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Thursday
January 4, 1996

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[Two Sessions]

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New Feature in the Reader Aids!

Beginning with the issue of December 4, 1995, a new listing will appear each day in the Reader Aids section of the Federal Register called ''Reminders''. The Reminders will have two sections: ''Rules Going Into Effect Today'' and ''Comments Due Next Week''. Rules Going Into Effect Today will remind readers about Rules documents published in the past which go into effect ''today''. Comments Due Next Week will remind readers about impending closing dates for comments on Proposed Rules documents published in past issues. Only those documents published in the Rules and Proposed Rules sections of the Federal Register will be eligible for inclusion in the Reminders.

The Reminders feature is intended as a reader aid only. Neither inclusion nor exclusion in the listing has any legal significance.

The Office of the Federal Register has been compiling data for the Reminders since the issue of November 1, 1995. No documents published prior to November 1, 1995 will be listed in Reminders.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 97

[Docket No. SD–95–001]

RIN 0581–AB39

Plant Variety Protection Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture is adopting as a final rule, with minor changes, the interim final rule that revised the Plant Variety Protection Regulations to conform to changes made in the Plant Variety Protection Act (PVPA). The changes will add an additional language option to the marking and labeling provisions for varieties that have an application pending or have received a certificate of protection. Other changes correct outdated information and provide consistency in language.

EFFECTIVE DATE: January 4, 1996.

FOR FURTHER INFORMATION CONTACT: Marsha A. Stanton, Commissioner, Plant Variety Protection Office, Telephone: (301)504–5518, FAX (301)504–5291.

SUPPLEMENTARY INFORMATION:

I. Executive Order 12866; Executive Order 12778

This final rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

This rule has also been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

II. Regulatory Flexibility Act

The Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612). The fees provided for in this document merely reflect a minimal increase in the costs currently borne by those entities which utilize Plant Variety Protection services.

III. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) the information collection requirements included in 7 CFR Part 97 have been approved previously by the Office of Management and Budget and have been assigned OMB control number 0581–0055.

IV. Background Information

The Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*) (PVPA) authorizes the Secretary to issue Certificates of Plant Variety Protection which afford variety ownership rights similar to patent rights. As a member of the International Union for the Protection of New Varieties of Plants (UPOV) the United States participated in negotiations which resulted in the March 19, 1991 UPOV Convention. The PVPA was amended on October 6, 1994 to conform to the new UPOV Convention and the amendments became effective on April 4, 1995. The interim rule amending 7 CFR part 97 was published at 60 FR 17188 on April 4, 1995 with a request for comments.

One hundred four comments were received. The majority of comments recommended a change to Sections 97.140 and 97.141, which cover optional marking and labeling provisions for varieties that have an application pending or have received a certificate of protection. Under the current regulations the labeling change suggested in the comments could be stated; but, because of the number of comments, a specific change to the final rule has been made. The final rule specifies that owners may label varieties pending or granted protection under the 1994 revisions with ''PVPA 1994—Unauthorized Sales for Reproductive Purposes Prohibited''.

Seven other non-substantive changes in the final rule have been made. The following paragraphs outline the changes which were made to correct grammar, provide consistency, or remove outdated references.

References to the Science Division in Sections 97.2 and 97.5(c) have been changed to ''Science and Technology Division'' to reflect the division's name change which was effective Oct. 1, 1995.

Section 97.3(c) is revised to correct the reference to the Federal Seed Act. The obsolete Public Law number, P.L. 92–463, is removed. Reference to the Federal Seed Act by name is maintained.

An outdated phone number is removed from second sentence of footnote referred to in Section 97.5(b)(4). The phone number will not be published as part of the regulations due to the difficulty of corrections if the phone number changes.

In Section 97.6, which deals with the requirement that the application must be accompanied by a seed sample or verification that a viable cell culture will be deposited in a public depository, is revised by adding language to require verification of deposit of self-sterile (self-incompatible) parents of hybrids. The PVPA requires deposition of viable seed or any propagating material necessary to reproduce the variety. The extension of protection to tuber-propagated and first generation hybrid varieties requires deposition of material other than basic seed. Deposition of propagating material for tuber crops was added in the interim final rule; however, language pertaining to hybrids whose parents are self-sterile was inadvertently omitted. The modification to the final rule will make deposit of material to propagate these varieties consistent with that for other types of varieties.

Section 97.19 is revised for grammatical purposes. The second occurrence of ''the'' is removed.

Section 97.21 is revised to be consistent with other sections of the rule requiring a payment of fee. A fee for extensions was added in the interim rule in section 97.15.

Finally, the authority citation is revised and simplified.

Pursuant to 5 U.S.C. 553, it is found that good cause exists for not

postponing the effective date of this rule until 30 days after publication in the Federal Register because (1) the interim rule was published in the Federal Register for public comment, (2) the changes made in this final action are for clarity and are considered non-substantive, and (3) no useful purpose would be accomplished in delaying the effective date of this action.

List of Subjects in 7 CFR Part 97

Novel Seed variety certification, Plant variety and protection.

Accordingly the interim rule amending 7 CFR Part 97, which was published at 60 FR 17188 on April 4, 1995, is adopted as a final rule with the following changes:

PART 97—PLANT VARIETY AND PROTECTION

1. The authority citation for Part 97 is revised to read as follows:

Authority: Plant Variety Protection Act, as amended, 7 U.S.C. 2321 *et seq.*; and Sec. 14, Plant Variety Protection Act amendments of 1994, 7 U.S.C. 2401 note.

2. In § 97.2, the definition for Office or Plant Variety Protection Office is revised to read as follows:

§ 97.2 Meaning of words.

* * * * *

Office or Plant Variety Protection Office. The Plant Variety Protection Office, Science and Technology Division, AMS, USDA.

* * * * *

§ 97.3 [Amended]

3. In § 97.3, paragraph (c), the words ''(Pub. L. 92–463)'' are removed.

4. In § 97.5, paragraph (b)(4), footnote number (1) is revised to read as follows:

§ 97.5 General requirements.

