) The servicer may not charge the fee absent the act or failure to act referred to in (1);

(3) The ability to charge the fee, the circumstances in which the fee may be charged, and an explanation of how the fee is calculated are set forth in the pooling and servicing agreement; and

(4) The amount paid to investors in the trust will not be reduced by the amount of any such fee waived by the servicer.

T. ''Qualified Equipment Note Secured By A Lease'' means an equipment note:

(1) Which is secured by equipment which is leased;

(2) Which is secured by the obligation of the lessee to pay rent under the equipment lease; and

(3) With respect to which the trust's security interest in the equipment is at least as protective of the rights of the trust as would be the case if the equipment note were secured only by the equipment and not the lease.

U. ''Qualified Motor Vehicle Lease'' means a lease of a motor vehicle where:

(1) The trust holds a security interest in the lease;

(2) The trust holds a security interest in the leased motor vehicle; and

(3) The trust's security interest in the leased motor vehicle is at least as protective of the trust's rights as would be the case if the trust consisted of motor vehicle installment loan contracts.

V. ''Pooling and Servicing Agreement'' means the agreement or agreements among a sponsor, a servicer and the trustee establishing a trust. In the case of certificates which are denominated as debt instruments, ''Pooling and Servicing Agreement'' also includes the indenture entered into by the trustee of the trust issuing such certificates and the indenture trustee.

W. ''ST'' means SouthTrust Securities, Inc. and its affiliates.

The Department notes that this proposed exemption is included within the meaning of the term ''Underwriter Exemption'' as it is defined in section V(h) of Prohibited Transaction Exemption 95–60 (60 FR 35925, July 12, 1995), the Class Exemption for Certain Transactions Involving Insurance Company General Accounts at 35932.

Summary of Facts and Representations

1. ST is the wholly-owned, separately capitalized investment banking subsidiary of South Trust Corporation (the Bank), a Birmingham, Alabama based bank holding company which had assets of $24.8 billion as of September 30, 1996 and operates eight affiliate banks with more than 500 offices in Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina and Tennessee. The Bank also owns and operates subsidiaries that engage in data processing, trust, leasing, mortgage

banking, and investment and brokerage services.

ST was originally incorporated as SouthTrust Brokerage Services in 1985. In 1989, the investment division of SouthTrust Bank of Alabama was merged into SouthTrust Brokerage Services, Inc., and the name of the corporation was changed to SouthTrust Securities, Inc. ST maintains its principal place in Birmingham, Alabama. ST is a registered broker-dealer with the Securities and Exchange Commission. As a member of the National Association of Securities Dealers, ST maintains a fixed income securities brokerage service for the initial placement and remarketing of offerings originated by the firm as well as other issues traded in the secondary market.

Pursuant to a July 10, 1989 order of the Board of Governors of the Federal Reserve System, ST is authorized to engage, to a limited extent, in underwriting and dealing in certain securities through a bank holding company subsidiary. The underwriting activities include one- to four-family mortgage-related securities, municipal revenue bonds, commercial paper, and consumer receivable-related securities. Pursuant to this order, ST may also provide full service brokerage services and investment advice and buy and sell securities solely as agent for the account of customers. This order is subject to the condition that ST does not derive more than 10% of its average gross revenues from such activities during any two year rolling period.

Affiliates of ST began securitizing assets in 1993. Since that time ST's affiliates have securitized nursing home loans and multi-family conduit loans. The professionals of ST have also been active participants in the area of tax-exempt financing, including housing, public finance and industrial development issues. ST itself began securitizing assets in 1996 when it completed a securitization of mobile home loans in a private placement. It is anticipated that ST will be involved as an underwriter or placement agent in the future in asset securitizations.

Trust Assets

2. ST seeks exemptive relief to permit plans to invest in pass-through certificates representing undivided interests in the following categories of trusts: (1) Single and multi-family residential or commercial mortgage investment trusts; [28] (2) motor vehicle receivable investment trusts; (3) consumer or commercial receivables investment trusts; and (4) guaranteed governmental mortgage pool certificate investment trusts.[29]

3. Commercial mortgage investment trusts may include mortgages on ground leases of real property. Commercial mortgages are frequently secured by ground leases on the underlying property, rather than by fee simple interests. The separation of the fee simple interest and the ground lease interest is generally done for tax reasons. Properly structured, the pledge of the ground lease to secure a mortgage provides a lender with the same level of security as would be provided by a pledge of the related fee simple interest. The terms of the ground leases pledged to secure leasehold mortgages will in all cases be at least ten years longer than the term of such mortgages.[30]

Trust Structure

4. Each trust is established under a pooling and servicing agreement between a sponsor, a servicer and a trustee. The sponsor or servicer of a trust selects assets to be included in the trust. These assets are receivables which may have been originated by a sponsor or servicer of the trust, an affiliate of the sponsor or servicer, or by an unrelated lender and subsequently acquired by the trust sponsor or servicer.[31]

On or prior to the closing date, the sponsor acquires legal title to all assets selected for the trust, establishes the trust and designates an independent entity as trustee. On the closing date, the sponsor conveys to the trust legal title to the assets, and the trustee issues certificates representing fractional undivided interests in the trust assets. ST, alone or together with other broker-dealers, acts as underwriter or placement agent with respect to the sale of the certificates. All of the public offerings of certificates presently contemplated are to be underwritten by ST on a firm commitment basis. In addition, ST anticipates that it may privately place certificates on both a firm commitment and an agency basis. ST may also act as the lead underwriter for a syndicate of securities underwriters.

Certificateholders will be entitled to receive monthly, quarterly or semi-annual installments of principal and/or interest, or lease payments due on the receivables, adjusted, in the case of payments of interest, to a specified rate—the pass-through rate—which may be fixed or variable.

When installments or payments are made on a semi-annual basis, funds are not permitted to be commingled with the servicer's assets for longer than would be permitted for a monthly-pay security. A segregated account is established in the name of the trustee (on behalf of certificateholders) to hold funds received between distribution dates. The account is under the sole control of the trustee, who invests the account's assets in short-term securities which have received a rating comparable to the rating assigned to the certificates. In some cases, the servicer may be permitted to make a single deposit into the account once a month. When the servicer makes such monthly deposits, payments received from obligors by the servicer may be commingled with the servicer's assets during the month prior to deposit. Usually, the period of time between receipt of funds by the servicer and deposit of these funds in a segregated account does not exceed one month. Furthermore, in those cases where distributions are made semi-annually, the servicer will furnish a report on the operation of the trust to the trustee on a monthly basis. At or about the time this report is delivered to the trustee, it will be made available to

[28] The Department notes that PTE 83–1 [48 FR 895, January 7, 1983], a class exemption for mortgage pool investment trusts, would generally apply to trusts containing single-family residential mortgages, provided that the applicable conditions of PTE 83–1 are met. ST requests relief for single-family residential mortgages in this exemption because it would prefer one exemption for all trusts of similar structure. However, ST has stated that it may still avail itself of the exemptive relief provided by PTE 83–1.

[29] Guaranteed governmental mortgage pool certificates are mortgage-backed securities with respect to which interest and principal payable is guaranteed by the Government National Mortgage Association (GNMA), the Federal Home Loan Mortgage Corporation (FHLMC), or the Federal National Mortgage Association (FNMA). The Department's regulation relating to the definition of plan assets (29 CFR 2510.3–101(i)) provides that where a plan acquires a guaranteed governmental mortgage pool certificate, the plan's assets include the certificate and all of its rights with respect to such certificate under applicable law, but do not, solely by reason of the plan's holding of such certificate, include any of the mortgages underlying such certificate. The applicant is requesting exemptive relief for trusts containing guaranteed governmental mortgage pool certificates because the certificates in the trusts may be plan assets.

[30] Trust assets may also include obligations that are secured by leasehold interests on residential real property. See PTE 90–32 involving Prudential-Bache Securities, Inc. (55 FR 23147, June 6, 1990 at 23150).

[31] It is the view of the Department that section III.B.(4) includes within the definition of the term ''trust'' rights under any yield supplement or similar arrangement which obligates the sponsor or master servicer, or another party specified in the relevant pooling and servicing agreement, to supplement the interest rates otherwise payable on the obligations described in section III.B.(1), in accordance with the terms of a yield supplement arrangement described in the pooling and servicing agreement, provided that such arrangements do not involve swap agreement or other notional principal contracts.

certificateholders and delivered to or made available to each rating agency that has rated the certificates.

5. Some of the certificates will be multi-class certificates. ST requests exemptive relief for two types of multi-class certificates: ''strip'' certificates and ''fast-pay/slow-pay'' certificates. Strip certificates are a type of security in which the stream of interest payments on receivables is split from the flow of principal payments and separate classes of certificates are established, each representing rights to disproportionate payments of principal and interest.[32]

''Fast-pay/slow-pay'' certificates involve the issuance of classes of certificates having different stated maturities or the same maturities with different payment schedules. Interest and/or principal payments received on the underlying receivables are distributed first to the class of certificates having the earliest stated maturity of principal, and/or earlier payment schedule, and only when that class of certificates has been paid in full (or has received a specified amount) will distributions be made with respect to the second class of certificates. Distributions on certificates having later stated maturities will proceed in like manner until all the certificateholders have been paid in full. The only difference between this multi-class pass-through arrangement and a single-class pass-through arrangement is the order in which distributions are made to certificateholders. In each case, certificateholders will have a beneficial ownership interest in the underlying assets. In neither case will the rights of a plan purchasing a certificate be subordinated to the rights of another certificateholder in the event of default on any of the underlying obligations. In particular, if the amount available for distribution to certificateholders is less than the amount required to be so distributed, all senior certificateholders then entitled to receive distributions will share in the amount distributed on a pro rata basis.[33]

[32] It is the Department's understanding that where a plan invests in REMIC ''residual'' interest certificates to which this exemption applies, some of the income received by the plan as a result of such investment may be considered unrelated business taxable income to the plan, which is subject to income tax under the Code. The Department emphasizes that the prudence requirement of section 404(a)(1)(B) of the Act would require plan fiduciaries to carefully consider this and other tax consequences prior to causing plan assets to be invested in certificates pursuant to this exemption.

[33] If a trust issues subordinated certificates, holders of such subordinated certificates may not share in the amount distributed on a pro rata basis with the senior certificateholders. The Department notes that the exemption does not provide relief for plan investment in such subordinated certificates.

6. For tax reasons, the trust must be maintained as an essentially passive entity. Therefore, both the sponsor's discretion and the servicer's discretion with respect to assets included in a trust are severely limited. Pooling and servicing agreements provide for the substitution of receivables by the sponsor only in the event of defects in documentation discovered within a short time after the issuance of trust certificates (within 120 days, except in the case of obligations having an original term of 30 years, in which case the period will not exceed two years). Any receivable so substituted is required to have characteristics substantially similar to the replaced receivable and will be at least as creditworthy as the replaced receivable.

In some cases, the affected receivable would be repurchased, with the purchase price applied as a payment on the affected receivable and passed through to certificateholders.

Parties to Transactions

7. The *originator* of a receivable is the entity that initially lends money to a borrower (obligor), such as a home-owner or automobile purchaser, or leases property to a lessee. The originator may either retain a receivable in its portfolio or sell it to a purchaser, such as a trust sponsor.

Originators of receivables included in the trusts will be entities that originate receivables in the ordinary course of their business, including finance companies for whom such origination constitutes the bulk of their operations, financial institutions for whom such origination constitutes a substantial part of their operations, and any kind of manufacturer, merchant, or service enterprise for whom such origination is an incidental part of its operations. Each trust may contain assets of one or more originators. The originator of the receivables may also function as the trust sponsor or servicer.

8. The *sponsor* will be one of three entities: (i) A special-purpose or other corporation unaffiliated with the servicer, (ii) a special-purpose or other corporation affiliated with the servicer, or (iii) the servicer itself. Where the sponsor is not also the servicer, the sponsor's role will generally be limited to acquiring the receivables to be included in the trust, establishing the trust, designating the trustee, and assigning the receivables to the trust.

9. The *trustee* of a trust is the legal owner of the obligations in the trust. The trustee is also a party to or beneficiary of all the documents and instruments deposited in the trust, and as such is responsible for enforcing all the rights created thereby in favor of certificateholders.

The trustee will be an independent entity, and therefore will be unrelated to ST, the trust sponsor or the servicer. ST represents that the trustee will be a substantial financial institution or trust company experienced in trust activities. The trustee receives a fee for its services, which will be paid by the servicer or sponsor. The method of compensating the trustee which is specified in the pooling and servicing agreement will be disclosed in the prospectus or private placement memorandum relating to the offering of the certificates.

10. The *servicer* of a trust administers the receivables on behalf of the certificateholders. The servicer's functions typically involve, among other things, notifying borrowers of amounts due on receivables, maintaining records of payments received on receivables and instituting foreclosure or similar proceedings in the event of default. In cases where a pool of receivables has been purchased from a number of different originators and deposited in a trust, the receivables may be ''subserviced'' by their respective originators and a single entity may ''master service'' the pool of receivables on behalf of the owners of the related series of certificates. Where this arrangement is adopted, a receivable continues to be serviced from the perspective of the borrower by the local subservicer, while the investor's perspective is that the entire pool of receivables is serviced by a single, central master servicer who collects payments from the local subservicers and passes them through to certificateholders.

Receivables of the type suitable for inclusion in a trust invariably are serviced with the assistance of a computer. After the sale, the servicer keeps the sold receivables on the computer system in order to continue monitoring the accounts. Although the records relating to sold receivables are kept in the same master file as receivables retained by the originator, the sold receivables are flagged as having been sold. To protect the investor's interest, the servicer ordinarily covenants that this ''sold flag'' will be included in all records relating to the sold receivables, including the master file, archives, tape extracts and printouts.

The sold flags are invisible to the obligor and do not affect the manner in which the servicer performs the billing,

posting and collection procedures related to the sold receivables. However, the servicer uses the sold flag to identify the receivables for the purpose of reporting all activity on those receivables after their sale to investors.

Depending on the type of receivable and the details of the servicer's computer system, in some cases the servicer's internal reports can be adapted for investor reporting with little or no modification. In other cases, the servicer may have to perform special calculations to fulfill the investor reporting responsibilities. These calculations can be performed on the servicer's main computer, or on a small computer with data supplied by the main system. In all cases, the numbers produced for the investors are reconciled to the servicer's books and reviewed by public accountants.

The *underwriter* will be a registered broker-dealer that acts as underwriter or placement agent with respect to the sale of the certificates. Public offerings of certificates are generally made on a firm commitment basis. Private placement of certificates may be made on a firm commitment or agency basis. The lead or co-managing underwriters may make a market in certificates offered to the public.

In some cases, the originator and servicer of receivables to be included in a trust and the sponsor of the trust (although they may themselves be related) will be unrelated to ST. In other cases, however, affiliates of ST may originate or service receivables included in a trust or may sponsor a trust.

Certificate Price, Pass-Through Rate and Fees

11. In some cases, the sponsor will obtain the receivables from various originators pursuant to existing contracts with such originators under which the sponsor continually buys receivables. In other cases, the sponsor will purchase the receivables at fair market value from the originator or a third party pursuant to a purchase and sale agreement related to the specific offering of certificates. In other cases, the sponsor will originate the receivables itself.

As compensation for the receivables transferred to the trust, the sponsor receives certificates representing the entire beneficial interest in the trust, or the cash proceeds of the sale of such certificates. If the sponsor receives certificates from the trust, the sponsor sells all or a portion of these certificates for cash to investors or securities underwriters.

12. The price of the certificates, both in the initial offering and in the secondary market, is affected by market forces, including investor demand, the pass-through interest rate on the certificates in relation to the rate payable on investments of similar types and quality, expectations as to the effect on yield resulting from prepayment of underlying receivables, and expectations as to the likelihood of timely payment.

The pass-through rate for certificates is equal to the interest rate on receivables included in the trust minus a specified servicing fee.[34] This rate is generally determined by the same market forces that determine the price of a certificate. The price of a certificate and its pass-through, or coupon, rate together determine the yield to investors. If an investor purchases a certificate at less than par, that discount augments the stated pass-through rate; conversely, a certificate purchased at a premium yields less than the stated coupon.

13. As compensation for performing its servicing duties, the servicer (who may also be the sponsor or an affiliate thereof, and receive fees for acting in that capacity) will retain the difference between payments received on the receivables in the trust and payments payable (at the pass-through rate) to certificateholders, except that in some cases a portion of the payments on receivables may be paid to a third party, such as a fee paid to a provider of credit support. The servicer may receive additional compensation by having the use of the amounts paid on the receivables between the time they are received by the servicer and the time they are due to the trust (which time is set forth in the pooling and servicing agreement). The servicer typically will be required to pay the administrative expenses of servicing the trust, including in some cases the trustee's fee, out of its servicing compensation.

The servicer is also compensated to the extent it may provide credit enhancement to the trust or otherwise arrange to obtain credit support from another party. This ''credit support fee'' may be aggregated with other servicing fees, and is either paid out of the interest income received on the receivables in excess of the pass-through rate or paid in a lump sum at the time the trust is established.

14. The servicer may be entitled to retain certain administrative fees paid by a third party, usually the obligor. These administrative fees fall into three categories: (a) prepayment fees; (b) late payment and payment extension fees; and (c) expenses, fees and charges associated with foreclosure or repossession, or other conversion of a secured position into cash proceeds, upon default of an obligation.

Compensation payable to the servicer will be set forth or referred to in the pooling and servicing agreement and described in reasonable detail in the prospectus or private placement memorandum relating to the certificates.

15. Payments on receivables may be made by obligors to the servicer at various times during the period preceding any date on which pass-through payments to the trust are due. In some cases, the pooling and servicing agreement may permit the servicer to place these payments in non-interest bearing accounts maintained with itself or to commingle such payments with its own funds prior to the distribution dates. In these cases, the servicer would be entitled to the benefit derived from the use of the funds between the date of payment on a receivable and the pass-through date. Commingled payments may not be protected from the creditors of the servicer in the event of the servicer's bankruptcy or receivership. In those instances when payments on receivables are held in non-interest bearing accounts or are commingled with the servicer's own funds, the servicer is required to deposit these payments by a date specified in the pooling and servicing agreement into an account from which the trustee makes payments to certificateholders.

16. The underwriter will receive a fee in connection with the securities underwriting or private placement of certificates. In a firm commitment underwriting, this fee would consist of the difference between what the underwriter receives for the certificates that it distributes and what it pays the sponsor for those certificates. In a private placement, the fee normally takes the form of an agency commission paid by the sponsor. In a best efforts underwriting in which the underwriter would sell certificates in a public offering on an agency basis, the underwriter would receive an agency commission rather than a fee based on the difference between the price at which the certificates are sold to the public and what it pays the sponsor. In some private placements, the underwriter may buy certificates as principal, in which case its compensation would be the difference between what it receives for the certificates that it sells and what it pays the sponsor for these certificates.

[34] The pass-through rate on certificates representing interests in trusts holding leases is determined by breaking down lease payments into ''principal'' and ''interest'' components based on an implicit interest rate.

Purchase of Receivables by the Servicer

17. The applicant represents that as the principal amount of the receivables in a trust is reduced by payments, the cost of administering the trust generally increases, making the servicing of the trust prohibitively expensive at some point. Consequently, the pooling and servicing agreement generally provides that the servicer may purchase the receivables remaining in the trust when the aggregate unpaid balance payable on the receivables is reduced to a specified percentage (usually 5 to 10 percent) of the initial aggregate unpaid balance.

The purchase price of a receivable is specified in the pooling and servicing agreement and will be at least equal to: (1) The unpaid principal balance on the receivable plus accrued interest, less any unreimbursed advances of principal made by the servicer; or (2) the greater of (a) the amount in (1) or (b) the fair market value of such obligations in the case of a REMIC, or the fair market value of the receivables in the case of a trust that is not a REMIC.

Certificate Ratings

18. The certificates will have received one of the three highest ratings available from either S&P's, Moody's, D&P or Fitch. Insurance or other credit support (such as surety bonds, letters of credit, guarantees, or overcollateralization) will be obtained by the trust sponsor to the extent necessary for the certificates to attain the desired rating. The amount of this credit support is set by the rating agencies at a level that is a multiple of the worst historical net credit loss experience for the type of obligations included in the issuing trust.

Provision of Credit Support

19. In some cases, the master servicer, or an affiliate of the master servicer, may provide credit support to the trust (i.e. act as an insurer). In these cases, the master servicer, in its capacity as servicer, will first advance funds to the full extent that it determines that such advances will be recoverable (a) out of late payments by the obligors, (b) from the credit support provider (which may be the master servicer or an affiliate thereof) or, (c) in the case of a trust that issues subordinated certificates, from amounts otherwise distributable to holders of subordinated certificates, and the master servicer will advance such funds in a timely manner. When the servicer is the provider of the credit support and provides its own funds to cover defaulted payments, it will do so either on the initiative of the trustee, or on its own initiative on behalf of the trustee, but in either event it will provide such funds to cover payments to the full extent of its obligations under the credit support mechanism. In some cases, however, the master servicer may not be obligated to advance funds but instead would be called upon to provide funds to cover defaulted payments to the full extent of its obligations as insurer. Moreover, a master servicer typically can recover advances either from the provider of credit support or from future payments on the affected assets.

If the master servicer fails to advance funds, fails to call upon the credit support mechanism to provide funds to cover delinquent payments, or otherwise fails in its duties, the trustee would be required and would be able to enforce the certificateholders' rights, as both a party to the pooling and servicing agreement and the owner of the trust estate, including rights under the credit support mechanism. Therefore, the trustee, who is independent of the servicer, will have the ultimate right to enforce the credit support arrangement.

When a master servicer advances funds, the amount so advanced is recoverable by the master servicer out of future payments on receivables held by the trust to the extent not covered by credit support. However, where the master servicer provides credit support to the trust, there are protections in place to guard against a delay in calling upon the credit support to take advantage of the fact that the credit support declines proportionally with the decrease in the principal amount of the obligations in the trust as payments on receivables are passed through to investors. These safeguards include:

(a) There is often a disincentive to postponing credit losses because the sooner repossession or foreclosure activities are commenced, the more value that can be realized on the security for the obligation;

(b) The master servicer has servicing guidelines which include a general policy as to the allowable delinquency period after which an obligation ordinarily will be deemed uncollectible. The pooling and servicing agreement will require the master servicer to follow its normal servicing guidelines and will set forth the master servicer's general policy as to the period of time after which delinquent obligations ordinarily will be considered uncollectible;

(c) As frequently as payments are due on the receivables included in the trust (monthly, quarterly or semi-annually, as set forth in the pooling and servicing agreement), the master servicer is required to report to the independent trustee the amount of all past-due payments and the amount of all servicer advances, along with other current information as to collections on the receivables and draws upon the credit support. Further, the master servicer is required to deliver to the trustee annually a certificate of an executive officer of the master servicer stating that a review of the servicing activities has been made under such officer's supervision, and either stating that the master servicer has fulfilled all of its obligations under the pooling and servicing agreement or, if the master servicer has defaulted under any of its obligations, specifying any such default. The master servicer's reports are reviewed at least annually by independent accountants to ensure that the master servicer is following its normal servicing standards and that the master servicer's reports conform to the master servicer's internal accounting records. The results of the independent accountants' review are delivered to the trustee; and

(d) The credit support has a ''floor'' dollar amount that protects investors against the possibility that a large number of credit losses might occur towards the end of the life of the trust, whether due to servicer advances or any other cause. Once the floor amount has been reached, the servicer lacks an incentive to postpone the recognition of credit losses because the credit support amount thereafter is subject to reduction only for actual draws. From the time that the floor amount is effective until the end of the life of the trust, there are no proportionate reductions in the credit support amount caused by reductions in the pool principal balance. Indeed, since the floor is a fixed dollar amount, the amount of credit support ordinarily increases as a percentage of the pool principal balance during the period that the floor is in effect.

Disclosure

20. In connection with the original issuance of certificates, the prospectus or private placement memorandum will be furnished to investing plans. The prospectus or private placement memorandum will contain information material to a fiduciary's decision to invest in the certificates, including:

(a) Information concerning the payment terms of the certificates, the rating of the certificates, and any material risk factors with respect to the certificates;

(b) A description of the trust as a legal entity and a description of how the trust was formed by the seller/servicer or other sponsor of the transaction;

(c) Identification of the independent trustee for the trust;

(d) A description of the receivables contained in the trust, including the types of receivables, the diversification of the receivables, their principal terms, and their material legal aspects;

(e) A description of the sponsor and servicer;

(f) A description of the pooling and servicing agreement, including a description of the seller's principal representations and warranties as to the trust assets and the trustee's remedy for any breach thereof; a description of the procedures for collection of payments on receivables and for making distributions to investors, and a description of the accounts into which such payments are deposited and from which such distributions are made; identification of the servicing compensation and any fees for credit enhancement that are deducted from payments on receivables before distributions are made to investors; a description of periodic statements provided to the trustee, and provided to or made available to investors by the trustee; and a description of the events that constitute events of default under the pooling and servicing contract and a description of the trustee's and the investors' remedies incident thereto;

(g) A description of the credit support;

(h) A general discussion of the principal federal income tax consequences of the purchase, ownership and disposition of the pass-through securities by a typical investor;

(i) A description of the underwriters' plan for distributing the pass-through securities to investors; and

(j) Information about the scope and nature of the secondary market, if any, for the certificates.

21. Reports indicating the amount of payments of principal and interest are provided to certificateholders at least as frequently as distributions are made to certificateholders. Certificateholders will also be provided with periodic information statements setting forth material information concerning the underlying assets, including, where applicable, information as to the amount and number of delinquent and defaulted loans or receivables.

22. In the case of a trust that offers and sells certificates in a registered public offering, the trustee, the servicer or the sponsor will file such periodic reports as may be required to be filed under the Securities Exchange Act of 1934. Although some trusts that offer certificates in a public offering will file quarterly reports on Form 10–Q and Annual Reports on Form 10–K, many trusts obtain, by application to the Securities and Exchange Commission, a complete exemption from the requirement to file quarterly reports on Form 10–Q and a modification of the disclosure requirements for annual reports on Form 10–K. If such an exemption is obtained, these trusts normally would continue to have the obligation to file current reports on Form 8–K to report material developments concerning the trust and the certificates. While the Securities and Exchange Commission's interpretation of the periodic reporting requirements is subject to change, periodic reports concerning a trust will be filed to the extent required under the Securities Exchange Act of 1934.

23. At or about the time distributions are made to certificateholders, a report will be delivered to the trustee as to the status of the trust and its assets, including underlying obligations. Such report will typically contain information regarding the trust's assets, payments received or collected by the servicer, the amount of prepayments, delinquencies, servicer advances, defaults and foreclosures, the amount of any payments made pursuant to any credit support, and the amount of compensation payable to the servicer. Such report also will be delivered to or made available to the rating agency or agencies that have rated the trust's certificates.

In addition, promptly after each distribution date, certificateholders will receive a statement prepared by the servicer, paying agent or trustee summarizing information regarding the trust and its assets. Such statement will include information regarding the trust and its assets, including underlying receivables. Such statement will typically contain information regarding payments and prepayments, delinquencies, the remaining amount of the guaranty or other credit support and a breakdown of payments between principal and interest.

Forward Delivery Commitments

24. To date, no forward delivery commitments have been entered into by ST in connection with the offering of any certificates, but ST may contemplate entering into such commitments. The utility of forward delivery commitments has been recognized with respect to offering similar certificates backed by pools of residential mortgages, and ST may find it desirable in the future to enter into such commitments for the purchase of certificates.

Secondary Market Transactions

25. ST anticipates that it may make a market in certificates for which it is lead or co-managing underwriter.

Retroactive Relief

26. ST represents that it has not assumed that retroactive relief would be granted prior to the date of its application, and therefore has not engaged in transactions related to mortgage-backed and asset-backed securities based on such an assumption. However, ST requests the exemptive relief granted to be retroactive to October 25, 1996, the date of its application, and would like to rely on such retroactive relief for transactions entered into prior to the date exemptive relief may be granted.

Summary

27. In summary, the applicant represents that the transactions for which exemptive relief is requested satisfy the statutory criteria of section 408(a) of the Act due to the following:

(a) The trusts contain ''fixed pools'' of assets. There is little discretion on the part of the trust sponsor to substitute receivables contained in the trust once the trust has been formed;

(b) Certificates in which plans invest will have been rated in one of the three highest rating categories by S&P's, Moody's, D&P or Fitch. Credit support will be obtained to the extent necessary to attain the desired rating;

(c) All transactions for which ST seeks exemptive relief will be governed by the pooling and servicing agreement, which is made available to plan fiduciaries for their review prior to the plan's investment in certificates;

(d) Exemptive relief from sections 406(b) and 407 for sales to plans is substantially limited; and

(e) ST may make a secondary market in certificates.

Discussion of Proposed Exemption

I. Differences between Proposed Exemption and Class Exemption PTE 83–1

The exemptive relief proposed herein is similar to that provided in PTE 81–7 [46 FR 7520, January 23, 1981], Class Exemption for Certain Transactions Involving Mortgage Pool Investment Trusts, amended and restated as PTE 83–1 [48 FR 895, January 7, 1983].

PTE 83–1 applies to mortgage pool investment trusts consisting of interest-bearing obligations secured by first or second mortgages or deeds of trust on single-family residential property. The exemption provides relief from sections 406(a) and 407 for the sale, exchange or

transfer in the initial issuance of mortgage pool certificates between the trust sponsor and a plan, when the sponsor, trustee or insurer of the trust is a party-in-interest with respect to the plan, and the continued holding of such certificates, provided that the conditions set forth in the exemption are met. PTE 83–1 also provides exemptive relief from section 406 (b)(1) and (b)(2) of the Act for the above-described transactions when the sponsor, trustee or insurer of the trust is a fiduciary with respect to the plan assets invested in such certificates, provided that additional conditions set forth in the exemption are met. In particular, section 406(b) relief is conditioned upon the approval of the transaction by an independent fiduciary. Moreover, the total value of certificates purchased by a plan must not exceed 25 percent of the amount of the issue, and at least 50 percent of the aggregate amount of the issue must be acquired by persons independent of the trust sponsor, trustee or insurer. Finally, PTE 83–1 provides conditional exemptive relief from section 406(a) and (b) of the Act for transactions in connection with the servicing and operation of the mortgage trust.

Under PTE 83–1, exemptive relief for the above transactions is conditioned upon the sponsor and the trustee of the mortgage trust maintaining a system for insuring or otherwise protecting the pooled mortgage loans and the property securing such loans, and for indemnifying certificateholders against reductions in pass-through payments due to defaults in loan payments or property damage. This system must provide such protection and indemnification up to an amount not less than the greater of one percent of the aggregate principal balance of all trust mortgages or the principal balance of the largest mortgage.

The exemptive relief proposed herein differs from that provided by PTE 83–1 in the following major respects: (1) The proposed exemption provides individual exemptive relief rather than class relief; (2) The proposed exemption covers transactions involving trusts containing a broader range of assets than single-family residential mortgages; (3) Instead of requiring a system for insuring the pooled receivables, the proposed exemption conditions relief upon the certificates having received one of the three highest ratings available from S&P's, Moody's, D&P or Fitch (insurance or other credit support would be obtained only to the extent necessary for the certificates to attain the desired rating); and (4) The proposed exemption provides more limited section 406(b) and section 407 relief for sales transactions.

II. Ratings of Certificates

After consideration of the representations of the applicant and information provided by S&P's, Moody's, D&P and Fitch, the Department has decided to condition exemptive relief upon the certificates having attained a rating in one of the three highest generic rating categories from S&P's, Moody's, D&P or Fitch. The Department believes that the rating condition will permit the applicant flexibility in structuring trusts containing a variety of mortgages and other receivables while ensuring that the interests of plans investing in certificates are protected. The Department also believes that the ratings are indicative of the relative safety of investments in trusts containing secured receivables. The Department is conditioning the proposed exemptive relief upon each particular type of asset-backed security having been rated in one of the three highest rating categories for at least one year and having been sold to investors other than plans for at least one year.[35]

III. Limited Section 406(b) and Section 407(a) Relief for Sales

ST represents that in some cases a trust sponsor, trustee, servicer, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates may be a pre-existing party in interest with respect to an investing plan.[36] In these cases, a direct or indirect sale of certificates by that party in interest to the plan would be a prohibited sale or exchange of property under section 406(a)(1)(A) of the Act.[37] Likewise, issues are raised under section 406(a)(1)(D) of the Act where a plan fiduciary causes a plan to purchase certificates where trust funds will be used to benefit a party in interest.

Additionally, ST represents that a trust sponsor, servicer, trustee, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates representing an interest in a trust may be a fiduciary with respect to an investing plan. ST represents that the exercise of fiduciary authority by any of these parties to cause the plan to invest in certificates representing an interest in the trust would violate section 406(b)(1), and in some cases section 406(b)(2), of the Act.

Moreover, ST represents that to the extent there is a plan asset ''look through'' to the underlying assets of a trust, the investment in certificates by a plan covering employees of an obligor with respect to receivables contained in a trust may be prohibited by sections 406(a) and 407(a) of the Act.

After consideration of the issues involved, the Department has determined to provide the limited sections 406(b) and 407(a) relief as specified in the proposed exemption.

NOTICE TO INTERESTED PERSONS: The applicant represents that because those potentially interested participants and beneficiaries cannot all be identified, the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the Federal Register. Comments and requests for a hearing must be received by the Department not later than 30 days from the date of publication of this notice of proposed exemption in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Gary Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary

[35] In referring to different ''types'' of asset-backed securities, the Department means certificates representing interests in trusts containing different ''types'' of receivables, such as single family residential mortgages, multi-family residential mortgages, commercial mortgages, home equity loans, auto loan receivables, installment obligations for consumer durables secured by purchase money security interests, etc. The Department intends this condition to require that certificates in which a plan invests are of the type that have been rated (in one of the three highest generic rating categories by S&P's, D&P, Fitch or Moody's) and purchased by investors other than plans for at least one year prior to the plan's investment pursuant to the proposed exemption. In this regard, the Department does not intend to require that the particular assets contained in a trust must have been ''seasoned'' (e.g., originated at least one year prior to the plan's investment in the trust).

[36] In this regard, we note that the exemptive relief proposed herein is limited to certificates with respect to which ST or any of its affiliates is either (a) the sole underwriter or manager or co-manager of the underwriting syndicate, or (b) a selling or placement agent.

[37] The applicant represents that where a trust sponsor is an affiliate of ST, sales to plans by the sponsor may be exempt under PTE 75–1, Part II (relating to purchases and sales of securities by broker-dealers and their affiliates), if ST is not a fiduciary with respect to plan assets to be invested in certificates.

responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 26th day of November, 1996.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 96–30720 Filed 12–2–96; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96–137]

NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee, NASA–NIH Advisory Subcommittee on Behavioral and Biomedical Research; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Life and Microgravity Sciences and Applications Advisory Committee, NASA–NIH Advisory Subcommittee on Behavioral and Biomedical Research.

DATES: December 19, 1996, 8:30 a.m. to 5:30 p.m.; and December 20, 1996, 8:00 a.m. to 12:30 p.m.

ADDRESSES: NASA Headquarters, Room 7H46, 300 E Street SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Diana P. Hoyt, Code UP, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1893.

SUPPLEMENTARY INFORMATION: The meeting will be closed to the public on Thursday, December 19, 1996, from 5:00 p.m. to 5:30 p.m. in accordance with 5 U.S.C. 552b (c)(6), to allow for discussion on qualifications of individuals being considered for membership to the Committee. The remainder of the meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Review of the office of Life and Microgravity Sciences and Applications Status
—Status of NASA–NIH Activities
—Neurolab
—Behavioral Studies
—Pharmacology
—Global Health and Remote Sensing
—Update on Centrifuge
—NASA–Mir Studies
—ISS Prioritization
—Science Institute
—Committee Discussion Regarding Future Activities

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: November 25, 1996.

Leslie M. Nolan,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 96–30771 Filed 12–2–96; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Meeting; Sunshine Act

TIME AND DATE: 5:00 p.m., Friday, December 6, 1996.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Open.

MATTER TO BE CONSIDERED:

1. Request from a Federal Credit Union to Convert to a Community Charter.
2. Request from a Federal Credit Union to Convert to a Group Community Charter.

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone 703–518–6304.

Beckey Baker,

Secretary of the Board.

[FR Doc. 96–30905 Filed 11–29–96; 2:37 pm]

BILLING CODE 7535–01–M

NUCLEAR REGULATORY COMMISSION

[DOCKET No. 50–368]

Arkansas Nuclear One, Unit 2; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–6 issued to Entergy Operations, Inc. for operation of Arkansas Nuclear One, Unit 2 (ANO–2) located in Pope County, Arkansas.

The proposed amendment would change the Small-Break Loss-of-Coolant Accident (SBLOCA) evaluation code CENPD–137, Supplement 1–P, as the preferred evaluation method. This methodology has been applied with a steam generator tube plugging limit of 30% and an associated 10% reduction in Reactor Coolant System (RCS) flow.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Criterion 1—Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The proposed change to reference CENPD–137, Supplement 1–P is administrative in nature. The current referenced SBLOCA methodology is being supplemented with a more recently approved methodology which has demonstrated acceptable results with respect to 10 CFR 50.46 for the ANO–2 SBLOCA analysis. CENPD–137, Supplement 1–P has been independently reviewed and approved by the NRC. Technical specifications will continue to require operation within the core operational limits for each cycle reload calculated by the approved reload design methodologies. Cycle-specific evaluations performed in accordance with 10 CFR 50.59 demonstrate that changes in fuel cycle design do not involve an unreviewed safety question. Although there is an increase in the results (PCT, maximum cladding oxidation, and core-wide cladding oxidation) of the SBLOCA analysis, the increase is primarily due to the methodology change. The more recently approved methodology allows steam generator tube plugging up to 30% for SBLOCA analysis, but the increase in the results due to steam generator tube plugging is very small when compared to the increase due to the methodology change. The safety analyses will continue to be performed utilizing NRC-approved methodologies, and specific reload changes will be evaluated per 10 CFR 50.59.