* * * * *

[1] Copies and translations of foreign laws and regulations will be requested only if they are not in the files of the Plant Variety Protection Office. Applicants may learn whether such a request will be made by writing to the address given in paragraph (c) of this section.

§ 97.5 [Amended]

5. In § 97.5(c), the second sentence is amended by adding the words ''and Technology'' after the word ''Science''.

6. In § 97.6, paragraph (d) is revised to read as follows:

§ 97.6 Application for certificate.

* * * * *

(d) The applicant shall submit with the application:

(1) At least 2,500 seeds of the viable basic seed required to reproduce the variety;

(2) With the application for a tuber propagated variety, verification that a viable cell culture has been deposited in a public depository approved by the Commissioner and will be maintained for the duration of the certificate; or

(3) With the application for a hybrid from self-incompatible parents, verification that a plot of vegetative material for each parent has been established in a public depository approved by the Commissioner and will be maintained for the duration of the certificate.

§ 97.19 [Amended]

7. In § 97.19, the introductory text is amended by removing ''the'' after the words ''Journal shall show''.

§ 97.21 [Amended]

8. In § 97.21, the second sentence is amended by adding the words ''and appropriate fee'' immediately following the words ''A request for extension''.

9. In § 97.140, the last sentence is revised to read as follows:

§ 97.140 After filing.

* * * * *

Where applicable, ''PVPA 1994'' or ''PVPA 1994—Unauthorized Sales for Reproductive Purposes Prohibited'' may be added to the notice.

10. In § 97.141, the last sentence is revised to read as follows:

§ 97.141 After issuance.

* * * * *

Where applicable, ''PVPA 1994'' or ''PVPA 1994—Unauthorized Sales for Reproductive Purposes Prohibited'' may be added to the notice.

Dated: December 27, 1995.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 96–75 Filed 1–3–96; 8:45 am]

BILLING CODE 3410–02–P

[Docket No. FV95–979–1IFR; Amendment 1]

Melons Grown in South Texas; Increased Expenses and Establishment of Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Amended interim final rule with request for comments.

SUMMARY: This interim final rule amends a previous interim final rule which authorized administrative expenses for the South Texas Melon Committee (Committee) under M.O. No. 979. This interim final rule increases the level of authorized expenses and establishes an assessment rate to generate funds to pay those expenses. Authorization of this increased budget enables the Committee to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

DATES: Effective October 1, 1995, through September 30, 1996. Comments received by February 5, 1996, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this action. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, FAX 202–720–5698. Comments should reference the docket number and the date and page number of this issue of the Federal Register and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Martha Sue Clark, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone 202–720–9918, or Belinda G. Garza, McAllen Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, 1313 East Hackberry, McAllen, TX 78501, telephone 210–682–2833.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 156 and Order No. 979 (7 CFR part 979), regulating the handling of melons grown in South Texas, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order provisions now in effect, South Texas melons are subject to assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable melons handled during the 1995–96 fiscal period, which began October 1, 1995,

and ends September 30, 1996. This interim final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 40 producers of South Texas melons under this marketing order, and approximately 19 handlers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. The majority of South Texas melon producers and handlers may be classified as small entities.

The budget of expenses for the 1995–96 fiscal period was prepared by the South Texas Melon Committee, the agency responsible for local administration of the marketing order, and submitted to the Department of Agriculture for approval. The members of the Committee are producers and handlers of South Texas melons. They are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of South Texas melons. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the Committee's expenses.

Committee administrative expenses of $234,044 for personnel, office, and compliance expenses were recommended in a mail vote. The assessment rate and funding for the research projects were to be recommended at a later Committee meeting. The Committee administrative expenses of $234,044 were published in the Federal Register as an interim final rule October 23, 1995 (60 FR 54294). That interim final rule added § 979.218, authorizing expenses for the Committee, and provided that interested persons could file comments through November 22, 1995. No comments were filed.

The Committee subsequently met on December 12, 1995, and unanimously recommended an increase of $1,000 for administrative expenses, plus $160,115 in research expenses, for a total budget of $395,159. Budget items for 1995–96 which have increased compared to those budgeted for 1994–95 (in parentheses) are: Manager's salary, $19,094 ($15,172), office salaries, $24,000 ($22,000), payroll taxes, $4,000 ($3,100), insurance, $8,000 ($6,250), rent and utilities, $6,500 ($6,000), supplies, $2,000 ($1,500), postage, $1,500 ($1,000), telephone and telegraph, $4,000 ($2,500), furniture and fixtures, $2,000 ($1,000), equipment rental and maintenance, $3,500 ($2,500), contingencies, $6,000 ($5,278), Committee expenses, $2,000 ($700), manager's travel, $5,000 ($3,000), variety evaluation, $10,875 ($9,186) and $3,750 for deferred compensation (manager's retirement), which was not a line item expense last year. Items which have decreased compared to the amount budgeted for 1994–95 (in parentheses) are: field travel, $4,000 ($5,000), and field salary, $5,500 ($8,000). All other items are budgeted at last year's amounts, including $86,716 for a disease management program, $18,700 for an insect management program, $32,674 for breeding and variety development, and $11,150 for control of melon diseases.

The initial 1995–96 budget, published on October 23, 1995, did not establish an assessment rate. Therefore, the Committee also unanimously recommended an assessment rate of $0.07 per carton, the same as last year. This rate, when applied to anticipated shipments of approximately 4,500,000 cartons, will yield $315,000 in assessment income, which, along with $80,159 from the reserve, will be adequate to cover budgeted expenses. Funds in the reserve as of October 31, 1995, were $398,821, which is within the maximum permitted by the order of two fiscal periods' expenses.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register because: (1) The Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; (2) the fiscal period began on October 1, 1995, and the marketing order requires that the rate of assessment for the fiscal period apply to all assessable melons handled during the fiscal period; (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to that taken for the 1994–95 fiscal period; and (4) this interim final rule provides a 30-day comment period, and all comments timely received will be considered prior to finalization of this action.

List of Subjects in 7 CFR Part 979

Marketing agreements, Melons, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 979 is amended as follows:

PART 979—MELONS GROWN IN SOUTH TEXAS

1. The authority citation for 7 CFR part 979 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 979.218 is revised to read as follows:

Note: This section will not appear in the Code of Federal Regulations.

§ 979.218 Expenses and assessment rate.

Expenses of $395,159 by the South Texas Melon Committee are authorized and an assessment rate of $0.07 per carton is established for the fiscal period ending September 30, 1996. Unexpended funds may be carried over as a reserve.

Dated: December 27, 1995

Sharon Bomer Lauritsen,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service

[FR Doc. 96–74 Filed 1–3–96; 8:45 am]

BILLING CODE 3410–02–P

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7 CFR Part 3017

RIN 0503–AA12

Nonprocurement Debarment and Suspension

AGENCY: Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This final rule amends the USDA regulations that implement Executive Order (E.O.) 12549, ''Debarment and Suspension.'' E.O. 12549 required executive departments and agencies to issue regulations, consistent with guidelines issued by the Office of Management and Budget (OMB), to establish governmentwide effect for an agency's nonprocurement debarment and suspension actions. These changes will enhance USDA participation in the governmentwide nonprocurement debarment and suspension system by making appropriate modifications to the coverage of the regulations and clarifying the relationship of the regulations to other USDA procedures for establishing participant ineligibility for specific programs.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: Gary W. Butler, Deputy Assistant General Counsel, Office of the General Counsel, (202) 720–2577.

SUPPLEMENTARY INFORMATION: As part of the Federal Government's initiatives to curb fraud, waste, and abuse, E.O. 12549, ''Debarment and Suspension,'' was signed on February 18, 1986. E.O. 12549 required executive departments and agencies to issue regulations to establish governmentwide effect for each agency's nonprocurement debarment and suspension actions. Section 3 of E.O. 12549 required that such regulations be consistent with guidelines issued by OMB.

On October 20, 1987, 20 executive departments and agencies published a proposed common rule (52 FR 39035–39042) which implemented the final OMB guidelines that had been published on May 29, 1987 (52 FR 20360–20369). USDA did not join the proposed common rule, but rather published a proposed rule that addressed some problems peculiar to USDA while being consistent with the OMB guidelines.

On May 26, 1988, 27 executive departments and agencies published a final common rule (53 FR 19159–19211) and OMB adopted the final common rule as its amended final guidelines. Upon reconsideration of the issue of joining the common rule, USDA published a final rule on January 30, 1989 (54 FR 4729), which followed the text of the final common rule published on May 26, 1988. However, USDA limited the scope of coverage of the rule (7 CFR part 3017) to domestic assistance transactions and added material generally to reflect internal organization and procedures. Following extended consultations with OMB, USDA has determined that the coverage of this rule should be amended by removing the provision that limits the coverage of the rule to domestic assistance transactions.

Accordingly, on September 26, 1995, USDA published in the Federal Register (60 FR 49519–49523) a notice of proposed rule making (NPRM) to amend 7 CFR part 3017 to make the scope of the USDA rule consistent with the scope of the common rule as adopted by most other agencies. USDA, however, proposed making additional specific exceptions from coverage of the common rule, as implemented by USDA, that are deemed in the public interest. The rational for such additional specific exceptions from coverage was explained fully in the NPRM.

USDA solicited comments concerning our proposal for 60 days ending November 27, 1995. We received no timely comments in response to the NPRM. We, however, did receive one subsequent comment that was wholly supportive of the USDA proposal. Therefore, based on the rationale set forth in the NPRM, USDA is adopting the provisions of the proposal as the final rule.

Impact Analysis

Executive Order 12866

This rule has been determined to be ''significant,'' and it has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act of 1980

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires that, for each rule with a ''significant economic impact on a substantial number of small entities,'' an analysis must be prepared describing the rule's impact on small entities and identifying any significant alternatives to the rule that would minimize the economic impact on the small entities.

USDA certifies that these regulations will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

USDA certifies that this rule will not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1980, 44 U.S.C. Chapter 35.

List of Subjects in 7 CFR Part 3017

Administrative practice and procedure, Grant administration, Grant programs (Agriculture).

For the reasons set forth in the preamble, USDA amends 7 CFR part 3017 as follows:

PART 3017—GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) AND GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (GRANTS)

1. The authority citation for part 3017 is revised to read as follows:

Authority: 5 U.S.C. 301; 41 U.S.C. 701 *et seq.*; E.O. 12549, 51 FR 6370, 3 CFR, 1986 Comp., p. 189.

2. Section 3017.110 is amended by revising paragraph (a) (3) to read as follows:

§ 3017.110 Coverage.

(a) * * *

(3) *Department of Agriculture covered transactions.* (i) With respect to paragraph (a)(1) of this section, for USDA's export and foreign assistance programs, covered transactions will include only primary covered transactions. Any lower tier transactions with respect to UDSA's export and foreign assistance programs will not be

considered lower tier covered transactions for the purposes of this part. The export or substitution of Federal timber governed by the Forest Resources Conservation and Shortage Relief Act of 1990, 16 U.S.C. 620 *et seq.* (the ''Export Act''), is specifically excluded from the coverage of this rule. The Export Act provides separate statutory authority to debar persons engaged in both primary covered transactions and lower tier transactions.

(ii) With respect to paragraph (a)(1)(ii)(B) of this section, for USDA's domestic food assistance programs, only the initial such procurement contract and the first tier subcontract under that procurement contract shall be considered lower tier covered transactions.