Therefore, this change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2—Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

The proposed change to reference the current NRC-approved SBLOCA methodology is administrative in nature. The more recently approved methodology has demonstrated acceptable results for ANO–2. No changes to plant operating procedures or operating parameters are proposed. The safety analyses will continue to be performed utilizing NRC-approved methodologies, and specific reload changes will be evaluated per 10 CFR 50.59. No new equipment is being introduced, and no equipment is being operated in a manner inconsistent with its design.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3—Does Not Involve a Significant Reduction in the Margin of Safety.

The proposed change to reference the NRC-approved CENPD–137, Supplement 1–P SBLOCA methodology is administrative in nature. The margin of safety as defined by 10 CFR 50.46 has not been significantly reduced. There is an increase in the results (PCT, maximum cladding oxidation, and core-wide cladding oxidation) of the SBLOCA analysis utilizing this methodology; however, the increase is primarily due to the methodology change and remains within the limits specified in 10 CFR 50.46. The more recently approved methodology allows steam generator tube plugging up to 30% for SBLOCA analysis, but the increase in the results due to steam generator tube plugging is very small when compared to the increase due to the methodology change.

The development of limits for a particular cycle will continue to conform to the methods described in NRC-approved documentation. Technical specifications will continue to require that the core be operated within these limits and specify appropriate actions to be taken if the limits are violated. Each reload undergoes a 10 CFR 50.59 safety review to assure that operation of the unit within the cycle-specific limits will not involve an unreviewed safety question. The safety analyses will continue to be performed utilizing NRC-approved methodologies.

Therefore, this change does not involve a significant reduction in the margin of safety.

Therefore, based upon the reasoning presented above and the previous discussion of the amendment request, Entergy Operations has determined that the requested change does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By January 2, 1997, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene.

Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to William D. Beckner, Director, Project Directorate IV–1: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Mr. Nicholas S. Reynolds, Winston & Strawn, 1400 L Street, NW, Washington, DC 20005–3502, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a) (1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated November 24, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Dated at Rockville, Maryland, this 26th day of November 1996.

For the Nuclear Regulatory Commission.

Kombiz Salehi,

Acting Project Manager, Project Directorate IV–1, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–30712 Filed 12–2–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–498]

Houston Lighting and Power Company, City Public Board of San Antonio, Central Power and Light Company, City of Austin, Texas; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Houston Lighting & Power Company, et al., (the licensee) to withdraw its February 29, 1996, application for proposed amendment to Facility Operating License No. NPF–76 for the South Texas Project, Unit No. 1, located in Matagorda County, Texas.

The proposed amendment would have included the addition of Technical Specification 3.10.8 to allow a one-time only extension of the standby diesel generator (SDG) allowed outage time for a cumulative of 21 days on ''A'' train SDG. In addition, it would have also allowed a one-time only extension of the allowed outage time on ''A'' train essential cooling water loop for a cumulative 7 days. This one-time only change would have become effective on April 10, 1996, and expire on May 15, 1996.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the Federal Register on March 8, 1996 (61 FR 9502). However, by letter dated November 5, 1996, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated February 29, 1996, and the licensee's letter dated November 5, 1996, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488.

Dated at Rockville, Maryland, this 25th day of November 1996.

For the Nuclear Regulatory Commission.

Thomas W. Alexion,

Project Manager, Project Directorate IV–1, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–30711 Filed 12–2–96; 8:45 am]

BILLING CODE 7590–01–P

Sunshine Act Meeting

DATE: Weeks of December 2, 9, 16 and 23, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of December 2

Friday, December 6

9:30 a.m.
Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting)
(Contact: John Larkins, 301–415–7360)

11:00 a.m.
Affirmation Session (Public Meeting)
(Please Note: This item will be affirmed immediately following the conclusion of the preceding meeting.)
a. Certification of Two Evolutionary Designs (tentative)
(Contact: Andy Bates, 301–415–1663)

Week of December 9—Tentative

Thursday, December 12

3:30 p.m.
Affirmation Session (Public Meeting) (if needed)

Week of December 16—Tentative

Monday, December 16

2:00 p.m.
Briefing on Inspection Criteria, Evolution of Assessment, and SALP System (Public Meeting)

Tuesday, December 17

2:00 p.m.
Meeting with Chairman of Nuclear Safety Research Review Committee (NSRRC) (Public Meeting)
(Contact: Jose Cortez, 301–415–6596)

3:00 p.m.
Affirmation Session (Public Meeting)

Week of December 23—Tentative

There are no meetings scheduled for the Week of December 23.

By a vote of 4–0 on November 22, the Commission determined pursuant to U.S.C. 552b(e) and 10 CFR Sec. 9.107(a) of the Commission's rules that ''Affirmation of Petitions for Commission Review of Director's Decision on Certification of Gaseous Diffusion Plants'' be Held on November 22, and on less than one week's notice to the public.

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 415–1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at:

http://www.nrc.gov/SECY/smj/schedule.htm

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

Dated: November 29, 1996.

William M. Hill, Jr.

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 96–30909 Filed 11–29–96; 2:49 pm]

BILLING CODE 7590–01–M

Updated Standard Review Plan Chapter 7: Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and request for comments.

SUMMARY: The Nuclear Regulatory Commission (NRC) has prepared an update to Chapter 7 of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,'' (SRP) for review and comments. The updated SRP Chapter 7 incorporates changes in the NRC review criteria in the area of instrumentation and control (I&C) systems, particularly digital computer-based I&C systems of nuclear power plants that have occurred since the last major revision of the SRP in 1981.

The revisions were derived from the following programmatic areas: NRC regulatory documents issued after the 1981 SRP revision; NRC staff positions related to digital I&C retrofits at operating nuclear power plants as documented in relevant safety evaluation reports; industry consensus standards applicable to I&C systems; NRC staff positions related to evolutionary and advanced light water reactor design reviews as presented in SECY–91–292, ''Digital Computer Systems for Advanced Light Water Reactors,'' and the Staff Requirements Memorandum on SECY–93–087, ''Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light Water Reactor (ALWR) Designs;'' NRC design certification safety evaluation reports for the General Electric Advanced Boiling Water Reactor Design and the ABB–CE System 80+ Design; and nuclear power plant operating experience.

DATES: The comment period expires January 31, 1997. Comments received after this date will be considered if practical to do so, but the Commission is able to assure consideration only of comments received on or before this date.

ADDRESSES: Mail comments to: Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publication Services, Mail Stop T–6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Comments may be hand delivered to 11545 Rockville Pike, Rockville, MD between 7:45 a.m. and 4:15 p.m. on Federal work-days. Comments may be submitted electronically as specified in the supplementary information section of this notice.

FOR FURTHER INFORMATION CONTACT: Matthew Chiramal, Instrumentation and Controls Branch, Office of Nuclear Reactor Regulation, Mail Stop O–8H3, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Telephone No. (301) 415–2845.

SUPPLEMENTARY INFORMATION: The proposed revised text to Chapter 7 of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants—LWR Edition,'' (SRP), is being published as a draft report for comments. Further NRC staff review and evaluation, including resolution of public comments, will be needed before a final revision of Chapter 7 of the SRP can be published.

The draft Chapter 7 of the SRP that is available for public review consists of revised SRP sections and appendices with side-bars that show the major technical changes resulting from the updating of the existing SRP Chapter 7 sections and new sections, appendices and branch technical positions. Three new sections are added: Section 7.0, Introduction, Section 7.8, Diverse Instrumentation and Control Systems, and Section 7.9, Data Communication Systems. Section 7.1 which contains the general I&C system requirements and guidance has been revised to incorporate (1) references to new regulatory guides (RGs) and branch technical positions (BTPs) on digital computer-based I&C system issues, (2) review areas, acceptance criteria, and review process for digital computer-based I&C systems, and (3) discussion of standard plant reviews. Sections 7.2 through 7.9 that focus on specific nuclear power plant I&C systems have been revised to add reference to the digital I&C system guidance contained in the revised Section 7.1. Two new appendices have been added and three have been revised. Appendix 7.0–A is a new appendix that describes the overall NRC review process for digital computer-based I&C systems and new Appendix 7.1–C provides guidance with

respect to the NRC review according to IEEE Standard 603. Revised Appendix 7.1–A addresses rule changes (10 CFR Part 52 and revisions to 10 CFR Part 50) and identifies new regulatory guides on the digital system design process. Revised Appendix 7.1–B incorporates digital I&C system topics into the review for compliance with the requirements of IEEE Standard 279 as stated in 10 CFR 50.55a(h). Revised Appendix 7–A includes the new BTPs.

The updated SRP Chapter 7 does not, by itself, establish any new or revised requirements. It incorporates lessons learned from the completed reviews of I&C systems in the advanced light water reactors and digital I&C system retrofits of operating reactors. The review guidance described in the updated SRP Chapter 7 will be used by the NRC staff in the evaluation of submittals in connection with applications for construction permits, standard design certifications and design approvals, combined operating licenses, and operating plant license amendments.

Work related to updating SRP Chapter 7 was performed in accordance with the guidance in NUREG–1447, ''Standard Review Plan Update and Development Program—Implementing Procedures Document,'' dated May 1992.

The purpose of this notice is to solicit public comment on whether the revised text accurately and fully reflects established NRC staff review criteria, positions and existing regulations. The updated draft SRP Chapter 7 and the supporting referenced documents provide traceability back to the changes made to the SRP Chapter 7 currently in effect. The draft SRP Chapter 7 is made available to the public as part of the NRC's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Comments will be considered and revisions made to the draft SRP Chapter 7 as appropriate based on the comments received. The final SRP Chapter 7 update will be issued in approximately mid-1997. SRP Chapter 7 will be revised periodically, as appropriate, to accommodate future new technologies, information, and experience. The NRC encourages comment from interested parties; however, public review is not intended to reopen a dialogue on the merits of the requirements themselves, but should be focused on the purpose stated above. The NRC also requests specific comments on whether an appropriate level of detailed guidance has been provided for the NRC staff reviewers in the proposed Chapter 7 update particularly with regard to digital I&C review criteria.

Electronic Submission of Comments

The draft SRP Chapter 7 can be accessed from the NRC Homepage on the World Wide Web—URL: http://www.nrc.gov under the ''News and Information'' or the ''Nuclear Reactors'' menu options by selecting ''Standard Review Plan Chapter 7, Instrumentation and Controls—Draft report for comments.'' Specific guidance is provided on-line to guide the user on the various options available for reading, commenting on, and downloading the document.

Chapter 7 of the SRP is available in printed form on paper for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC 20555.

A limited number of copies of the draft SRP Chapter 7 in the printed form on paper are available free, to the extent of supply, upon written request to the Office of Administration, Distribution Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Dated at Rockville, Maryland, this 25th day of November, 1996.

For the Nuclear Regulatory Commission.

Jared Wermiel,

Chief, Instrumentation and Controls Branch, Division of Reactor Controls and Human Factors, Office of Nuclear Reactor Regulation.

[FR Doc. 96–30713 Filed 12–2–96; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

The National Partnership Council

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

TIME AND DATE: 1:00 p.m., December 11, 1996.

PLACE: OPM Conference Center, Room 1350, Theodore Roosevelt Building, 1900 E Street, NW., Washington, DC 20415–0001. The conference center is located on the first floor.

STATUS: This meeting will be open to the public. Seating will be available on a first-come, first-served basis. Individuals with special access needs wishing to attend should contact OPM at the number shown below to obtain appropriate accommodations.

MATTERS TO BE CONSIDERED: The National Partnership Council (NPC) will approve and adopt its 1996 Report to the President and will work on its strategic action plan and meeting calendar for 1997.

CONTACT PERSON FOR MORE INFORMATION: Michael Cushing, Director, Center for Partnership and Labor-Management Relations, Office of Personnel Management, Theodore Roosevelt Building, 1900 E Street, NW., Room 7H28, Washington, DC 20415–0001, (202) 606–0010.

SUPPLEMENTARY INFORMATION: We invite interested persons and organizations to submit written comments. Mail or deliver your comments to Michael Cushing at the address shown above. To be considered at the December 11 meeting, written comments should be received by December 6.

Office of Personnel Management

James B. King,

Director.

[FR Doc. 96–30822 Filed 12–2–96; 8:45 am]

BILLING CODE 6325–01–M

RAILROAD RETIREMENT BOARD

Proposed Data Collection Available for Public Comment and Recommendations

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

COMMENTS ARE INVITED ON: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection

Employer's Quarterly Report of Contributions Under the Railroad Unemployment Insurance Act; OMB 3220–0012. Under Section 8 of the Railroad Unemployment Insurance Act (RUIA), as amended by the Railroad Unemployment Improvement Act of 1988 (Pub. L. 100–647), the amount of each employer's contribution is determined by the RRB, primarily on the basis of RUIA benefit payments made to the employees of that employer. These experience based contributions take into account the frequency, volume

and duration of RUIA benefits, both unemployment and sickness, attributable to a railroad's employees. Each employer's contribution rate includes a component for administrative expenses and a component to cover costs shared by all employers. The regulations prescribing the manner and conditions for remitting the contributions and for adjusting overpayments or underpayments of contributions are contained in 20 CFR 345.

RRB Form DC–1, Employer's Quarterly Report of Contributions Under the Railroad Unemployment Insurance Act, is utilized by the RRB for the reporting and remitting of quarterly contributions by railroad employers. One response is requested quarterly of each respondent. Completion is mandatory. The RRB proposed a minor editorial revision to Form DC–1 to insert language required by the Paperwork Reduction Act of 1995.

Estimate of Annual Respondent Burden

The estimated annual respondent burden is as follows:

Form #(s)	Annual re-sponses	Time (min)	Burden (hrs)
DC–1	2,200	25	917

ADDITIONAL INFORMATION OR COMMENTS: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092. Written comments should be received within 60 days of this notice.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 96–30734 Filed 12–2–96; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22351; File No. 812–10248]

The Chubb Series Trust, et al.

November 25, 1996.

AGENCY: U.S. Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the ''the 1940 Act'').

APPLICANTS: The Chubb Series Trust (the ''Trust''), Chubb Investment Advisory Corporation (''Chubb Investment Advisory'') and Morgan Guaranty Trust Company of New York (''Morgan'').

RELEVANT ACT SECTIONS: Order requested pursuant to Section 6(c) of the 1940 Act from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and subparagraph (b)(15) of Rules 6e–2 and 6e–3(T) thereunder.

SUMMARY OF APPLICATION: Applicants seek an order granting exemptions from the 1940 Act to the extent necessary to permit shares of any current or future series of the Trust and shares of any other investment company that is designed to fund variable insurance products and for which Chubb Investment Advisory or Morgan or any of their affiliates may serve as investment adviser, administrator, manager, principal underwriter or sponsor (the Trust and such other investment companies are hereinafter referred to collectively as the ''Funds'') to be sold to and held by: (i) variable annuity and variable life insurance separate accounts of both affiliated and unaffiliated life insurance companies (''Participating Insurance Companies''); and (ii) qualified pension and retirement plans outside the separate account context (''Plans'').

FILING DATE: The application was filed on July 12, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the Secretary of the SEC and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 20, 1996, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the SEC.

ADDRESSES: SEC, Secretary, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, The Chubb Series Trust and Chubb Investment Advisory Corporation, One Granite Place, Concord, New Hampshire 03301, Attn. General Counsel, or Morgan Guaranty Trust Company of New York, 60 Wall Street, New York, New York 10260, Attn. Funds Management Division.

FOR FURTHER INFORMATION CONTACT: Edward P. Macdonald, Staff Attorney, or Patrice M. Pitts, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the Public Reference Branch of the SEC.

Applicants' Representations

1. The Trust, organized as a Delaware business trust on October 28, 1993, is registered under the 1940 Act as an open-end management investment company. The Trust currently consists of five separate series. Additional series may be added in the future.

2. Chubb Investment Advisory, a wholly-owned subsidiary of Chubb Life Insurance Company of America (''Chubb Life''), is registered under the Investment Advisers Act of 1940, as amended, and serves as the Trust's investment manager.

3. Morgan, a New York trust company which conducts a general banking and trust business, serves as the Trust's sub-investment adviser. Morgan is a wholly-owned subsidiary of J.P. Morgan & Co. Incorporated, a bank holding company organized under the laws of Delaware.

4. Trust shares currently are offered only to separate accounts established by Chubb Life or its affiliated insurance companies to fund flexible premium life insurance policies. Applicants desire that the Funds have the flexibility to offer their shares to insurance company separate accounts that fund variable annuity and variable life insurance contracts (including single premium, scheduled premium, modified single premium and flexible premium) (collectively, ''Variable Contracts'') established be affiliated or unaffiliated insurance companies.

5. Applicants state that Fund shares also may be offered directly to Plans outside the separate account context. The Plans may choose any of the Funds as the sole investment option under the Plan or as one of several investment options. Fund shares sold to Plans will be held by the trustee of the Plans as mandated by Section 403(a) of the Employee Retirement Income Security Act (''ERISA'').

Applicants' Legal Analysis

1. In connection with the funding of scheduled premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–2(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act. The relief provided by Rule 6e–2 extends to a separate account's investment adviser,

principal underwriter, and sponsor or depositor. The exemptions granted by Rule 6e–2(b)(15) are available, however, only where the management investment company underlying the separate account offers its shares ''exclusively to variable life insurance separate accounts of the life insurer, or any affiliated life insurance company.''

2. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts of a single insurance company (or of two or more affiliated insurance companies) is referred to as ''mixed funding.'' The use of a common management investment company as the underlying investment medium for variable annuity and/or variable life insurance separate accounts of unaffiliated insurance companies is referred to as ''shared funding.'' ''Mixed and shared funding'' denotes the use of a common management investment company to fund the variable annuity and variable life insurance separate accounts of affiliated and unaffiliated insurance companies. The relief granted by Rule 6e–2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an underlying fund that also offers its shares to a variable annuity separate account of the same company or of any other affiliated or unaffiliated life insurance company. Therefore, Rule 6e–2(b)(15) precludes mixed and shared funding.

3. In connection with the funding of flexible premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act. The exemptive relief extends to a separate account's investment adviser, principal underwriter, and sponsor or depositor. The exemptions granted to a separate account by Rule 6e-3(T)(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies which offer their shares ''exclusively to separate accounts of the life insurer, or of any affiliated life insurance company, offering either scheduled contracts or flexible contracts, or both; or which also offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company.'' Thus, Rule 6e–3(T) permits mixed funding with respect to a flexible premium variable life insurance separate account, but precludes shared funding.

4. Applicants state that various factors have kept certain insurance companies from offering variable annuity and variable life insurance contracts. These factors include: the cost of organizing and operating an investment funding medium; the lack of expertise with respect to investment managers (principally with respect to stock and money market investments); and the lack of name recognition by the public of certain insurers as investment professionals. Applicants maintain that use of the Funds as common investment media for the Variable Contracts would ease these concerns. Participating Insurance Companies would benefit not only from the investment and administrative expertise of the Funds' investment advisers, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Applicants submit that mixed and shared funding would benefit Variable Contract owners by: (a) eliminating a significant portion of the costs of establishing and administering separate funds; (b) permitting a greater amount of assets to be available for investment by the Funds, thereby promoting economies of scale, permitting greater safety of investments through greater diversification, and making the addition of new portfolios more feasible; and (c) encouraging more insurance companies to offer variable insurance contracts, resulting in increased competition with respect to both the design and the pricing of variable insurance contracts, which can be expected to result in greater product variation and lower charges.

5. Applicants assert that the relief granted by sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T) should not be affected by the proposed sale of Fund shares to Plans Applicants note, however, that because the relief under sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T) is available only where shares are offered exclusively to separate accounts of life insurance companies, additional exemptive relief is necessary if shares of the Funds also are to be sold to Plans.

6. Applicants state that current tax law permits the Funds to increase their asset base through the sale of Fund shares to the Plans. Applicants state that Section 817(h) of the Internal Revenue Code of 1986, as amended (the ''Code''), imposes certain diversification requirements on the underlying assets of Variable Contracts invested in the Funds. The Code provides that such Variable Contracts shall not be treated as an annuity contract or life insurance contract for any period in which the underlying assets are not adequately diversified in accordance with regulations prescribed by the Treasury Department. The regulations provide that, to meet the diversification requirements, all of the beneficial interests in the investment company must be held by the segregated asset accounts of one or more insurance companies. Treas. Reg. § 1.817–5 (1989). The regulations do contain certain exceptions to this requirement, however, one of which allows shares in an investment company to be held by the trustee of a qualified pension or retirement plan without adversely affecting the ability of shares in the same investment company also to be held by the separate accounts of insurance companies in connection with their variable contracts. Treas. Reg. § 1.817–5(f)(3)(iii).

7. Applicants state that the promulgation of Rules 6e–2 and 6e–3(T) under the 1940 Act preceded the issuance of these Treasury regulations, and that the sale of shares of the same investment company to both separate accounts and Plans could not have been envisioned at the time of the adoption of Rules 6e–2 (b)(15) and 6e-3(T) (b)(15).

8. Applicants therefore request relief from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act, and sub-paragraph (b)(15) of Rules 6e–2 and 6e-3(T) thereunder, to the extent necessary to permit shares of the Funds to be offered and sold now and in the future to separate accounts of Participating Insurance Companies in connection with both mixed and shared funding and to be sold directly to Plans.

9. Section 9(a) of the 1940 Act provides that it is unlawful for any person to serve as an investment adviser to, or principal underwriter for, any registered open-end investment company if an affiliated person of that person is subject to a disqualification enumerated in Section 9(a)(1) or (2).

10. Rules 6e–2 (b)(15) and 6e–3(T)(b)(15) provide exemptions from Section 9(a) under certain circumstances, subject to the limitations on mixed and shared funding. The relief provided by sub-paragraph (b)(15)(i) of Rules 6e–2 and 6e–3(T) permits a person disqualified under Section 9(a) to serve as an officer, director, or employee of the life insurer, or any of its affiliates, so long as that person does not participate directly in the management or administration of the underlying fund. The relief provided by sub-paragraph (b)(15)(ii) of Rules 6e–2 and 6e–3(T) permits the life insurer to serve as the underlying fund's investment adviser or principal underwriter, provided that none of the insurer's personnel who are ineligible

pursuant to Section 9(a) participate in the management or administration of the fund.

11. Applicants state that the partial relief from Section 9(a) found in sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T), in effect, limits the amount of monitoring necessary to ensure compliance with Section 9 to that which is appropriate in light of the policy and purposes of that Section. Applicants state that those rules recognize that it is not necessary for the protection of investors or the purposes fairly intended by the policy and provisions of the 1940 Act to apply the provisions of Section 9(a) to the many individuals in an insurance company complex, most of whom will have no involvement in matters pertaining to investment companies within that organization. Applicants note that the Participating Insurance Companies are not expected to play any role in the management or administration of the Funds. Therefore, Applicants assert, applying the restrictions of Section 9(a) serves no regulatory purpose. Applicants state that the relief requested should not be affected by the proposed sale of Fund shares to the Plans because the Plans are not investment companies and are not, therefore, subject to Section 9(a).

12. Sections 13(a), 15(a) and 15(b) of the 1940 Act require ''pass-through'' voting with respect to underlying investment company shares held by a separate account. Sub-paragraph (b)(15)(iii) of Rules 6e–2 and 6e–3(T) under the 1940 Act provides partial exemptions from the pass-through voting requirement. More specifically, sub-paragraph (b)(15)(iii)(A) of Rules 6e–2 and 6e–3(T) provides that the insurance company may disregard the voting instructions of its contract owners with respect to the investment of an underlying investment company, or any contract between an investment company and its investment adviser, when required to do so by an insurance regulatory authority.

13. Sub-paragraph (b)(15)(iii)(B) of Rule 6e–2 and sub-paragraph (b)(15)(iii)(A)(*2*) of Rule 6e–3(T) provide that the insurance company may disregard voting instructions of its contract owners if the contract owners initiate any change in underlying investment company's investment objectives, principal underwriter, or any investment adviser, provided that disregarding such voting instructions is reasonable and subject to the other provisions of paragraphs (b)(5)(ii) and (b)(7)(ii) (B) and (C) of each rule.

14. Applicants state that Rule 6e–2 recognizes that variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation of insurance. Applicants maintain, therefore, that in adopting Rule 6e–2, the Commission expressly recognized that exemptions from pass-through voting requirements were necessary ''to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer.'' Applicants state that flexible premium variable life insurance contracts and variable annuity contracts are subject to substantially the same state insurance regulatory authority, and therefore, corresponding provisions of Rule 6e–3(T) presumably were adopted in recognition of the same considerations as the Commission applied in adopting Rule 6e–2. Applicants submit that these considerations are no less important or necessary when an insurance company funds its separate accounts on a mixed and shared funding basis, and that such funding does not compromise the goals of the insurance regulatory authorities or of the Commission.

15. Applicants further state that the sale of Fund shares to Plans does not affect the relief requested in this regard. As previously noted, Fund shares sold to Plans will be held by the trustees of such Plans as required by Section 403(a) of ERISA. Section 403(a) also provides that the trustees must have exclusive authority and discretion to manage and control the assets of the Plan with two exceptions: (a) when the Plan expressly provides that the trustees are subject to the direction of a named fiduciary who is not a trustee, in which case the trustees are subject to proper directions made in accordance with the terms of the Plan and not contrary to ERISA; and (b) when the authority to manage, acquire or dispose of assets of the Plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA.

16. Unless one of the two exceptions stated in Section 403(a) applies, Plan trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the shares held unless the right to vote such shares is reserved to the trustees or to the named fiduciary. In any event, there is no pass-through voting to the participants in such Plans. Accordingly, Applicants note that, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present with Plans.

17. Applicants further assert that investment in the Funds by Plans will not create any of the voting complications occasioned by mixed and shared funding because Plan investor voting rights cannot be frustrated by veto rights of insurers or state regulators.

18. Applicants state that some Plans may provide participants with the right to give voting instructions. Applicants submit that there is no reason to believe that participants in Plans generally, or those in a particular Plan, either as a single group or in combination with other Plans, would vote in a manner that would disadvantage Variable Contract owners. Accordingly, Applicants assert that the purchase of Fund shares by Plans that provide voting rights to participants does not present any complications not otherwise occasioned by mixed and shared funding.

19. Applicants state that no increased conflicts of interest would be present by the granting of the requested relief. Applicants assert that shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. Applicants note that where different Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require action that is inconsistent with the requirements of insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. Applicants submit that this possibility is no different or greater than exists where a single insurer and its affiliates offer their insurance products in several states.

20. Applicants further submit that affiliation does not reduce the potential for differences in state regulatory requirements. In any event, the conditions (adapted from the conditions included in Rule 6e–3(T) (b)(15)) discussed below are designed to safeguard against any adverse effects that these differences may produce. If a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Funds.

21. Applicants also argue that affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company could disregard

Variable Contract owner voting instructions. Potential disagreement is limited by the requirement that the Participating Insurance Company's disregard of voting instructions be both reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard Variable Contract owner instructions represents a minority position or would preclude a majority vote approving a particular change, such Participating Insurance Company may be required, at the election of the relevant Fund, to withdraw its separate account's investment in that Fund. No charge or penalty will be imposed as a result of such a withdrawal.

22. Applicants submit that there is no reason why the investment policies of a Fund with mixed funding would, or should, be materially different from what those policies would, or should, be if such investment company or series thereof funded only variable annuity or variable life insurance contracts. Applicants therefore argue that there is no reason to believe that conflicts of interest would result from mixed funding. Moreover, Applicants represent that the Funds will not be managed to favor or disfavor any particular insurer or type of Variable Contract.

23. Applicants note that Section 817(h) of the Code imposes certain diversification requirements on the underlying assets of variable annuity and variable life insurance contracts held in the portfolios of management investment companies. Treasury Regulation § 1.817–5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits ''qualified pension or retirement plans'' and separate accounts to share the same underlying management investment company. Therefore, Applicants have concluded that neither the Code, the Treasury regulations, nor the revenue rulings thereunder present any inherent conflicts of interest if Plans, variable annuity and variable life insurance separate accounts all invest in the same management investment company.

24. Applicants note that while there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Plans, these tax consequences do not raise any conflicts of interest. When distributions are to be made, and the separate account or the Plan is unable to net purchase payments to make the distributions, the separate account or the Plan will redeem shares of the Funds at their respective net asset value. The Plan will then make distributions in accordance with the terms of the Plan. The life insurance company will make distributions in accordance with the terms of the Variable Contract.

25. Applicants state that they do not see any greater potential for material irreconcilable conflicts arising between the interests of participants under the Plans and owners of the Variable Contracts issued by the separate accounts of Participating Insurance Companies from possible future changes in the federal tax laws than that which already exists between variable annuity contract owners and variable life insurance contract owners.

26. With respect to voting rights, Applicants state that it is possible to provide an equitable means of giving such voting rights to Variable Contract owners and to Plans. Applicants represent that a Fund will inform each shareholder, including each separate account and Plan, of information necessary for the shareholder meeting, including their respective share ownership in the respective Funds. A Participating Insurance Company will then solicit voting instructions in accordance with the ''pass-through'' voting requirements of Rules 6e–2 and 6e–3(T).

27. Applicants argue that the ability of the Funds to sell their respective shares directly to Plans does not create a ''senior security,'' as such terms is defined under Section 18(g) of the 1940 Act, with respect to any Variable Contract owner as opposed to a participant under a Plan. Regardless of the rights and benefits of Plan participants and Variable Contract owners under the respective Plans and Variable Contracts, the Plans and the separate accounts have rights only with respect to their shares of the Funds. Such shares may be redeemed only at net asset value. No shareholder of any of the Funds has any preference over any other shareholder with respect to distributions of assets or payment of dividends.

28. Applicants state that there are no conflicts of interest between Variable Contract owners and Plan participants with respect to the state insurance commissioners' veto powers over investment objectives. The state insurance commissioners have been given the veto power in recognition of the fact that insurance company separate accounts cannot simply redeem or transfer Fund shares; to accomplish such redemptions and transfers, complex and time consuming transactions must be undertaken. By contrast, trustees of Plans or the participants in participant-directed Plans can make the decision quickly and implement redemption of shares from a Fund and reinvest the monies in another funding vehicle without the same regulatory impediments or, as in the case with most Plans, even hold cash pending a suitable investment. Based on the foregoing, Applicants represent that even should the interests of Variable Contract owners and the interests of Plans and Plan participants conflict, the conflicts can be resolved almost immediately in that trustees of the Plans can, independently, redeem shares out of the Funds.

29. Applicants state that, regardless of the types of Fund shareholders, a Fund's adviser is legally obligated to manage the Funds in accordance with each Fund's investment objectives, policies and restrictions as well as any guidelines established by the Fund's Board. Applicants assert that Chubb Investment Advisory and Morgan will manage the Funds without consideration for the identity of shareholders.

Applicant's Conditions

Applicants have consented to the following conditions:

1. A majority of the Board of Trustees or Directors (each, a ''Board'') of each Fund shall consist of persons who are not ''interested persons'' thereof, as defined by Section 2(a)(19) of the 1940 Act and the Rules thereunder and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of death, disqualification, or bona fide resignation of any Board member, then the operation of this condition shall be suspended: (a) for a period of 45 days, if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days, if a vote of shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. Each Fund's Board will monitor the Fund for the existence of any material irreconcilable conflict between the interests of Variable Contract owners of all separate accounts and of Plan participants and Plans investing in the Fund, and determine what action, if any, should be taken in response to such conflicts. A material irreconcilable conflict may arise for a variety of reasons, including: (a) an action by any state insurance regulatory authority; (b) a change in applicable federal or state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling, no-action or interpretive letter, or any similar action by insurance, tax, or securities regulatory

authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Funds are being managed; (e) a difference in voting instructions given by owners or variable annuity and variable life insurance contracts; (f) a decision by a Participating Insurance Company to disregard the voting instructions of Variable Contract owners; or (g) if applicable, a decision by a Plan to disregard the voting instruction of Plan participants.

3. Chubb Investment Advisory and Morgan (or any other investment adviser of a Fund), any Participating Insurance Company and any Plan that executes a fund participation agreement upon becoming an owner of 10% or more of the assets of a Fund (collectively, ''Participants'') will report any potential or existing conflicts to the relevant Board. Participants will be obligated to assist the relevant Board in carrying out its responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This responsibility includes, but is not limited to, an obligation by each Participating Insurance Company to inform the Board whenever Variable Contract owner voting instructions are disregarded and, if pass-through voting is applicable, an obligation by each Plan to inform the Board whenever Plan participant voting instructions are disregarded. The responsibility to report such information and conflicts and to assist the Boards will be contractual obligations of all Participating Insurance Companies and Plans investing in the Funds under their agreements governing participation in the Funds, and such agreements shall provide that these responsibilities will be carried out only with a view to the interests of Variable Contract owners and, if applicable, Plan participants.

4. If a majority of a Fund's Board members, or a majority of its disinterested Board members, determine that a material irreconcilable conflict exists, the relevant Participating Insurance Companies and Plans, at their expense and to the extent reasonably practical (as determined by a majority of the disinterested Board members), shall take whatever steps are necessary to remedy or eliminate the material irreconcilable conflict. Such steps could include: (a) withdrawing the assets allocable to some or all of the separate accounts from the Fund or any of its series and reinvesting such assets in a different investment medium, which may include another series of the Fund or another Fund; (b) in the case of a Participating Insurance Company, submitting the question as to whether such segregation should be implemented to a vote of all affected Variable Contract owners and, as appropriate, segregating the assets of any appropriate group (*i.e.*, variable annuity or variable life insurance contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected Variable Contract owners the option of making such a change; and (c) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of a Participating Insurance Company's decision to disregard contract owner voting instructions and that decision represents a minority position or would preclude a majority vote, the Participating Insurance Company may be required, at the election of the Fund, to withdraw its separate account's investment in such Fund, and no charge or penalty will be imposed as a result of such withdrawal. If a material irreconcilable conflict arises because of a Plan's decision to disregard Plan participant voting instructions, if applicable, and that decisions represents a minority position or would preclude a majority vote, the Plan may be required, at the election of the Fund, to withdraw its investment in such Fund, and no charge or penalty will be imposed as a result of such withdrawal. The responsibility to take remedial action in the event of a Board determination of a material irreconcilable conflict and to bear the cost of such remedial action will be a contractual obligation of all Participating Insurance Companies and Plans under their agreements governing participating in the Funds. These responsibilities shall be carried out only with a view to the interests of Contract owners and, as applicable, Plan participants.

5. For purposes of condition 4, a majority of the disinterested members of the relevant Board shall determine whether any proposed action adequately remedies any material irreconcilable conflict. In no event will a Fund or Chubb Investment Advisory or Morgan (or any other investment adviser of the Funds) be required to establish a new funding medium for any Variable Contract. No Participating Insurance Company shall be required by condition 4 to establish a new funding medium for any Variable Contract if a majority of Variable Contract owners materially and adversely affected by the irreconcilable material conflict vote to decline such offer. No Plan shall be required by condition 4 to establish a new funding medium for such Plan if (a) a majority of Plan participants materially and adversely affected by the material irreconcilable material conflict vote to decline such offer, or (b) pursuant to governing plan documents and applicable law, the Plan makes such decision without a vote by Plan participants.

6. Participants will be informed promptly in writing of a Board's determination of the existence of a material irreconcilable conflict and its implications.

7. Participating Insurance Companies will provide pass-through voting privileges to all Variable Contract owners so long as the Commission continues to interpret the 1940 Act as requiring pass-through voting privileges for Variable Contract owners. Accordingly, such Participating Insurance Companies, where applicable, will vote shares of the Fund held in its separate accounts in a manner consistent with voting instructions timely received from Variable Contract owners. In addition, each Participating Insurance Company will vote shares of a Fund held in its separate accounts for which it has not received timely voting instructions, as well as shares it owns, in the same proportion as those shares for which it has received voting instructions. Participating Insurance Companies will be responsible for assuring that each of their separate accounts investing in a Fund calculates voting privileges in a manner consistent with all other Participating Insurance Companies. The obligation to calculate voting privileges and to vote a Fund's shares in a manner consistent with all other separate accounts investing in the Fund will be a contractual obligation of all Participating Insurance Companies under the agreements governing their participation in the Fund. Each Plan will vote as required by applicable law and governing Plan documents.

8. All reports of potential or existing conflicts of interest received by a Board, and all Board action with regard to (a) determining the existence of a conflict, (b) notifying Participants of a conflict, and (c) determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the appropriate Board or other appropriate records. Such minutes or other records shall be made available to the Commission upon request.

9. Each Fund will notify all Participating Insurance Companies that separate account prospectus disclosure regarding potential risks of mixed and

shared funding may be appropriate. Each Fund shall disclose in its prospectus that: (a) Its shares may be offered to insurance company separate accounts that fund both variable annuity and variable life insurance contracts, and to Plans; (b) differences in tax treatment or other considerations may cause the interests of various Variable Contract owners participating in the Fund and the interests of Plans investing in the Fund to conflict; and (c) the Board will monitor the Fund for any material conflicts and determine what action, if any, should be taken.

10. Each Fund will comply with all the provisions of the 1940 Act requiring voting by shareholders (for these purposes, the persons having a voting interest in the shares of the Funds). In particular, each such Fund either will provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the 1940 Act not to require such meetings) or comply with Section 16(c) of the 1940 Act (although none of the Funds shall be one of the trusts described in Section 16(c) of the 1940 Act) as well as Section 16(a) and, if applicable, Section 16(b) of the 1940 Act. Further, each Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of Board members and with whatever rules the Commission may promulgate with respect thereto.

11. If and to the extent Rule 6e–2 or Rule 6e–3(T) is amended, or if Rule 6e–3 under the 1940 Act is adopted, to provide exemptive relief from any provisions of the 1940 Act or the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Funds and/or the Participants, as appropriate, shall take such steps as may be necessary to comply with Rule 6e2 or Rule 6e–3(T), as amended, and Rule 6e–3, as adopted, to the extent such rules are applicable.

12. No less than annually, the Participants shall submit to each Board such reports, materials or data as each Board may reasonably request so that such Boards may carry out fully the obligations imposed upon them by the conditions stated in this application. Such reports, materials and data shall be submitted more frequently if deemed appropriate by the Boards. The obligations of Participating Insurance Companies and Plans to provide these reports, materials and data upon reasonable request of a Board shall be a contractual obligation of all Participating Insurance Companies and Plans under the agreements governing their participation in the Funds.

13. If a Plan should become an owner of 10% or more of the assets of a Fund, such Plan will execute a participation agreement with such Fund which includes the conditions set forth herein to the extent applicable. A Plan will execute an application containing an acknowledgment of this condition upon such Plan's initial purchase of the shares of any Fund.

Conclusion

For the reasons set forth above, Applicants represent that the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–30679 Filed 12–2–96; 8:45 am]

BILLING CODE 8010–01–M

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Technitrol, Inc., Common Stock, $0.125, Par Value; Common Stock Purchase Rights) File No. 1–5375

November 26, 1996.

Technitrol, Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified securities (''Securities'') from listing and registration on the American Stock Exchange, Inc. (''Amex'').

The reasons alleged in the application for withdrawing the Securities from listing and registration include the following:

The decision of the Board on this matter followed a study and was based upon the belief that listing the Common Stock on the NYSE will be more beneficial to shareholders of the Company for the following reasons:

1. The Company believes that listing its Common Stock on the NYSE will result in increased visibility and sponsorship for the Common Stock of the Company that is presently available on the Amex.

2. The Company believes that the NYSE will offer the Company's shareholders more liquidity than is presently available on the Amex and less volatility in quoted prices per share when trading volume is light.

Any interested person may, on or before December 18, 1996, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the exchanges and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–30680 Filed 12–2–96; 8:45 am]

BILLING CODE 8010–01–M

[Release 34–37983; File No. 600–23]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Order Approving Application for Extension of Temporary Registration as a Clearing Agency

November 25, 1996.

On October 7, 1996, the Government Securities Clearing Corporation (''GSCC'') filed with the Securities and Exchange Commission (''Commission'') a request pursuant to Section 19(a) of the Securities Exchange Act of 1934 (''Act'')[1] that the Commission grant GSCC full registration as a clearing agency under Section 17A of the Act[2] or in the alternative extend GSCC's temporary registration as a clearing agency until such time as the Commission is able to grant GSCC permanent registration.[3] The Commission published notice of GSCC's request in the Federal Register on October 25, 1996.[4] No comments were received. This order extends GSCC's

[1] 15 U.S.C. § 78s(a) (1988).

[2] 15 U.S.C. § 78q–1 (1988).

[3] Letter from Sal Ricca, President and Chief Operating Officer, GSCC, to Richard Lindsey, Director, Division of Market Regulation, Commission (October 2, 1996) (''Registration Letter'').

[4] Securities Exchange Act Release No. 37844 (October 21, 1996), 61 FR 55341.

temporary registration as a clearing agency through May 31, 1997.[5]

GSCC provides clearance and settlement service for its members' transactions in government securities. GSCC offers its members services for next-day settling trades, forward settling trades, auction takedown activity, repurchase transactions, the multilateral netting of trades, the novation of netted trades, and daily marking-to-the-market. In connection with GSCC's clearance and settlement services, GSCC provides a centralized loss allocation procedure and maintains margin to offset netting and settlement risks.

At the time of GSCC's initial temporary registration, the Commission granted GSCC an exemption from compliance with the fair representation requirements in Section 17A(b)(3)(C) of the Act.[6] GSCC's current selection process for its board of directors permits any GSCC member to nominate candidates for election to the board and to vote for candidates so nominated. However, the shareholder agreement requires that six directors be dealer participants, three directors be broker participants, and three directors be clearing agent bank participants.[7] As part of GSCC's request for full clearing agency registration, GSCC has requested that the Commission withdraw GSCC's exemption from the fair representation requirements.[8]

While GSCC states that it believes that its current selection process for its board of directors assures members fair representation, GSCC also states that it plans to modify the method of electing directors.[9] Therefore, the Commission will defer its decision on whether GSCC meets the fair representation requirements until GSCC submits its new selection procedures and the Commission has had an opportunity to evaluate it. The Commission also believes that at this time GSCC's temporary registration as a clearing agency and GSCC's exemption from the fair representation standards of Section 17A(b)(3)(C) should be continued.

It is therefore ordered that GSCC's temporary registration as a clearing agency (File No. 600–23) be and hereby is extended through May 31, 1997, subject to the terms set forth above.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–30677 Filed 12–2–96; 8:45 am]

BILLING CODE 8010–01–M

[5] On May 24, 1988, the Commission granted GSCC's initial application for registration as a clearing agency pursuant to Sections 17A and 19(a) of the Act and Rule 17Ab2–1 [17 CFR 240.17Ab2–1 (1966)] thereunder for a period of three years. Securities Exchange Act Release No. 25740 (May 24, 1988), 53 FR 19639. The Commission subsequently has extended GSCC's registration until November 30, Securities Exchange Act Release Nos. 29067 (April 11, 1991), 56 FR 15652; 32385 (June 3, 1993), 58 FR 32405; 35787 (May 31, 1995), 60 FR 30324; and 36508 (November 27, 1995), 60 FR 61719.

[6] 15 U.S.C. § 78q–1(b)(3)(C) (1988).

[7] In its order granting GSCC its initial temporary approval, the Commission stated that while the composition of GSCC's board of directors reasonably reflected GSCC's anticipated initial membership, the Commission believed that it would be appropriate to defer to a later date its determination of whether GSCC's process for selecting its board of directors assures participants fair representation. This decision was based on the fact that GSCC planned on expanding its services during the temporary registration period and on the uncertainty with regard to GSCC's future participant base.

[8] Registration Letter, *supra* note 3.

[9] *Id.*

[Release No. 34–37986; International Series Release No. 1032; File No. 600–20]

Self-Regulatory Organizations; International Securities Clearing Corporation; Notice of Filing and Order Granting Approval of a Request for an Extension of Temporary Registration as a Clearing Agency Until May 31, 1997

November 25, 1996.

Notice is hereby given that on October 10, 1996, the International Securities Clearing Corporation (''ISCC'') filed with the Securities and Exchange Commission (''Commission'') an application pursuant to Section 19(a)(1) of the Securities Exchange Act of 1934 (''Act''),[1] to extend ISCC's temporary registration as a clearing agency.[2] The Commission is publishing this notice and order to solicit comments from interested persons and to extend ISCC's temporary registration as a clearing agency through May 31, 1997.

On May 12, 1989, the Commission granted the application of ISCC for registration as a clearing agency pursuant to Sections 17A and 19(a) of the Act[3] and Rule 17Ab2–1(c)[4] thereunder on a temporary basis for a period of eighteen months.[5] At that time, the Commission granted to ISCC a temporary exemption from compliance with Section 17A(b)(3)(C) of the Act[6] which requires that the rules of a clearing agency assure the fair representation of its shareholders (or members) and participants in the selection of its directors and administration of its affairs.[7] Since that time, the Commission has extended ISCC's temporary registration through November 30, 1996.[8]

One of the primary reasons for ISCC's registration as a clearing agency was to enable it to provide for the safe and efficient clearance and settlement of international securities transactions by providing links to centralized, efficient processing systems in the United States and in foreign financial institutions. ISCC continues to develop its capacity to offer these services.[9]

As a part of its temporary registration, ISCC was granted an exemption from the fair representation request of Section 17A(b)(3)(C) of the Act due to ISCC's limited participant base. In its letter dated October 10, 1996, ISCC noted that it had filed a proposed rule change which it believes will enable ISCC to comply with the fair representation requirements. Because ISCC's proposal is still undergoing Commission review, the Commission is extending ISCC's temporary registration from clearing agency registration and ISCC's exemption from the fair representation requirements of Section 17A(b)(3)(c).

Interested persons are invited to submit written data, views, and arguments concerning the foregoing application. Such written data, views, and arguments will be considered by the Commission in granting permanent registration or instituting proceedings to determine whether registration should be denied in accordance with Section 19(a)(1) of the Act.[10] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the application and all written comments will be available for

[10] 17 CFR 200.30–3(a)(50)(i) (1996).

[1] 15 U.S.C. § 78s(a)(1) (1988).

[2] Letter from Julie Beyers, Associate Counsel, ISCC, to Christine Sibille, Division of Market Regulation, Commission (October 10, 1996).

[3] 15 U.S.C. §§ 78q–1 and 78s(a) (1988).

[4] 17 C.F.R. 240.17Ab2–1(c) (1996).

[5] Securities Exchange Act Release No. 26812 (May 12, 1989), 54 FR 21691.

[6] 15 U.S.C. § 78q–1(b)(3)(C) (1988).

[7] Currently, ISCC's Board of Directors is authorized for a maximum of twenty-two members. The twenty-two directors on the board of National Securities Clearing Corporation (''NSCC''), the sole shareholder of ISCC, serve as ISCC's board of directors.

[8] Securities Exchange Act Release Nos. 28606 (November 16, 1990), 55 FR 47976; 30005 (November 27, 1991), 56 FR 63747; 33233 (November 22, 1993), 58 FR 63195; and 36529 (November 29, 1995), 60 FR 62511.

[9] For example, ISCC has added two service providers, Standard Chartered Bank and S.D. Indeval, S.A. de C.V., to its Global Clearance Network to provide settlement and custody services in the Asian-Pacific Region and Mexico, respectively. Securities Exchange Act Release Nos. 36902 (February 28, 1996), 61 FR 8995 and 36605 (January 30, 1996), 61 FR 4508.

[10] 15 U.S.C. § 78s(a)(1) (1988).

inspection at the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. All submissions should refer to File No. 600–20 and should be submitted by January 2, 1997.

It is therefore ordered, that ISCC's registration as a clearing agency (File No. 600–20) be and hereby is temporarily approved through May 31, 1997.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–30678 Filed 12–2–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37987; File No. SR–NASD–96–39]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Incorporated Amending the Requirements for the Use in Advertisements and Sales Literature of Investment Company Rankings

November 25, 1996.

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 October 17, 1996,[1] the National Association of Securities Dealers, Inc. (''NASD'' or ''Association'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is herewith filing a proposed rule change to Rule IM–2210–3 of the NASD's Conduct Rules to allow for the use in advertisements and sales literature of investment company rankings that represent short, medium and long term performance. Below is the text of the proposed rule change. Proposed new language is italicized; proposed deletions are in brackets.

IM–2210–3. Use of Rankings in Investment Companies Advertisements and Sales Literature

(d) Time Periods

(1) Any investment company ranking set forth in an advertisement or sales literature must be, at a minimum, current to the most recent calendar quarter ended, in the case of advertising, prior to the submission for publication, or, in the case of sales literature, prior to use.

(2) Except for money market mutual funds:

(A) advertisements and sales literature must not use any rankings, *other than rankings based on yield*, based on a period of less than one year.

(B) any investment company ranking based on total return must be accompanied by rankings based on total return for [the] *a* one year period for investment companies in existence for one year; [the] one and five year periods for investment companies in existence for at least five years; and [the] one, five and ten year periods for investment companies in existence for at least ten years supplied by the same Ranking Entity [in the category], *relating to the same investment category, and based on the same time period; provided that, if rankings for such one, five and ten year time periods are not published by the Ranking Entity, then rankings representing short, medium and long term performance must be provided in place of rankings for the required time periods.*

(C) an investment company ranking based on yield may be based only on the current SEC standardized yield. An investment company ranking based on the current SEC standardized yield must be accompanied by rankings based on total return for [the] *a* one year period for investment companies in existence for one year; [the] one and five year periods for investment companies in existence for at least five years; and [the] one, five and ten year periods for investment companies in existence for at least ten years supplied by the same Ranking entity [in the category], *relating to the same investment category,* and based on the same time period*; provided that, if rankings for such, one, five and ten year time periods are not published by the Ranking Entity, then rankings representing short, medium and long term performance must be provided in place of rankings for the required time periods.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule 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 of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 1994, the Commission approved what is now IM–2210–3 of the NASD Conduct Rules, which provides guidelines for the use of rankings in investment companies' advertisements and sales literature (''Guidelines'').[2] Among other things, the Guidelines require that all rankings used in advertising and sales literature by member firms to promote non-money market mutual fund performance include rankings over one, and, if available, five and ten year periods. Prior to the Guidelines, there were no specific standards for the use of rankings. Members generally had selected rankings for whatever time period that produced the most favorable rankings for an investment company.

Since the approval of the Rankings Guidelines, staff of NASD Regulation, Inc. (''NASDR'') have considered the issue of whether to allow for greater flexibility in the use of time periods other than those prescribed by the Guidelines. The staff notes that some rankings, which are based on adjusted total return to reflect criteria and methodologies established and imposed by the ranking entities, use time periods that do not meet the three specifically prescribed time periods contained within the Guidelines. For example, one ranking entity has developed a ranking system that summarizes an investment company's risk/reward profile for 3, 5 and 10 year periods. This system provides a composite ranking that seeks to measure how well an investment company has balanced return and risk in the past. This ranking entity does not intend that its risk adjusted rankings measure one year time periods and considers such measurements to be statistically meaningless and potentially misleading.

NASDR believes that performance-adjusted rankings which use different time periods than those prescribed by the Guidelines can help investment company investors make informed investment decisions if presented in a way that is not misleading. NASDR staff determined that the Guidelines, as originally approved, should be revised consistent with the original goal that would prevent selectivity of time periods.

The proposed rule change revises subparagraphs (2) (B) and (C) to

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[11] 17 C.F.R. § 240.30–3(a)(50) (1996).

[1] On November 21, 1996, the NASD filed Amendment No. 1 with the Commission. The amendment clarified that rankings based on yield may be based on periods of less than one year. The amendment also made technical amendments to the text of the rule. *See* Letter from John Ramsay, Deputy General Counsel, NASD Regulation, Inc. to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated November 20, 1996.

[2] Securities Exchange Act Release No. 34354 (July 12, 1994), 59 FR 36461 (July 18, 1994).

paragraph (d) of IM–2210–3. The proposed rule change clarifies that the use of one, five and ten year time periods is required if such time periods are published by the ranking entity.[3] If rankings for the required time periods are not published by the ranking entity, the proposed rule change provides that rankings representing short, medium and long term performance must be provided in place of rankings for the required time periods. In its discussions of how the terms ''short,'' ''medium'' and ''long term'' might be interpreted, NASDR staff considered time frames of 1–4 years, 5–5 years and 10 years or more, respectively, as an acceptable interpretation. The proposed rule change also replaces the phrase ''in the category,'' in subparagraphs (2) (B) and (C) with the phrase ''relating to the same investment category.'' to clarify that when members provide rankings for advertisements and sales literature, rankings for the prescribed time periods must be for the same investment category of subcategory as the total return ranking that is being accompanied by the prescribed ranking.

The proposed rule change makes clear that the Guidelines apply to rankings that use time periods other than the one, five, and ten year periods prescribed in the Guidelines if rankings for the required time periods are not published by the ranking entity. On the one hand, the proposed rule change provides an option that relaxes the requirement to use standardized time periods. At the same time, this option still assures that rankings will continue to be reflected over an extended period and therefore provide more than just a ''snapshot'' view. NASDR believes that the proposed rule change provides a flexible framework within which ranking entities using different methodologies can provide useful information to investors in a way that is not harmful or misleading.

2. Statutory Basis

The proposed rule change is consistent with the provisions of Sections 15A(b)(6) of the Act, [4] which require that the Association adopt and amend its rules to promote just and equitable principles of trade and generally provide for the protection of customers and the public interest, in that the proposed rule change continues to prohibit the use in advertising and sales literature of rankings containing arbitrarily selected time periods while allowing time periods other than those originally prescribed by the rule in a way that is not misleading.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received by the NASD.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 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 at the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–96–39 and should be submitted by December 24, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–30676 Filed 12–2–96; 8:45 am]

BILLING CODE 8010–01–M

[3] The Guidelines define ''Ranking Entity'' as ''* * * any entity that provides general information about investment companies to the public, that is independent of the investment company and its affiliates, and whose services are not procured by the investment company or any of its affiliates to assign the investment company a ranking.''

[4] 15 U.S.C. § 78*o*–3.

[5] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

MMG Ventures, L.P. (License No. 03/03–5205); Notice of Issuance of a Small Business Investment Company License

On July 26, 1995, an application was filed by MMG Ventures, L.P., 217 E. Redwood Street—Suite 2241, Baltimore, Maryland, with the Small Business Administration (SBA) pursuant to Section 107.102 of the Regulations governing small business investment companies (13 C.F.R. 107.102 (1996)) for a license to operate as a small business investment company.

Notice is hereby given that, pursuant to Section 301(d) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 03/03–5206 on September 30, 1996 to MMG Ventures, L.P. to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: November 19, 1996.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 96–30689 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

Stratford Equity Partners, L.P. (License No. 06/76–0313); Notice of Issuance of a Small Business Investment Company License

On December 15, 1995, an application was filed by Stratford Equity Partners, L.P., 200 Crescent Court, Suite 1600, Dallas, Texas, with the Small Business Administration (SBA) pursuant to Section 107.102 of the Regulations governing small business investment companies (13 C.F.R. 107.102 (1996)) for a license to operate as a small business investment company.

Notice is hereby given that, pursuant to Section 301(c) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 06/76–0313 on September 30, 1996 to Stratford Equity

Partners, L.P. to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: November 19, 1996.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 96–30693 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

Wasserstein Perella SBIC, L.P. (License No. 02/72–0569); Notice of Issuance of a Small Business Investment Company License

On December 7, 1994, an application was filed by Wasserstein Perella SBIC, L.P., 31 West 52nd Street, New York, New York, with the Small Business Administration (SBA) pursuant to Section 107.102 of the Regulations governing small business investment companies (13 C.F.R. 107.102 (1996)) for a license to operate as a small business investment company.

Notice is hereby given that, pursuant to Section 301(c) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 02/72–0569 on November 1, 1996 to Wasserstein Perella SBIC, L.P. to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: November 19, 1996.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 96–30692 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2916]

Florida; Declaration of Disaster Loan Area

Pinellas County and the contiguous counties of Hillsborough and Pasco in the State of Florida constitute a disaster area as a result of civil unrest in the City of St. Petersburg which occurred on October 24 and November 11, 1996. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on January 24, 1997 and for economic injury until the close of business on August 25, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308, or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 291615 and for economic injury the number is 925700.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 25, 1996.

John T. Spotila,

Acting Administrator.

[FR Doc. 96–30694 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2915]

Territory of Guam; Declaration of Disaster Loan Area

The Territory of Guam is hereby declared a disaster area as a result of damages caused by Typhoon Dale which occurred on November 8, 1996. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on January 21, 1997 and for economic injury until the close of business on August 21, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 4 Office, 1825 Bell Street, Suite 208, Sacramento, CA 95825, or other locally announced locations. The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.250
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 291506 and for economic injury the number is 925600.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: November 21, 1996.

Ginger Lew,

Acting Administrator.

[FR Doc. 96–30690 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

[License No. 06/06–0244]

SBI Capital Corporation; Notice of Surrender of Licensee

Notice is hereby given that SBI Capital Corporation, 6305 Beverly Hill Lane, Houston, Texas 77057, has surrendered its License to operate as a small business investment company under the Small Business Investment Act of 1958, as amended (the Act). SBI Capital Corporation was licensed by the Small Business Administration on October 22, 1981.

Under the authority vested by the Act and pursuant to the Regulations promulgated thereunder, the surrender of the License was accepted on this date, and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: November 19, 1996.

Donald A. Christensen,

Associate Administrator for Investment.

[FR Doc. 96–30691 Filed 12–2–96; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements

AGENCY: Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork

Reduction Act of 1995 (44 U.S.C. chapter 35). The Federal Register Notice, Notice of Proposed Rulemaking (NPRM) with a 60-day comment period soliciting comments on the following collection of information was published on September 10, 1996 [61 FR 47704].

DATES: Comments on this notice must be received on or before January 2, 1997.

ADDRESSES: Written comments on the DOT information collection requests should be forwarded, as quickly as possible, to Edward Clarke, Office of Management and Budget, New Executive Office Building, Room 10202, Washington, D.C. 20503. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB official of your intent immediately.

FOR FURTHER INFORMATION CONTACT: Copies of the DOT information collection request submitted to OMB may be obtained from Mr. Charles McGuire, Office of the Secretary, Office of Aviation Analysis, X–57, Department of Transportation, Telephone number (202) 366–4534.

SUPPLEMENTARY INFORMATION: Section 3507 of Title 44 of the United States Code, as adopted by the Paperwork Reduction Act of 1995, requires that agencies prepare a notice for publication in the Federal Register, listing those information collection requests submitted to OMB for approval or renewal under that Act. OMB reviews and approves agency submissions in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms and the reporting and recordkeeping requirements. OMB approval of an information collection requirement must be renewed at least once every three years.

Title: Passenger Manifest.

OMB Control Number: 2105—new.

Type of Request: New collection.

Affected Public: U.S. and foreign carriers, travel agents and the traveling public.

Abstract: In some international aviation disasters in the past, the State Department did not have a complete and accurate passenger manifest information for use in notifying the families of victims in a timely manner. This information collection requirement would require U. S. air carriers, foreign air carriers, and travel agents to collect complete and accurate passenger manifest information for U.S. citizens and lawful permanent residents in order that the families can be notified in a timely manner.

Need for Information: U.S. And foreign air carries will be able to provide the passenger manifest information for U.S. citizens and lawful permanent residents to Department of Transportation and Department of State in the case of an aviation accident no later than three hours following notification of the disaster.

Estimated Total Annual Burden on Respondents: 1.1 to 1.4 million hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW, Washington, DC 20503, Attention DOT Desk Officer.

Comments are Invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, D.C. on November 26, 1996.

Phillip A. Leach,

Information Collection Officer, United States Department of Transportation.

[FR Doc. 96–30723 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–62–P

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending November 22, 1996

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 Applications, or Motions 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 Number: OST–96–1963.

Date filed: November 18, 1996.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 16, 1996.

Description:

Application of Delta Air Lines, Inc. pursuant to 48 U.S.C. Section 41102 and Subpart Q of the Department's Rules of Practice, applies for (1) a new or amended certificate of public convenience and necessity to authorize it to provide scheduled foreign air transportation from a point or points in the United States to Manaus, Brasilia, Rio de Janeiro, Sao Paulo, Recife, Porto Alegre, Belem, Belo Horizonte, and Salvador de Bahia, Brazil and beyond Brazil to Argentina, Uruguay, Paraguay and Chile, and (2) designation and allocation of 14 U.S.-Brazil frequencies available for U.S.-Brazil combination services under the terms of the 1989 U.S.-Brazil Air Transport Services Agreement.

Docket Number: OST–96–1964.

Date filed: November 18, 1996.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 16, 1996.

Description:

Application of Continental Airlines, Inc. pursuant to 49 U.S.C. Sections 41108 and 41102 and Subpart Q of the Department's Rules of Practice, applies for a certificate of public convenience and necessity authorizing it to provide scheduled foreign air transportation of persons, property and mail between the United States and Brazil and to combine this authority with Continental's other exemption and certificate authority consistent with applicable international agreements.

Docket Number: OST–96–1968.

Date filed: November 19, 1996.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 17, 1996.

Description:

Application of American Airlines, Inc. pursuant to Notice served November 5, 1996 and 49 U.S.C. 41108 and Subpart Q of the Department's Regulations, applies for certificate of public convenience and necessity authorizing foreign air transportation of persons, property and mail between the United States and points in India.

Docket Number: OST–96–1976.

Date filed: November 20, 1996.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 18, 1996.

Description:

Application of Condor Flugdienst GMBH pursuant to 49 U.S.C. Section 41304 and Subpart the Regulations, requests an amendment to its foreign air carrier permit to provide scheduled and nonscheduled foreign air transportation of persons, property and mail between Germany and the United States.

Docket Number: OST–96–1977.
Date filed: November 20, 1996.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: December 18, 1996.
Description:
Application of Hawaiian Airlines, Inc., pursuant to 49 U.S.C. Sections 41102, 41108, and Subpart Q of the Regulations, applies for a certificate of public convenience and necessity authorizing scheduled foreign air transportation of persons, property, and mail between any point in the United States and any point in Canada, subject to a condition that service to Vancouver, Montreal and Toronto shall be separately authorized, to the extent necessary for such service to be consistent with the phase-in provisions for those three cities in the United States-Canada Air Transport Agreement signed on February 24, 1995.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 96–30698 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–62–P

Aviation Proceedings; Agreements Filed During the Week Ending 11/22/96

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–96–1961.
Date filed: November 18, 1996.
Parties: Members of the International Air Transport Association.
Subject: TC123 Telex Mail Vote 836, Amend South Atlantic-Europe Fares, Resos 057o (r–1) & 047o (r–2), Intended effective date: March 1, 1997.

Docket Number: ST–96–1962.
Date filed: November 18, 1996.
Parties: Members of the International Air Transport Association.
Subject: Comp Telex Mail Vote 837, Amendment to Mileage Manual (Reso 011a), Intended effective date: April 1, 1997.

Docket Number: OST–96–1971.
Date filed: November 20, 1996.
Parties: Members of the International Air Transport Association.
Subject: PTC23 AFR–TC3 0002 dated November 15, 1996, R1–2; PTC23 AFR–TC3 0003 dated November 15, 1996, R3–5; PTC23 AFR–TC3 0004 dated November 15, 1996, R6, R–1—002qq, R–2—065y, R–3—003b, R–4—071t, R–5—086v, R–6—015v. Intended effective date: as early as December 15, 1996.

Docket Number: OST–96–1972.
Date filed: November 20, 1996.
Parties: Members of the International Air Transport Association.
Subject: Comp Telex Mail Vote 840, Composite Fare Construction Resos, R–1—010e, R–2—002ee, R–3—017f. Intended effective date: February 1, 1997.

Docket Number: OST–96–1973.
Date filed: November 20, 1996.
Parties: Members of the International Air Transport Association.
Subject: TC12 Telex Mail Vote 839, North Atlantic-Africa Reso 002—Readopting Resolution, Intended effective date: January 1, 1997.

Docket Number: OST–96–1974.
Date filed: November 20, 1996.
Parties: Members of the International Air Transport Association.
Subject: TC1 Telex Mail Vote 838, Fares within South America, R–1—051d, R–2—041d, R–3—061d, R–4—070j, R–5—071b, Intended effective date: December 1, 1996.

Docket Number: OST–96–1980.
Date filed: November 22, 1996.
Parties: Members of the International Air Transport Association.
Subject: PTC12 SATL–EUR 0007 dated November 1, 1996. South Atlantic-Europe Resos rl–24, PTC12 SATL–EUR 0008 dated November 19, 1996, PTC12 SATL–EUR FARES 0002 dated November 19, 1996, r–1—001a, r–9—064m, r–17—078f, r–2—001rr, r–10—070y, r–18—078LL, r–3—002, r–11—071mm, r–19—080c, r–4—005bb, r–12–071ey, r–20–080g, r–5–015v, r–13–073e, r–21–080r, r–6–017c, r–14–074x, r–22–085L, r–7–044m, r–15–075pp, r–23–087uu, r–8–054m, r–16—076w, r–24–092d, Intended effective date: April 1, 1997.

Docket Number: OST–96–1981.
Date filed: November 22, 1996.
Parties: Members of the International Air Transport Association.
Subject: PTC23 EUR–SWP 0004 dated November 15, 1996, Europe-Southwest Pacific Resos r1–20, PTC23 EUR–SWP 0005 dated November 19, 1996, PTC23 EUR–SWP Fares 0001 dated November 15, 1996, r–1–001b, r–8–057c, r–15–071ii, r–2–002, r–9–058c, r–16–071oo, r–3–15v, r–10–065c, r–17–076d, r–4–045c, r–11–067c, r–18–076f, r–5–047c, r–12–068c, r–19–078w, r–6–048c, r–13–070hh, r–20–079dd, r–7–055c, r–14–071gg, Intended effective date: April 1, 1997.

Docket Number: OST–96–1982.
Date filed: November 22, 1996.
Parties: Members of the International Air Transport Association.
Subject: PTC COMP 0038 dated November 22, 1996, Fare increase to cover increased fuel costs, Non-U.S. markets, Intended effective date: December 15, 1996.

Docket Number: OST–96–1983.
Date filed: November 22, 1996.
Parties: Members of the International Air Transport Association.
Subject: PTC COMP 0039 dated November 22, 1996, Fare increase to cover increased fuel costs, U.S. markets, Minutes—PTC COMP 0041 dated November 21, 1996, Intended effective date: December 15, 1996.

Paulette V. Twine,

Chief, Documentary Services.

[FR Doc. 96–30697 Filed 12–296; 8:45 am]

BILLING CODE 4910–62–P

Federal Railroad Administration

[FRA Docket No. RSOR–6, Notice No. 43]

RIN 2130–AA81

Alcohol/Drug Regulations: Temporary Post-Accident Blood Testing Procedures

AGENCY: Federal Railroad Administration (FRA).

ACTION: Notice.

SUMMARY: Some of the currently distributed FRA post-accident toxicology testing (PATT) kits contain blood tubes with expiration dates ranging from October 1996 to January 1997. Since the blood tube lots that are currently available will expire in a few months, FRA decided to delay replacing the expiring tubes until new lots of 18–24 month blood tubes become available in early 1997. This notice explains the procedures to be followed until FRA distributes replacement blood tubes.

FOR FURTHER INFORMATION CONTACT: Lamar Allen, Alcohol and Drug Program Manager (RRS–11), Office of Safety, FRA, 400 7th Street, S.W., Washington, D.C. 20590 (Telephone: (202) 632–3378) or Patricia V. Sun, Trial Attorney (RCC–11), Office of Chief Counsel, FRA, 400 7th Street, S.W., Washington, D.C. 20590 (Telephone: (202) 632–3183).

Background

Since 1986, FRA has included Vacutainer brand 10 milliliter (mL) evacuated blood collection tubes, manufactured by Becton Dickinson (Becton), in its post-accident toxicology testing (post-accident) kits. Each individual post-accident kit (there are three kits in each post-accident toxicology testing box) contains two Vacutainer brand grey-top glass tubes. These tubes, which have no interior coating, contain silicone, a rubber stopper lubricant, sodium fluoride, an antibacterial agent and mild anticoagulant, and potassium oxalate, an anticoagulant. On each tube, Becton has printed an expiration date, the date

until which it warrants that the tube has sufficient vacuum to draw blood and chemical additives that remain potent. Becton normally releases its blood tubes in lots which expire within 18–24 months of manufacture.

Many of FRA's post-accident kits that have been distributed to railroads contain blood tubes that will expire beginning this fall (from October 1996 to January 1997). The replacement blood tube lots that are now available have only a few months remaining before they expire. FRA has decided to delay tube replacement until newly prepared 18–24 month lots become available in early 1997.

Interim Procedures

Until the current inventory of blood tubes in the field is replaced in early 1997, FRA authorizes railroads to instruct local medical personnel to replace the expired tubes with their own stock of unexpired 10 mL grey-top tubes. (Substituted tubes must be 10 mL, not the 5 mL type, to ensure sufficient blood for analysis.) This action is requested, but not required, and need only be considered when expired tubes are discovered *during an actual post-accident collection*.

Tube replacement is always preferred to using expired tubes, but, if no opportunity for replacement arises, railroads are authorized to complete the post-accident collection using the expired blood tubes. FRA's post-accident testing program incorporates testing and analysis protocols designed to protect employees from unwarranted accusations of alcohol or drug use.

As explained below, grey-top tubes are the only commercial blood collection tubes generally available that contain sodium fluoride. They are FRA's tubes of choice for FRA's post-accident testing.

Scientific/Technical Issues

Although FRA's interim procedures require railroads to replace expired blood tubes with unexpired tubes if possible, FRA believes that use of an expired blood tube, if necessary, will not have a significant impact on the validity of post-accident test results. Discussed below are the two primary scientific/technical issues concerning the use of expired tubes: (1) the integrity of the vacuum present in the tube (to draw blood properly), and (2) the potency of the chemical additives.

Evacuated blood tubes that have recently expired (i.e., within the past several months) are not expected to show a dramatic decrease in tube vacuum. Moreover, a loss of vacuum only affects the efficiency of the medical professional's ability to draw a blood specimen from the donor. As pressure from the body's circulatory system forces blood into the evacuated tube, less vacuum will cause the blood to draw slower or not at all.

Until its expiration date, each grey-top blood tube is warranted by Becton to have 90% or more of its vacuum left (at an estimated deterioration rate of no greater than 5% per year). If a particular tube draws inefficiently due to lack of vacuum, a medical professional would ordinarily discard it and simply use another grey-top tube.

The presence or absence of the chemical additives contained in grey-top tubes does not affect the detection of any of the drugs tested for in FRA's post-accident testing panel, with the exception of parent cocaine. In fact, each grey-top blood tube contains sodium fluoride, an inorganic substance that contributes to the detectability of parent cocaine in blood, by helping to stabilize the spontaneous conversion of cocaine in vitro to cocaine metabolites (specifically to ecgonine methyl ester, or EME). However, sodium fluoride does not impact either the stability or the ability to detect the principal cocaine metabolite of interest, benzoylecgonine (BE). Whether the amount of sodium fluoride present in grey-top blood tubes is sufficient to retard conversion of parent cocaine continues to be a matter of scientific interest [see Iscenschmid et al, 1989; Brogan et al, 1992; Baselt et al, 1993; others]. Moreover, other factors, including the pH of the sample and the temperature of storage, can also affect the stability of parent cocaine in blood.

Since it is an inorganic compound, sodium fluoride oxidizes very slowly and in a vacuum environment is unlikely to deteriorate dramatically in the first few months after tube expiration. In the period between expiration of the older grey-top tubes and replacement with new ones, anticipated to be 90 days or less, there will be little, if any, significant difference in FRA's ability to detect parent cocaine. More importantly, there is *no possibility* that a ''false positive'' for cocaine or any of its metabolites would occur because of an expired blood tube.

Sodium fluoride is also widely established as an effective antimicrobial agent in retarding endogenous alcohol production [see Harper and Correy, 1988; Anderson and Prouty, 1995; Sulkowski et al, 1995; and others]. The production of ethyl alcohol in the body is a well known phenomenon, especially in post-mortem samples. In the presence of certain contaminating microorganisms, alcohol identical to that found in alcoholic beverages may be created. That is, under certain extreme conditions, alcohol can appear in an individual's urine, blood, or tissues without having been ingested. For alcohol to be produced under these circumstances, both glucose and certain bacteria or yeast must be present. Other factors, such as the storage temperature of the specimen or the condition of the body (if the donor is deceased), can also be significant. Obviously, endogenous production of alcohol is of concern in the post-accident alcohol testing of both surviving and deceased crew members.

The presence of alcohol-producing bacteria or yeast and glucose in a blood sample of a surviving crew member can occur only through a combination of disease processes and is extremely rare. Direct contamination of a specimen is also extremely unlikely given the collection and laboratory protocols of FRA's post-accident testing program, and the presence of sodium fluoride in sufficient amounts, such as the amounts contained in Vacutainer grey-top collection tubes.

For surviving crew members, even if the sodium fluoride in the tube were rendered totally inert by age, its absence would not be a problem unless contaminating bacteria or yeast were present. The blood tube itself, with its remaining vacuum, also serves to physically protect against that eventuality. In addition, FRA has in the past tested specifically for contaminating bacteria or yeast in both the urine and the blood, if their presence is suspected.

For deceased crew members, postmortem alcohol generation is always a potential issue when interpreting a positive alcohol result. In FRA's post-accident testing, there have been several cases where, given severe trauma and the correct environmental factors, alcohol was produced post-mortem in detectable amounts, even in the presence of fully potent sodium fluoride.

To account for this possibility, FRA has taken and will continue to take whatever scientific and technical steps are necessary to protect post-accident specimen donors from an incorrect interpretation of a positive test result. Among the procedures used by FRA to rule out an alcohol positive as coming from endogenous production are: examining other tissues or fluids (i.e., urine, brain, vitreous) which may have been protected from trauma or decomposition; determining that the distribution of alcohol in the various body fluids and tissues is inconsistent with that expected in a living person; detecting the presence of other volatiles

or physiological byproducts which can sometimes be present during post-mortem decomposition; repetitive analyses of a specimen to determine if the alcohol concentration is increasing; and determining the identity of any microorganisms present to assess whether they have alcohol-producing capability.

Authority: 49 U.S.C. 20103, 20107, 20111, 20112, 20113, 20140, 21301, 21304, and 49 CFR 1.49(m).

Issued in Washington, D.C. on November 27, 1996.

Grady C. Cothen,

Deputy Associate Administrator for Safety.

[FR Doc. 96–30759 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–06–P

Notice of Safety Bulletin

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of safety bulletin.

SUMMARY: The FRA is issuing a Safety Bulletin addressing recommended safety practices for Direct Train Control (DTC) operations.

FOR FURTHER INFORMATION CONTACT: Doug Taylor, Staff Director, Operating Practices Division, Office of Safety Assurance and Compliance, FRA, 400 Seventh Street, S.W., Washington, D.C. 20590 (telephone 202–632–3346).

SUPPLEMENTARY INFORMATION: Preliminary investigatory findings following the head-on collision of two CSX freight trains at Smithfield, West Virginia, on August 20, 1996, indicate that existing carrier Direct Train Control [1] rules and procedures should be enhanced in order to reduce the risk of similar collisions. Therefore, the following three safety practices are recommended in DTC territory:

In non-signalled DTC territory—when a train holds an ''after arrival of'' block authority:

1. After the train to be met has been visually identified by engine number and the rear end marker has passed the point of restriction, the train being restricted shall establish positive radio contact with the train to be met in order to confirm the identity of the passing train. If radio contact cannot be established, the train dispatcher shall be contacted to provide the required confirmation. The train identification information received from the train to be met or from the dispatcher shall be recorded in writing by both the conductor and engineer, i.e., Engine *(number)* has passed *(location)* at *(time).*

In all DTC territory:

2. Once a movement authority is in effect, no alterations may be made other than those specifically prescribed by carrier operating rules.