(iii) With respect to paragraph (a)(2) of this section, the following USDA transactions also are not covered: transactions under programs which provide statutory entitlements and make available loans to individuals and entities in their capacity as producers of agricultural commodities; transactions under conservation programs; transactions under warehouse licensing programs; the receipt of licenses, permits, certificates, and indemnification under regulatory programs conducted in the interest of public health and safety and animal and plant health and safety; the receipt of official grading and inspection services, animal damage control services, public health and safety inspection services, and animal and plant health and safety inspection services; if the person is a State or local government, the provision of official grading and inspection services, animal damage control services, public health and safety inspection services, animal and plant health and safety inspection services; and permits, licenses, exchanges and other acquisitions of real property, rights of way, and easements under natural resource management programs.

* * * * *

3. Section 3017.115 is amended by adding a new paragraph (d) to read as follows:

§ 3017.115 Policy.

* * * * *

(d) In any case in which an administrative exclusion is considered under an authority other than this part, USDA will initiate, where appropriate, a debarment or suspension action under this part for the protection of the entire Federal Government.

4. Section 3017.200 is amended by adding a new paragraph (d) to read as follows:

§ 3017.200 Debarment or suspension.

* * * * *

(d) *Department of Agriculture excepted transactions.* With respect to paragraph (c) of this section, the following USDA transactions also are excepted: transactions under programs which provide statutory entitlements and make available loans to individuals and entities in their capacity as producers of agricultural commodities; transations under conservation programs; transactions under warehouse licensing programs; the receipt of licenses, permits, certificates, and indemnification under regulatory programs conducted in the interest of public health and safety and animal and plant health and safety; the receipt of official grading and inspection services, animal damage control services, public health and safety inspection services, and animal and plant health and safety inspection services; if the person is a State or local government, the provision of official grading and inspection services, animal damage control services, public health and safety inspection services, and animal and plant health and safety inspection services; and permits, licenses, exchanges, and other acquisitions of real property, rights of way, and easements under natural resource management programs.

Dated: December 21, 1995.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 96–76 Filed 1–3–96; 8:45 am]

BILLING CODE 3410–01–M

FEDERAL RESERVE SYSTEM

12 CFR Part 268

[Docket No. R–0894]

Rules Regarding Equal Opportunity

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (the Board) has amended its Rules Regarding Equal Opportunity (Rules) to correct an ambiguity in the provision regarding access to the investigative file. The Rules set out the complaint processing procedures governing complaints by Board employees and applicants for employment alleging discrimination in employment, and related matters.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: J. Mills Williams, Senior Attorney (202/452–3701), or Stephen L. Siciliano, Special Assistant to the General Counsel for Administrative Law (202/452–3920), Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551. For users of Telecommunication Device for the Deaf (TDD) only, contact Dorothea Thompson (202/452–3544).

SUPPLEMENTARY INFORMATION: The amendment to the Rules is hereby issued as a final rule. The Board sought comments on the proposed amendment on August 31, 1995 (60 FR 45385), and no comments were received. No changes have been made in the amendment as proposed.

The Board's Rules Regarding Equal Opportunity (12 CFR part 268) prior to this amendment provided that a person who files an administrative complaint of discrimination under the Rules must be given a copy of the investigative file relative to the complaint within 180 days after the filing of the complaint with the Board, unless the time is otherwise extended. 12 CFR 268.207(f). The Rules further provided that the ''Board may unilaterally extend the time period * * * where it must sanitize a complaint file that may contain confidential information of the Board under 12 CFR part 261, or other privileged information of the Board * * *.'' 12 CFR 268.207(e). The corresponding language in the federal sector complaint processing regulation of the Equal Employment Opportunity Commission (Commission) provides that an ''agency may unilaterally extend the time period * * * where it must sanitize a complaint file that may contain information classified pursuant to Executive Order 12356, or successor orders, as secret in the interest of national defense or foreign policy * * *.'' 29 CFR 1614.108(e).

The Board's Rules require that, at the completion of an investigation, the investigative file be made available to each complainant. 12 CFR 268.207(f). It was and continues to be the Board's intention to provide that confidential information of the Board that is relevant to the complaint be included in the investigative file made available to the complainant and to the complainant's personal representative.

The Board was concerned, however, that the prior language of § 268.207(e) could be interpreted as preventing confidential Board information that is relevant to a complainant from being included in the investigative file and thus being made available to a complainant. The Board believes that its Rules must make clear that, where relevant, confidential information of the

Board may be included in a complaint file. Accordingly, § 268.207(e) of the Rules has been amended to provide that the time period for completing an investigation may be unilaterally extended by the Board only where classified national security information must be sanitized. This amendment conforms the Rules to the corresponding provision in the complaint processing regulation of the Commission.

In addition, a new paragraph (§ 268.207(e)(2)) has been added to § 268.207(e) of the Board's Rules that expressly authorizes the placement by the investigator, the EEO Programs Director, or another appropriate officer of the Board of relevant confidential information in the investigative file that is provided to a complainant and to his or her personal representative.

The new paragraph contains a provision making clear that those who have access to an investigative file, such as the complainant and the complainant's personal representative, containing any confidential information are subject to all applicable restrictions in existing law governing the disclosure of such information, in particular, the Board's Rules Regarding Availability of Information (12 CFR Part 261) and, where applicable, the Privacy Act. This means that confidential information in an investigatory file may be disclosed further only to the extent permitted by such restrictions.

The Board notes, in this regard, that its restrictions on unauthorized disclosure of confidential information by persons in possession of such information bind all such persons, not merely those who are employees of the Board. 12 CFR 261.8(c), 261.13(e), 261.14.

The Board's Rules Regarding Availability of Information (12 CFR 261 subpart C) provide a mechanism by which a person having confidential information of the Board may request permission to disclose further such information, however. Accordingly, application may be made to the Board's General Counsel under 12 CFR 261.13 for approval of further production or disclosure by a complainant or personal representative of confidential information.

In addition, aside from confidential supervisory information, a particular investigatory file may include information that is subject to the Privacy Act. Such information also may not be disclosed to or by the complainant unless disclosure is authorized consistent with the requirements and/or prohibitions of the Privacy Act (5 U.S.C. 552a).[1] Information subject to Executive Order 12356 may not at any point be included in the investigatory file and would not be made available to the complainant or to his/her personal representative.