3. Conductors and engineers should retain for seven days copies of all en route movement authorities transmitted by radio. These records should be periodically inspected by carrier officials.

In addition to these recommended safety practices, FRA emphasizes that strict adherence to existing FRA safety regulations will enhance safety of these rail operations. Railroad officials and employees should be particularly aware of the following regulations and their effect on the safety of DTC operations:

FRA regulations at 49 CFR 220.61(b)(5) require that both the conductor and engineer shall have a copy of all movement authorities transmitted by radio. FRA has traditionally interpreted this to mean that the conductor and the engineer shall *each* have a copy. Both crewmembers having their own copy of all movement authorities will, in accordance with the purpose of the rule, provide needed safety checks on unauthorized train movements.

FRA regulations at 49 CFR 217.9(b)(1) require that a carrier's program of operational tests and inspections provide for operational testing and inspection under the various operating conditions on the railroad. Consequently, operational tests and inspections conducted in accordance therewith must include a representative number of tests and inspections specifically covering operations in DTC territory.

Issued in Washington, D.C. on November 25, 1996.

Bruce Fine,

Associate Administrator for Safety.

[FR Doc. 96–30737 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–06–P

Surface Transportation Board

[STB Finance Docket No. 33298]

Pioneer Railcorp—Acquisition of Control Exemption—Shawnee Terminal Railway Company, Inc.

Pioneer Railcorp. (Pioneer), a noncarrier holding company, has filed a notice of exemption to acquire, through stock purchase, Shawnee Terminal Railway Company, Inc., a Class III shortline railroad, operating in the State of Illinois.[1]

The earliest the transaction could be consummated was November 21, 1996, the effective date of the exemption (7 days after the exemption was filed).

Pioneer owns and controls eleven existing Class III shortline rail carriers: West Michigan Railroad Co., operating in Michigan; Fort Smith Railroad Co., operating in Arkansas; Alabama Railroad Co., operating in Alabama; Mississippi Central Railroad Co., operating in Mississippi and Tennessee; Alabama & Florida Railway Co., operating in Alabama; Decatur Junction Railway Co., operating in Illinois; Vandalia Railroad Company, operating in Illinois; Minnesota Central Railroad Co., operating in Minnesota; KNRECO, Inc., d/b/a/ Keokuk Junction Railway, operating in Iowa and Illinois; Columbia & Northern Railway Co., which has a right to operate in Mississipi; and Rochelle Railroad Co., which operates in Illinois.

Pioneer states that: (i) The railroads will not connect with each other or any railroad in their corporate family; (ii) the acquisition of control is not part of a series of anticipated transactions that would connect the eleven railroads with each other or any railroad in their corporate family; and (iii) the transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance

[1] This is an umbrella term and refers to methods of operation known variously as Direct Traffic Control (DTC), Track Warrant Control (TWC), Track Permit Control Systems (TPCS), Form D control system (DCS), and similar methods of authorizing train movements.

[1] *See Shawnee Terminal Railway Company, Inc.—Acquisition and Operation Exemption—Cairo Terminal Railroad Company,* Finance Docket No. 33127 (STB served Oct. 11, 1996).

Docket No. 33298, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, NW., Washington, DC 20423. In addition, a copy of each pleading must be served on Daniel A. LaKemper, Esq., Pioneer Railcorp, 1318 S. Johanson Road, Peoria, IL 61607.

Decided: November 25, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–30716 Filed 12–2–96; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 96–80]

Crystallinity of Ceramic Floor and Wall Tile

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

ACTION: Final notice on testing of floor and wall tile for percent of crystallinity necessary to satisfy Harmonized Tariff Schedule of the United States criteria that a ''ceramic article'' be a shaped product ''of crystalline or substantially crystalline structure.''

SUMMARY: Customs has completed a review of the responses received as a result of our request for comments on the testing for the percent of crystallinity of certain articles of imported floor and wall tiles. These articles are classified for Customs purposes under subheadings covered by U.S. Note 1 to Chapter 69 of the Harmonized Tariff Schedule of the United States (HTSUS). There are many products imported under Chapter 69 that have vastly different physical requirements than floor and wall tiles. For this reason this study has been limited to the physical parameter of crystallinity of floor and wall tiles.

EFFECTIVE DATE: Any changes in Customs laboratory testing procedures will be effective regarding merchandise received for testing on or after December 3, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Robert L. Zimmerman, Jr., Office of Laboratories & Scientific Services, (504) 589–6311.

SUPPLEMENTARY INFORMATION:

Background

From time to time U.S. Customs Service employees take representative samples from importations for the purpose of verifying that the importation is properly being entered into the commerce of the United States under the correct subheading of the Harmonized Tariff Schedule of the United States (HTSUS) and other pertinent laws and regulations. Additional U.S. Note 1 to Chapter 69 of the HTSUS states:

> For the purposes of this chapter, a ''ceramic article is a shaped article having a glazed or unglazed body of *crystalline or substantially crystalline structure*, the body of which is composed essentially of inorganic nonmetallic substances and is formed and subsequently hardened by such heat treatment that the body, if reheated to pyrometric cone 020, would not become more dense, harder, or less porous, but does not include any glass articles''. [Emphasis added.]

As part of the Customs efforts to increase voluntary compliance with the law and regulations, inform the public, and involve the importing public in problem resolution, by a notice published in the Federal Register on September 6, 1995 (60 FR 46329), Customs stated that it wished to define the concept of ''substantially crystalline'' in scientific terms based on state-of-the-art ceramic technology. However, before making any changes, comments were invited on this issue.

Discussion of Comments

The following discussion and conclusion applies only to floor and wall tile described in Chapter 69, HTSUS. As a result of the notice, Customs received six responses. The respondents have offered several issues which are discussed individually.

Issue 1: The degree of crystallinity of a ceramic is not addressed in any of the major standards that govern the manufacture of ceramic articles.

Response: This comment was made by five of the six respondents. The American Society for Testing and Materials (over 30 ASTM standards including C373, most found in Volume 15.02), the International Standards Organization (ISO standards 13006 and 10454.1 through 10454.17), and the European Network (EN standards 87, 98–105, 121, 122, 155, 159, 163, 176–178, 186–188, and 202) each have either accepted standards or draft standards for the production of ceramic floor and wall tile. Each standard writing body has a definition for a ceramic floor and wall tile, but none address the issue of crystallinity in their definition. According to one respondent, crystallinity is not an important factor to the industry. From all of the information gathered on this subject, Customs acknowledges that the degree of crystallinity is not an issue to the tile industry. The fact that the issue is not as critical to the industry as the other criteria stated in U.S. Note 1, e.g., fired to pyrometric cone 020, porosity, etc. may lead Customs to lessen the weight of the crystallinity criteria for floor and wall tile. However, in the absence of legislative change to the wording of U.S. Note 1 to Chapter 69 the issue must be addressed for Customs purposes.

Issue 2: X-ray diffraction (XRD) is currently the technique of choice for determining the degree of crystallinity in these products.

Response: Four of the respondents noted this fact. Three went on to discuss the significant cost, skill and effort the method demands. One respondent notes that XRD should be viewed as a qualitative test for the purpose of determining crystallinity. Customs acknowledges that, with one exception, all of the facts presented by the respondents regarding XRD are true. The exception is that, if done properly, XRD can give quantitative results. It is possible that, due to the discussion of Issues 1 and 3, only a type of screening technique is required.

Issue 3: The purpose of the crystallinity criteria is to differentiate a ceramic tile from a glass article.

Response: While only one respondent made note of the U.S. Tariff Commission Tariff Classification Study (''Schedule 5–Nonmetallic Minerals and Products,'' Nov. 15, 1960, pg 77–78) discussion of crystallinity as it applies to ceramic articles, the study is very important in determining the intent of the language of U.S. Note 1 to Chapter 69. The respondent states that the use of the concept of crystallinity is to differentiate a ceramic product from a glass product. From a technical standpoint, this is reasonable since glass articles are nearly completely amorphous, while ceramic goods normally contain some degree of crystallinity. Depending on the raw materials used to make the product and the manufacturing process used to engineer the physical qualities into the product that are necessary for its intended use, the degree of crystallinity may vary significantly. Furthermore, the HTSUS describes a different process for the manufacture of ceramics compared to the process of glass-making. This may be used to differentiate a ceramic article from a glass article for Customs purposes.

Issue 4: Court ruling regarding ''substantially crystalline.''

Response: One respondent refers to the *Eastalco* decision. In *Eastalco Aluminum Co.* V. *United States,* 13 CIT

864, 726 F. Supp. 1342 (1989), affirmed in 9 CAFC 16, 916 F. 2d 1568 (1990), the Court considered whether certain carbon blocks were ''ceramic articles'' for tariff classification purposes. The Court held that a low level of crystallinity (determined to be approximately 5%) was insufficient to meet the ''substantially crystalline'' requirement found in the tariff schedules. In responding to plaintiff's argument, the CIT stated, ''[w]hile fifty percent may not be the appropriate dividing line on the issue of what constitutes substantial crystallinity * * * the quantitative test has shown that a very low level of crystallinity is involved * * *.'' Hence, the Court did not reach the question of the appropriate dividing line for determining substantial crystallinity. In any event, for technical reasons, Customs considers this case to be largely inapplicable here. Graphite (a crystalline form of carbon) was a constituent material used to fabricate the blocks at issue in *Eastalco.* These blocks are normally used to line ovens and furnaces that must handle extremely high temperatures. Floor and wall tiles have a vastly different construction and application; they will, therefore, have quite different physical characteristics. In sum, it is logical that the percent of crystallinity needed to satisfy the subjective term ''substantially crystalline'' may be different for products that are vastly different.

Issue 5: Professional opinion of percent of crystallinity.

Response: All but one of the respondents who are scientists/engineers state that, in their professional opinion, only a minimal level of crystallinity should be required for a floor or wall tile to be considered ''substantially crystalline.'' One scientist did not offer an opinion on a minimum level of crystallinity. One of the ceramic engineers introduces a concept that the crystalline content of nearly all, if not all glass, ''never exceeds a few percent (less than 5%).'' Customs finds these opinions to be significant.

Conclusion

After careful consideration of all of the comments received concerning the issues noted above, as of the effective date of this notice in the Federal Register, in making decisions on tariff classification Customs will consider the term ''crystalline or substantially crystalline'' as used in U.S. Note 1 to Chapter 69, as it pertains to floor and wall tile, to be satisfied for articles having a level of crystallinity that is clearly discernable by x-ray diffraction or other analytical methodology that is generally accepted by the scientific community. Normally, a qualitative analysis, using the XRD technique, that indicates some degree of crystallinity exists in the article would be sufficient to verify that the floor or wall tile article has a sufficient crystalline nature to satisfy the criteria ''crystalline or substantially crystalline structure'' for Customs purposes.

Dated: November 26, 1996.

George D. Heavey,

Director, Laboratories and Scientific Services.

[FR Doc. 96–30664 Filed 12–2–96; 8:45 am]

BILLING CODE 4820–02–P

UNITED STATES INFORMATION AGENCY

Proposed Collection; Comment Request

AGENCY: United States Information Agency.

ACTION: Proposed collection; Comment request.

SUMMARY: The United States Information Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on an information collection requirement concerning the public use form entitled ''Surveys, Interviews, and Other Audience Research for Radio and TV Marti''. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)).

The information collection activity involved with this program is conducted pursuant to the mandate given to the United States Information Agency in accordance with P.L. 98–11, the Radio Broadcasting to Cuba Act, to provide for the broadcasting of accurate information to the people of Cuba and for other purposes. In addition, Public Law 98–11 was amended by Public Law 101–246, which established the authority for TV Marti.

DATE: Comments are due on or before February 3, 1997.

COPIES: Copies of the Request for Clearance (OMB 83–I), supporting statement, and other documents that will be submitted to OMB for approval may be obtained from the USIA Clearance Officer. Comments should be submitted to the office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USIA, and also to the USIA Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Agency Clearance Officer, Ms. Jeannette Giovetti, United States Information Agency, M/ADD, 301 Fourth Street, S.W., Washington, D.C. 20547, telephone (202) 619–4408; and OMB review: Ms. Victoria Wassmer, Office of Information And Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10202, NEOB, Washington, D.C. 20503, Telephone (202) 395–3176.

SUPPLEMENTARY INFORMATION: Public reporting burden for this collection of information (Paper Work Reduction Project: OMB No. 3116–0197) is estimated to average 1.15 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Responses are voluntary and respondents will be required to respond only one time.

Comments are requested on the proposed information collection concerning (a) whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information has practical utility; (b) the accuracy of the Agency's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Send comments regarding this burden estimate or any other aspect of this collection of information to the United States Information Agency, M/ADD, 301 Fourth Street, S.W., Washington, D.C. 20547; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10202, NEOB, Washington, D.C. 20503.

CURRENT ACTIONS: USIA is requesting reinstatement of this collection for a three-year period and approval for a revision to the burden hours.

TITLE: Surveys, Interviews, and Other Audience Research for Radio and TV Marti.

ABSTRACT: Data from this information collection are used by USIA's Office of Cuba Broadcasting (OCB) in fulfillment of its mandate to evaluate effectiveness of Radio and TV Marti operations by estimating the audience size and composition for broadcasts; and assess signal reception, credibility and relevance of programming through this research.

Proposed Frequency of Responses:

No. of Respondents.....1,788
Recordkeeping Hours 1.15

Total Annual Burden 2,052

Dated: November 26, 1996.

Rose Royal,

Federal Register Liaison.

[FR Doc. 96–30758 Filed 12–2–96; 8:45 am]

BILLING CODE 8230–01–M

Federal Register

Tuesday
December 3, 1996

Part II

Department of Housing and Urban Development

Notice of Funding Availability for CDBG Small Cities Development Grants for Fiscal Year 1997; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4174–N–01]

Notice of Funding Availability for: the HUD-Administered Small Cities Community Development Block Grant (CDBG) Program, Development Grants—Fiscal Year 1997; and the Section 108 Loan Guarantee Program for Small Communities in New York State

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability (NOFA) for CDBG Small Cities Development Grants for Fiscal Year (FY) 1997.

SUMMARY: This Notice of Funding Availability (NOFA) announces the availability of CDBG Small Cities development grants and guaranteed loans to fund eligible development activities related to the New York canal system. This NOFA is part of the Canal Corridor Initiative, a multiyear effort designed to revitalize the economic base of communities in upstate New York through development projects and job creation along the canal system and connecting waterways.

Eligible development activities are expected to be funded through a combination of resources, including Community Development Block Grant (CDBG) funds made available through this NOFA under the HUD-administered Small Cities CDBG program and the Section 108 Loan Guarantee program. HUD expects to provide funds for the selected development projects through a combination of CDBG and Section 108 in an aggregate amount of approximately $120 million or more depending upon the proposals submitted.

HUD expects that the typical project proposal would be a Section 108-eligible development project that builds on the unique locational opportunities afforded by the New York canal system and connecting waterways to foster commercial revitalization, business growth and expansion, and job creation that will result in the economic and physical revitalization of the project area. Such projects would utilize funds made available by the Section 108 Loan Guarantee program to provide the ''up-front'' financing, along with other public or private resources to the extent financially feasible. The loan guaranteed by section 108 would be expected to be repaid with a combination of the CDBG funds requested as part of this application, future CDBG appropriations, and the ''cash flows'' generated by the assisted project. This NOFA makes available between $3 million and $9 million in FY 1997 funding through the HUD-administered Small Cities CDBG program for the first year of multiyear plans requested through applications. In the event that HUD does not receive sufficient numbers of applications that are fundable in the aggregate amount that HUD is setting aside in this NOFA, HUD may publish a subsequent NOFA soliciting applications for the remainder of the funds that HUD intends to set aside for this initiative. Multiyear plans approved will not propose an amount of grant funds totaling more than $60 million for all years.

HUD encourages applications from joint applicants in accordance with 24 CFR 570.422. The nature of riverfront revitalization is such that waterfront projects undertaken in tandem at different points along the waterfront creates a ''regional synergy'' that enhances the success of all projects in the region.

Combining Section 108 Loans with Multiyear Plans for CDBG Funding to Create a Financial Package

Under the Section 108 program and pursuant to 24 CFR 570.705(a)(2)(iii), a New York State nonentitled community/public entity eligible to receive HUD-administered CDBG Small Cities funds may borrow an aggregate amount of funds guaranteed under the Section 108 Loan Guarantee program that is five times the greater of:

(A) The most recent CDBG Small Cities grant approved for the applicant,

(B) The average of the most recent three CDBG Small Cities grants approved for the applicant (excluding any CDBG grant in the same fiscal year as the Section 108 Loan Guarantee commitment), or

(C) The average amount of CDBG Small Cities grants made to units of general local government in New York State in the previous fiscal year.

In FY 1996, the average New York State CDBG Small Cities grant amount awarded was $600,723. This means that under the Section 108 program, a typical New York State nonentitled community or county may borrow approximately $3 million. Given current Section 108 Loan Guarantee rates and a 20-year financing term, the average annual straight line principal and interest payment of a $3 million guaranteed Section 108 loan would be approximately $305,000 per year. In this example, a $100,000 a year CDBG grant for the 20 years would have the effect of reducing the effective interest rate to approximately 3 percent per annum. This helps communities undertake development projects that might not otherwise be financially feasible.

In addition to any other security arrangement that may be permitted or required pursuant to 24 CFR 570.705(b), and in order to reduce the risk to HUD and individual borrowers beginning in fiscal year 1998, HUD will establish a debt service reserve with CDBG Small Cities funds that will be used to make the first year's Section 108 debt obligation payments when they come due (ending in August of any year under the current system). Early in the next fiscal year, HUD will replenish the debt service reserve for purposes of the next year's payments with another Small Cities grant under the noncompetitive authority of 24 CFR 570.432. HUD intends to, subject to the conditions stated in § 570.432 including the availability of appropriations, continue to replenish the debt service reserve account each year for each grant made under this NOFA as long as any related Section 108 loan remains outstanding.

This NOFA sets out program guidelines that will govern the application, application review, and award process for the CDBG New York State Small Cities grants made available as part of the financial package for Canal Corridor Initiative projects.

DATES: Applications are due on or prior to January 2, 1997. Applications, if mailed, must be postmarked by the United States Postal Service no later than midnight on January 2, 1997. Overnight delivery items received within ten (10) days after January 2, 1997 will be deemed to have been received by that date, upon submission of documentary evidence that they were placed in transit with the overnight delivery service by no later than December 31, 1996. If an application is hand-delivered to the New York or the Buffalo Office, the application must be delivered to the appropriate office by no later than 4:00 p.m. on the deadline date.

The above-stated application deadline is firm as to date and hour. In the interest of fairness to all competing applicants, HUD will treat as ineligible for consideration any application that is not received by 4:00 p.m. on, or postmarked by January 2, 1997. Applicants should take this policy into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

ADDRESSES: Completed applications will be accepted at the following addresses:

1. *For the nonentitled CDBG jurisdictions in and county of Ulster and nonparticipating jurisdictions in the urban county of Dutchess:* Department of Housing and Urban Development, Office of Community Planning and Development, Attention: Small Cities Coordinator, 26 Federal Plaza, New York, NY 10278–0068. Telephone (212) 264–0771; and

2. *For the nonentitled CDBG jurisdictions in and counties of Albany, Cayuga, Clinton, Columbia, Erie, Essex, Greene, Herkimer, Madison, Monroe, Montgomery, Niagara, Oneida, Onondaga, Ontario, Orleans, Oswego, Rensselaer, Saratoga, Schenectady, Schuyler, Seneca, Tompkins, Warren, Washington, Wayne and Yates:* Department of Housing and Urban Development, Community Planning and Development Division, Attention: Small Cities Coordinator, 465 Main Street, Lafayette Court, Buffalo, NY 14203–1780. Telephone (716) 551–5742.

FOR FURTHER INFORMATION CONTACT: Robert Duncan, Deputy Director, Office of Block Grant Assistance, Department of Housing and Urban Development, Room 7286, 451 Seventh Street, SW, Washington, DC 20410, Telephone (202) 708–3587; or Mr. Joseph D'Agosta, New York Regional Director, Office of Community Planning and Development, Department of Housing and Urban Development, 26 Federal Plaza, New York, NY 10278–0068, Telephone (212) 264–0771.

Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements contained in this NOFA have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The OMB control number, when assigned, will be announced by separate notice in the Federal Register. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number. Prior to this submission to OMB, HUD had, on June 3, 1996 (61 FR 27926) published in the Federal Register a notice and request for comments on the New York State Small Cities CDBG program concerning the collection of information for that program. The deadline for the submission of comments was August 2, 1996. HUD's request for an OMB control number takes into account the comments received in response to that June 3, 1996 notice.

I. Purpose and Substantive Description

A. Authorities and Background

1. Authority

Title I, Housing and Community Development Act of 1974 (the HCD Act) (42 U.S.C. 5301–5320); 24 CFR part 570, subpart F.

2. Background

Title I of the Housing and Community Development Act of 1974 authorizes the Community Development Block Grant (CDBG) program. Section 106 of Title I permits the States to elect to assume the administrative responsibility for the CDBG program for nonentitled areas within their jurisdiction. Section 106 provides that HUD will administer the CDBG program for nonentitled areas within any State that does not elect to assume the administrative responsibility for the program. Subpart F of 24 CFR part 570 sets out the requirements for HUD's administration of the CDBG program in nonentitled areas (Small Cities program). The State of New York has not elected to implement the CDBG Small Cities program.

With respect to this NOFA, subpart F, at 24 CFR 570.421(a)(6), ''Economic development grants,'' provides that in the event that a nonentitlement New York State Small Cities applicant needs a CDBG Small Cities grant, in addition to a Section 108 Loan Guarantee, to make its economic development project viable, HUD may fund such applications, as they are determined to be fundable in a specific amount up to the sum set aside for development projects in this Notice of Funding Availability. This NOFA proposes to maximize the utilization of Section 108 guaranteed loans in conjunction with multiyear plans for use of CDBG funds to undertake eligible development projects. As a result of this approach, the funds announced in this NOFA provide eligible small communities and counties in New York State with a unique opportunity to propose programs that focus on canal-related economic development projects to expand economic and job opportunities and act as a catalyst to spur community and neighborhood economic revitalization. HUD encourages eligible communities to propose programs that are creative and innovative in addressing their development needs. Although the focus of 24 CFR 570.421(a)(6) is broadly described as economic development, as a technical matter any activity eligible for Section 108 Loan Guarantee assistance under 24 CFR 570.703 is eligible under this NOFA (except as stated in section I.C.3.a. of this NOFA, below). As emphasized in the selection factors (see section II.C. of this NOFA), however, the overall purpose of the eligible activity, or group of eligible activities, proposed for funding in response to this NOFA is the economic development of the area served by the proposed project.

Because of the integral relationship of CDBG grant funds and the Section 108 Loan Guarantees, the scale of development projects solicited, and the expectation of a long-term stream of CDBG funds (subject to future appropriations) to make such projects economically feasible, this NOFA solicits applications for multiyear plans. If an applicant's multiyear plan is selected on a competitive basis, the first year will be funded, and HUD may fund future years on a noncompetitive basis subject to acceptable performance, submission of an acceptable application and certifications, and the provision of adequate appropriations for the CDBG New York nonentitlement Small Cities program.

3. Other Program Requirements

a. *Abbreviated Consolidated Plan.* Each jurisdiction that applies for funds under this NOFA must have submitted a consolidated plan, as provided at 24 CFR part 91. A jurisdiction that does not expect to be a participating jurisdiction in the HOME program under 24 CFR part 92, may submit (or may have submitted) an abbreviated consolidated plan that is appropriate to the types and amounts of assistance sought from HUD. (See 24 CFR 91.235.) If an applicant has an abbreviated consolidated plan previously approved by HUD, the applicant may update it, if necessary, if the CDBG development activities proposed in the application contain any new non-housing community development activity.

Any applicant that plans to undertake a housing activity with funds under this NOFA needs to prepare and submit, at a minimum, an abbreviated consolidated plan that is appropriate to the types and amounts of housing assistance sought under this NOFA. Even if the community's Small Cities application is approved, HUD must also approve the consolidated plan before the community may receive Small Cities funding. Further, that applicant must also include a certification that any housing activities in its CDBG Small Cities application are consistent with the consolidated plan. An applicant seeking funds under this NOFA to address non-housing community

development needs should prepare an abbreviated consolidated plan that describes the jurisdiction's priority non-housing community development needs eligible for assistance under the CDBG program by eligibility category, reflecting the needs of families for each type of activity, as appropriate, in terms of dollar amounts estimated to meet the priority need for the type of activity (see 24 CFR 91.235(c)(2)). The abbreviated consolidated plan is subject to the same citizen participation requirements as is the jurisdiction's Small Cities CDBG application. Both must meet the citizen participation requirements before they may be submitted to HUD. (See 24 CFR 570.431) A Section 108 Loan Guarantee application would also have to meet these requirements if the jurisdiction submits one to HUD for consideration.

If possible, applicants should endeavor to submit the abbreviated consolidated plan in advance of the Small Cities application due date. The latest time at which the abbreviated consolidated plan will be accepted by HUD for the HUD-administered Small Cities program in New York will be the application due date for the Small Cities application. Failure to submit the abbreviated consolidated plan by the due date is not a curable technical deficiency. Questions regarding the abbreviated consolidated plan should be directed to the appropriate HUD field office.

Any application that is fundable, but does not have an approved consolidated plan, will receive a conditional approval subject to HUD's approval of the abbreviated consolidated plan. If HUD is unable to approve the abbreviated consolidated plan within a reasonable period of time, but not less than 60 days from the date that the conditional approval is announced, HUD reserves the right to rescind the award. In such event the funding will be awarded to the highest rated fundable applicant that did not receive funding under this competition.

b. *Section 3.* Assistance provided under this NOFA is subject to the requirements of section 3 of the Housing and Urban Development Act of 1968, and the implementing regulations in 24 CFR part 135. One of the purposes of this NOFA, which is consistent with section 3, is to give, to the greatest extent feasible and consistent with Federal, State, and local laws and regulations, job training, employment and other contracting opportunities generated from certain HUD financial assistance to low- and very low-income persons. Public entities awarded funds under this NOFA that intend to use the funds for housing rehabilitation, housing construction, or other public construction must comply with the applicable requirements set forth in the regulations.

c. *CDBG Program Requirements.* The provisions of 24 CFR part 570, subpart F, as applicable, shall apply to CDBG grants made under this NOFA.

4. Accountability in the Provision of HUD Assistance: Documentation and Public Access Requirements; Applicant/Recipient Disclosures

HUD has promulgated a final rule to implement section 102 of the Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) (Pub. L. 101–235; approved December 15, 1989). The final rule is codified at 24 CFR part 4. Section 102 contains a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. On January 16, 1992 (57 FR 1942), HUD published a final rule implementing section 102. Although the rule has been amended and now appears in part 4, the January 16, 1992 notice provided the public (including applicants for, and recipients of, HUD assistance) with further information on the implementation of section 102. The documentation, public access, and applicant and recipient disclosure requirements of section 102 apply to assistance awarded under this NOFA as follows:

a. *HUD Responsibilities.* (1) Documentation and Public Access. HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its Federal Register notice of all recipients of HUD assistance awarded on a competitive basis.

(2) Disclosures. HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period of less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15.

b. *Units of General Local Government Responsibilities.* Units of general local government awarded assistance under this NOFA are subject to the provisions of either paragraph b.(1), *or* paragraph b.(2) *and* b.(3), below. For units of local government awarded assistance under this NOFA which in turn make the assistance available on a NONCOMPETITIVE BASIS for a specific project or activity to a subrecipient, or a ''Community Based Development Organization'' (CBDO) as defined in 24 CFR 570.204, paragraph b(1) applies. For units of local government awarded assistance under this NOFA, which in turn make the assistance available on a COMPETITIVE BASIS for a specific project or activity to a subrecipient, or a CBDO, paragraphs b. (2) *and* (3) apply.

(1) Disclosures. The units of general local government receiving assistance under this NOFA must make all applicant disclosure reports available to the public for three years. Required update reports must be made available along with the applicant disclosure reports, but in no case for a period less than three years. Each unit of general local government may use HUD Form 2880 to collect the disclosures, or may develop its own form.

(2) Documentation and Public Access. The recipient unit of general local government must ensure that documentation and other information regarding each application submitted to the recipient by a subrecipient or CBDO applicant are adequate to indicate the basis upon which assistance was provided or denied. The unit of general local government must make this material, including any letters of support, available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Unit of general local government recipients must also notify the public of the subrecipients or CBDO's that receive the assistance. Each recipient will develop documentation, public access, and notification procedures for its programs.

(3) Disclosures. Units of general local government receiving assistance under this NOFA must make all applicant disclosure reports available to the public for five years. Required update reports must be made available along with the applicant disclosure reports, but in no case for a period less than three years. Each unit of general local government may use HUD Form 2880 to

collect the disclosures, or may develop its own form.

B. Allocation of Grant Amounts and Section 108 Loan Guarantee Commitments

1. Total Available Funding

The nonentitlement CDBG funds for New York State for FY 1997 total approximately $55,982,000. Of that amount, this NOFA sets aside between $3 million and $9 million for eligible development grants for projects that increase economic opportunities related to the New York State Canal System or connecting waterways (see section I.C.1. of this NOFA, below, regarding eligible applicants).

2. Maximum Grant Amounts

The maximum CDBG grant amount that will be awarded from FY 1997 funds for an eligible development project pursuant to this NOFA is $900,000. For a multiyear plan, HUD expects that no more than $5 million will be made available in funds under this NOFA and future years' CDBG funds (subject to appropriations) to pay the Section 108-guaranteed debt obligation per grantee over the life of the plan. Thus in the aggregate for all plans, HUD expects that no more than $60 million will be available (subject to appropriations) for Section 108 loan payments over the life of all multiyear plans approved, limiting the set-asides of CDBG funds for multiyear plans to an average of $3 million per year over a 20-year period.

3. Availability of Section 108 Loan Guarantees

HUD expects to make $80 million in Section 108 Loan Guarantee commitments, or higher, depending on the CDBG development applications approved in conjunction with grants made under this NOFA.

4. Multiyear Requests and Repayment of Section 108 Loans With CDBG Funds

a. *General.* Pursuant to 24 CFR 570.432, HUD expects to approve multiyear plans of up to twenty (20) years, for use of CDBG funds for the sole purpose of paying any amounts due on debt obligations issued by such unit of general local government (or its designated public agency) and guaranteed by the Secretary pursuant to section 108 of the Housing and Community Development Act of 1974, as amended.

b. *Submission of multiyear request and plan.* Each application for a CDBG development grant under this NOFA should include a multiyear plan for CDBG funds, the use of which will be limited to paying projected amounts due on Section 108-guaranteed debt obligations over the projected term of the loan.

The multiyear plans will be rated competitively against each other based on the selection criteria in section II.C. of this NOFA. Each applicant's multiyear plan must discuss the total amount of the Section 108 Loan Guarantee commitment that will be requested, the term of the Section 108 guaranteed loan, a repayment schedule for the Section 108 guaranteed loan that clearly identifies the amount and source of the projected funds, including the CDBG funds proposed to be used to repay the Section 108 guaranteed loan over the course of the multiyear plan. The multiyear period may not exceed 20 years.

HUD intends to fund succeeding years of the plan on a noncompetitive basis, subject to acceptable performance, submission of an acceptable application and certifications, and the provision of adequate appropriations for the HUD-administered Small Cities program. HUD reserves the right to lower the amount of funds for succeeding years if respective recipients are not in compliance with performance requirements and applicable regulations. The application must list for each year of the multiyear period the projected amount of CDBG funds requested for each year. The amount of CDBG funds requested for each year need not be the same amount; however, the amount requested for each year should relate to the anticipated amounts appropriate to meet the CDBG portion of the debt obligation on the Section 108 guaranteed loan, consistent with section I.B.2. of this NOFA, above. For subsequent years of the multiyear period and pursuant to 24 CFR 570.432, HUD will adjust the actual CDBG grant amount awarded to such amounts required for the sole purpose of paying any principal and interest amounts due on the loan guaranteed by Section 108 as provided under the Section 108 note contract, or in the event of a default any amounts due under the guarantee.

C. Eligibility

1. Eligible Applicants

Eligible applicants are units of general local government in New York State (excluding metropolitan cities, urban counties, units of government that are participating in urban counties or metropolitan cities even if only part of the participating unit of government is located in the urban county or metropolitan city, and Indian tribes eligible for assistance under section 106 of the HCD Act) that are proposing development activities related to the New York State Canal System or connecting waterways, including, but not limited to the Hudson River, Cayuga Lake, Seneca Lake, Lake Champlain, Lake George, Lake Erie, and Lake Ontario. Eligible applicants are further limited to the nonentitled CDBG jurisdictions in and counties of Albany, Cayuga, Clinton, Columbia, Erie, Essex, Greene, Herkimer, Madison, Montgomery, Niagara, Oneida, Onondaga, Ontario, Orleans, Oswego, Rensselaer, Saratoga, Schenectady, Schuyler, Seneca, Tompkins, Ulster, Warren, Washington, Wayne, and Yates, and the nonparticipating jurisdictions in the urban counties of Dutchess and Monroe.

2. Joint Applicants

There may be several instances in which several communities have common economic development opportunities that are more feasible if an eligible development project were carried out jointly rather than on an individual basis. In such cases, HUD encourages these communities to develop regional solutions to regional problems and propose a joint application from all affected communities. This NOFA authorizes eligible units of general local government under section I.C.1. of this NOFA, above, to submit a joint application to carry out an eligible development project that addresses common problems faced by all of the jurisdictions. A joint application must be pursuant to a written cooperation agreement submitted with the application. The cooperation agreement must authorize one of the participating units of government to act as the lead applicant that will submit the application to HUD, and must delineate the responsibilities of each participating unit of government with respect to the Small Cities program. (See 24 CFR 570.422 for requirements regarding joint applications.) Except as otherwise noted, a joint application must meet all of the requirements of this NOFA as an application from a single unit of general local government. Applications under this NOFA may be submitted individually or jointly, subject to 24 CFR 570.422. However, Section 108 Loan Guarantee applications must be submitted individually and in accordance with 24 CFR 570.704 by each unit of general local government that will receive a guarantee and issue guaranteed obligations.

3. Activities Eligible for CDBG Small Cities Grants Under This NOFA

Eligible activities are development activities related to the New York State Canal System or connecting waterways, including, but not limited to the Hudson River, Cayuga Lake, Seneca Lake, Lake Champlain, Lake George, Lake Erie and Lake Ontario. Development activities must also meet the criteria below:

a. Eligible development projects and activities to be financed with FY 1997 CDBG funds include the following:

(1) The activities listed under the Section 108 Loan Guarantee program at 24 CFR 570.703, except subparagraphs (j) Construction of housing by non-profit organizations, and (m) regarding activities by ''colonias;'' and

(2) Capitalization of a Section 108 debt service reserve/loan loss reserve as part of the financing of activities that are otherwise eligible under this NOFA. A debt service reserve created from Small Cities grant funds should not, however, exceed one year's Section 108 needs.

b. Eligible activities to be funded during FY 1998 and later years under multiyear plans proposed pursuant to this NOFA are limited to the repayment of any amounts due on debt obligations issued by a units of general local government and guaranteed by the Secretary pursuant to section 108 of the HCD Act. This includes planned repayments from CDBG funds, as well as amounts due in the event of default, as applicable.

4. National Objectives and Primary Objective

Each activity must meet one of the national objectives (i.e., benefit to low- and moderate-income persons, elimination of slums or blighting conditions, or meeting imminent threats to the health and safety of the community). Pursuant to 24 CFR 570.420(e)(2), not less than 70 percent of the total of grant funds from a grant made under this NOFA and Section 108 Loan Guarantee funds received within a fiscal year must be expended for activities that benefit low- and moderate-income persons under the criteria of § 570.208(a) or § 570.208(d)(5) or (6).

5. Limitations on the Ratio of CDBG Grant Funds to Section 108 Loan Guarantee Funds

HUD reserves the right, within the maximum grant limit of $900,000 provided in section I.B.2. of this NOFA, above, to determine a minimum or a maximum amount of any CDBG grant award under this NOFA with the difference from the amount requested, if any, to be made up (to the maximum extent feasible to fund the eligible development project) with loan funds guaranteed by Section 108. HUD also reserves the right to determine the amount and number of years of the multiyear plan, or Section 108 Loan Guarantee award per applicant, application, or project and to modify requests accordingly.

HUD expects to approve CDBG grant amounts for approvable applications at a range of ratios of CDBG grant funds awarded to new Section 108 Loan Guarantee commitments. For example, an applicant could request a CDBG grant of $100,000 and propose to leverage $2.5 million in new Section 108 Loan Guarantee commitments, and another applicant could request a CDBG grant of $1 million and propose to leverage $5 million in new Section 108 Loan Guarantee commitments. However, in no event will HUD make an award in which the cumulative amount of CDBG funds proposed for the full multiyear period exceeds the amount of new Section 108 commitments. All applicants should discuss why their canal-related development project requires the particular level of CDBG grant assistance to Section 108 Loan Guarantee funds that is proposed.

In the case of an applicant that has received a prior CDBG grant award for an activity proposed in this application, HUD reserves the right to consider the amount of the previous CDBG award and the grant amount requested in response to this NOFA, and to adjust the amount of a CDBG award under this NOFA, including, if appropriate, not making an award.

In the event the applicant is awarded a CDBG grant that has been reduced below the original request, the applicant will be required to modify its project plans and application to conform to the terms of HUD approval before execution of a grant agreement and/or a Section 108 Loan Guarantee commitment. HUD reserves the right to reduce or de-obligate the CDBG grant award if an approvable Section 108 Loan Guarantee application is not submitted by the grantee in the required amounts on a timely basis (see section II.B.1.b. After approval of the CDBG grant, any program amendments must meet the provisions of 24 CFR 570.427.