In addition, the Board has made a technical correction to § 268.304(a)(3)(i)(A) by substituting a reference to Executive Order No. 12356, dealing with national security classified information, for the former reference (Executive Order No. 10450). The Board has determined that this technical correction is not subject to provisions of the Administrative Procedure Act regarding notice and public comment because good cause exists to support the conclusion that notice and public procedure thereon are unnecessary. 5 U.S.C. 553(b)(B) and (d).

List of Subjects in 12 CFR Part 268

Administrative practice and procedure, Aged, Civil rights, Equal employment opportunity, Federal buildings and facilities, Federal Reserve System, Government employees, Individuals with disabilities, Religious discrimination, Sex discrimination, Wages.

For the reasons set forth in the preamble, the Board amends 12 CFR part 268 as set forth below:

PART 268—RULES REGARDING EQUAL OPPORTUNITY

1. The authority citation for part 268 continues to read as follows:

Authority: 12 U.S.C. 244 and 248(i), (k) and (l).

2. In § 268.207, paragraph (e) is revised to read as follows:

§ 268.207 Investigation of complaints.

* * * * *

(e)(1) The Board shall complete its investigation within 180 days of the date of the filing of an individual complaint or within the time period contained in the determination of the Commission on review of a dismissal pursuant to § 268.206 of this part. By written agreement within those time periods, the complainant and the Board may voluntarily extend the time period for not more than an additional 90 days. The Board may unilaterally extend the time period or any period of extension for not more than 30 days where it must sanitize an investigative file that may contain information classified pursuant to Executive Order No. 12356, or successor orders, as secret in the interest of national defense or foreign policy, provided the Board notifies the complainant of the extension.

(2) Confidential supervisory information, as defined in 12 CFR 261.2(b), and other confidential information of the Board may be included in the investigative file by the investigator, the EEO Programs Director, or another appropriate officer of the Board, where such information is relevant to the complaint. Neither the complainant nor the complainant's personal representative may make further disclosure of such information, however, except in compliance with the Board's Rules Regarding Availability of Information, 12 CFR part 261, and where applicable, the Board's Rules Regarding Access to and Review of Personal Information in Systems of Records, 12 CFR part 261a.

* * * * *

§ 268.304 [Amended]

3. In § 268.304(a)(3)(i)(A), remove the words ''Executive Order No. 10450 (3 CFR, 1949–1953 Comp., P. 936)'' and add in their place, the words ''Executive Order No. 12356 (3 CFR, 1982 Comp.; p. 166)''.

By order of the Board of Governors of the Federal Reserve System, December 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–90 Filed 1–3–96; 8:45 am]

BILLING CODE 6210–01–P

[1] Information subject to the Privacy Act may thereafter be disclosed when necessary in accordance with the *routine* use provision. 12 CFR 261a.10(b)(3). See Board System of Records, BGFRS–*5, Federal Reserve Regulatory Service* ¶ 8–338. A federal criminal statute regarding the unauthorized conversion of Board property may restrict disclosure of confidential Board information in certain cases unless authorization has been specifically given. 18 U.S.C. 641.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. 26344; Amendment No. 23–43]

RIN 2120–AD30

Small Airplane Airworthiness Review Program Amendment No. 3; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Correction; final rule with request for comments.

SUMMARY: This final rule contains corrections to the final regulation (Amendment 23–43), which was published April 9, 1993 (58 FR 18958). The regulation amended the powerplant and equipment airworthiness standards for normal, utility, acrobatic, and commuter category airplanes. This

amendment replaces two paragraphs that were inadvertently deleted by Amendment No. 23–43.

DATES: This final rule becomes effective January 4, 1996. Comments must be submitted on or before April 3, 1996.

ADDRESSES: Comments should be submitted in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 26344, 800 Independence Avenue, SW., Washington, DC 20591. Comments delivered must be marked Docket No. 26344. Comments may be inspected in Room 915G weekdays between 8:30 a.m. and 5:00 p.m., except on Federal holidays.

In addition, the FAA is maintaining a duplicate information docket of comments in the Office of the Assistant Chief Counsel, ACE–7, Federal Aviation Administration, Central Region, 601 East 12th Street, Kansas City, Missouri 64106. Comments in the duplicate information docket may be inspected in the Office of the Assistant Chief Counsel weekdays, except Federal holidays, between the hours of 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Norman Vetter, ACE–111, Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone (816) 426–5688.

SUPPLEMENTARY INFORMATION:

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting immediate flight safety and, thus, was not preceded by notice and opportunity to comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this rule will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 26344.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that must be issued immediately to correct an unsafe condition in aircraft, and is not a significant regulatory action under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

Availability

Any person may obtain a copy of this amendment by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–200, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the amendment number.

Persons interested in being placed on the mailing list for future NPRM's and rules 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.

Background

The final regulations that are the subject of this amendment, Amendment 23–43 (58 FR 18958, April 9, 1993), inadvertently removed paragraphs § 23.965 (b)(4) and (b)(5). These paragraphs were never intended to be removed and their removal was not proposed in the NPRM for Amendment 23–43.

Need for Correction

As published, the final regulations contain inadvertently deleted paragraphs 23.965 (b)(4) and (b)(5), which contain substantive requirements that were not intended to be removed and are considered essential to aviation safety.

Discussion of Amendments

Section 23.965

The FAA proposed to amend paragraphs (b)(1) through (b)(3) of § 23.965 in Amendment 23–43. However, the amendatory language removed paragraphs (b)(4) and (b)(5). This amendment corrects the error by reinserting those paragraphs into the regulations.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

The Amendments

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 23 to read as follows:

PART 23—AIRWORTHINESS STANDARDS: NORMAL, UTILITY, ACROBATIC, AND COMMUTER CATEGORY AIRPLANES

1. The authority citation for part 23 continues to read as follows:

Authority: 49 U.S.C. 40113 and 44701; 49 U.S.C. 106(g).