6. Environmental Review Requirement

The HUD environmental review procedures contained in 24 CFR part 58 apply to this program, according to 24 CFR 570.604. Under part 58, grantees assume all of the responsibilities for environmental review, decisionmaking, and action pursuant to the National Environmental Policy Act of 1969 and the other provisions of law specified by the Secretary in 24 CFR part 58 that would apply to the Secretary were he to undertake such projects as Federal projects.

II. The Application Process

Eligible applicants seeking CDBG assistance must apply in accordance with this NOFA. The CDBG application shall be accompanied by a request for Section 108 Loan Guarantee commitments, as further described in section II.B. of this NOFA, below. Application requirements for the Section 108 program are found in § 570.704.

A. Timing of submission

Applications for CDBG assistance must be submitted for receipt in the manner described under ''Dates'' and ''Addresses,'' above.

B. Submission Requirements

1. The CDBG application (an original plus two copies) shall be accompanied by a request for loan guarantee assistance under Section 108. If more than one jurisdiction applies jointly, each entity that will receive a guarantee and issue guaranteed obligations must submit a separate request. Each request for Section 108 Loan Guarantee can be either one or more of the following:

a. A formal application for Section 108 Loan Guarantee(s), including the documents listed at 24 CFR 570.704(b);

b. A brief description of a Section 108 Loan Guarantee application(s) to be submitted within 60 days (with HUD reserving the right to extend such period for good cause on a case-by-case basis) of a notice of CDBG selection (CDBG awards will be conditioned on approval of actual Section 108 loan commitments). This description must be sufficient to support the basic eligibility of the proposed project or activities for Section 108 assistance;

c. A request for a Section 108 Loan Guarantee amendment (analogous to subparagraph a. or b. above) that proposes to increase the amount of a previously approved application.

d. Applicants should note that an application for a Section 108 Loan Guarantee commitment requires that the applicant certify that it has made efforts to obtain financing without the use of the Section 108 Loan Guarantee and that it cannot complete such financing consistent with the timely execution of the program plans without the Section 108 Loan Guarantee.

2. In addition, an application for CDBG grant funds shall include the following:

a. A completed Standard Form 424, Application for Federal Assistance.

b. A signed copy of certifications required under the CDBG program, including, but not limited to the Drug-Free Workplace Certification, and the Certification Regarding Lobbying pursuant to section 319 of the Department of Interior Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352), generally prohibiting use of appropriated funds, and, if applicable, Disclosure of Lobbying Activities (SF–LLL). The applicant may use the lobbying certification published with this NOFA.

c. Form HUD–2880, Applicant/Recipient Disclosure/Update Report, as required under 24 CFR 4.9 through 4.13. The applicant may use the form published with this NOFA.

d. Abbreviated consolidated plan, if applicable;

e. A narrative statement, in accordance with section I.A.3.a. of this NOFA, consisting of the following:

(1) A description of the activities that will be carried out with the CDBG grant funds and Section 108 Loan Guarantee funds. The narrative statement should explain how the use of CDBG grant funds together with Section 108 Loan Guarantee funds will meet the selection criteria in section II.C. of this NOFA, below;

(2) A description of the multiyear plan for CDBG funds, the use of which will be limited to paying projected amounts due on Section 108 guaranteed loan debt obligations over the projected term of the loan that is guaranteed by the Section 108 Loan Guarantee. Each applicant's multiyear plan must discuss the total amount of the Section 108 Loan Guarantee commitments that will be requested, the term of the Section 108 guaranteed loans, a repayment schedule for the Section 108 guaranteed loans that clearly identifies the amount and source of the projected funds, including the CDBG funds proposed to be used to repay the Section 108 guaranteed loans over the course of the multiyear plan. The multiyear period may not exceed 20 years. The description must list, for each year of the multiyear period, the projected amount of CDBG funds that will be needed each year to meet the Section 108 debt obligation. The amount of CDBG funds requested for each year need not be the same amount; however, the amount requested for each year should relate to the anticipated amounts appropriate to meet the CDBG portion of the payment on the Section 108 guaranteed loans, consistent with the maximum grant amounts specified in section I.B.2. of this NOFA; and

(3) The description of the activities to be carried out with the CDBG grant and Section 108 Loan Guarantee funds should also describe how they will create visible change and are part of a larger comprehensive revitalization effort, and how they meet the selection criteria, including performance measures and benchmarks for these activities; identify and describe the project service area; and, as an aid to reviewing the multiyear plan, include a draft business plan with financial projections for not less than a 5-year period.

In addition to the above, HUD encourages applicants to submit maps and related information generated by the community's consolidated plan computer software with their applications, and depictions of proposed projects.

(Note that the Office of Community Planning and Development's Consolidated Plan computer software is available for applicants to use in defining their project area, planning and coordinating revitalization activities, and illustrating how activities will physically and economically revitalize the project area. HUD encourages applicants to submit maps and other data generated with this software with their applications.)

d. The narrative statement and the response to all of the selection criteria in section II.D. of this NOFA, below, should preferably not exceed thirty (30) 8.5″ by 11″ typewritten pages.

D. Selection Criteria

All applications will be considered for selection based on the following criteria. As described in section II.B.2.d. of this NOFA, above, each applicant's response to the narrative statement and all of the selection criteria should preferably not exceed thirty (30) 8.5″ by 11″ typewritten pages. Each application will receive only one score.

A maximum of 184 points is possible under this NOFA, with the maximum points for each factor being:

	Points
Need—absolute number of persons in poverty	22
Need—percent of persons in poverty	22
Program Impact	125
Outstanding performance—FHEO	15
Total	184

Each of the four factors is outlined below. All points for each factor are rounded to the nearest whole number.

1. Need—Absolute Number of Persons in Poverty—(up to 22 points). HUD uses 1990 census data to determine the absolute number of persons in poverty residing within the applicant unit of general local government. Applicants which are county governments are rated separately from all other applicants. Applicants in each group are compared in terms of the number of persons whose incomes are below the poverty level. Individual scores are obtained by dividing each applicant's absolute number of persons in poverty by the greatest number of persons in poverty of any applicant, and multiplying by 22.

2. Need—Percent of Persons in Poverty—(up to 22 points). HUD uses 1990 census data to determine the percent of persons in poverty residing within the applicant unit of general local government. Applicants in each group are compared in terms of the percentage of their population below the poverty level. Individual scores are obtained by dividing each applicant's percentage of persons in poverty by the highest percentage of persons in poverty of any applicant, and multiplying by 22.

3. Program Impact—(up to 125 points)

Within this selection factor, points will be awarded as follows:

a. Quality of the Plan—(up to 60 points). In reviewing the applicant's response to this criterion, HUD will consider the following:

(1) *Economic and commercial revitalization.* The extent to which the proposed canal-related development project will contribute to the physical and economic revitalization of a waterfront district, and the impact of the project in strengthening the economic health of the entire community.

(2) *Regional impact.* The extent to which the proposed canal-related development project relates to other waterfront development projects in the region to create a regional synergy which contributes to regional economic growth, including job creation, increased business activity and tourism.

(3) *Job creation.* The extent to which the proposed canal-related development project assisted by the requested CDBG grant, Section 108 Loan Guarantees, and the multiyear CDBG program will create jobs, principally for low- and moderate-income persons.

(4) *Innovation and creativity.* The extent to which the applicant incorporated innovation and/or creativity in the design and proposed implementation of the activities to be carried out with Section 108/CDBG funds.

(5) *Feasibility of the development proposal.* HUD will consider the feasibility and quality of the applicant's canal-related development proposal for the use of CDBG funds and Section 108

guaranteed loans to address the applicant's economic and community development needs, and the extent to which the canal-related development proposal is logically, feasibly, and substantially likely to achieve its stated purpose. In evaluating feasibility, HUD will also consider the extent to which the proposal includes public/private partnerships, i.e. the involvement of groups such as nonprofit organizations, developers, financial institutions, and others integral to the implementation of the project.

(6) *Impact of the project in utilizing the canal or related waterways to economically and physically revitalize the area.*

b. Extent of Need for CDBG Assistance to Financially Support the Section 108 Loans and the Project—(up to 20 points). HUD will use the following information to evaluate this criterion. In utilizing this information, HUD will consider the extent to which the applicant's response demonstrates the financial need for the CDBG grant to support financially the loans guaranteed by the Section 108 Loan Guarantee commitments. Note that if the applicant proposes a generic loan fund to assist a certain category of project or business, the applicant should demonstrate the impact of the use of the CDBG funds to assist the project and the relationship of those funds to the use of Section 108 loans. Relevant information may include:

(1) Project costs and financial requirements;

(2) The amount of any debt service or operating reserve accounts to be established in connection with the development project;

(3) The reasonableness of the costs of any credit enhancement paid with CDBG grant funds;

(4) The amount of program income (if any) to be received each year during the repayment period for the guaranteed loans;

(5) Interest rates on those loans to third parties (other than subrecipients) (either as an absolute rate or as a plus/minus spread to the Section 108 rate);

(6) Underwriting guidelines used (or expected to be used) in determining project feasibility;

(7) The amount of anticipated ''cash flow'' the project is projected to generate that will be available to make debt service payments on the Section 108—guaranteed loans; and

(8) Other relevant information.

c. The Extent to Which the Proposal, Compared to Other Canal-Related Development Proposals Submitted Pursuant to this NOFA, Leverages Other Non-Federal Public and Private Resources, in Addition to Loan Funds Guaranteed Under the Section 108 Loan Guarantee Program—(up to 20 points). Leveraged funds include State and local public funding and private financing.

d. The Capacity or Potential Capacity of the CDBG applicant and the Section 108 Public Entities to Carry Out the Plan Successfully—(up to 20 points). This may include factors such as the applicant's performance in the administration of its CDBG, HOME, or other programs; its previous experience, if any, in administering a Section 108 Loan Guarantee or CDBG grant; its performance and capacity in carrying out development projects; its ability to conduct prudent underwriting; its capacity to manage and service loans made with the guaranteed loan funds or CDBG grant funds; and its capacity to carry out its projects and programs in a timely manner. The applicant should also describe any recent experience it has had in carrying out programs similar to the one proposed in the application.

The capacity of subrecipients, nonprofit organizations, and other entities that have a role in implementing the proposed program will be included in this review. HUD may rely on information from performance reports, financial status information, monitoring reports, audit reports and other information available to HUD in making its determination under this criterion.

e. Place-based factor—(5 points). The Secretary's Representative for New York/New Jersey will award 5 points to those proposals that demonstrate that the canal-related development project proposed to be funded under this NOFA is part of and follows an applicant's existing comprehensive and coordinated strategic plan for community and economic revitalization.

4. Fair Housing and Equal Opportunity Evaluation—(up to 15 points). Documentation for the 15 points for these items is the responsibility of the applicant. Claims of outstanding performance must be based upon actual accomplishments. Clear, precise documentation will be required. Maps must have a census tract (CT) or block numbering area (BNA), and they must be in accordance with the 1990 Census data. Additionally, maps must identify the locations of areas with minorities by census tract or BNA. If there are no minority areas, applicants must state so on the map. Only population data from the 1990 Census will be acceptable for purposes of this section.

Please note that a ''minority'' is a person belonging to, or culturally identified as, a member of any one of the following racial/ethnic categories: Black, Hispanic, Asian or Pacific Islander, and American Indian or Alaskan Native. For the purposes of this section, the term ''minority'' does not include women as a separate category.

Counties claiming points under this criterion must use county-wide statistics (excluding entitlement communities). In the case of joint applications, points will be awarded based on the performance of the lead entity only.

The following will be used to judge outstanding performance in these areas. Please note that points for outstanding performance may be claimed under each criterion:

a. Housing Achievements—(up to 12 points total).

(1) *Provision of Assisted Housing—(up to 6 points).* Providing assisted housing for low- and moderate-income families, located in a manner which provides housing choice in areas outside of minority or low- and moderate-income concentrations.

Points will be awarded if both of the following criteria are met:

(a) More than one-third of the housing assistance provided by the applicant in the last five (5) years (excluding Section 8 existing and housing assistance provided in place) has been in census tracts (CT) or block numbering areas (BNA) having a percentage of minority population which is less than the minority population in the community as a whole; and

(b) With regard to the Section 8 Existing Housing program, a community must show the location (CT or BNA) of its currently occupied family units by race/ethnicity. Points will be awarded if more than one-half of the minority assisted families occupy units in areas which have a lower percentage of minority population than that of the community as a whole.

A community with no minorities must show the extent to which its assisted housing is located outside areas of concentrations of low- and moderate-income persons. In order to receive points under this criteria, applicants should follow the process outlined in (a) and (b) above, substituting low- and moderate-income persons and families for minority persons or families. Applicants addressing the first criterion must use a map indicating the location of all assisted housing and a narrative indicating the number of units and the type of assisted housing. The map also must show the general location of low- and moderate-income households and minority households, giving the numbers and percentages for both.

To qualify as housing assistance provided, the units being claimed must be part of a project located outside minority or lower income concentrated

areas which has, at a minimum, received a firm commitment from the funding agency.

(c) Points also may be awarded for efforts which enable low- and moderate-income persons to remain in their neighborhood when such neighborhoods are experiencing revitalization and substantial displacement as a result of private reinvestment. Applicants requesting points under this criterion would not need to meet the requirements of (a) and (b) in order to receive points. Points will be awarded if more than one-half of the families displaced were able to remain in their original neighborhood through the assistance of the applicant. Applicants must show that:

—The neighborhood experienced revitalization;
—The amount of displacement was substantial;
—Displacement was caused by private reinvestment;
—Low- and moderate-income persons were permitted to remain in the neighborhood as a result of action taken by the applicant.

If the community is inhabited predominantly by persons who are members of minority and/or low-income groups, points will be awarded if there is a balanced distribution of assisted housing throughout the community.

(2) *Implementation of a Fair Housing Action Plan—(up to 6 points).*

The applicant must describe how it has implemented a Fair Housing Action Plan of its own or participated in a regional or countywide Fair Housing Action Plan. For the purposes of this NOFA, a Fair Housing Action Plan is a document that delineates specific actions to address fair housing problems in the area covered by the applicant. The plan should list Fair Housing actions, set priorities and time period for completion and include measures against which performance shall be evaluated, identify resources from local, State, and private agencies and organizations that have agreed to finance or support fair housing actions, and define the responsibilities of each group or organization. If the applicant is implementing a Fair Housing Plan, the application must include the plan being implemented, the actions taken to implement the plan, and the actions taken to address the fair housing problems. The applicant should provide written documentation of commitments from all involved parties.

b. Equal Opportunity Employment—(up to 3 points). Under this factor, the applicant must document that its percentage of minority permanent full-time employees is greater than the percentage of minorities within the county or the community, whichever is higher. Applicants with no full-time employees may claim points based on part-time employment provided that they document that the only permanent employment is on a part-time basis.

c. Entrepreneurial Efforts and Local Equal Employment. HUD encourages the use of minority contracting, although it will not be used as an evaluation factor in this NOFA.

D. Selection Process

All applications will be ranked in order of points assigned, with the applications receiving more points ranking above those receiving fewer points. Applications will be funded in rank order.

As discussed in section I.C.5. of this NOFA, above, HUD reserves the right to determine a minimum and a maximum amount of any CDBG award or Section 108 commitment per applicant, application, or project, the amount or number of years for which multiyear CDBG funding is proposed, and to modify requests accordingly. In addition, if HUD determines that an application rated, ranked, and fundable could be funded at a lesser CDBG grant amount than requested, consistent with feasibility of the funded project or activities and the purposes of the Act, HUD reserves the right to reduce the amount of the CDBG award and/or increase or decrease the Section 108 Loan Guarantee commitments, if necessary, in accordance with such determination.

HUD may decide not to award the full amount of CDBG grant funds available under this NOFA, and may make any remaining amounts available under a future NOFA.

To review and rate applications, HUD will establish a panel consisting predominantly of HUD employees assigned to the New York Field Offices. HUD will appoint HUD's New York/New Jersey State Secretary's Representative to rate selection criterion II.C.3.e.— ''Place-based factor.'' HUD may also include other HUD staff and persons not currently employed by HUD to obtain certain expertise and outside points of view, including views from other Federal agencies.

E. Timing of Grant Awards

To the extent full Section 108 applications are submitted concurrently with the CDBG grant application, HUD's approval of the related Section 108 Loan Guarantee commitments will in most cases be granted contemporaneously with CDBG grant approval. However, the CDBG grant may be awarded prior to HUD approval of the Section 108 commitments if HUD determines that such award will further the purposes of the Act. CDBG funds shall not be disbursed to the public entity before the issuance of the related Section 108 guaranteed obligations. CDBG awards will be announced within 30 days of the application due date, which is January 2, 1997.

F. Program Administration

In order to be consistent with the local nature of the program, funds awarded under this NOFA will be administered by the New York State CPD Office.

G. Funding Award Process

In accordance with section 102 of the HUD Reform Act and HUD's regulation at 24 CFR part 4, HUD will notify the public, by notice published in the Federal Register, of all award decisions made by HUD under this competition. In accordance with the requirements of section 102 of the Reform Act and HUD's regulations at 24 CFR part 4, HUD also will ensure that documentation and other information regarding each application submitted under this Notice of Funding availability is sufficient to indicate the basis upon which assistance was provided or denied. Additionally, in accordance with the Reform Act and the regulations, HUD will make this material available for public inspection for a period of five years, beginning not less than 30 calendar days after the date on which assistance is provided.

III. Technical Assistance

Prior to the application deadline, the New York Offices will provide technical assistance on request to individual applicants, including explaining and responding to questions regarding program regulations and the NOFA. In addition, HUD will conduct informational meetings around the State to discuss the Small Cities program, and will conduct application workshops in conjunction with these meetings. HUD employees are prohibited in these sessions, however, from advising applicants how to make substantive improvements to their applicants and from disclosing other covered selection information described at 24 CFR 4.26. Please contact the Buffalo or New York Offices for further information regarding these meetings. In order to ensure that the application deadline is met, it is strongly suggested that applicants begin preparing their applications immediately and not wait for the informational meetings.

IV. Corrections to Deficient Applications

Under no circumstances will HUD accept from the applicant unsolicited information regarding the application after the application deadline has passed.

HUD may advise applicants of technical deficiencies in applications and permit them to be corrected. A technical deficiency would be an error or oversight which, if corrected, would not alter, in either a positive or negative fashion, the review and rating of the application. Examples of curable technical deficiencies would be a failure to submit the proper certifications or failure to submit an application containing an original signature by an authorized official. Situations not considered curable would be, for example, a failure to submit program impact descriptions.

HUD will notify applicants in writing of any curable technical deficiencies in applications. Applicants will have 14 calendar days from the date of HUD's correspondence to reply and correct the deficiency. If the deficiency is not corrected within this time period, HUD will reject the application as incomplete.

Applicants should note that if an abbreviated consolidated plan is not submitted, the failure to submit a it in a timely manner is not considered a curable deficiency.

V. Other Matters

Environmental Impact

In accordance with 24 CFR 50.19(c)(5) of HUD's regulations (as issued in a final rule on September 27, 1996 (61 FR 50914), this NOFA provides funding under, and does not alter environmental requirements of, a regulation previously published in the Federal Register. Therefore, this NOFA is categorically excluded from the requirements of the National Environmental Policy Act. The environmental review provisions of this regulation are in 24 CFR 570.604.

Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that this NOFA will not have substantial, direct effects on States, on their political subdivisions, or on their relationship with the Federal Government, or on the distribution of power and responsibilities between them and other levels of government. While the NOFA will provide financial assistance through the Small Cities program to New York State, none of its provisions will have an effect on the relationship between the Federal Government and New York State, or the State's political subdivisions.

Family

The General Counsel, as the Designated Official for Executive Order 12606, *The Family*, has determined that the policies announced in this NOFA would not have the potential for significant impact on family formation, maintenance, and general well-being within the meaning of the Order. No significant change in existing HUD policies and programs will result from issuance of this NOFA, as those policies and programs relate to family concerns.

Section 102 of the HUD Reform Act

Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) and the final rule codified at 24 CFR part 4, subpart A, published on April 1, 1996 (61 FR 1448), contain a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. On January 14, 1992, HUD published, at 57 FR 1942, a notice that also provides information on the implementation of section 102. The documentation, public access, and disclosure requirements of section 102 are applicable to assistance awarded under this NOFA as follows:

Documentation and public access requirements. HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its Federal Register notice of all recipients of HUD assistance awarded on a competitive basis.

Disclosures. HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15.

Section 103 of the HUD Reform Act

Section 103 of the Department of Housing and Urban Development Reform Act of 1989, and HUD's implementing regulation codified at subpart B of 24 CFR part 4, applies to the funding competition announced today. These requirements continue to apply until the announcement of the selection of successful applicants. HUD employees, including those conducting technical assistance sessions or workshops and those involved in the review of applications and in the making of funding decisions, are limited by section 103 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under section 103 and subpart B of 24 CFR part 4.

Applicants or employees who have ethics related questions should contact the HUD Ethics Law Division at (202) 708–3815.

(This is not a toll-free number.)

Prohibition Against Lobbying Activities

The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352) and the implementing regulations at 24 CFR part 87. These authorities prohibit recipients of Federal contracts, grants, or loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance.

Dated: November 22, 1996.

Andrew Cuomo,

Assistant Secretary for Community Planning and Development.

Certification Required By Title I of the Housing and Community Development Act of 1974, as Amended, With Respect to the Community Development Block Grant Program

In accordance with the Housing and Community Development Act of 1974, as amended, the Applicant certifies that:

(a) It possesses legal authority to make a grant submission and to execute a community development and housing program;

(b) Its governing body has duly adopted or passed as an official act a resolution, motion or similar action authorizing the person identified as the official representative of the applicant to submit the subject application and all understandings and assurances contained therein, and directing and authorizing the person identified as the official representative of the applicant to act in connection with the submission of the application and to provide such additional information as may be required;

(c) Prior to submission of its application to HUD, the applicant has met the citizen participation requirements of 24 CFR 570.431;

(d) It is following a detailed citizen participation plan which:

(1) Provides for and encourages citizen participation, with particular emphasis on participation by persons of low and moderate income who are residents of slum and blighted areas in which funds are proposed to be used, and provides for participation of residents in low and moderate income neighborhoods as defined by the local jurisdiction;

(2) Provides citizens with reasonable and timely access to local meetings, information, and records relating to the applicant's proposed use of funds, as required by the regulations of the Secretary, and relating to the actual use of funds under the Act;

(3) Provides for technical assistance to groups representative of persons of low and moderate income that request such assistance in developing proposals with the level and type of assistance to be determined by the applicant;

(4) Provides for public hearings to obtain citizen views and to respond to proposals and questions at all stages of the community development program, including at least the development of needs, the review of proposed activities, and review of program performance, which hearings shall be held after adequate notice, at times and locations convenient to potential or actual beneficiaries, and with accommodation for the handicapped;

(5) Provides for a timely written answer to written complaints and grievances, within 15 working days where practicable; and

(6) Identifies how the needs of non-English speaking residents will be met in the case of public hearings where a significant number of non-English speaking residents can be reasonably expected to participate;

(e) The grant will be conducted and administered in compliance with:

(1) Title VI of the Civil Rights Act of 1964 (Public Law 88–352, 42 U.S.C. 2000d *et seq.*); and

(2) The Fair Housing Act (42 U.S.C. 3601–20);

(f) It will affirmatively further fair housing;

(g) It has developed its application so as to give maximum feasible priority to activities which benefit low and moderate income families or aid in the prevention or elimination of slums or blight; the application may also include activities which the applicant certifies are designed to meet other community development needs having a particular urgency because existing conditions pose a serious and immediate threat to the health or welfare of the community, and where other financial resources are not available to meet such needs; except that the grant shall principally benefit persons of low and moderate income in a manner that ensures that not less than 70 percent of such funds are used for activities that benefit such persons;

(h) It has developed a community development plan for the grant period which identifies community development and housing needs and specifies both short and long term community development objectives that have been developed in accordance with the primary objective and requirements of the Act;

(i) Any proposed housing activities are consistent with its abbreviated Consolidated Plan submitted or being submitted to HUD for approval pursuant to 24 CFR 570.420(d) and 24 CFR 91.235.

(j) It will not attempt to recover any capital costs of public improvements assisted in whole or in part with funds provided under section 106 of the Act or with amounts resulting from a guarantee under section 108 of the Act by assessing any amount against properties owned and occupied by persons of low and moderate income, including any fee charged or assessment made as a condition of obtaining access to such public improvements, unless:

(1) Funds received under section 106 of the Act are used to pay the proportion of such fee or assessment that relates to the capital costs of such public improvements that are financed from revenue sources other than under Title I of the Act; or

(2) For purposes of assessing any amount against properties owned and occupied by persons of moderate income, the applicant certifies to the Secretary that it lacks sufficient funds received under section 106 of the Act to comply with the requirements of subparagraph (1) above;

(k) Its notification, inspection, testing and abatement procedures concerning lead-based paint will comply with 24 CFR 570.608;

(l) It will comply with the acquisition and relocation requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, as required under 24 CFR 570.606(b) and Federal implementing regulations; and the requirements in 24 CFR 570.606(c) governing the residential antidisplacement and relocation assistance plan under section 104(d) of the Act (including a certification that the applicant is following such a plan); and the relocation requirements of 24 CFR 570.606(d) governing optional relocation assistance under section 105(a)(11) of the Act;

(m) It has adopted and is enforcing:

(1) A policy prohibiting the use of excessive force by law enforcement agencies within its jurisdiction against any individuals engaged in nonviolent civil rights demonstrations; and

2. A policy of enforcing applicable State and local laws against physically barring entrance to or exit from a facility or location which is the subject of such nonviolent civil rights demonstrations within its jurisdiction;

(n) To the best of its knowledge and belief:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of it, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement;

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for

influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, it will complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions; and

(3) It will require that the language of paragraph (n) of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly;

(o) It will or will continue to provide a drug-free workplace by:

(1) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the applicant's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(2) Establishing an ongoing drug-free awareness program to inform employees about—

(a) The dangers of drug abuse in the workplace;

(b) The applicant's policy of maintaining a drug-free workplace;

(c) Any available drug counseling, rehabilitation, and employee assistance programs; and

(d) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(3) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (1);

(4) Notifying the employee in the statement required by paragraph (1) that, as a condition of employment under the grant, the employee will—

(a) Abide by the terms of the statement; and

(b) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(5) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (4)(b) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(6) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (4)(b), with respect to any employee who is so convicted—

(a) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(b) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (1),(2), (3), (4), (5) and (6).

(8) The applicant may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

_____

_____

_____

_____

_____

Check ____ if there are workplaces on file that are not identified here; and

(p) It will comply with the other provisions of the Act and with other applicable laws.

_____

Signature

_____

Title

_____

Date

Appendix to CDBG Certifications

Instructions Concerning Lobbying and Drug-Free Workplace Requirements

A. Lobbying Certification—Paragraph n

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

B. Drug-Free Workplace Certification—Paragraph o

1. By signing and/or submitting this application or grant agreement, the applicant is providing the certification set out in paragraph (o).

2. The certification set out in paragraph (o) is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the applicant knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, HUD, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. For applicants other than individuals, Alternate I applies. (This is the information to which applicants certify).

4. For applicants who are individuals, Alternate II applies. (Not applicable to CDBG applicants.)

5. Workplaces under grants, for applicants other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the applicant does not identify the workplaces at the time of application, or upon award, if there is no application, the applicant must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the applicant's drug-free workplace requirements.

6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio stations).

7. If the workplace identified to the agency changes during the performance of the grant, the applicant shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Applicants' attention is called, in particular, to the following definitions from these rules:

''Controlled substance'' means a controlled substance in Schedules I through V of the Controlled Substances

Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

''Conviction'' means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

''Criminal drug statute'' means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

''Employee'' means the employee of a applicant directly engaged in the performance of work under a grant, including: (i) All ''direct charge'' employees; (ii) all ''indirect charge'' employees unless their impact or involvement is insignificant to the performance of the grant; and (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are not on the applicant's payroll. This definition does not include workers not on the payroll of the applicant (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the applicant's payroll; or employees of subrecipients or subcontractors in covered workplaces).

BILLING CODE 4210–29–P

Application for Federal Assistance

OMB Approval No. 0348-0043

	2. Date Submitted	Applicant Identifier
1. **Type of Submission:**	3. Date Received by State	State Application Identifier
Application ☐ Construction ☐ Non-Construction **Preapplication** ☐ Construction ☐ Non-Construction	4. Date Received by Federal Agency	Federal Identifier

5. **Applicant Information**

Legal Name	Organizational Unit
Address (give city, county, State, and zip code):	Name, telephone number, and facsimile number of the person to be contacted on matters involving this application (give area codes)

6. **Employer Identification Number (EIN):**

☐☐—☐☐☐☐☐☐☐☐☐

8. **Type of Application:**

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (specify):

7. **Type of Applicant:** (enter appropriate letter in box) ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify):

9. **Name of Federal Agency:**

10. **Catalog of Federal Domestic Assistance Number:**

☐☐—☐☐☐

Title:

11. **Descriptive Title of Applicant's Project:**

12. **Areas Affected by Project** (cities, counties, States, etc.):

13. **Proposed Project:**		14. **Congressional Districts of:**	
Start Date	Ending Date	a. Applicant	b. Project

15. **Estimated Funding:**		
a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. **Total**	$	.00

16. **Is Application Subject to Review by State Executive Order 12372 Process?**

a. **Yes** This preapplication/application was made available to the State Executive Order 12372 Process for review on:

Date:_____

b. **No** ☐ Program is not covered by E.O. 12372

or ☐ Program has not been selected by State for review.

17. **Is the Applicant Delinquent on Any Federal Debt?**

☐ Yes If "Yes," explain below or attach an explanation ☐ No

18. To the best of my knowledge and belief, all data in this application/preapplication are true and correct, the document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded.

a. Typed Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

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form **SF-424** (4/92)
Prescribed by OMB Circular A-102

Instructions for the SF-424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item Entry

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item Entry

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

Disclosure of Lobbying Activities

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse side for Instructions.)

1. Type of Federal Action:
☐ a. contract
☐ b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐ a. bid/offer/application
☐ b. initial award
c. post-award

3. Report Type:
☐ a. initial filing
☐ b. material change
For Material Change Only:
year _____ quarter _____
date of last report _____

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee Tier _____, if known:

Congressional District, if known:

5. If Reporting Entity in No. 4 is Subawardee, enter Name and Address of Prime:

Congressional District, if known:

6. Federal Department/Agency:

7. Federal Program Name/Description:

CFDA Number, if applicable: _____

8. Federal Action Number, if known:

9. Award Amount, if known:
$

10a. Name and Address of Lobbying Registrant
(if individual, last name, first name, MI):

b. Individuals Performing Services (including address if different from No. 10a.)
(last name, first name, MI):

11. Information requested through this form is authorized by Sec.319, Pub. L. 101-121, 103 Stat. 750, as amended by sec. 10; Pub. L. 104-65, Stat. 700 (31 U.S.C. 1352). This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semiannually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ **Date:** _____

Federal Use Only:

Authorized for Local Reproduction
Standard Form-LLL (1/96)

Instructions for Completion of SF-LLL, Disclosure of Lobbying Activities

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or any employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient, Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Applicant/Recipient Disclosure/Update Report

U.S. Department of Housing and Urban Development
Office of Ethics

OMB Approval No. 2510-0011 (exp. 3/31/98)

Instructions. (See Public Reporting Statement and Privacy Act Statement and detailed instructions on page 4.)

Part I Applicant/Recipient Information **Indicate whether this is an Initial Report** ☐ **or an Update Report** ☐

1. Applicant/Recipient Name, Address, and Phone (include area code)

Social Security Number or Employer ID Number

2. Project Assisted/ to be Assisted (Project/Activity name and/or number and its location by Street address, City, and State)

3. Assistance Requested/Received	4. HUD Program	5. Amount Requested/Received
		$

Part II. Threshold Determinations -- Applicants Only

1. Are you requesting HUD assistance for a specific project or activity, as provided by 24 CFR Part 12, Subpart C, **and** have you received, or can you reasonably expect to receive, an aggregate amount of all forms of covered assistance from HUD, States, and units of general local government, in excess of $200,000 during the Federal fiscal year (October 1 through September 30) in which the application is submitted? ☐ **Yes** ☐ **No**

   If Yes, you must complete the remainder of this report.

   If No, you must sign the certification below and answer the next question.

   I hereby certify that this information is true. (Signature)_____ Date _____

2. Is this application for a specific housing project that involves other government assistance? ☐ **Yes** ☐ **No**

   If Yes, you must complete the remainder of this report.

   If No, you must sign this certification.

   I hereby certify that this information is true. (Signature)_____ Date _____

If your answers to both questions are No, you do not need to complete Parts III, IV, or V, but you must sign the certification at the end of the report.

Part III. Other Government Assistance Provided/Requested

Department/State/Local Agency Name and Address	Program	Type of Assistance	Amount Requested/Provided

Is there other government assistance that is reportable in this Part and in Part V, but that is reported only in Part V? ☐ Yes ☐ No

If there is no other government assistance, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

form **HUD-2880** (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

Part IV. Interested Parties

Alphabetical list of all persons with a reportable financial interest in the project or activity (for individuals, give the last name first)	Social Security Number or Employee ID Number	Type of Participation in Project/Activity	Financial Interest in Project/Activity ($ and %)

If there are no persons with a reportable financial interest, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

form **HUD-2880** (3/92)
ref. Sec 102, HRA 1989; PL. 101 - 235

Part V. Report on Expected Sources and Uses of Funds

Source

If there are no sources of funds, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

Use

If there are no uses of funds, you must certify that this information is true.

I hereby certify that this information is true. (Signature) _____ Date _____

Certification

Warning: If you knowingly make a false statement on this form, you may be subject to civil or criminal penalties under Section 1001 of Title 18 of the United States Code. In addition, any person who knowingly and materially violates any required disclosure of information, including intentional non-disclosure, is subject to civil money penalty not to exceed $10,000 for each violation.

I certify that this information is true and complete.

Signature	Date

Public reporting burden for this collection of information is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Management Officer, Paperwork Reduction Project (2510-0011), Office of Information Technology, U.S. Department of Housing and Urban Development, Washington, D.C. 20410-3600. This agency may not conduct or sponsor, and a person is not required to respond to, a collection information unless that collecton displays a valid OMB control number.

Do not send this form to the above address.

Privacy Act Statement. Except for Social Security Numbers (SSNs) and Employer Identification Numbers (EINs), the Department of Housing and Urban Development (HUD) is authorized to collect all the information required by this form under section 102 of the Department of Housing and Urban Development Reform Act of 1989, 42 U.S.C. 3531. Disclosure of SSNs and EINs is optional. The SSN or EIN is used as a unique identifier. The information you provide will enable HUD to carry out its responsibilities under Sections 102(b), (c), and (d) of the Department of Housing and Urban Development Reform Act of 1989, Pub. L. 101-235, approved December 15, 1989. These provisions will help ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. They will also help ensure that HUD assistance for a specific housing project under Section 102(d) is not more than is necessary to make the project feasible after taking account of other government assistance. HUD will make available to the public all applicant disclosure reports for five years in the case of applications for competitive assistance, and for generally three years in the case of other applications. Update reports will be made available along with the disclosure reports, but in no case for a period generally less than three years. All reports, both initial reports and update reports, will be made available in accordance with the Freedom of Information Act (5 U.S.C. §552) and HUD's implementing regulations at 24 CFR Part 15. HUD will use the information in evaluating individual assistance applications and in performing internal administrative analyses to assist in the management of specific HUD programs. The information will also be used in making the determination under Section 102(d) whether HUD assistance for a specific housing project is more than is necessary to make the project feasible after taking account of other government assistance. You must provide all the required information. Failure to provide any required information may delay the processing of your application, and may result in sanctions and penalties, including imposition of the administrative and civil money penalties specified under 24 CFR §12.34.

Note: This form only covers assistance made available by the Department. States and units of general local government that carry out responsibilities under Sections 102(b) and (c) of the Reform Act must develop their own procedures for complying with the Act.

Instructions (See Note 1 on last page.)

I. Overview. Subpart C of 24 CFR Part 12 provides for (1) initial reports from applicants for HUD assistance and (2) update reports from recipients of HUD assistance. An overview of these requirements follows.

A. Applicant disclosure (initial) reports: General. All applicants for assistance from HUD for a specific project or activity must make a number of disclosures, if the applicant meets a dollar threshold for the receipt of covered assistance during the fiscal year in which the application is submitted. The applicant must also make the disclosures if it requests assistance from HUD for a specific housing project that involves assistance from other governmental sources.

Applicants subject to Subpart C must make the following disclosures:

Assistance from other government sources in connection with the project,

The financial interests of persons in the project,

The sources of funds to be made available for the project, and

The uses to which the funds are to be put.

B. Update reports: General. All recipients of covered assistance must submit update reports to the Department to reflect substantial changes to the initial applicant disclosure reports.

C. Applicant disclosure reports: Specific guidance. The applicant must complete all parts of this disclosure form if **either** of the following **two** circumstances in paragraph 1. or 2., below, applies:

1.a. Nature of Assistance. The applicant submits an application for assistance for a specific project or activity (See Note 2) in which:

HUD makes assistance available to a recipient for a specific project or activity; or

HUD makes assistance available to an entity (other than a State or a unit of general local government), such as a public housing agency (PHA), for a specific project or activity, where the application is required by statute or regulation to be submitted to HUD for any purpose; **and**

b. Dollar Threshold. The applicant has received, or can reasonably expect to receive, an aggregate amount of all forms of assistance (See Note 3) from HUD, States, and units of general local government, in excess of $200,000 during the Federal fiscal year (October 1 through September 30) in which the application is submitted. (See Note 4)

2. The applicant submits an application for assistance for a specific housing project that involves other government assistance. (See Note 5) Note: There is no dollar threshold for this criterion: **any** other government assistance triggers the requirement. (See Note 6)

If the Application meets **neither** of these two criteria, the applicant need only complete Parts I and II of this report, as well as the certification at the end of the report. If the Application meets **either** of these criteria, the applicant must complete the entire report.

The applicant disclosure report must be submitted with the application for the assistance involved.

D. Update reports: Specific guidance. During the period in which an application for covered assistance is pending, or in which the assistance is being provided (as indicated in the relevant grant or other agreement), the applicant must make the following additional disclosures:

1. Any information that should have been disclosed in connection with the application, but that was omitted.

2. Any information that would have been subject to disclosure in connection with the application, but that arose at a later time, including information concerning an interested party that now meets the applicable disclosure threshold referred to in Part IV, below.

3. For changes in previously disclosed other government assistance:

For programs administered by the Assistant Secretary for Community Planning and Development, any change in other government assistance that exceeds the amount of such assistance that was previously disclosed by $250,000 or by 10 percent of the assistance (whichever is lower).

For all other programs, any change in other government assistance that exceeds the amount of such assistance that was previously disclosed.

4. For changes in previously disclosed financial interests, any change in the amount of the financial interest of a person that exceeds the amount of the previously disclosed interests by $50,000 or by 10 percent of such interests (whichever is lower).

5. For changes in previously disclosed sources or uses of funds:

a. For programs administered by the Assistant Secretary for Community Planning and Development:

Any change in a source of funds that exceeds the amount of all previously disclosed sources of funds by $250,000 or by 10 percent of those sources (whichever is lower); and

Any change in a use of funds under paragraph (b)(1)(iii) that exceeds the amount of all previously disclosed uses of funds by $250,000 or by 10 percent of those uses (whichever is lower).

b. For all programs, other than those administered by the Assistant Secretary for Community Planning and Development:

For projects receiving a tax credit under Federal, State, or local law, any change in a source of funds that was previously disclosed.

For all other projects, any change in a source of funds that exceeds the lower of:

The amount previously disclosed for that source of funds by $250,000, or by 10 percent of the amount previously disclosed for that source, whichever is lower; or

The amount previously disclosed for all sources of funds by $250,000, or by 10 percent of the amount previously disclosed for all sources of funds, whichever is lower.

c. For all programs, other than those administered by the Assistant Secretary for Community Planning and Development:

For projects receiving a tax credit under Federal, State, or local law, any change in a use of funds that was previously disclosed.

For all other projects, any change in a use of funds that exceeds the lower of:

The amount previously disclosed for that use of funds by $250,000, or by 10 percent of the amount previously disclosed for that use, whichever is lower; or

The amount previously disclosed for all uses of funds by $250,000, or by 10 percent of the amount previously disclosed for all uses of funds, whichever is lower.

Note: Update reports must be submitted within 30 days of the change requiring the update. The requirement to provide update reports only applies if the application for the underlying assistance was submitted on or after the effective date of Subpart C.

II. Line-by-Line Instructions.

A. Part I. Applicant/Recipient Information.

All applicants for HUD assistance specified in Section I.C.1.a., above, as well as all recipients required to submit an update report under Section I.D., above, must complete the information required by Part I. The applicant/recipient must indicate whether the disclosure is an initial or an update report. Line-by-line guidance for Part I follows:

1. Enter the full name, address, city, State, zip code, and telephone number (including area code) of the applicant/recipient. Where the applicant/recipient is an individual, the last name, first name, and middle initial must be entered. Entry of the applicant/recipient's SSN or EIN, as appropriate, is optional.

2. Applicants enter the name and full address of the project or activity for which the HUD assistance is sought. Recipients enter the name and full address of the HUD-assisted project or activity to which the update report relates. The most appropriate government identifying number must be used (e.g., RFP No.; IFB No.; grant announcement No.; or contract, grant, or loan No.) Include prefixes.

3. Applicants describe the HUD assistance referred to in Section I.C.1.a. that is being requested. Recipients describe the HUD assistance to which the update report relates.

4. Applicants enter the HUD program name under which the assistance is being requested. Recipients enter the HUD program name under which the assistance, that relates to the update report, was provided.

5. Applicants enter the amount of HUD assistance that is being requested. Recipients enter the amount of HUD assistance that has been provided and to which the update report relates. The amounts are those stated in the application or award documentation. NOTE: In the case of assistance that is provided pursuant to contract over a period of time (such as project-based assistance under section 8 of the United States Housing Act of 1937), the amount of assistance to be reported includes all amounts that are to be provided over the term of the contract, irrespective of when they are to be received.

Note: In the case of Mortgage Insurance under 24 CFR Subtitle B, Chapter II, the mortgagor is responsible for making the applicant disclosures, and the mortgagee is responsible for furnishing the mortgagor's disclosures to the Department. Update reports must be submitted directly to HUD by the mortgagor.

Note: In the case of the Project-Based Certificate program under 24 CFR Part 882, Subpart G, the owner is responsible for making the applicant disclosures, and the PHA is responsible for furnishing the owner's disclosures to HUD. Update reports must be submitted through the PHA by the owner.

B. Part II. Threshold Determinations — Applicants Only

Part II contains information to help the applicant determine whether the remainder of the form must be completed. **Recipients filing Update Reports should not complete this Part.**

1. The first question asks whether the applicant meets the Nature of Assistance and Dollar Threshold requirements set forth in Section I.C.1. above.

If the answer is Yes, the applicant must complete the remainder of the form. If the answer is No, the form asks the applicant to certify that its response is correct, and to complete the next question.

2. The second question asks whether the application is for a specific housing project that involves other government assistance, as described in Section I.C.2. above.

If the answer is Yes, the applicant must complete the remainder of the form. If the answer is No, the form asks the applicant to certify that its response is correct.

If the answer to both questions1 and 2 is No, the applicant need not complete Parts III, IV, or V of the report, but must sign the certification at the end of the form.

C. Part III. Other Government Assistance.

This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports. Applicants must report any other government assistance involved in the project or activity for which assistance is sought. Recipients must report any other government assistance involved in the project or activity, to the extent required under Section I.D.1., 2., or 3., above.

Other government assistance is defined in note 5 on the last page. For purposes of this definition, other government assistance is expected to be made available if, based on an assessment of all the circumstances involved, there are reasonable grounds to anticipate that the assistance will be forthcoming.

Both applicant and recipient disclosures must include all other government assistance involved with the HUD assistance, as well as any other government assistance that was made available before the request, but that has continuing vitality at the time of the request. Examples of this latter category include tax credits that provide for a number of years of tax benefits, and grant assistance that continues to benefit the project at the time of the assistance request.

The following information must be provided:

1. Enter the name and address, city, State, and zip code of the government agency making the assistance available. Include at least one organizational level below the agency name. For example, U.S. Department of Transportation, U.S. Coast Guard; Department of Safety, Highway Patrol.

2. Enter the program name and any relevant identifying numbers, or other means of identification, for the other government assistance.

3. State the type of other government assistance (e.g., loan, grant, loan insurance).

4. Enter the dollar amount of the other government assistance that is, or is expected to be, made available with respect to the project or activities for which the HUD assistance is sought (applicants) or has been provided (recipients).

If the applicant has no other government assistance to disclose, it must certify that this assertion is correct.

To avoid duplication, if there is other government assistance under this Part and Part V, the applicant/recipient should check the appropriate box in this Part and list the information in Part V, clearly designating which sources are other government assistance.

D. Part IV. Interested Parties.

This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports.

Applicants must provide information on:

(1) All developers, contractors, or consultants involved in the application for the assistance or in the planning, development, or implementation of the project or activity and

(2) any other person who has a financial interest in the project or activity for which the assistance is sought that exceeds $50,000 or 10 percent of the assistance (whichever is lower).

Recipients must make the additional disclosures refferred to in Section I.D.1.,2., or 4, above.

Note: A financial interest means any financial involvement in the project or activity, including (but not limited to) situations in which an individual or entity has an equity interest in the project or activity, shares in any profit on resale or any distribution of surplus cash or other assets of the project or activity, or receives compensation for any goods or services provided in connection with the project or activity. Residency of an individual in housing for which assistance is being sought is not, by itself, considered a covered financial interest.

The information required below must be provided.

1. Enter the full names and addresses of all persons referred to in paragraph (1) or (2) of this Part. If the person is an entity, the listing must include the full name of each officer, director, and principal stockholder of the entity. All names must be listed alphabetically, and the names of individuals must be shown with their last names first.

2. Entry of the Social Security Number (SSN) or Employee Identification Number (EIN), as appropriate, for each person listed is optional.

3. Enter the type of participation in the project or activity for each person listed: i.e., the person's specific role in the project (e.g., contractor, consultant, planner, investor).

4. Enter the financial interest in the project or activity for each person listed. The interest must be expressed both as a dollar amount and as a percentage of the amount of the HUD assistance involved.

If the applicant has no persons with financial interests to disclose, it must certify that this assertion is correct.

5. Part V. Report on Sources and Uses of Funds. This Part is to be completed by both applicants filing applicant disclosure reports and recipients filing update reports.

The applicant disclosure report must specify all expected sources of funds — both from HUD and from any other source — that have been, or are to be, made available for the project or activity. Non-HUD sources of funds typically include (but are not limited to) other government assistance referred to in Part III, equity, and amounts from foundations and private contributions. The report must also specify all expected uses to which funds are to be put. All sources and uses of funds must be listed, if, based on an assessment of all the circumstances involved, there are reasonable grounds to anticipate that the source or use will be forthcoming.

Note that if any of the source/use information required by this report has been provided elsewhere in this application package, the applicant need not repeat the information, but need only refer to the form and location to incorporate it into this report. (It is likely that some of the information required by this report has been provided on SF 424A, and on various budget forms accompanying the application.) If this report requires information beyond that provided elsewhere in the application package, the applicant must include in this report all the additional information required.

Recipients must submit an update report for any change in previously disclosed sources and uses of funds as provided in Section I.D.5., above.

General Instructions — sources of funds

Each reportable source of funds must indicate:

a. The name and address, city, State, and zip code of the individual or entity making the assistance available. At least one organizational level below the agency name should be included. For example, U.S. Department of Transportation, U.S. Coast Guard; Department of Safety, Highway Patrol.

b. The program name and any relevant identifying numbers, or other means of identification, for the assistance.

c. The type of assistance (e.g., loan, grant, loan insurance).

Specific instructions — sources of funds.

(1) For programs administered by the Assistant Secretaries for Fair Housing and Equal Opportunity and Policy Development and Research, each source of funds must indicate the total amount of approved, and received; and must be listed in descending order according to the amount indicated.

(2) For programs administered by the Assistant Secretaries for Housing-Federal Housing Commissioner, Community Planning and Development, and Public and Indian Housing, each source of funds must indicate the total amount of funds involved, and must be listed in descending order according to the amount indicated.

(3) If Tax Credits are involved, the report must indicate all syndication proceeds and equity involved.

General instructions—uses of funds.

Each reportable use of funds must clearly identify the purpose to which they are to be put. Reasonable aggregations may be used, such as "total structure" to include a number of structural costs, such as roof, evevators, exterior masonry, etc.

Specific instructions -- uses of funds.

(1) For programs administered by the Assistant Secretaries for Fair Housing and Equal Opportunity and Policy Development and Research, each use of funds must indicate the total amount of funds involved; must be broken down by amount committed, budgeted, and planned; and must be listed in descending order according to the amount indicated.

(ii) For programs administered by the Assistant Secretaries for Housing-Federal Housing Commissioner, Community Planning and Development, and Public and Indian Housing, each use of funds must indicate the total amount of funds involved and must be listed in descending order according to the amount involved.

(iii) If any program administered by the Assistant Secretary for Housing-Federal Housing Commissioner is involved, the report must indicate all uses paid from HUD sources and other sources, including syndication proceeds. Uses paid should include the following amounts.

AMPO
Architect's fee — design
Architect's fee — supervision
Bond premium
Builder's general overhead
Builder's profit
Construction interest
Consultant fee
Contingency Reserve
Cost certification audit fee
FHA examination fee
FHA inspection fee
FHA MIP
Financing fee
FNMA / GNMA fee
General requirements
Insurance
Legal — construction
Legal — organization
Other fees
Purchase price
Supplemental management fund
Taxes
Title and recording
Operating deficit reserve
Resident initiative fund
Syndication expenses
Working capital reserve
Total land improvement
Total structures

Uses paid from syndication must include the following amounts:

Additional acquisition price and expenses
Bridge loan interest
Development fee
Operating deficit reserve
Resident initiative fund
Syndication expenses
Working capital reserve

Footnotes:

1. All citations are to 24 CFR Part 12, which was published in the Federal Register on March 14, 1991 at 56 Fed. Reg. 11032.
2. A list of the covered assistance programs can be found at 24 CFR §12.30, or in the rules or administrative instructions governing the program involved. Note: The list of covered programs will be updated perodically.
3. Assistance means any contract, grant, loan, cooperative agreement, or other form of assistance, including the insurance or guarantee of a loan or mortgage, that is provided with respect to a specific project or activity under a program administered by the Department. The term does not include contracts, such as procurements contracts, that are subject to the Federal Acquisition Regulation (FAR) (48 CFR Chapter 1).
4. See 24 CFR §§12.32 (a)(2) and (3) for detailed guidance on how the threshold is calculated.
5. "Other government assistance" is defined to include any loan, grant, guarantee, insurance, payment, rebate, subsidy, credit, tax benefit, or any other form of direct or indirect assistance from the Federal government (other than that requested from HUD in the application), a State, or a unit of general local government, or any agency or instrumentality thereof, that is, or is expected to be made, available with respect to the project or activities for which the assistance is sought.
6. For further guidance on this criterion, and for a list of covered programs, see 24 CFR §12.50.
7. For purposes of Part 12, a person means an individual (including a consultant, lobbyist, or lawyer); corporation; company; association; authority; firm; partnership; society; State, unit of general local government, or other government entity, or agency thereof (including a public housing agency); Indian tribe; and any other organization or group of people.

[FR Doc. 96–30440 Filed 11–25–96; 11:03 am]

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Federal Register

Tuesday
December 3, 1996

Part III

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

Coal Moisture; Proposed Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

RIN 1029–AB78

Coal Moisture

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) proposes to amend its regulations governing how the excess moisture allowance is determined for reclamation fee purposes. This action will define terms and phrases related to the collection and testing of coal samples used to determine the inherent and total moisture of coal; identify acceptable American Society for Testing and Materials (ASTM) standard sampling and testing methods for high and low-rank coals; prescribe frequencies for collecting and testing coal samples; and provide the coal industry with formulas for use in calculating an excess moisture tonnage allowance for the purpose of reducing the weight of coal subject to the abandoned mine land reclamation fee.

The proposed regulatory revision is necessary to clarify and simplify technical guidance for all users, and to provide the coal industry with standard criteria for calculating an excess moisture allowance on all coals subject to reclamation fee payment. The intended effect of this proposal is to enhance compliance with the provisions of section 402 of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the ACT). Operator use of the prescribed criteria will ensure that all tonnage reductions for excess moisture are taken on the same basis.

DATES: Written comments: OSM will accept written comments on the proposed rule until 5 p.m. Eastern time on February 3, 1997.

Public Hearings: OSM will accept requests for public hearings until 5 p.m. Eastern time on January 2, 1997.

ADDRESSES: Written comments: Hand-deliver or mail to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 120, 1951 Constitution Avenue, NW., Washington, D.C. 20240.

Comments may also be sent through the Internet to OSM's Administrative Record, Internet address: OSMRules@OSMRE.GOV. Copies of any messages received electronically will be filed with the Administrative Record.

Request for public hearings: Submit requests to Dr. Kewal Kohli, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 9 Parkway Center, Pittsburgh, PA 15220, telephone (412) 937–2175.

FOR FURTHER INFORMATION CONTACT: Dr. Kewal Kohli, telephone (412) 937–2175.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

Written Comments

Written comments submitted on the proposed rule should be specific, should be confined to issues pertinent to the proposed rule, and should explain the reason for any recommended change. Where practical, commenters should submit three copies of their comments. Comments received after the close of the comment period (see **DATES**) or delivered to addresses other than those listed above (see **ADDRESSES**), may not be considered or included in the Administrative Record for the final rule.

Public Hearings

OSM will hold public hearings on the proposed rule by request only. The times, dates, and addresses for all hearings will be announced in the Federal Register at least 7 days prior to any hearings which are to be held. Upon request, OSM will hold a public hearing on the proposed rule in Washington, D.C. and in the State of Colorado. Individuals wishing to attend, but not testify at any hearing should contact the person identified under **FOR FURTHER INFORMATION CONTACT** beforehand to verify that the hearing will be held, should also contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Any person interested in participating at a hearing at a particular location, or any disabled individual who requires special accommodation to attend a public hearing, should inform Dr. Kohli (see **FOR FURTHER INFORMATION CONTACT**) either orally or in writing of the desired hearing location by 5 p.m. Eastern time on January 2, 1997. If no one has contacted Dr. Kohli to express an interest in participating in a hearing at a given location by that date the hearing will not be held. If only one person expresses an interest, a public meeting rather than a hearing may be held and the results will be included in the Administrative Record.

If a hearing is held, it will continue until all persons wishing to testify have been heard. To assist the transcriber and ensure an accurate record, OSM requests that persons who testify at a hearing provide the transcriber a written copy of their testimony.

To assist OSM in preparing appropriate questions, OSM also requests that persons who plan to testify submit to OSM at the address previously specified for the submission of written comments (see **ADDRESSES**) an advance copy of their testimony.

II. Background

Section 402(a) of the SMCRA requires all operators of coal mining operations subject to its provisions to pay a reclamation fee on each ton of coal produced. In December 1977 OSM first promulgated regulations to implement this provisions (42 FR 62714, December 13, 1977). Briefly, the regulations require that the Abandoned Mine Land (AML) fees must be paid on the actual gross weight of the coal, at the time of the first transaction (sale, transfer of ownership, or use) involving the coal. This regulation has been in effect basically unchanged since 1977. In 1982, OSM revised the regulatory language to clarify the point in time of fee determination and to stress that the actual gross weight of the coal must be used for fee calculation. At that time OSM also specifically noted that no fees were owed on impurities physically removed before the sale, transfer of possession or use. In 1988, OSM again revised this regulation to allow an operator who mined coal after July 1, 1988, to elect to take an allowance for moisture contained in the coal at the time of sale that is determined to be in excess of the inherent, or natural bed moisture, in the coal.

Initially, OSM adopted the excess moisture allowance to address an inconsistency in the methods of determining coal weight under various Federal taxation requirements. At the time OSM proposed to amend its regulation to allow a deduction for excess moisture, the ASTM Committee on Coal and Coke, whose membership included representatives of the Internal Revenue Service (IRS) and OSM, was conducting a study to develop and/or confirm precision statements for the ASTM standard test method used to estimate the bed moisture in high-rank coals, ASTM D1412–85, as it applied to coals of all ranks. In a letter of November 18, 1987, the IRS submitted the following comment in response to the OSM proposal, ''the results of the ASTM or a similar study should be received before one test is prescribed for use by all taxpayers.''

As an interim measure, until adequate and fully reliable testing procedures became available for coals of all ranks, OSM's 1988 adopted regulation incorporated a suggestion made by the IRS. OSM decided to rely on a facts and circumstances test to allow an operator to elect to take an allowance for excess moisture provided the operator could demonstrate, through competent evidence, that there was a reasonable basis for determining the existence and amount of excess moisture. OSM's standard of reasonableness required an operator to provide sufficient documentation to sustain the weight reduction. Although no specific time periods were prescribed for testing, an operator was also required to prove that time frames chosen to measure the existence and amount of excess moisture were reasonable.

The preamble to the 1988 rule discussed OSM's willingness to accept the standard ASTM test methods to determine inherent moisture, ASTM D1412–85, and total moisture, ASTM D3302–82, pending the availability of more suitable alternatives. OSM recognized that these tests were not always reliable for this purpose and acknowledged its willingness to accept other testing methods for some sub-bituminous and lignite coals. OSM also stated its intent to develop technical guidance to assist operators and to assure uniform application of the excess moisture allowance throughout the industry.

As a result of the 1988 regulatory revision, under both OSM's regulatory requirements, and the IRS Ruling (86–96), an operator may claim a reduction in coal subject to reclamation fees, and a reduction in coal subject to the black lung tax, by estimating the excess moisture contained in the coal. OSM has notified the IRS of its intent to propose a revision to its current regulation, and will continue to consult with the IRS throughout this rulemaking process.

The final rule which OSM adopted in 1988, at 30 CFR § 870.12, allows an operator to elect to reduce the weight of coal tonnage subject to reclamation fee payment by a percentage of excess moisture estimated to be contained in the coal at the time of fee assessment. OSM defines the term ''excess moisture'' as the difference between ''total moisture'' and ''inherent moisture.'' The ASTM definitions are used for the terms ''total moisture'' and ''inherent moisture,'' at 30 CFR § 870.5.

Standard laboratory test methods must be used to determine the estimated amount of excess moisture contained in the coal that is used as the basis for an excess moisture allowance. The excess moisture contained in mined coal must be found by collecting a coal sample and testing the sample to determine a percentage of inherent moisture estimated to be in the undisturbed coal as it lies in the seam. The operator must also collect and test coal at the shipping point to find the estimated total moisture percentage in as-shipped coal. The percentage of excess moisture that may be deducted from the weight of the coal for fee payment purposes is then calculated by finding the difference between the total moisture percentage and the inherent moisture percentage.

OSM has issued five AML Payer Letters to provide technical guidance to the coal industry and assist with the application of this regulation. OSM has also published this guidance in the OSM Payer Handbooks. The first AML Payer Letter, issued on June 16, 1988, provided for the operator to: Make an inventory of any coal mined prior to July 1, 1988, that was stockpiled, or otherwise stored on the mine site; use the ASTM D1412 test as the standard test method to determine the estimated percentage of inherent moisture; establish an accurate estimate of the coal seam's baseline inherent moisture by taking one inherent moisture test in each month of the first 24 months a coal seam is in continuous operation; and, take one annual inherent moisture test after completion of the baseline study period. The baseline can be based, in part, on information from existing sources such as the United States Geological Survey or the Department of Energy, provided the operator uses its own sampling and testing data to validate or update data obtained from these sources. An operator can use either ASTM Standard Test Method for Total Moisture in Coal, D3302, or ASTM Standard Practice for Proximate Analysis of Coal and Coke, test method D3172, to determine an estimated total moisture percentage. Total moisture is tested at the time of the initial bona fide sale, transfer of ownership, or use of the coal. Operators are advised to maintain a full description and rationale for any deviations from standard test methods, according to 30 CFR § 870.18(d).

The second AML Payer Letter, issued on September 28, 1988, provided ten different examples illustrating how to calculate an excess moisture allowance under various circumstances for coal that was either raw, clean, or blended. That Letter also provides instructions for completing the Coal Production and Reclamation Fee Report (Coal Reclamation Fee Report), Form OSM–1, to report the excess moisture allowance.

A third AML Payer Letter dated July 17, 1989, acknowledged that OSM would accept: Total moisture tests performed by the operator's customer, provided the operator maintains documentation to support the test results; and, moisture percentages accepted by another taxing authority only when the percentages were supported by actual test data. This Letter provided notice that OSM would not accept the use of a core sample to establish inherent moisture. The use of a weighted average in calculations, and the type of test documentation an operator would need to maintain are illustrated.

On September 14, 1990, OSM issued its fourth AML Payer Letter. This Letter consolidated and replaced the guidance in the three previous AML Payer letters on testing, completion of the Form OSM–1, and computing the excess moisture allowance under various scenarios. OSM also re-emphasized that total moisture should be determined for each day's shipments.

In an AML Payer Letter issued on July 15, 1993, OSM was able to expand its testing frequency guidelines for inherent moisture to include quarterly testing as an alternative to monthly testing. This came about as a result of research conducted by the OSM engineering staff on actual excess moisture allowances taken for more than 4 years. The AML Payer Letter advised operators that OSM would accept either quarterly inherent moisture estimates based on tests taken once in a quarter, or monthly tests. The ASTM had adopted the use of a corehole sample to test for inherent moisture. The AML Payer Letter informed the industry that OSM also accepts the use of corehole samples to test coal for inherent moisture. OSM advised the industry that it cannot accept residual moisture as inherent moisture because residual moisture and inherent moisture are not equal. This AML Payer Letter also informed the industry that OSM will provide notice when it proposes to adopt an alternative procedure that will more accurately establish inherent moisture in low-rank coal.

OSM's audits of excess moisture reduced tonnages find that operators frequently fail to conform to inherent moisture test procedures described in AML Payer Letters, and do not provide adequate support for procedures they do use. Some operators mining large volumes of low-rank coal base tonnage reductions on test data that is known to be unreliable.

In October 1992, OSM conducted its own independent sampling and testing program in Wyoming's Powder River

Basin to assess the reliability of existing ASTM methods and procedures for determining inherent moisture in low-rank coal. In March 1993, OSM met with operators in Gillette, Wyoming, to provide them with the results of its study and inform them that OSM was considering regulatory requirements for inherent moisture testing. This rulemaking proposes to adopt a new requirement for establishing inherent moisture in low rank coal based, in part, on the results of OSM's Powder River Basin sampling and testing program.

III. Discussion of the Proposed Rules

At this time OSM is proposing to revise its regulations governing the excess moisture allowance to codify regulatory technical requirements to be met by an operator who elects to take an excess moisture allowance in either high- or low-rank coals. The proposal incorporates by reference ASTM standards used for collecting and testing a coal sample as specified in § 870.19(a), Table 1 and Table 2, and § 870.20(a), Tables 3, 4, and 5, as published in the 1994 Annual Book of ASTM Standards, Volume 05.05. A copy of the ASTM standards is available for inspection at the OSM Headquarters Office, Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 120, 1951 Constitution Avenue, NW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St., Washington, DC. The proposed rule establishes a frequency for using ASTM standard test methods on coals of all ranks, and adopts the method approved by the ASTM to establish inherent moisture in low-rank coal, the ASTM D1412–93, Appendix XI. Use of this procedure for low-rank coal would ensure excess moisture allowances taken on low-rank coals are on a comparable basis to those taken on high-rank coal, and all excess moisture allowances are fair and equitable. OSM's proposal also includes an option that would provide operators with a method to calculate an allowance for the inherent moisture present in as-shipped coal. This would be of particular benefit when an operator sells large volumes of coal, and/or sells coal with a substantial variance between the total and inherent moisture.

Definitions—Section 870.5

OSM would modify the existing definition for excess moisture by including, by reference, a formula for use in calculating excess moisture in high- and low-rank coals. The formula to be used for high-rank coals is found in a new § 870.19 and the formula for low-rank coals is in a new § 870.20. The existing definition of inherent moisture would be expanded to incorporate by reference the specific ASTM sample collection methods and test procedures shown in § 870.19, Table 2, Calculating INHERENT moisture percentage in HIGH-rank coal, and § 870.20, Table 4, and Table 5, Calculating INHERENT moisture percentage in LOW-rank coal. The existing definition of total moisture would be expanded to incorporate by reference ASTM criteria in § 870.19, Table 1, for Calculating the TOTAL moisture percentage in HIGH-rank coal, and § 870.20, Table 3, for Calculating the TOTAL moisture percentage in LOW-rank coal. The expansion of the existing definitions to incorporate by reference specific ASTM sample collection methods and test procedures would provide precise technical standards to facilitate operator compliance with OSM's requirements, and to ensure that the same basis is used to calculate all excess moisture allowances.

General Rules for Calculating Excess Moisture—Section 870.18

OSM proposes to modify 30 CFR § 870.18, Excess moisture content allowance at § 870.18 (a), (b), and (c). Section 870.18(a) requires an operator to demonstrate through competent evidence that the basis for determining the existence and amount of excess moisture is reasonable. OSM requires documentation to be updated as needed to prove an excess moisture allowance taken by an operator continues to be valid. Section 870.18(b) requires standard laboratory analyses for testing inherent and total moisture. Section 870.18(c) requires an operator who blends coal mined from multiple seams prior to the initial sale, transfer or use of the coal to test for variations in the inherent moisture amounts from different seams.

This proposal would replace the reasonableness standard found at § 870.18(a), the generic laboratory test requirement at § 870.18(b), and the requirement for a separate test of coal from each seam mined prior to blending the coal for sale, transfer of ownership or use. OSM proposes a revision to the existing regulation that would recognize the distinct differences in high- and low-rank coals in new §§ 870.19 and 870.20. Section 870.19 proposes acceptable standards for collecting and testing a sample of high-rank coal to establish the percentage of inherent and total moisture contained in the coal, and calculate the excess moisture allowance. Section 870.20 proposes like standards for calculating the excess moisture allowance for low-rank coal.

Revised section 870.18(c) would add definitions to further explain the meaning of terms as they are used in new §§ 870.19 and 870.20. ''As-shipped coal'' and ''tipple coal'' is defined as the coal found at the mine or loading facility. A precise meaning for a ''channel sample'' and ''core sample'' is given and the definitions incorporate by reference the specific ASTM procedure used to take the particular kind of sample. The ''correction factor'' is added as the method used to establish the difference between the equilibrium moisture and inherent moisture in low-rank coal under § 870.20. ''Equilibrium moisture'' is defined as the method used to estimate the inherent moisture in all coals, and ASTM D1412 and ASTM D1412, Appendix XI, are incorporated by reference. Types of ''high-rank coals'' and ''low-rank coals'' are defined to explain how these terms are used throughout § 870.5 and §§ 870.18–20.

How To Calculate Excess Moisture in HIGH-Rank Coal—Section 870.19

A new § 870.19 would provide standard criteria for an operator to use to establish excess moisture in high-rank coal. Table 1 includes the ASTM standard sample collection method, ASTM D2234–89, *Standard Test Methods for Collection of a Gross Sample*; and test procedure, ASTM–D3302–91, *Standard Test Method for Total Moisture in Coal*, that OSM would accept for use as the basis for calculating the percentage of total moisture in as-shipped high-rank coal each day the coal is either shipped or used.

The daily total moisture test results would be converted to quarterly figures to be reported to OSM on the OSM–1 Coal Reclamation Fee Report. To calculate the quarterly total moisture percentage an operator would: (1) multiply the daily total moisture percentage by the tonnage shipped or used that day, to find the daily total moisture tonnage; and, (2) add the daily total moisture tonnage for each day in the quarter; and, (3) add the daily tonnage shipped or used in the quarter, to find the total tonnage shipped or used during the quarter. Then, divide the sum of the daily total moisture tonnage, step (2), by the sum of the daily tonnage shipped or used in the quarter, step (3). This will result in the total moisture percentage in high-rank coal for the quarter which would be reported on the OSM–1, Coal Reclamation Fee Report.

Table 2 provides three methods for sampling high-rank coal, and testing the sample to determine the inherent moisture percentage that would be acceptable to OSM. To collect a coal

sample directly from a coal seam an operator could use either a core or a channel sample method. If a core sample is collected the operator would be required to collect the sample using procedures in ASTM D5192–91, *Standard Practice for Collection of Coal Samples from Core* and to use laboratory procedures in ASTM D1412–93, *Standard Test Method for Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30 °C* to estimate the inherent moisture in the sample. If a channel sample method is used the operator would be required to collect the sample using procedures in ASTM D4596–93, *Standard Practice for Collection of Channel Samples of Coal in a Mine* and to use laboratory procedures in either ASTM D1412–93, *Standard Test Method for Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30 °C*, or ASTM D3302–91, *Standard Test Method for Total Moisture in Coal* to estimate the inherent moisture in the sample. To collect a sample of blended coal, as-shipped coal, tipple coal, commingled coal, or coal from slurry ponds an operator would use Procedures in ASTM D2234–89, *Standard Test Methods for Collection of a Gross Sample* and laboratory procedures in ASTM D1412–93, *Standard Test Method for Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30 °C* would be required to estimate the inherent moisture in the sample.

An operator would be required to select one of two options for timing inherent moisture tests, either quarterly or monthly. If a quarterly inherent moisture test is chosen, the operator would have to report the results of one inherent moisture test taken at any time during the quarter on the OSM–1 form for the quarter in which the test was taken. If monthly inherent moisture testing is preferred, the operator would be required to create a 24-month inherent moisture baseline during the first 24-months a coal seam is in continuous operation. To create the 24-month inherent moisture baseline an operator would have to collect and test one sample in each month of the calendar quarter. The quarterly inherent moisture percentage reported to OSM for the first 8 quarters a seam is in continuous operation would then be based on a weighted average of the 3-monthly inherent moisture test results. To determine the quarterly weighted average inherent moisture percentage an operator would have to: (1) multiply the inherent moisture percentage for one month by the number of tons produced or shipped in that month to find the monthly inherent moisture tonnage; (2) add the inherent moisture tonnage determined in (1) for each of the 3 months to find the quarterly inherent moisture tonnage; (3) divide the inherent moisture tonnage found in (2) by the total number of tons produced or shipped during the three months of the quarter; and, (4) report the weighted average percentage for the quarter to OSM on the OSM–1 form. After the first 24-months an operator would have to use an updated rolling average percentage to report inherent moisture percentages for all subsequent quarters in which a coal seam is continuously mined. The rolling average percentage would be calculated by: adding the results of one inherent moisture test of one coal sample collected during every 12-month period to the inherent moisture percentages for the preceding 23 tests, and dividing the sum of these tests by 24.

Section 870.19(a) provides instruction on how an operator would calculate the excess moisture in high-rank coal by using one of two methods. One method involves the simple subtraction of the inherent moisture percentage from the total moisture percentage as it is found in the existing rule. OSM expects that most operators of small to medium size mines would likely prefer to continue to use this method. A new alternative formula is added as a second method in § 870.19(a) that would allow an adjustment in the excess moisture calculation for a percentage of inherent moisture contained in the as-shipped coal. Some operators who either mine a large volume of coal, or mine coal with a significant variance in total and inherent moisture, have requested OSM's approval to use this formula for calculating a tonnage reduction for excess moisture. OSM is now proposing this option as an alternative to the existing formula used to determine the excess moisture percentage. The excess moisture percentage found in § 870.19(a) is multiplied by the tonnage shipped or used during the quarter to determine the excess moisture reduced tonnage for the quarter under § 870.19(b).

How to calculate excess moisture in LOW-rank coal—Section 870.20

A new § 870.20 would provide standard criteria for an operator to use to establish excess moisture in low-rank coal. Table 3 includes the ASTM standard sample collection method, ASTM D2234–89, *Standard Test Methods for Collection of a Gross Sample*, and test procedure, ASTM–D 3302–91, *Standard Test Method for Total Moisture in Coal*, that OSM would accept for use as the basis for calculating the percentage of total moisture in as shipped low-rank coal each day the coal is either shipped or used.

The daily total moisture test results would be converted to quarterly figures to be reported to OSM on the OSM–1 Coal Reclamation Fee Report. To calculate the quarterly total moisture percentage an operator would: (1) multiply the daily total moisture percentage by the tonnage shipped or used that day, to find the daily total moisture tonnage; (2) add the daily total moisture tonnage for each day in the quarter; and, (3) add the daily tonnage shipped or used in the quarter, to find the total tonnage shipped or used during the quarter. Then, divide the sum of the daily total moisture tonnage, step (2), by the sum of the daily tonnage shipped or used in the quarter, step (3). This will result in the total moisture percentage in low-rank coal for the quarter which would be reported on the OMS–1, Coal Reclamation Fee Report.

Table 4 provides instructions on how an operator would determine the inherent moisture percentage of coal mined from a bench of low-rank coal by: collecting one sample of as-shipped coal in each month of the calendar quarter using ASTM D2234–89, *Standard Test Methods for Collection of a Gross Sample of Coal*; and, testing each sample for equilibrium moisture following laboratory procedures in ASTM D1412–93, *Standard Test Method for Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30 °C.*

The operator would calculate the inherent moisture percentage to report to OSM for the quarter by averaging the results from the 3 monthly equilibrium moisture tests, and adding the correction factor. Table 5 provides the methodology for establishing the correction factor for all coal mined from each bench of low-rank coal.

Table 5 provides the method an operator would be required to use to establish a correction factor during the first quarter an excess moisture allowance is taken on low-rank coal mined from a bench. The correction factor would be found by using ASTM D1412 Appendix XI, *Standard Test Method for Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30 °C* to collect 5 samples of coal from a freshly exposed, unweathered coal seam face during each month of the quarter. Each of the 15 samples, 5 in each quarter, would be tested for inherent moisture and equilibrium moisture as required by ASTM D1412 Appendix XI, *Standard Test Method for*

Equilibrium Moisture of Coal at 96 to 97 Percent Relative Humidity and 30°C.

The operator would be required to establish the correction factor for the first quarter and all later quarters by: averaging the 15 monthly inherent moisture test results; and, averaging the 15 monthly equilibrium moisture test results; and, subtracting the average inherent moisture from the average equilibrium moisture. The correction factor would apply only to coal mined from the bench that is sampled. The correction factor could be changed at any time provided new samples are taken and all procedures shown in Table 5 are repeated.

IV. Procedural Matters

Federal Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, OSM is requesting comments from the public and the Office of Management and Budget (OMB) on the information collections contained in this proposed rulemaking. Comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of OSM, including whether the information will have practical utility; (b) the accuracy of OSM's estimate of the burdens of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collection on the respondents, including the use of automated collection techniques or other forms of information technology. No person is required to respond to a collection of information unless it displays a currently valid OMB Control Number. OSM's Control Numbers are displayed in 30 CFR Parts 710–955.

30 CFR Part 870

Title: Abandoned mine reclamation fund—fee collection and coal production reporting.

OMB Control Number: 1029–0090.

Abstract: Section 402 of the Surface Mining Control and Reclamation Act of 1977 requires operators of coal mining operations to pay a reclamation fee to the Secretary for deposit in the Abandoned Mine Reclamation Fund for the purpose of reclaiming lands mined and left abandoned, or inadequately reclaimed, prior to the Act's effective date. Reclamation fees are to be paid on each ton of coal produced.

Section 870.18 of the regulations allows an operator to take an excess moisture content allowance when calculating the amount of reclamation fees that are owed. Top substantiate the calculated moisture deduction claimed, an operator (or other entity responsible for the payment of the reclamation fee) is required to document by standard laboratory analysis the excess moisture content for each coal seam mined. This documentation must be updated as necessary to establish the continuing validity of the excess moisture content allowance taken by the operator.