2. Section 23.965, paragraph (b), is amended by adding paragraphs (b)(4) and (b)(5) to read as follows:

§ 23.965 Fuel tank tests.

(b) * * *

(4) Under paragraph (b)(3) (ii) and (iii) of this section, the time of test must be adjusted to accomplish the same number of vibration cycles that would be accomplished in 25 hours at the frequency specified in paragraph (b)(3)(i) of this section.

(5) During the test, the tank assembly must be rocked at a rate of 16 to 20 complete cycles per minute, through an angle of 15° on either side of the horizontal (30° total), about an axis parallel to the axis of the fuselage, for 25 hours.

Issued in Washington, DC, on December 28, 1995.

Michael Gallagher,

Acting Director, Aircraft Certification Service.

[FR Doc. 96–135 Filed 1–3–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 35

[Docket No. 94–ANE–61; Special Condition No. 35–ANE–03]

Special Conditions; Hamilton Standard Model 568F Propeller

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for Hamilton Standard Model 568F propeller. This propeller is constructed using all composite blades, a novel and unusual design feature. Part 35 of the Federal Aviation Regulations (FAR's) currently does not address the airworthiness considerations associated with propellers constructed using all composite blades. These special conditions contain additional safety standards which the Administrator finds necessary to establish a level of safety equivalent to that established by the airworthiness standards of part 35 of the FAR's.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: Martin Buckman, Engine and Propeller Standards Staff, ANE–110, Engine and Propeller Directorate, Aircraft Certification Service, FAA, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803–5229; telephone (617) 238–7112, fax (617) 238–7199.

SUPPLEMENTARY INFORMATION:

Background

On January 26, 1994, Hamilton Standard applied for type certification for a new Model 568F propeller. This propeller is constructed using all composite blades, a novel and unusual design feature. A Notice of Proposed Special Conditions was published in the Federal Register on January 20, 1995 (60 FR 4116) for the Hamilton Standard Model 568F propeller constructed with composite material. Propellers constructed entirely of composite material have additional airworthiness considerations not currently addressed by part 35 of the Federal Aviation Regulations (FAR). Those additional airworthiness considerations associated with propellers constructed using all composite blades are propeller integrity following a bird strike, propeller integrity following a lightning strike, and propeller fatigue strength when exposed to the deteriorating effects of in-service use and the environment.

Type Certificate Basis

Under the provisions of § 21.17 of the FAR's, Hamilton Standard must show that the Model 568F propeller meets the requirements of the applicable regulations in effect on the date of the application. Those FAR's are § 21.21 and part 35, effective February 1, 1965, as amended.

The Administrator finds that the applicable airworthiness regulations in part 35, as amended, do not contain adequate or appropriate safety standards for the Model 568F propeller because it is constructed using composite material. Therefore, the Administrator prescribes special conditions under the provisions of § 21.16 of the FAR's to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR's after public notice and opportunity for comment, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Novel or Unusual Design Features

Hamilton Standard Model 568F propeller incorporates propeller blades constructed using composite material. This material has fibers that are woven or aligned in specific directions to give the material directional strength properties. These properties depend on the type of fiber, the orientation and concentration of fiber, and matrix material. Composite materials could exhibit multiple modes of failure. Propellers constructed of composite material must demonstrate airworthiness when considering these novel design features.

The requirements of part 35 of the FAR's were established to address the airworthiness considerations associated with wood and metal propellers used primarily on reciprocating engines. Propeller blades of this type are generally thicker than composite blades, and have demonstrated good service experience following a bird strike. Propeller blades constructed using composite material are generally thinner when used on turbine engines, and are typically installed on high performance aircraft. High performance aircraft generally fly at high airspeeds with correspondingly high impact forces associated with a bird strike. Thus, composite propellers must demonstrate propeller integrity following a bird strike.

In addition, part 35 of the FAR's do not currently require a demonstration of propeller integrity following a lightning strike. No safety considerations arise from lightning strikes on propellers constructed of metal because the electrical current is safely conducted through the metal blade without damage to the propeller. Fixed pitched, wooden propellers are generally used on engines installed on small, general aviation aircraft that typically do not encounter flying conditions conducive to lightning strikes. Composite propeller blades, however, may be used on turbine engines and high performance aircraft which have an increased risk of lightning strikes. Composite blades may not safely conduct or dissipate the electrical current from a lightning strike. Severe damage can result if the propellers are not properly protected. Therefore, composite blades must demonstrate propeller integrity following a lightning strike. Information on testing for lightning protection is set out in SAE Report AE4L, entitled, ''Lightning Test Waveforms and Techniques for Aerospace Vehicles and Hardware,'' dated June 20, 1978.

Lastly, the current certification requirements address fatigue evaluation only of metal propeller blades or hubs, and those metal components of non-metallic blade assemblies. Allowable design stress limits for composite blades must consider the deteriorating effects of the environment and in-service use, particularly those effects from temperature, moisture, erosion and chemical attack. Composite blades also present new and different considerations for retention of the blades in the propeller hub.

Discussion of Comments

Interested persons have been afforded the opportunity to participate in the making of these special conditions. Due consideration has been given to comments received.

One commenter is concerned that the terms ''reasonable and foreseeable'' in paragraph (3) FATIGUE EVALUATION of the special condition is a vague interpretation, and will result in large variation in how this requirement is applied.

The FAA disagrees. The special conditions are written with the accepted terminology from § 35.37, Fatigue limit tests, of the FAR's, which states that ''The fatigue evaluation must include consideration of all reasonably foreseeable vibration load patterns.'' This terminology has been established because each propeller installation presents a unique set of operating conditions that must be incorporated

into the fatigue evaluation. The inclusion of specific aircraft operating conditions may result in the fatigue evaluation of operating conditions of minor significance while leaving out conditions of major significance.

One commenter agreed with the three proposed special conditions as written and proposed two additional special conditions concerning ice strikes due to ice shedding from the airframe and ice accretion due to the heat transfer properties of composite materials.