Need For and Use: The information submitted will be used by OSM auditors to verify an operator's compliance with Section 402 of the Act and the requirements of the regulation at 30 CFR 870.18, 870.19, and 870.20. During an audit, operators must substantiate how the calculation for excess moisture was determined. Operators must retain their records for a 6-year period to allow for the audit of tax records. Courts have ruled that the AML fee is an excise tax. The applicable provision of the Energy Policy Act of 1992 (Section 2515) extended the fee through 2004.

Respondents: Approximately 1,050 coal mining operators who take the coal moisture deduction allowance.

Total Annual Burden: OSM estimates that 2 hours will be required to prepare and maintain the documentation for audit purposes per respondent. The total annual burden is estimated to be 2,100 hours.

Send comments regarding these burden estimates or any other aspect of these information collection requirements by January 2, 1997, to the Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, SIB 120, 1951 Constitution Avenue, NW., Washington, DC 20240; and the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Interior Desk Officer, 725 17th Street, NW, Washington, DC 20503.

Please refer to OMB Control Number 1029–090 in any correspondence.

Executive Order 12988 on Civil Justice Reform

The Department of the Interior has determined that this proposed rule meets the requirements of sections (3)(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform (56 FR 55195).

Executive Order 12866

This proposed rule has been determined to be significant under Executive Order 12866 and has been reviewed by the Office of Management and Budget.

The proposed rule is not considered economically significant under section 3(f)(1) of Executive Order 12866 and will not have a significant economic effect on the coal mining industry, or on regional or national economies. OSM is attempting to provide a viable methodology that will enable coal mine operators to calculate the correct allowance for excess moisture. OSM is not attempting to specify any given amount, or percentage, as an excess moisture allowance. For that reason it is not possible to predict the cost that this revision will have in terms of the amount of the additional AML fees that the industry will pay and the government collect or the industry save and the government not collect. Based on AML tonnages reported, and the total moisture allowances taken for 1995, the industry saved approximately $5,284,000 (rounded) in terms of the tonnage reported. With regard to benefits, the proposed rule will ensure that all excess moisture allowances are fair and equitable. OSM's proposal also includes an option that would provide operators with a method to calculate an allowance for the inherent moisture present in as-shipped coal. This would be of particular benefit when an operator sells large volumes of coal, and/or sells coal with a substantial variance between the total and inherent moisture.

To assist OSM in complying with the requirements of Executive Order 12866, OSM invites comments on the potential costs and benefits of the proposed rule.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Department of the Interior has determined that this rule would not have a significant economic effect on a substantial number of small entities for the reason stated below. This proposed rule will provide two methods for operators to calculate the excess moisture in high-rank coal. OSM expects that most operators of small to medium size mines would likely prefer to continue to use the current method of calculation while operators who either mine a large volume of coal, or mine coal with a significant variance in total and inherent moisture, will use the proposed option as an alternative to the existing formula used to determine the excess moisture percentage. Thus, for small operators any change from current practices would be optional.

Unfunded Mandates Reform Act

This rule is not expected to impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

National Environmental Policy Act

OSM has prepared a draft environmental assessment (EA) of this proposed rule and has made a tentative finding that the proposed rule would not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). It is anticipated that a Finding of No Significant Impact (FONSI) will be approved for the final rule in accordance with OSM procedures under NEPA. The EA is on file in the OSM Administrative Record at the address specified previously (see **ADDRESSES**). An EA will be completed on the final rule and a finding made on the significance of any resulting impacts prior to promulgation of the final rule.

Author

The principal author of this proposed rule is Dr. Kewal Kohli, Mining Engineer, Office of Surface Mining, U.S. Department of the Interior, 3 Parkway Center, Pittsburgh, PA 15220.

Inquiries with respect to the proposed rule should be directed to Dr. Kohli at the address and telephone specified under **FOR FURTHER INFORMATION CONTACT.**

List of Subjects in 30 CFR Part 870

Incorporation by reference, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: June 24, 1996.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

Accordingly, it is proposed to amend 30 CFR part 870 as set forth below:

PART 870—ABANDONED MINE RECLAMATION FUND—FEE COLLECTION AND COAL PRODUCTION REPORTING

1. The authority citation for part 870 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 870.5 is amended by revising definitions of ''excess moisture,'' ''inherent moisture'' and ''total moisture'' to read as follows:

§ 870.5 Definitions.

* * * * *

Excess moisture means the difference between total moisture and inherent moisture, calculated according to § 870.19 for high-rank coals or the difference between total moisture and inherent moisture calculated according to § 870.20 for low-rank coals.

* * * * *

Inherent moisture means moisture that exists as an integral part of the coal seam in its natural state, including water in pores, but excluding that present in macroscopically visible fractures, as determined according to § 870.19(a) or § 870.20(a).

* * * * *

Total moisture means the measure of weight loss in an air atmosphere under rigidly controlled conditions of temperature, time and air flow, as determined according to either § 870.19(a) or § 870.20(a).

* * * * *

3. Section 870.18 is revised to read as follows:

§ 870.18 General rules for calculating excess moisture.

If you are an operator who mined coal after June 1988, you may deduct the weight of excess moisture in the coal to determine reclamation fees you owe under § 870.12(b)(3)(i). Excess moisture is the difference between total moisture and inherent moisture. To calculate excess moisture in HIGH-rank coal, follow § 870.19. To calculate excess moisture in LOW-rank coal, follow § 870.20. Report your calculations on OSM–1, Coal Reclamation Fee Report, for every calendar quarter in which you claim a deduction. Some cautions:

(a) You or a customer of yours may do any test required by §§ 870.19 and 870.20. But whoever does a test, you are to keep test results and all related records for at least six years after the test date.

(b) If OSM disallows any or all of an allowance for excess moisture, you must submit an additional fee plus interest computed according to § 870.15(c) and penalties computed according to § 870.15(f).

(c) The following definitions are applicable to §§ 870.19 and 870.20. Applicable ASTM standards are incorporated by reference as published in the 1994 Annual Book of ASTM Standards, Volume 05.05. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each applicable ASTM standard is incorporated as it exists on the date of the approval, and a notice of any change in it will be published in the Federal Register. You may obtain copies from the ASTM, 1916 Race Street, Philadelphia, Pennsylvania, 19103–1187. A copy of the ASTM standards is available for inspection at the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 120, 1951 Constitution Avenue, NW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St., NW., Suite 700, Washington, DC.

Note: The incorporation by reference and availability of inspection copies are pending approval by the Office of the Federal Register.

(1) *As-shipped coal* means raw or prepared coal that is loaded for shipment from the mine or loading facility.

(2) *Channel sample* means a sample of coal collected according to ASTM standard D4596–93 from a channel extending from the top to the bottom of a coal seam.

(3) *Core sample* means a cylindrical sample of coal that represents the thickness of a coal seam penetrated by drilling according to ASTM standard D5192–91.

(4) *Correction factor* means the difference between the equilibrium moisture and the inherent moisture in low rank coals for the purpose of § 870.20(a).

(5) *Equilibrium moisture* means an estimate of the inherent moisture in all coals. The equilibrium moisture is determined according to ASTM standard D1412–93 and accompanying appendices, as appropriate.

(6) *High-rank coals* means anthracite, bituminous, and subbituminous A and B coals.

(7) *Low-rank coals* means subbituminous C and lignite coals.

(8) *Tipple coal* means coal from a mine or loading facility that is ready for shipment.

4. Sections 870.19 and 870.20 are added to read as follows:

§ 870.19 **How to calculate excess moisture in high-rank coal.**

Here are the requirements for calculating the excess moisture in high-rank coal for a calendar quarter. Applicable ASTM standards are incorporated by reference as published in the 1994 Annual Book of ASTM Standards, Volume 05.05. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each applicable ASTM standard is incorporated as it exists on the date of the approval, and a notice of any change in it will be published in the Federal Register. You may obtain copies from the ASTM, 1916 Race Street, Philadelphia, Pennsylvania, 19103–1187. A copy of the ASTM standards is available for inspection at the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 120, 1951 Constitution Avenue, NW., Washington, DC, or at the Office of the Federal Register, 800 North

Capitol St., NW., Suite 700, Washington, DC.

Note: The incorporation by reference and availability of inspection copies are pending approval by the Office of the Federal Register.

(a)(1) Calculate the excess moisture percentage using one of these equations:

$$EM = TM - IM$$

or

$$EM = TM - \left(IM \times \frac{100 - TM}{100 - IM} \right)$$

(2) EM equals excess moisture percentage. TM equals total as-shipped moisture percentage calculated according to Table 1 of this section. IM equals inherent moisture percentage calculated according to Table 2 of this section.

(b) Multiply the excess moisture percentage by the tonnage shipped or used during the quarter.

TABLE 1 TO § 870.19.—CALCULATING TOTAL MOISTURE PERCENTAGE IN HIGH-RANK COAL [1]

Collect and test each day you ship or use coal	Convert daily test results to quarterly figures and report them
Collect a sample of as-shipped or used coal. Follow procedures in ASTM D2234–89 Test the sample for daily total moisture percentage. Follow laboratory procedures in ASTM D3302–91.	1. Multiply daily total moisture percentage by daily tonnage shipped or used. You now have daily total moisture tonnage. 2. Add up daily total moisture tonnage for the quarter. 3. Add up daily tonnage shipped or used in the quarter. 4. Divide 2 by 3. Report this total moisture percentage in high-rank coal for the quarter on OSM–1, Coal Reclamation Fee Report.

[1] See § 870.19 for the incorporation by reference of the ASTM standards.

TABLE 2 TO § 870.19.—CALCULATING INHERENT MOISTURE PERCENTAGE IN HIGH-RANK COAL [1]

Choose from 3 ways to collect and test	Choose from 2 ways to time the tests and convert the results for quarterly reporting
First Collect a core sample. Follow procedures in ASTM D5192–91. Test the sample to estimate inherent moisture. Follow laboratory procedures in ASTM D1412–93.	First Collect and test once each quarter. Report test results by quarter on OSM–1. Test results need no converting; they are in quarterly units already.
Or second Collect a channel sample. Follow procedures in ASTM D4596–93. Test the sample to estimate inherent moisture. Follow laboratory procedures in ASTM D1412–93 or ASTM D3302–91.	Or second Create a 24-month baseline and update as follows: *For reporting months 1–24...* Collect and test one sample each month. Each quarter, calculate a weighted average percentage of inherent moisture: • Multiply a month's inherent moisture percentage by tons produced or shipped. You now have the month's inherent moisture tonnage. • Add up 3 months of that inherent moisture tonnage. • Divide by tons produced or shipped in those 3 months. Report the quarter's weighted average percentage on OSM–1.
Or third Collect a sample of blended coal, as-shipped coal, tipple coal, commingled coal, or coal from slurry ponds. Follow procedures in ASTM D2234–89. Test the sample to estimate inherent moisture. Follow laboratory procedures in ASTM D1412–93.	*For all subsequent months...* Collect and test one sample for inherent moisture every 12 months. Calculate—and report in the following 4 quarters—one updated rolling average percentage: • Add to the annual sample percentage the inherent moisture percentages for the preceding 23 tests. • Divide by 24. Report the quarter's weighted average percentage on OSM–1.

[1] See § 870.19 for the incorporation by reference of the ASTM standards.

§ 870.20 How to calculate excess moisture in LOW-rank coal.

Here are the requirements for calculating the excess moisture in low-rank coal for a calendar quarter. Applicable ASTM standards are incorporated by reference as published in the 1994 Annual Book of ASTM Standards, Volume 05.05. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each applicable ASTM standard is incorporated as it exists on the date of the approval, and a notice of any change in it will be published in the Federal Register. You may obtain copies from the ASTM, 1916 Race Street, Philadelphia, Pennsylvania, 19103–1187. A copy of the ASTM standards is available for inspection at the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 120, 1951 Constitution Avenue, NW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St., NW., Suite 700, Washington, DC.

Note: The incorporation by reference and availability of inspection copies are pending approval by the Office of the Federal Register.

(a)(1) Calculate the excess moisture percentage using one of these equations:

$$EM = TM - IM$$

or

$$EM = TM - \left(IM \times \frac{100 - TM}{100 - IM} \right)$$

(2) EM equals excess moisture percentage. TM equals total as-shipped moisture percentage calculated according to Table 1 of this section. IM equals inherent moisture percentage calculated according to Tables 2 and 3 of this section.

(b) Multiply the excess moisture percentage by the tonnage shipped or used during the quarter.

TABLE 1 TO § 870.20.—CALCULATING TOTAL MOISTURE PERCENTAGE IN LOW-RANK COAL[1]

Collect and test each day you ship or use coal	Convert test results to quarterly figures and report them
Collect a sample of as-shipped or used coal. Follow procedures in ASTM D2234–89. Test the sample for daily total moisture percentage. Follow laboratory procedures in ASTM D3302–91.	Convert daily total moisture percentage to quarterly total moisture percentage: 1. Multiply daily total moisture percentage by daily tonnage shipped or used. You now have daily total moisture tonnage. 2. Add up daily total moisture tonnage for the quarter. 3. Add up daily tonnage shipped or used in the quarter. 4. Divide 2 by 3. Report this total moisture percentage in low-rank coal for the quarter on OSM–1, Coal Reclamation Fee Report.

[1] See § 870.20 for the incorporation by reference of the ASTM standards.

TABLE 2 TO § 870.20.—CALCULATING INHERENT MOISTURE PERCENTAGE IN LOW-RANK COAL [1]

Collect and test once a month	Convert test results to quarterly figures and report them
Collect 1 sample of as-shipped coal. Follow procedures in ASTM D2234–89. Test the sample for equilibrium moisture. Follow laboratory procedures in ASTM D1412–93.	Calculate inherent moisture percentage for the quarter: • Average the 3 equilibrium moisture results from your monthly tests. • Add to this average a Correction Factor that you calculate for the first quarter according to Table 5 below. Report this inherent moisture percentage for the quarter on OSM–1.

[1] See § 870.20 for the incorporation by reference of the ASTM standards.

TABLE 3 TO § 870.20.—CALCULATING THE CORRECTION FACTOR FOR TABLE 4 [1]

Collect and test each month in the first quarter	Convert test results into a correction factor for all quarterly reports
Collect 5 samples of a freshly exposed, unweathered coal seam face. Follow procedures in ASTM D1412–93 Appendix XI. Test each sample for two things: • Inherent moisture • Equilibrium moisture. Follow laboratory procedures in ASTM D1412–93 Appendix XI.	Use the test results to calculate a correction factor: • Average the 15 inherent moisture results from your monthly tests. • Average the 15 equilibrium moisture results from your monthly tests. • Subtract the average equilibrium moisture from the average inherent moisture. You now have a correction factor for the first quarter the deduction is taken, and all later quarters. Use it in Table 4 above. You may change the correction factor at any time by repeating the steps in this table. A correction factor applies to only the bench you sample.

[1] See § 870.20 for the incorporation by reference of the ASTM standards.

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Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Part 135

Commercial Passenger-Carrying Operations in Single-Engine Aircraft under Instrument Flight Rules; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 135

[Docket No. 28743; Notice No. 96–14]

RIN 2120–AG22

Commercial Passenger-Carrying Operations in Single-Engine Aircraft under Instrument Flight Rules

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Aviation Administration (FAA) is proposing to revise the conditions and limitations in Part 135 for instrument flight rule (IFR), passenger-carrying operations in single-engine aircraft. The proposed rule will expand the passenger-carrying provisions of the current rule, add equipment requirements, as well as maintenance requirements to monitor engine reliability, and delete the limited IFR provisions of the existing rule for both single and multi-engine aircraft. Currently, operation of single-engine aircraft carrying passengers is authorized for visual flight rules (VFR) or for limited operations in instrument meteorological conditions (IMC). Single-engine cargo operations are authorized to operate under IFR without these limitations. VFR flight into IMC is the most significant cause of fatal accidents in Alaska and is a serious problem for single-engine aircraft nationally. This action would increase the safety of single-engine, passenger-carrying operations by allowing planned instrument flight in the IFR system and by imposing certain other conditions and limitations.

DATES: Comments must be received by February 3, 1997.

ADDRESSES: Comments on this notice should be submitted in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC–200), Room 915–G, Docket No. 28743, 800 Independence Ave., SW, Washington, DC 20591. Comments must be marked Docket No. 28743. Comments also may be submitted electronically to the following Internet address: nprmcmts@faa.dot.gov. Comments may be examined in room 915G weekdays between 8:30 a.m. and 5 p.m. except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Katherine Hakala, Flight Standards Service, Federal Aviation Administration, 800 Independence Ave, SW, Washington, DC 20591 (202) 267–8166/3760.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federal, or economic impact that might result from adopting the proposals in this notice are also invited. Substantive comments should be accompanied by cost estimates, if appropriate. Comments should identify the regulatory docket or notice number and should be submitted in triplicate to the Rules Docket address specified above. All comments received on or before the specified closing date for comments will be considered by the Administrator before taking action on this proposed rulemaking. The proposals contained in this notice may be changed in light of comments received. All comments received will be available, both before and after the closing dates for comments, in the Rules Docket, for examination by interested persons. A report summarizing each substantive contact with FAA personnel concerned with this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a pre-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 28743.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded, using a modem and suitable communications software, from the FAA regulations section of the Fedworld electronic bulletin board service ((703) 321–3339), the Federal Register's electronic bulletin board service ((202) 512–1661), or the FAA's Aviation Rulemaking Advisory Committee Bulletin Board service ((800) 322–2722 or (202) 267–5948).

Internet users may reach the FAA's web page at http://www.faa.gov or the Federal Register's web page a http://www.access.gpo.gov/su__docs for access to recently published rulemaking documents.

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Ave, SW, Washington, DC 20591, or by calling (202) 267–9677. Communications must identify the notice number or docket number of this NPRM.

Persons interested in being placed on the mailing list for future NPRMs should request from the above office a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Rationale

In the past, the rationale against single-engine IFR passenger-carrying operations centered on the hazards of losing an engine. Analysis indicates, however, a far more significant accident category: flight under visual flight rules (VFR) into instrument meteorological conditions (IMC). A recent NTSB study of aviation in Alaska indicated that VFR flight into IMC caused a disproportionate number of fatal accidents in part 135 operations in that state. Multi-engine airplanes are able to file and fly with passengers under IFR, while single-engine airplanes are only able (with few exceptions) to carry passengers under VFR. Thus, multi-engine airplanes have the advantage of contact with ATC, position following, en route and terminal weather information, and the higher altitude ensuring obstacle clearance and radio reception in the IFR system. The FAA Administrator, in a November 18, 1994, letter to pilots (''Winter Operations Emphasis Program 1994,'' available in the docket), expressed his concern about the number of accidents that occur when pilots are flying just below a low ceiling and collide with the terrain. He stated that one of the safest steps available was to take advantage of the IFR system. Aircraft flying at published cruising altitude that guarantees obstacle clearance and radio reception have considerably more time to glide to a landing and maneuver to a safe landing area than those flying below the ceiling.

The number of accidents involving VFR flight into IMC is substantial. It is concern with this safety hazard that prompted the FAA to reconsider its limitations on single-engine IFR flight with passengers under part 135. Additionally, the FAA has considered the action of Canada that allowed single-engine passenger-carrying IFR under certain conditions, and the petitions for exemption of the Alaska Air Carrier Association and individual operators. While this action will not eliminate VFR flight into IFR conditions accidents, it is expected that it will reduce the accident rate.

Background

Prior to October 10, 1978, passenger-carrying, single-engine instrument flight rule (SEIFR) operations were permitted

if an aircraft could descend to VFR conditions in the event of an engine failure. This provision allowed operations in IMC or over-the-top of a ceiling, as long as VFR conditions existed below that ceiling (i.e., a buffer zone). In 1978, part 135 was substantially revised for passenger-carrying operations over the top or in IFR conditions to require an aircraft to be able to descend under VFR if its engine fails (43 FR 46742, October 10, 1978). This revision also provided for ''limited IFR'' operations which, if VFR conditions were forecast within 15 minutes flying time, allowed flight in IMC for the first 15 minutes of flight, and thereafter only if those IFR conditions were unforecast. The pilot can operate in IFR conditions if unforecast weather conditions are encountered while en route on a flight planned to be conducted under VFR. The pilot can make an IFR approach at the destination airport if unforecast weather conditions are encountered that do not allow an approach under VFR. This rule had the effect of eliminating the buffer zone provisions, restricting planned flights under IFR in IMC, and restricting VFR over-the-top flights to scattered or broken sky conditions. An exception to the two-pilot requirement, or autopilot requirement, is provided for limited IFR operations in § 135.103. Limited IFR can be conducted as a single-pilot operation in aircraft with nine or fewer passenger seats. Cargo-only, single-engine aircraft can operate under IFR or over the top without these restrictions.

Since 1978, the FAA has received 12 petitions for exemptions from or amendments to § 135.181 to allow the use of all or specific models of single-engine aircraft in passenger-carrying IFR operations. The most recent petitions are still pending. Internationally, commercial operators in several countries have sought permission to conduct passenger operations in IMC with single-engine aircraft. Canada, following a cooperative effort with the engine manufacturers, aircraft manufacturers, and users that produced a well-documented case, has allowed SEIFR passenger-carrying operations in turbine-powered airplanes since February 1993, with a number of specific requirements for equipment and training. Other countries are also considering permitting SEIFR passenger-carrying operations.

In response to the petitions, the Canadian action, and changes in technology that have resulted in increasingly reliable engines and aircraft systems, the FAA asked its Office of Integrated Safety Analysis to conduct a study to determine if demonstrable differences exist between single- and multi-engine aircraft in visual meteorological conditions (VMC) and IMC. The study, Part 135 Single-Engine Instrument Flight Rules Operations in Instrument Meteorological Conditions, February 24, 1994, (available in the docket) reviewed the basis for the Canadian action and available data from a number of sources on powerplant/systems reliability and activity exposure data.

In September 1994, the FAA asked the Aviation Rulemaking Advisory Committee (ARAC) to review the Canadian policy on SEIFR, re-examine FAA policies for commercial IMC and night operations by single-engine aircraft, determine conditions or limitations that such operations should meet, and recommend any changes. The ARAC formed a working group that included representatives of the FAA, Transport Canada-Aviation, the European Joint Aviation Authority, Australian Civil Aviation, several European national aviation authorities, aircraft and engine manufacturers, trade associations, pilot unions, and commercial operators. The committee recommended that § 135.181 be revised to permit SEIFR passenger-carrying operations provided certain requirements for equipment and training were met. The ARAC proposal, although not technically limited to a particular type of aircraft, proposed certain conditions that are met at present only by turbine-powered aircraft. The ARAC also recommended approval of the Alaska Air Carrier Association's (AACA) petition for exemption, which covers both turbine-powered and reciprocating engine aircraft. Both the ARAC and the FAA study focused on the issue of engine reliability.

Recently, the National Transportation Safety Board (NTSB) completed a study of operations in Alaska Aviation Safety In Alaska, (Safety Study NTSB/SS–95/03, PB95–917006). The NTSB noted that unlike the rest of the U.S., commuter airline service in Alaska is ''dominated by single-engine airplanes powered by a reciprocating engine operating under VFR and crewed by one pilot.'' After reviewing Alaska aviation accidents from 1988 to 1993 (which include single and multi-engine aircraft), the NTSB concluded that ''VFR flight into IMC that results in fatal accidents continues to be the most significant safety problem in Alaskan aviation.'' VFR flight in IMC in Alaska accounted for 67 percent (6 of 9) fatal commuter airline accidents and 47 percent (7 of 15) fatal air taxi accidents. Overall, in Alaska, VFR flight into IMC accounted for only 15 percent of the total accidents, but 54 percent of the fatal accidents. The NTSB recommended that the FAA proceed with rulemaking to allow SEIFR passenger-carrying operations in turbine-powered aircraft and evaluate whether extending the rule to all single-engine aircraft would provide a positive effect on safety.

Prior to the Alaska aviation study, the NTSB conducted a study of the emergency medical service (EMS) helicopters because their accident rate was twice the rate experienced by part 135 on demand helicopter operations and one and half times the rate for all turbine-powered helicopters. For the report, ''Safety Study—Commercial Emergency Medical Service Helicopter Operations'' (NTSB 1988), an exploration of the rapidly growing commercial EMS helicopter industry and its operations, the NTSB investigated and evaluated 59 helicopter accidents. The Board determined that marginal weather conditions and inadvertent flight into IMC remain the most serious hazard that VFR helicopters encounter. ''The Board believes that although the IFR system is not designed optimally for IFR helicopters and that the nature of the EMS helicopter mission further complicates this problem, the safety advantages offered by IFR helicopters flown by current and proficient pilots are great enough that EMS programs should seriously consider obtaining this capability.''

The Alaska Air Carriers Association in its petition for exemption has stated, and the NTSB study confirmed, that in many areas, only single-engine aircraft can be operated because of the limitations of the landing strips, which severely restrict the availability of air transport in these areas. The petitioners further stated that under the current rule, unless clear weather is forecast over the entire route from 15 minutes from the departure airport to the destination, passenger-carrying, single-engine commercial operations are not permitted. In many areas, aircraft are the only means of transportation; weather forecasts, when available, rarely predict continuing VFR conditions. Alaska, they stated, was particularly disadvantaged by the current rule. Recent legislation requires the FAA to consider the special needs of Alaska when developing its rules.

As suggested by the NTSB, the FAA reviewed accident data from 1983 to 1996 on both reciprocating and turbine engines. Data indicated that there were 67 accidents in on-demand operations that involved VFR flight into IFR

conditions; single-engine aircraft were involved in 75 percent of these accidents. Although the number of such accidents is known, the rate of such accidents cannot be determined because the FAA does not collect data on the number of flights or flight hours for on-demand operations under part 135; therefore, it is not possible to evaluate existing data on accidents involving turbine-powered and reciprocating-powered single-engine aircraft.

Disposition of Pending Petitions

The FAA currently has similar petitions for exemptions to § 135.181 from the Alaskan Air Carriers Association, Mid-Atlantic Freight, Atlantic Aero, Wright Air Service, Inc., Taquan Air Service, Inc., and Telford Aviation, Inc. In developing this Notice of Proposed Rulemaking, the FAA considered the merits of each of the individual petitions and proposed appropriate points and recommendations from them. This notice formally disposes of those petitions.

Discussion of the Proposed Rule

The purpose of this rule is to improve the safety of single-engine, passenger-carrying operations by allowing operators to take advantage of the IFR system. This proposal would allow planned flight at a minimum en route altitude that ensures obstacle clearance and ATC communications over a published route, thereby reducing the occurrence of continued VFR flight into IMC. Parts 91 and 135 currently require additional aircraft equipment, pilot training, experience, and qualification, and weather and fuel requirements to operate under IFR. Operations under the existing limited IFR rules must meet the requirements for IFR operations with the exception that a second pilot or autopilot authorization is not needed. The current equipment, pilot, weather, fuel, and other differences for VFR and IFR operations are outlined in the Table at the end this section. This NPRM proposes to remove the limited IFR operations and allow SEIFR operations with additional conditions and limitations that will further enhance the safety of SEIFR operations over VFR and limited IFR operations.

The FAA is proposing to change part 135 to allow passenger-carrying SEIFR subject to the following conditions:

- A means of engine trend monitoring would be required in addition to the inspection requirements of 14 CFR part 91; and
- Two independent electrical power generating sources or, in addition to the original electrical power source, a standby battery that can maintain 150 percent of the minimum electrical load for at least one hour would be required.

In addition, the limited IFR conditions of current § 135.181 would be eliminated. The proposed rule changes would not affect cargo-only operations.

The FAA originally limited passenger-carrying SEIFR operations because of concern about the consequences of engine loss. The February 1994 FAA study, which focused on the difference between single-engine and multi-engine aircraft, found that data that specifically address the issue of the reliability of single-engine aircraft in IMC under part 135 are necessarily limited to cargo-only operations because relatively few passenger-carrying operations occur under these conditions. In addition, the FAA does not require manufacturers and operators of small aircraft and powerplants to have established databases capable of providing information needed to support reliability evaluations. Data available collected from various sources were found to be frequently incomplete and inconsistent in reporting format, limiting their usefulness.

The 1994 FAA study analysis of NTSB data for part 135 on-demand airplane accidents for 1988 to 1990 indicated that although propulsion system accidents account for a higher percent of total accidents for single-engine (18 percent) than for multi-engine airplanes (6 percent), only 2 of the 24 accidents caused by propulsion systems occurred in IMC. Accidents involving propulsion system failure in IMC appear to be very infrequent occurrences. This can be attributed in part to the limits on passenger-carrying operations of aircraft in IMC; however, cargo-only IFR operations are included in these data. Weather was a casual factor in 24 percent of all accidents; improper flightcrew actions contributed to 95 percent of weather-related accidents. Mechanical problems, however, were a factor in only one-single-engine and one multi-engine weather-related accident, suggesting that accidents involving equipment failure during flight in instrument conditions are relatively rare events in on-demand air carrier operations. The data also show that most accidents in IMC result in fatal or serious injuries, regardless of the type of flight plan or class of airplane. FAA data on part 135 accidents involving single-engine aircraft from 1985 to 1992 indicated that the most common causes of accidents were weather, poor in-flight planning and decision-making, and other weather-related errors resulting from attempts to maintain VFR flight.

Analysis of part 135 scheduled airplane accident data revealed patterns in accident causal factors that are very similar to those for on demand operations. Analysis of business airplane accidents that occurred during part 91 operations provided additional perspective on the relative contribution of systems and equipment reliability problems to accidents. Accidents involving propulsion and other system failures in IMC were infrequent occurrences even though part 91 operators are not subject to the same restrictions or level of regulation and oversight as part 135 operators.

The FAA recognizes that engine failure in a single-engine aircraft results in an inability to sustain flight. The FAA has determined, however, that allowing SEIFR passenger-carrying operations will enhance safety over VFR flights in marginal weather conditions and over flights under the limited IFR provisions of part 135. Aircraft operating under IFR are part of the national IFR system, which includes air traffic monitoring and control system; this system ensures that both pilots and air traffic controllers know where the aircraft is and can work together to avoid hazards and complete the flight safely. Immediate emergency assistance is available in the event of an emergency. Data from the Rescue Coordination Center have shown that should an accident occur, aircraft that were operating under the IFR system are located within a few hours; aircraft that were operating under the VFR system often take days to locate.

The FAA does not expect that operators currently flying multi-engine aircraft will switch to single-engine aircraft simply because of this rule change; decisions about the type of aircraft to operate are complex. Operators must weigh numerous factors when selecting aircraft, including customer base and geographical location. Whatever choice operators make, the FAA remains convinced that the proposed rule change will increase safety of single-engine, passenger-carrying operations.

New Requirements

In addition to the inspections requirements of part 43, the FAA is proposing to adopt the ARAC suggestion for engine wear and trend monitoring. Such monitoring provides an early indication of engine wear and increases engine reliability. The engine trend monitoring system would require an oil analysis at 100-hour inspection or every

annual inspection if less than 100 hours have accrued.

The oil analysis program is an important tool in determining the relative state of engine health. Samples of engine oil are collected at selected intervals (usually around the 100-hour interval or less) The oil samples are identified by make and model of engine, total time on the engine, and last oil and filter change. The sample is then sent to a laboratory in which the oil is subjected to a series of tests in which the amount of trace elements, such as iron and aluminum, are identified. A report is sent back to the operator recommending another 100 hours of operation or, because of an abnormal amount of a particular element found in the oil, a particular maintenance action; this action may be a simple filter change, or a borescope inspection, other maintenance inspection/test, or a complete teardown and rebuild of the engine. Regular oil analysis allows the operator to track the engine's condition accurately and predict failures before they would occur.

Current IFR requirements require a generator or generators (or alternator) able to supply all probable combinations of continuous in-flight electrical loads for required equipment and for recharging the battery. The FAA is also proposing to adopt a modification of the ARAC suggestion for two independent electrical power generating sources; the proposed rule would specifically allow a standby battery to serve as a second power source if the battery can maintain 150 percent of the minimum electrical load for at least one hour. This requirement introduces redundancy for the generator and alternator and ensures that, if a generator or alternator fails, the aircraft will still be able to use critical navigation and communication equipment, for a period of time in which to effect a safe approach and landing. The FAA will consider, and requests comments on other redundant or standby electrical systems.

Section 135.163 (h) currently requires two independent sources of energy (with means of selecting either) for powering all gyroscopic instruments. Of these sources, at least one must be an engine-driven pump or generator; each source must be capable of driving all gyroscopic instruments, and installed so that failure of one instrument or source does not interfere with the energy supply to the remaining instruments or the other energy source, unless, for single-engine aircraft, the rate-of-turn indicator has a source of energy separate from the bank and pitch and direction indicators.

The FAA considered requiring electrical or vacuum redundancy to drive the gyroscopic instruments, however, the precise configuration of that redundancy is not proposed. The FAA is requesting comments on the feasibility, benefit, and cost of two independent sources of energy for gyroscopic instruments for single engine aircraft. If, for single-engine aircraft, the rate of turn exception is maintained as stated in the current 135.163(h), the FAA will require that training and testing on emergency and partial panel operations be provided and evaluated. Comments are further requested on whether the rate-of-turn indicator powered from a separate source, coupled with required training and testing, should be considered adequate for single-engine IFR passenger operations.

Based on the comments received, the FAA may adopt additional provisions for a redundant source of power for the gyroscopic instruments or electrical systems in the final rule.

The FAA is proposing to delete the existing limited IFR provisions, which allow opeators to take off in IFR conditions if VFR conditions are forecast for the remainder of the route from a distance no further than 15 minutes flight time for the departure airport. This revision eliminates safety deficiencies of the conduct of ''unplanned'' IFR flight. Under the limited IFR rule, pilots can only conduct IFR operations en route and on an approach if weather conditions were unforecast, which means the pilots may not have planned for IFR and may have to develop and file a flight plan in flight, while coping with unexpected weather conditions. Limited IFR also allows these operations to be conducted as a single pilot operation, without a second pilot or autopilot that is required for other IFR operations. In addition, the limitations on weather forecasting have made this provisions impractical in many parts of the U.S.

It is the FAA's intent that, because multi-engine operators can already avail themselves of unrestricted IFR, the proposed removal of the limited IFR provision in § 135.181(c) (2) and the exception to the second-in-command requirement for limited IFR operations in § 135.103 would not impact these operators. The FAA invites comments from operators who used the limited IFR provision regarding the economic impact of this proposal.

The proposed changes would allow SEIFR operations in single-engine airplanes and turbine-powered helicopters that can be equipped for IFR flight. A number of single-engine reciprocating-powered airplanes will not be able to upgrade for IFR or would find the cost prohibitive. Single-engine, reciprocating-powered helicopters as they currently exist are not certificated for IFR operations. Consequently, they would not be affected by this rule change.

Other Issues Considered

The FAA reviewed suggestions made by the ARAC and the petitions submitted, but decided against adopting other limitations on SEIFR passenger-carrying operations. Some of the ARAC suggestions would have limited the rule to turbine-powered aircraft (e.g., use of auto-ignition/continuous ignition system); the suggested requirement for mean time between failure data and simulator training would have severely limited the rule, at least in the short-term, to a single aircraft, the Cessna Caravan. The FAA does not believe that such a limitation is justified because flying IFR improves the safety of all operations over flying VFR in marginal weather conditions and flight under the current limited IFR provisions.

A number of suggested requirements were not adopted because they are already covered under existing rules; for example, autopilot training and proficiency checks are currently required. The FAA decided that the suggested requirement for an air transport pilot certificate for commuter operations was unnecessary because of size and complexity of single-engine aircraft. Current requirements for single-engine, IFR provide for at least a commercial certificate with appropriate category and class ratings, and if required, type ratings, 1,200 hours of flight time including 500 hours of cross country, 100 hours of night, and at least 50 hours of actual instrument flight time. Other ARAC suggestions were not proposed because they go beyond what is required for aircraft certification (e.g., manual throttles and auto ignition); the FAA decided that it was inappropriate to alter certification rules through this rulemaking. The ARAC proposal for IFR-approved area navigation equipment that provides immediate identification of and heading to the nearest airport was not proposed in this NPRM. The safety benefit of this equipment has not been established. Finally, the FAA has not proposed the ARAC and other petitioners' suggestion for a radar altimeter. Such altimeters are only required for Category II and III operations; the FAA believes that the benefits of such altimeters for other operations have not been established to a sufficient degree to justify the considerable costs.

Canada adopted a limitation on flights in mountainous areas in its SEIFR rule; the AACA in its petition proposed a limitation for mountainous areas as defined by § 95.17. The Atlantic Aero, Inc. and Mid-Atlantic Freight Inc. 1994 petition for exemption proposed to limit SEIFR operations to routes where the minimum en route altitude (MEA) was no greater than 10,000 feet mean sea level (MSL). Taquan Air proposed to limit SEIFR operations to routes where the MEA was no greater than 12,000 feet MSL. The FAA decided that a mountainous terrain restriction was not needed. The definition of mountainous terrain in part 95 is very broad and would limit flight unnecessarily. Under part 95, almost all of Alaska, Hawaii, and the western third of the country are classified as mountainous. Single-engine cargo IFR operations and limited IFR operations are not similarly restricted. The FAA notes that some single-engine airplanes are limited by their service ceilings; others are limited by the lack of pressurization or oxygen. In some areas, the lack of navigational equipment also will limit flight over mountainous terrain. The FAA further notes that some pressurized single-engine aircraft can cruise at altitudes that provide much more time for making a safe landing should the engine fail. Finally, the difficulties of finding a safe landing area for all aircraft are not unique to mountainous terrain; densely populated areas may pose similar problems.

Section-by-Section Discussion of Proposed Changes

Section 135.83 would be amended to change the reference to § 135.181 to make it consistent with the revised rule.

Section 135.101 would be revised to eliminate the reference to § 135.103, which would be deleted, and to delete the work ''conditions'' after IFR. Deletion of the word ''conditions'' clarifies that any operation for which an IFR flight plan is filed must have a second pilot or an autopilot, even if the flight can be conducted in VFR conditions.

Section 135.103 would be deleted because it is no longer needed.