The FAA disagrees with the addition of the two additional special conditions for the following reasons. First, ice strikes due to ice shedding from the airframe is a concern for pusher type installations. The Hamilton Standard Model 568F propeller is a tractor configuration and therefore normally will not be exposed to ice shedding from the airframe. Second, heat transfer properties of the Hamilton Standard Model 568F composite blade are similar to other composite shell and all composite blades with deicing systems that have had a good service history. In addition for propeller installations that require deicing, the propeller manufacture provides a deicing system and the required documentation to the airframer for compliance with the current regulations.

Conclusion

This action affects only the Hamilton Standard Model 568F propeller and future propeller models within this series. It is not a rule of general application, and it affects only the manufacturer who applied to the FAA for approval of this propeller model.

List of Subjects in 14 CFR Part 35

Air Transportation, Aircraft, Aviation safety, Safety.

PART 35—[AMENDED]

The authority citation continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704; 14 CFR 11.28, 21.16.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration (FAA) issues the following special conditions for the Hamilton Standard Model 568F Propeller:

(a) For purposes of these special conditions, a hazardous condition is considered to exist for each of the following conditions:

(1) Loss of the propeller blade, or a major portion of a blade.

(2) Overspeed of the propellers.

(3) Unintended movement of the blade below the established minimum inflight blade angle, or to an angle that results in excessive drag.

(4) The inability to feather the propeller when necessary.

(b) In addition to the requirements of Federal Aviation Regulation part 35, the following must be shown:

(1) *BIRD STRIKE*

For propeller of composite construction it must be shown that:

The propeller can withstand a 4 pound bird strike at the blade's critical radial location when operating at takeoff RPM and liftoff (Vr) speed of a typical aircraft, without giving rise to a hazardous condition and while maintaining the capability to be feathered.

(2) *LIGHTNING STRIKE*

A lightning strike on a propeller of a composite construction shall not result in a hazardous condition. The propeller shall be capable of continued safe operation.

(3) *FATIGUE EVALUATION*

A fatigue evaluation must be provided and the fatigue limits determined for each propeller hub, blade, and each primary load carrying component of the propeller. The fatigue evaluation must consider all known and reasonable foreseeable vibration and cyclic load patterns that may be encountered in service. The fatigue limits must account for the effects of in-service deterioration, such as impact damage, nicks, grooves, galling, or bearing wear; for variations in production material properties; for environmental effects such as temperature, moisture, erosion, chemical attack, etc., that cause deterioration.

Issued in Burlington, Massachusetts, on December 19, 1995.

James C. Jones,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 96–56 Filed 1–3–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 94–AWA–3]

Modification of the Atlantic City International Airport Class C Airspace Area; NJ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment modifies the Class C airspace area at Atlantic City International Airport, Atlantic City, NJ. This action deletes the 1-mile airspace exclusion around the Nordheim Flying K Airport due to its closure, and returns this airspace to the surface area of the Class C airspace. In addition, this action reduces controller workload.

EFFECTIVE DATE: 0901 UTC, February 29, 1996.

FOR FURTHER INFORMATION CONTACT: William C. Nelson, Airspace and Obstruction Evaluation Branch (ATP–240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–9295.

SUPPLEMENTARY INFORMATION:

History

On April 12, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify the Class C airspace area at Atlantic City International Airport, Atlantic City, NJ (60 FR 18552). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received concerning the proposal. Except for editorial changes, this amendment is the same as that proposed in the notice. Class C airspace designations are published in paragraph 4000 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class C airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies the Class C airspace area at Atlantic City International Airport, Atlantic City, NJ, by eliminating the 1-mile radius airspace exclusion around the Nordheim Flying K Airport due to its closure. This amendment will return this airspace to the surface area of the Class C airspace.

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 final rule is not ''a significant regulatory action'' as defined in the Executive Order and the Department of Transportation Regulatory Policies and Procedures.

This final rule will modify the Class C airspace area at Atlantic City International Airport, Atlantic City, NJ. This action will delete the 1-mile airspace exclusion around Nordheim Flying K Airport and standardize air traffic operations.

Costs

The FAA has determined that the implementation of the final rule to modify the Class C airspace area at Atlantic City International Airport will result in little or no cost to either the agency or aircraft operators. The elimination of the 1-mile airspace exclusion around the Nordheim Flying K Airport will not reduce aviation safety nor increase the risk of a mid-air collision because that airport is closed. Also, the revision to aeronautical charts to reflect the airspace modification will be part of the routine and periodic updating of charts. Finally, the FAA will not incur any additional administrative costs for either personnel or equipment.

Benefits

The final rule will generate benefits for system users and the FAA primarily in the form of enhanced operational efficiency. The final rule will provide additional controlled airspace for aircraft landing and departing from the Atlantic City International Airport. Air traffic controllers will gain operational efficiency as they will be able to standardize traffic operations.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by Federal regulations. The RFA requires a Regulatory Flexibility Analysis if a final rule will have ''a significant economic impact on a substantial number of small entities.'' FAA Order 2100.14A outlines the FAA's procedures and criteria for implementing the RFA. Small entities are independently owned and operated small businesses and small not-for-profit organizations. A substantial number of small entities is defined as a number that is 11 or more and which is more than one-third of the small entities subject to this final rule.

The FAA determined that revising the Class C airspace area at Atlantic City International Airport will not result in a significant economic impact on a substantial number of small entities. This determination was made because there are little or no costs associated with this final rule.

International Trade Impact Assessment

This final rule will not constitute a barrier to international trade, including the export of U.S. goods and services to foreign countries and the import of foreign goods and services into the United States. This final rule will not impose costs on aircraft operators or aircraft manufacturers in the United States or foreign countries. The modification of the Class C airspace area will only affect U.S. terminal airspace operating procedures at and in the vicinity of Atlantic City, NJ. This final rule will not have international trade ramifications because it is a domestic airspace matter that will not impose additional costs or requirements on affected entities.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 4000—Subpart C—Class C Airspace

* * * * *

AEA NJ C Atlantic City International Airport, NJ [Revised]

Atlantic City International Airport, NJ
(Lat. 39°27′27″ N., long. 74°34′38″ W.)