Section 135.163 would be revised to add, for single-engine aircraft reference to alternators as well as the proposed requirement for two independent electrical power generating sources or a standby battery.

Section 135.181 would be revised by dropping all of the limited IFR conditions. Only the performance requirements for multi-engine aircraft would remain.

Section 135.421 would be revised to add the requirement for engine trend monitoring for aircraft used in passenger-carrying SEIFR operations.

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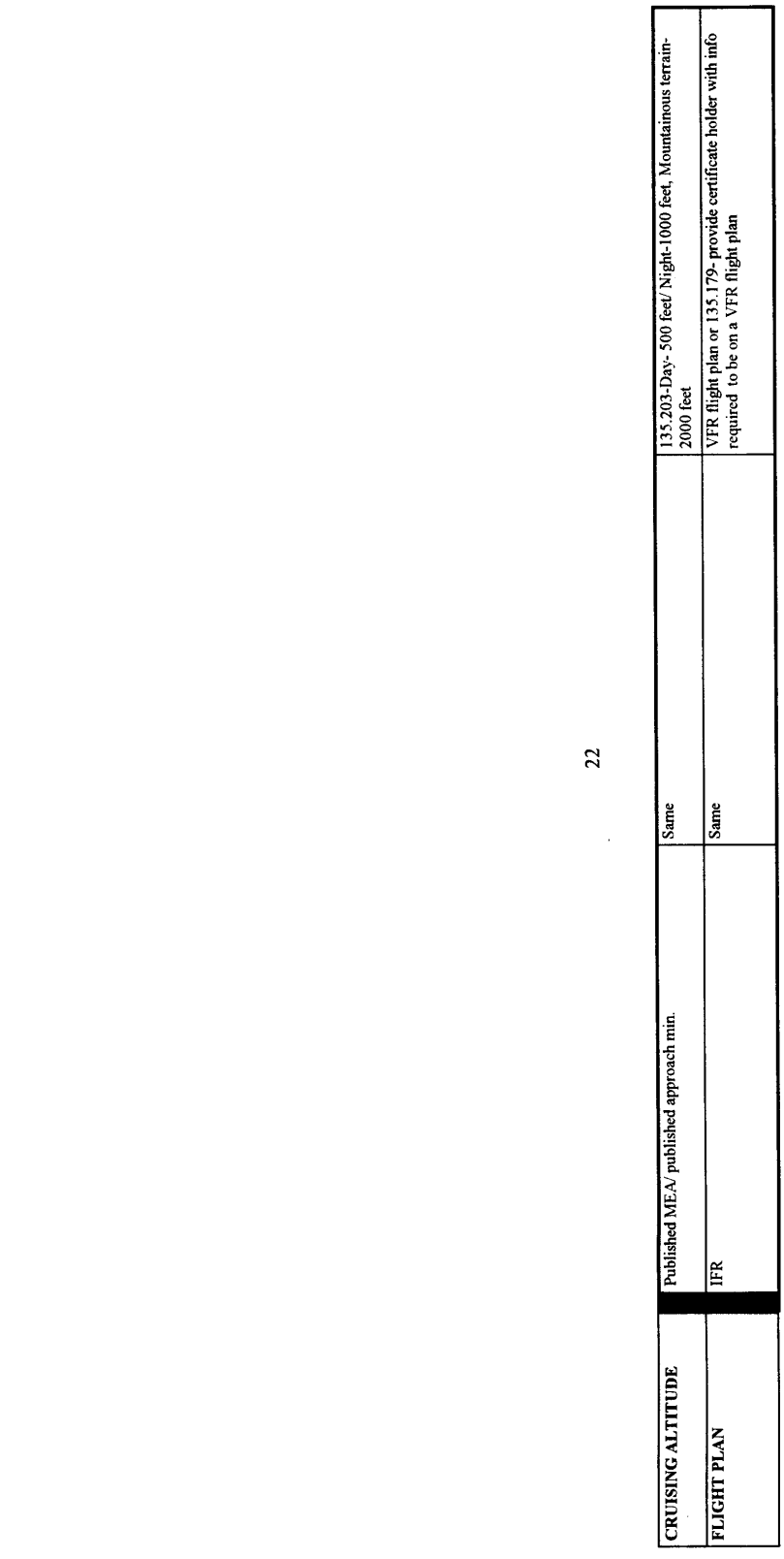
TABLE 1 - CURRENT EQUIPMENT REQUIREMENTS FOR IFR AND VFR OPERATIONS

	SEIFR--PASSENGER OPERATIONS	MULTIENGINE IFR-PASSENGER OPERATIONS	VFR- PASSENGER OPERATIONS
EQUIPMENT: CARRYING	135.163(a)- Vertical speed indicator	Same	Not required by operating rules
PASSENGERS			
	135.163(b)- Free-air temperature indicator	Same	Not required by operating rules.
	135.163(c)- Heated pitot tube for each airspeed indicator	Same	Not required by operating rules.
	135.163(d)- Power failure warning device or vacuum indicator to show power available for gyro instruments from each power source	Same	Not required by operating rules.
	135.163(e)- Alternate source of static pressure for altimeter,airspeed, & vertical speed indicators	Same	Not required by operating rules.
	135.163(f) -Generator or generators able to supply all probable combinations of continuous in-flight electrical loads for required equipment and for recharging battery--91.205(d) - Generator or alternator of adeq. capacity	135.163(g) - 2 generators each on a separate engine, of which any combi of 1/2 of total no. are rated sufficiently to supply elec loads of all required instruments and equipment for safe emerg. ops--ME Hel-generators mounted on main rotor drive train	91.205(c)- VFR Night-Adeq source of elec energy for all installed elec and radio equip/ 135.159(e) -VFR carrying pax at Night/ VFR over the top: Generator(s) able to supply all prob combi of contin. inflight elec loads for req. equip & recharge battery
	135.163(h)- 2 independent sources of energy, at least 1 engine-driven pump or generator, each able to drive all gyro instr/installed so fail. of 1 inst. or source does not interfere with energy supply unless rate of turn source separate from pitch & bank	Same except each engine-driven source of energy must be on separate engine	Not specified in operating rules.
	135.165(b) -A transmitter, except additional transmitter required for extended overwater operations	Same, except for 10+ turbojet or multi engine airplane in commuter ops: 2 transmitters-135.165(a)	135.161 -VFR carrying pax at night or over the top: 2 way radio communications to transmit and receive from ground facilities 25 miles away
	135.165(b)- Two microphones	Same	135.161-One required to meet communications requirement for VFR carrying pax at night or over the top
	135.165(b)- Two headsets or one headset and one speaker	Same	Not specified in operating rules
	135.165(b) -Marker beacon receiver	Same	Not required

	135.165(b)- 2 independent receivers for navigation --91.205(d)- nav equip approp to ground facilities to be used	Same	135.161(b) -Aircraft carrying pax VFR over top- radio nav equip to receive ground facility to be used/ 135.161(c)- Airplane carrying pax VFR night- radio nav equip to receive ground fac. to be used
	91.205(d)- Gyro rate-of-turn except for airplanes and rotorcraft with a third attitude inst. system	Same	135.159 -Carrying pax VFR at Night or VFR over the top:Gyro rate-of-turn except airplanes and helicopters with a third attitude instrument system or helicopters with a max cert TO wt of 6000 pounds or less
	91.205(d)- Slip skid indicator	Same	135.159(b)- Carrying pax VFR at Night or VFR over the top: slip skid indicator
	91.205(d)- Sensitive altimeter	Same	91.205 (b)- Altimeter
	91.205(d)- Clock	Same	Not required
	91.205(d)-Gyroscopic pitch and bank indicator (artificial horizon)	Same	135.159(c)- Carrying pax VFR at night or VFR over the top: Gyroscopic bank and pitch indicator
	91.205(d)- Gyroscopic direction indicator (directional gyro or equivalent)	Same	135.159(d)- Carrying pax VFR at night or VFR over the top: Gyroscopic direction indicator
	135.105- IFR conditions-Operative approved autopilot system authorized by ops specs. Autopilot capable of operating a/c controls to maintain flight and maneuver it about 3 axes(OR 2 pilots or limited IFR-135.101, 135.103)	Same	Not required
PILOT REQUIREMENT	135.101, 135.105, 135.103-IFR conditions-2nd in command required or single pilot with autopilot or in limited IFR	Same, except 2 pilots required if 10+ pax seats-135.99	One pilot
PILOT QUALIFICATIONS	135.243-Commercial and appropriate category and class and type rating, and instrument rating or ATP	135.243-Same, except PIC of turbojet, airplane with 10+ pax seats, or multiengine airplane in commuter ops must have ATP--Helicopter in scheduled interstate ops-ATP, appropriate type ratings and instrument rating	135.243-Same, except instrument rating or ATP not required for SE recip airplanes when non-scheduled(5 or less round trips a week) and does not transport mail
	135.243-1200 hours flight time, inc. 500 x-country,100 night,75 actual or sim. instrument time of which 50 were in flight	Same	135.243-500 hours of flight time, 100 x-country, 25 of which were at night
PILOT TESTING	135.293- Competency check each type aircraft ea yr for PIC and SIC, if req.	Same	Same

	135.297-Instrument proficiency check ea 6 mo. PIC- Includes autopilot check if authorized(Inst. prof. check may subst. for type a/c competency check/ can rotate check in types of authorized a/c)	Same	Not required
	135.299- Line check ea yr. for PIC	Same	Same
WEATHER AND AIRSPACE/AIRPORT REQUIREMENTS	135.215-Controlled airspace, airport must have approved instrument approach procedure (outside of controlled airspace as authorized by op specs)	Same	Can operate in uncontrolled airspace/no instrument approaches required
	135.213- Weather observations for IFR must be taken at the airport where ops are conducted/made by approved source	Same	135.213- PIC can use wx info based on own observations or on those of persons competent to supply observations
	135.219-Cannot takeoff unless reports or forecasts indicate wx at ETA will be at or above authorized IFR min.	Same	135.211-VFR over the top carrying pax: Wx at point of termination of over the top must allow descent to beneath ceiling under VFR or allows IFR approach & landing with flight clear of clouds unless radar appr./Descent under VFR if engine fails
	135.223- Alternate required if 1 hr before/after, ceiling less than 1500 ft above lowest circling MDA or above lowest published min. or 2000 ft above airport, whichever higher and vis is less than 3 miles or 2+lowest vis min, whichever greater	Same	No alternate required
	135.225- Can't begin approach without weather observer & wx above IFR landing min.	Same	Weather observer not required/ 135.213- PIC can use wx based on own observations or on those of persons competent to supply observations
	135.181- If reports or forecasts indicate VFR in 15 min,can takeoff in IFR conditions & fly in IFR to pt. no more than 15 min; operate in IFR conditions if unforecast wx encountered and make IFR appr if unfrcst wx./ All cargo can fly IFR cond.	Can operate in IFR conditions	135.181 -VFR over the top if wx rep or forecasts indicate VFR under ceiling. Must be able to descend under VFR if engine fails. Also see 135.211
	135.225- MDA or DH and vis increased by 100 ft and1/2mile for ea PIC of turbine airplane who does not have 100 hours as PIC in that type	Same	Not applicable
PERFORMANCE	No performance specified.	135.181- Weight that allows ME airplane to climb with critical eng. inop at least 50 ft/min at MEA or 5000 whichever higher/ 135.181(b) ME helic. same except MEA or 1500 ft whichever higher	No performance specified.
FUEL REQUIREMENTS	91.167- Complete flight + fuel to alternate (if required)+ 45 minutes reserve or, for helicopters, 30 minutes reserve	Same	135.209-30 min reserve day/ 45 night/ Helicopter 20 min. reserve



CRUISING ALTITUDE	Published MEA/ published approach min.	Same	135.203-Day- 500 feet/ Night-1000 feet, Mountainous terrain-2000 feet
FLIGHT PLAN	IFR	Same	VFR flight plan or 135.179- provide certificate holder with info required to be on a VFR flight plan

22

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Regulatory Evaluation Summary

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. In conducting these analyses, the FAA has determined that this rule: (1) Would generate benefits that justify its costs and is not ''significant regulatory action'' as defined in the Executive Order; (2) is not significant as defined in Department of Transportation Regulatory Policies and procedures; and (3) would not constitute a barrier to international trade. These analyses, available in the docket, are summarized below.

Cost-Benefit Analysis

The FAA proposes to update and revise the regulations to allow single-engine, passenger carrying aircraft to operate under the safer instrument flight rules. This proposal would require additional conditions and requirements that will further enhance the safety of single engine instrument flight rules (SEIFR) operations.

The cost of this proposed rule is estimated at $33.9 million ($27.5 million, discounted). The most costly provision is on the requirement for an autopilot, which is estimated at $25.6 million ($20.9 million discounted) and represents about 76 percent of the total. The FAA concludes that the expected quantitative benefits would be a minimum of $185.0 million or $129.9 million discounted. This action would increase the safety of single-engine passenger-carrying operations because it would allow them to operate under instrument flight rules. The proposal would reduce the incentive for operators to conduct low altitude operations under marginal weather conditions in order to not lose business. It would require operators to meet the more stringent requirements for such flights including additional aircraft equipment.

Initial Regulatory Flexibility Assessment

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily or disproportionately burdened by Federal Regulations. The RFA requires an analysis if a proposed rule would have ''a significant economic impact on a substantial number of small entities.'' The definitions of small entities and guidance material for making determinations required by the RFA are contained in the Federal Register (47 FR 32825, July 29, 1982). Federal Aviation Administration (FAA) order 2100.14A outlines the agency's procedures and criteria for implementing the RFA.

With respect to the propose rule, a ''small entity'' is an operator of aircraft for hire with nine or fewer aircraft. A ''significant economic impact on a small entity'' is defined as an annualized net compliance cost for operators of aircraft for hire which in 1996 dollars is $125,100 for scheduled operators whose aircraft have more than 60 seats. It is $69,900 for scheduled operators whose fleets have aircraft with seating capacities of 60 or fewer seats (other scheduled operators) and $4,900 for unscheduled operators. A substantial number of small entities is defined as a number that is 11 or more and which is more than one-third of small operators subject to the proposed rule:

The analysis shows that the annualized cost of the proposed rule (assuming no cost savings) is about $1,400 per aircraft and the annualized safety and non-safety benefits is about $2,050 per aircraft. Therefore, the annualized net savings is about $650 per aircraft.

The FAA has determined that operators with eight aircraft or more would incur a significant positive impact. However, fewer than one-third of the entities would incur a significant positive cost impact. Therefore, the FAA has determined that a substantial number of operators would not be positively or negatively impacted in a significant way.

International Trade Impact Statement

This proposed rule is not expected to have any impact on trade opportunities for U.S. firms doing business overseas or foreign firms doing business in the United States. The proposed rule would primarily affect U.S. operators of aircraft for hire that provide domestic service.

Unfunded Mandates Reform Act Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), enacted as Pub. L. 104–4 on March 22, 1995, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, 2 U.S.C. 1534(a), require the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed ''significant intergovernmental mandate.'' A ''significant intergovernmental mandate'' under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments, in the aggregate, of $100 million (adjusted annually for inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals.

This proposal rule does not meet the cost thresholds described above. Furthermore, this proposed rule would not impose a significant cost on small governments and would not uniquely affect those small governments. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Paperwork Reduction Act

This proposed rule contains not information collection requests requiring approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

International Civil Aviation Organization and Joint Aviation Regulations

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that this proposal, if adopted, would not present any major differences.

Federalism Implications

The changes proposed by this NPRM would not have a substantial direct effect on the States, on the relationship between the National Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that the proposed amendments would not have federalism implications requiring the preparation of a Federalism Assessment.

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Initial Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this proposed regulation is not significant under Executive Order 12866. In addition, the FAA certifies that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This proposal is not considered significant under DOT Order 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations.

List of Subjects in 14 CFR Part 135

Air taxis, Aircraft, Aviation safety, Safety, Single-engine aircraft.

For the reasons set out in the preamble, 14 CFR part 135 is proposed to be amended as set forth below:

PART 135—AIR TAXI OPERATORS AND COMMERCIAL OPERATORS

1. The authority citation for part 135 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

2. Section 135.101 is revised to read as follows:

§ 135.101 Second in command required under IFR.

Except as provided in § 135.105, no person may operate an aircraft carrying passengers under IFR unless there is a second in command in the aircraft.

3. Section 135.103 is removed and reserved.

4. Section 135.163 is amended to revise paragraphs (f) and (g) to read as follows:

§ 135.163 Equipment requirements: Aircraft carrying passengers under IFR.

* * * * *

(f) For a single-engine aircraft:

(1) two independent electrical power generating sources each of which is able to supply all probable combinations of continuous inflight electrical loads for required instruments and equipment; or

(2) in addition to single electrical power generating source, a standby battery that is capable of providing 150 percent of the minimum electrical load for at least one hour to operate navigation and communication equipment.

(g) For multi-engine aircraft, at least two generators or alternators each of which is on a separate engine, of which any combination of one-half of the total number are rated sufficiently to supply the electrical loads of all required instruments and equipment necessary for safe emergency operation of the aircraft except that for multi-engine helicopters, the two required generators may be mounted on the main rotor drive train; and

* * * * *

5. Section 135.181 is amended to revise paragraph (a)(1) and (c) to read as follows:

§ 135.181 Performance requirements: Multi-engine aircraft operated over-the-top or in IFR conditions.

(a) * * *

(1) Operate a single-engine aircraft carrying passengers over-the-top; or

* * * * *

(c) Without regard to paragraph (a) of this section, if the latest weather reports or forecasts, or any combination of them, indicate that the weather along the planned route (including takeoff and landing) allows flight under VFR under the ceiling (if a ceiling exists) and that the weather is forecast to remain so until at least 1 hour after the estimated time of arrival at the destination, a person may operate an aircraft over-the-top.

* * * * *

6. Section 135.421 is amended to add paragraph (c) to read as follows:

§ 135.421 Additional maintenance requirements.

* * * * *

(c) For each single engine aircraft to be used in passenger-carrying IFR operations, each certificate holder must incorporate into the manufacturer's recommended maintenance program or FAA approved maintenance program, an engine trend monitoring program including an oil analysis at each 100 hour interval and a record of the findings.

Issued in Washington, DC. on November 21, 1996.

Thomas C. Accardi,

Director, Flight Standards Service.

[FR Doc. 96–30365 Filed 12–2–96; 8:45 am]

BILLING CODE 4910–13–M

Federal Register

Tuesday
December 3, 1996

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 107 and 108

Falsification of Security Records; Interim Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 107 and 108

[Docket No. 28745; Amendment Nos. 107–9 and 108–14]

RIN 2120–AG27

Falsification of Security Records

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting rules that prohibit fraudulent or intentionally false statements in certain security records. This action responds to recent events indicating that persons may be making such statements in security records. This action is intended to provide a means for the FAA to take legal enforcement action against persons who make such statements, and thereby enhance the security of civil aviation.

DATES: Effective date November 27, 1996. Comments must be received by January 23, 1997.

ADDRESSES: Comments on this rule should be submitted in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC–200), Room 915–G, Docket No. 28745, 800 Independence Ave., SW, Washington, DC 20591. Comments must be marked Docket No. 28745. Comments also may be submitted electronically to the following Internet address: nprmcmts@faa.dot.gov. Comments may be examined in room 915G weekdays between 8:30 a.m. and 5 p.m. except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Robert Cammaroto and Linda C. Valencia, Office of Civil Aviation Security Policy and Planning, Civil Aviation Security Division, ACP–100, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–3413.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this rulemaking by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from this rule are also invited. Substantive comments should be accompanied by cost estimates. Comments must identify the regulatory docket and be submitted in triplicate to the Rules Docket address specified above.

Except as noted below, all comments received, as well as a report summarizing each substantive public contact with FAA personnel on this rulemaking, will be filed in the docket. The docket is available for public inspection before and after the comment closing date.

All comments received on or before the closing date will be considered by the Administrator. Late-filed comments will be considered to the extent practicable. The rule may be changed in light of the comments received.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a pre-addressed, stamped postcard with those comments on which the following statement is made: ''Comments to Docket No. 28745.'' The postcard will be date stamped and mailed to the commenter.

Background

It has recently come to the FAA's attention that persons may be submitting fraudulent or intentionally false statements in records used to obtain identification media from an airport operator that provides unescorted access to security identification display areas (SIDA's) on airports, and in other required records.

Part 107 of Title 14, Code of Federal Regulations, sets forth the requirements for airport security. Identification media must be worn at all times in the SIDA by all persons with unescorted access authority. The SIDA includes the most security-sensitive portions of the airport, including the areas immediately next to the terminals in which air carrier aircraft board and off-load passengers.

Section 107.31 requires that an access investigation be conducted for each person applying for unescorted access privileges to the SIDA. This investigation involves the completion of an application by the individual that requires various information, including a ten-year employment history. The most recent five years of employment must be verified. In specified circumstances the applicant's fingerprint must be obtained and an FBI criminal history records check must be conducted. The airport may not grant unescorted access to the SIDA for any person until the access investigation is completed and must deny unescorted access to any person who has one or more of the specified criminal convictions within the previous ten years.

Under § 107.31(f) the airport operator is deemed in compliance with § 107.31 if it accepts a certification from an air carrier that the air carrier has complied with 14 CFR § 108.33. (14 CFR Part 108 contains the security requirements for air carriers.) Section 108.33 provides for the same application, verification, and criminal records check process to be carried out by the air carrier. Air carriers are directly regulated by the FAA, and the FAA monitors their compliance with part 108.

Section 107.31(f) also provides that the airport operator is deemed in compliance if it accepts certification from an airport tenant, other than an air carrier, that the tenant has complied with § 107.31(b)(1) for its employees, unless a criminal history records check is required. Tenants are not directly regulated by the FAA, and the FAA has relied upon good faith adherence to the access investigation process to ensure that the appropriate security measures are carried out.

The FAA has recently determined that some tenants have submitted certifications to airport operators without having performed the required verification of the applicant's employment history. This leads the airport operator to issue identification media that permit unescorted access to the SIDA when the tenant has not verified prior employment or established that the applicants have no prohibited criminal convictions.

Further, the FAA has determined that there may be some fraudulent or intentionally false records of required screener training. These records are essential to the FAA's and the air carriers' monitoring of screener training. This training is essential to the effective detection of weapons and explosive devices to prevent their being placed aboard aircraft. Training and screening may be conducted by air carrier employees, or by a contractor of an air carrier.

Good Cause Justification for Immediate Adoption and No Notice

The FAA finds that good cause exists for issuing this final rule without prior notice and opportunity for comment. Prior notice is impracticable, unnecessary, and contrary to public interest.

It is impracticable to provide prior notice because the FAA would be prevented from adequately and immediately protecting persons traveling in air transportation through prohibiting the submission of fraudulent or intentionally false records for persons who directly carry out required security measures. Prior notice is unnecessary because these rules prohibit practices—fraud and intentional falsification—that

long have been understood by the public and the industry to be improper, and that may constitute criminal violations. No one has a right or justification to intentionally falsify records required by Federal regulation.

Prior notice would be contrary to public interest in that it would delay the FAA's ability to take action against those who make fraudulent or intentionally false statements in security records. Failure of the FAA to act now may cause a continuing security risk. By acting immediately, the FAA is providing additional deterrence to those who may falsify security records. It is in the public interest to make clear that such activities will not be tolerated and may be met with legal enforcement action.

For the same reasons, these rules are effective immediately. It must be clear that no intentional falsification of security records will be tolerated and the additional security afforded the traveling public should not be delayed.

Discussion of the Rules

The FDA is adopting new §§ 107.2 and 108.4. These rules specifically prohibit a person from making any fraudulent or intentionally false statement or entry on any security program, record, application, report, access or identification medium, or any other document that is kept, made, or used to show compliance under parts 107 or 108.

It is important that all such records be accurate. They are used to ensure that all required security measures have been carried out. Fraudulent or intentionally false records may conceal a significant security risk that should be addressed immediately.

Fraud or intentional falsification of required records may also be a violation of certain criminal statutes. These rules provide a civil enforcement remedy where appropriate.

These rules are modeled on similar provisions elsewhere in 14 CFR, such as §§ 21.2, 43.12, 61.59, and 65.20. These provisions have long been in the regulations and have worked well. An intentionally false statement consists of (1) a false representation, (2) in reference to a material fact, (3) made with knowledge of its falsity. A fraudulent statement consists of these three elements, plus (4) it was made with the intent to deceive, and (5) action was taken in reliance upon the representation. *See, Hart* v. *McLucus*, 535 F.2d 516, 519 (9th Cir. 1976). There have been many cases under the existing rules interpreting these terms, which will assist in understanding these rules.

These rules apply to all ''persons.'' Under 14 CFR § 1.1, ''person'' means an individual, firm, partnership, corporation, company, association, joint-stock association, or governmental entity. Thus, a company that is a tenant on an airport, or a company that contracts with an air carrier to provide screening services, is a person within the meaning of the rule. In the case of an intentionally false certification made by a tenant, potentially both the tenant and the individual making the certification could be held in violation of § 107.2.

Related Activity

The FAA is investigating the alleged incidents of false records, and in conducting audits to determine the extent of the problem. The FAA intends to raise this issue with airport consortia. The FAA is considering what additional regulatory action may be advisable in the future.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), there are no requirements for information collection associated with this final rule.

International Compatibility

The FAA has reviewed corresponding International Civil Aviation Organization international standards and recommended practices and Joint Aviation Airworthiness Authorities requirements and has identified no differences in these amendments and the foreign regulations.

Regulatory Evaluation

Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. In conducting the evaluation reflected in this document, the FAA has determined that this rule is not ''a significant regulatory action'' as defined in the Executive Order and the Department of Transportation Regulatory Policies and Procedures. The FAA invites the public to provide comments, and supporting data, on these determinations. All comments received will be considered.

Air carriers and airports have security programs which are intended to protect the public from the threat of aircraft hijacking and other criminal activities affecting air transportation. The FAA proposes to strengthen the rules against the falsification of security documents. Falsifying the information on such documents can have a detrimental effect on the ability to thwart terrorist and other criminal activities. The final rule will amend parts 107 and 108 to prevent such activities.

The FAA has not identified any costs with this proposal. The proposal does not obligate a person to take an action that is not otherwise required. Enforcement actions may be taken by the FAA against persons who violate the rules, at a cost to the agency, but the number of cases cannot be determined. In addition, because this final rule will not be included in the airport or the air carrier security programs, affected entities will not incur any costs to implement these proposed requirements.

The primary benefit of this rule is to deter falsification of important security records. It also provides the FAA with a compliance tool in the event that a person intentionally falsifies a security record in violation of the rule. The FAA cannot quantify the security benefits of this rule, but believes that this action will significantly enhance civil aviation security by increasing the reliability and integrity of security records.

Much of the effectiveness of the air carriers' and airports' security programs depends on strictly limiting access to the SIDA. Sophisticated criminal elements are actively seeking ways to gain access to the SIDA, and it is important that the FAA, air carriers, and airports guard against such terrorist activities. The consequences of not protecting such access can be catastrophic. Between 1982 and 1991, terrorist bombings of U.S. air carriers have resulted in 275 deaths and 24 injuries, while hijackings incidents have resulted in 24 deaths and 127 injuries.

Given the lack of cost and given the potential benefits of avoided fatalities and injuries, this evaluation finds this final rule cost beneficial.

Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA) of 1980 was enacted by Congress to ensure that small entities are not unnecessarily or disproportionately burdened by Government regulations. The RFA requires a Regulatory Flexibility Analysis if a rule has a significant economic impact on a substantial number of small business entities. FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, established threshold costs and small entity size standards for complying with RFA requirements. As was discussed above, there is no cost associated with this rule. Therefore, the FAA certifies that the rule does not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

In accordance with the Office of Management and Budget memorandum dated March 1983, federal agencies engaged in rulemaking activities are required to assess the effects of regulatory changes on international trade. The FAA finds that this final rule will not have an adverse impact on trade opportunities for either U.S. firms doing business overseas or foreign firms doing business in the United States. This finding is based on the fact that this rule will impose no costs on both domestic and foreign air carriers, so neither will have a trade advantage over the other.

Federalism Implications

The regulations herein will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this regulation is not a ''significant regulatory action'' under Executive Order 12866. In addition, the FAA certifies that this rule will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This rule is not considered significant under Order DOT 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations.

List of Subjects

14 CFR Part 107

Airports, Arms and munitions, Law enforcement officers, Reporting and recordkeeping requirements, Security measures.

14 CFR Part 108

Air carriers, Aircraft, Airmen, Airports, Arms and munitions, Explosives, Law enforcement officers, Reporting and recordkeeping requirements, Security measures, X-rays.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends parts 107 and 108 of title 14, Code of Federal Regulations (14 CFR parts 107 and 108) as follows:

PART 107—AIRPORT SECURITY

1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 106(g), 5103, 40113, 40119, 44701–44702, 44706, 44901–44905, 44907, 44913–44914, 44932, 44935–44936, 46105.

2. Section 107.1 is amended by removing the ''and'' after paragraph (a)(2), removing the period and adding in its place ''; and'' in paragraph (a)(3), and adding paragraph (a)(4) to read as follows:

§ 107.1 Applicability and definitions.

(a) * * *

(4) Each person who files an application or makes entries into any record or report that is kept, made, or used to show compliance under this part, or to exercise any privileges under this part.

* * * * *

3. Section 107.2 is added to read as follows:

§ 107.2 Falsification.

No person may make, or cause to be made, any of the following:

(a) Any fraudulent or intentionally false statement in any application for any security program, access medium, or identification medium, or any amendment thereto, under this part.

(b) Any fraudulent or intentionally false entry in any record or report that is kept, made, or used to show compliance with this part, or exercise any privileges under this part.

(c) Any reproduction or alteration, for fraudulent purpose, of any report, record, security program, access medium, or identification medium issued under this part.

PART 108—AIRPLANE OPERATOR SECURITY

4. The authority citation for part 108 continues to read as follows:

Authority: 49 U.S.C. 106(g), 5103, 40113, 40119, 44701–44702, 44705, 44901–44905, 44907, 44913–44914, 44932, 44935–44936, 46105.

5. Section 108.1 is amended by removing the ''and'' after paragraph (a)(2), removing the period and adding in its place a semi-colon in paragraph (a)(3), removing the period and adding in its place a ''; and'' in paragraph (a)(4), and adding paragraph (a)(5) to read as follows:

§ 108.1 Applicability.

(a) * * *

(5) Each person who files an application or makes entries into any record or report that is kept, made or used to show compliance under this part, or to exercise any privileges under this part.

* * * * *

6. Section 108.4 is added to read as follows:

§ 108.4 Falsification.

No person may make, or cause to be made, any of the following:

(a) Any fraudulent or intentionally false statement in any application for any security program, access medium, or identification medium, or any amendment thereto, under this part.

(b) Any fraudulent or intentionally false entry in any record or report that is kept, made, or used to show compliance with this part, or to exercise any privileges under this part.

(c) Any reproduction or alteration, for fraudulent purpose, of any report, record, security program, access medium, or identification medium issued under this part.

Issued in Washington, DC, on November 27, 1996.

Linda Hall Daschle,

Acting Administrator.

[FR Doc. 96–30776 Filed 11–27–96; 3:23 pm]

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Federal Register

Vol. 61, No. 233

Tuesday, December 3, 1996

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FEDERAL REGISTER PAGES AND DATES, DECEMBER

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

1 CFR

462 63944

3 CFR

Proclamations:
6959 63691

Administrative Orders:
Presidential Determinations:
No. 97–6 of November 26, 1996 63693
No. 97–7 of November 26, 1996 63695

5 CFR

Proposed Rules:
213 63762

7 CFR

723 63697
1464 63697
1806 63928
1910 63928
1922 63928
1944 63928
1951 63928
1955 63928
1956 63928
1965 63928
3550 63928

12 CFR

1 63972
7 63972
8 63700
12 63958
543 64007
544 64007
545 64007
552 64007
556 64007
575 64007
910 64021
912 64021

14 CFR

25 63952
39 ..... 63702, 63704, 63706, 63707
107 64242
108 64242

Proposed Rules:
39 63762
71 ..... 63764, 63765, 63766, 63767, 63768
135 64230

17 CFR

240 63709

18 CFR

Proposed Rules:
4 64031
375 64031

19 CFR

Proposed Rules:
122 64041

21 CFR

73 64027
510 63710
520 63711
524 63712

Proposed Rules:
892 63769

24 CFR

81 63944

Proposed Rules:
985 63930

29 CFR

4001 63988
4043 63988
4065 63988

30 CFR

Proposed Rules:
870 64220

32 CFR

318 63712

33 CFR

110 63715

37 CFR

1 64027
251 63715
252 63715
257 63715
259 63715

Proposed Rules:
202 64042

38 CFR

17 63719

40 CFR

52 ..... 64028, 64029
70 63928
180 63721
721 63726

Proposed Rules:
52 64042
70 64042
82 64045

42 CFR

401 63740
403 63740
405 63740
411 63740
413 63740

447.....63740
493.....63740

45 CFR

1610.....63749
1617.....63754
1632.....63755
1633.....63756

47 CFR

1.....63758
2.....63758
15.....63758
24.....63758
73.....63759
97.....63758

Proposed Rules:

Ch. I.....63774, 63778
1.....64045
73 .....63809, 63810, 63811

49 CFR

1.....64029
106.....64030
190.....64030

50 CFR

679.....63759

Proposed Rules:

285.....63812
630.....63812
644.....63812
648.....64046
678.....63812
679 .....63812, 63814, 64047

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT TODAY

AGRICULTURE DEPARTMENT
Commodity Credit Corporation
Loan and purchase programs:
Price support levels--
Peanuts; published 11-25-96

COMMERCE DEPARTMENT
Patent and Trademark Office
Patent cases:
Correspondence practice changes; signature and filing requirements; correction; published 12-3-96

ENVIRONMENTAL PROTECTION AGENCY
Air pollution control; new motor vehicles and engines:
Gasoline spark-ignition and diesel compression-ignition marine engines; emission standards; published 10-4-96
Air quality implementation plans; approval and promulgation; various States:
Colorado; published 10-4-96
Maryland; correction; published 12-3-96
New York; withdrawal; published 12-3-96

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Community facilities:
Youthbuild program; administrative costs; published 10-4-96

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Kiwifruit research, promotion, and consumer information order; comments due by 12-2-96; published 10-2-96

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Exportation and importation of animals and animal products:
Ports designation--
Atlanta, GA; comments due by 12-6-96; published 10-7-96
Federal Seed Act:
Imported seed and screenings; comments due by 12-3-96; published 10-4-96

AGRICULTURE DEPARTMENT
Farm Service Agency
Farm marketing quotas, acreage allotments, and production adjustments:
Peanuts; comments due by 12-3-96; published 11-25-96

COMMERCE DEPARTMENT
Export Administration Bureau
Export licensing:
Commerce control list--
Commercial communications satellites; enhanced national and foreign policy controls; comments due by 12-5-96; published 10-21-96

COMMERCE DEPARTMENT
Patent and Trademark Office
Patent cases:
Nucleotide and/or amino acid sequence listings; changes; comments due by 12-3-96; published 10-4-96
Patent practitioners; registration examination, continuing education requirement, and annual fee; comments due by 12-6-96; published 9-30-96

EDUCATION DEPARTMENT
Elementary and secondary education:
Impact aid program; comments due by 12-6-96; published 10-7-96
Postsecondary education:
Strengthening institutions program, strengthening historically black colleges and universities program, etc.; Federal regulatory review; comments due by 12-6-96; published 10-7-96

ENVIRONMENTAL PROTECTION AGENCY
Air programs:
Stratospheric ozone protection--
Refrigerant recycling; reclamation requirements extension; comments due by 12-2-96; published 11-1-96
Air quality implementation plans:
Preparation, adoption, and submittal--
Prevention of significant deterioration and nonattainment new source review; Federal regulatory review; comments due by 12-5-96; published 10-25-96
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 12-2-96; published 11-1-96
Colorado; comments due by 12-2-96; published 10-3-96
Maryland; comments due by 12-2-96; published 10-31-96
New Jersey; comments due by 12-2-96; published 10-31-96
New York et al.; comments due by 12-5-96; published 11-5-96
Virginia; comments due by 12-6-96; published 11-6-96
Hazardous waste:
State underground storage tank program approvals--
Massachusetts; comments due by 12-2-96; published 10-31-96
Pesticide programs:
Pesticides and ground water strategy; State management plan regulation; comments due by 12-6-96; published 11-6-96
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Sodium bicarbonate, etc.; comments due by 12-6-96; published 11-6-96
Superfund program:
National oil and hazardous substances contingency plan--
National priorities list update; comments due by 12-2-96; published 10-31-96
National priorities list update; comments due by 12-2-96; published 10-31-96

FEDERAL COMMUNICATIONS COMMISSION
Practice and procedure:
Omnibus Consolidated Appropriations Act of 1997--
Wireless communications service; thirty megahertz of spectrum; comments due by 12-4-96; published 11-20-96
Radio stations; table of assignments:
Kansas; comments due by 12-2-96; published 10-24-96
Minnesota; comments due by 12-2-96; published 10-24-96
New Mexico; comments due by 12-2-96; published 10-24-96

FEDERAL ELECTION COMMISSION
Reports by political committees:
Best efforts; comments due by 12-6-96; published 10-9-96

FEDERAL RESERVE SYSTEM
Bank holding companies and change in bank control (Regulation Y):
Board approval requirement to engage de novo in permissible nonbanking activities; comments due by 12-2-96; published 11-1-96

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD
Administrative errors correction; comments due by 12-5-96; published 11-5-96

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Food for human consumption:
Infant formula; current good manufacturing practice, quality control procedures, etc.; comments due by 12-6-96; published 9-23-96
Human drugs:
Sunscreens; photochemistry and photobiology; meeting; comments due by 12-6-96; published 8-15-96
Medical devices:
Current good manufacturing practice regulations; incorporation into quality system regulation; comments due by 12-6-96; published 10-7-96

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Community development block grants:
Hispanic-serving institutions work study program; comments due by 12-2-96; published 10-2-96