That airspace extending upward from the surface to and including 4,100 feet MSL within a 5-mile radius of the Atlantic City International Airport; and that airspace extending upward from 1,300 feet MSL to and including 4,100 feet MSL within a 10-mile radius of the airport.

* * * * *

Issued in Washington, DC, on December 20, 1995.

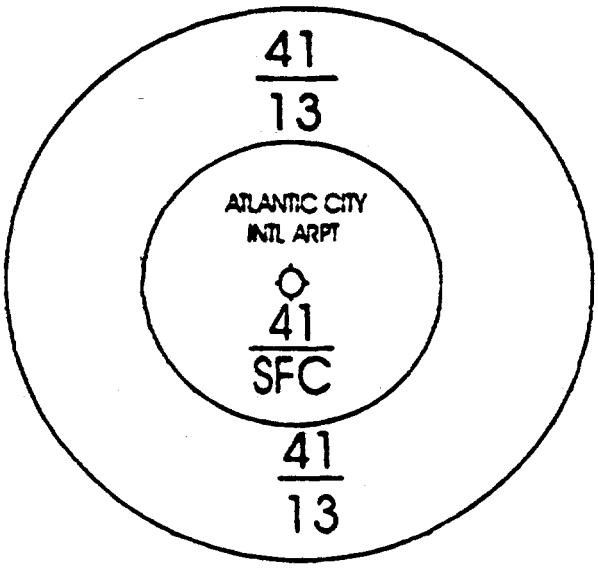
Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

BILLING CODE 4910–13–P

ATLANTIC CITY, NJ
CLASS C AIRSPACE AREA

(Not to be used for navigation)



Graphic prepared by the
FEDERAL AVIATION ADMINISTRATION
Publications Branch
(ATP-210)

[FR Doc. 96–68 Filed 1–3–96; 8:45 am]
BILLING CODE 4910–13–C

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 162

[T.D. 96–6]

RIN 1515–AB72

Search Warrants

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by removing a regulation limiting the authority of Customs officers to whom search warrants are issued. The current regulation restricts such officers from removing letters, documents and other records in certain circumstances. The regulation is inconsistent with the current state of the law.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: Lars-Erik Hjelm, Office of the Chief Counsel, at 202–927–6900.

SUPPLEMENTARY INFORMATION:

Background

Section 162.14 of the Customs Regulations (19 CFR 162.14) provides that Customs officers to whom a search warrant is issued may not remove letters, other documents and records during the execution of the warrant, unless such letters, other documents and records are instruments of crime which are seized pursuant to a lawful arrest. When it was drafted, the statutory basis for this regulation was found in section 595 of the Tariff Act of 1930 (19 U.S.C. 1595). Until 1986, section 595 only authorized Customs to obtain warrants for merchandise.

In 1986, section 595 was expanded to allow Customs to seize ''. . . any document . . . which is evidence of a violation . . . of any . . . law enforced or administered by the United States Customs Service.'' Pub. L. 99–570, Title III, § 3122, 100 Stat. 3207–87.

In addition to section 595, section 589 of the Tariff Act of 1930 (19 U.S.C. 1589a(2)), provides expanded authority for Customs officers with warrants to seize documents. Section 589 provides Customs officers with authority to execute and serve any warrant issued under the authority of the United States. As a search warrant issued under Rule 41 of the Federal Rules of Criminal Procedure (Fed. R. Crim. P., Rule 41, 18 U.S.C. App.) can now be issued for, among other things, documents constituting evidence of crimes (See *United States* v. *Thompson,* 495 F. 2d 165 (D.C. Cir 1974); *United States* v. *Michaelian,* 803 F. 2d 1042 (9th Cir. 1986)), it is clear that section 589 read in conjunction with Rule 41 provides Customs officers with authority to search for and seize documentary evidence. Further, the Supreme Court has made it clear that officers may seize incriminating evidence during the course of a lawful search. *Horton* v. *California,* 496 U.S. 128 (1990).

Inasmuch as section 162.14 of the Customs Regulations, no longer reflects the state of the law regarding the search and seizure authority of Customs officers, Customs proposed removing the regulation in a Notice of Proposed Rulemaking published in the Federal Register on July 12, 1995 (60 FR 35881). A correction document regarding the notice was published in the Federal Register (60 FR 37856) on July 24, 1995.

Determination

No comments were received in response to the Notice of Proposed Rulemaking. After further review, Customs has determined to proceed with the removal of section 162.14, Customs Regulations (19 CFR 162.14).

Regulatory Flexibility Act and Executive Order 12866

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and based upon the information set forth above, it is certified that the removal of § 162.14 will not have a significant economic impact on a substantial number of small entities. Accordingly, the amendment is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

This document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

List of Subjects in Part 162

Administrative practice and procedure, Customs duties and inspection, Drug traffic control, Exports, Law enforcement, Marijuana, Penalties, Reporting and recordkeeping requirements, Search warrants, Seizures and forfeitures.

Amendment to the Regulations

For the reasons set forth in the preamble, part 162 of the Customs Regulations is amended as set forth below.

PART 162—RECORDKEEPING, INSPECTION, SEARCH AND SEIZURE

1. The general authority for part 162 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1624.

§ 162.14 [Removed]

2. Section 162.14 is removed.

William F. Riley,

Acting Commissioner of Customs.

Approved: December 28, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–133 Filed 1–3–96; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address from American Cyanamid Co. to American Cyanamid, Division of American Home Products.

EFFECTIVE DATE: January 4, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, has informed FDA of a change of sponsor name and address to American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name and address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''American Cyanamid Co.'' and by adding in its place a new entry for ''American Cyanamid, Division of America Home Products,'' and in the table in paragraph (c)(2) in the entry for ''010042'' by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501	010042
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * * *	* * *
010042	American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501.
* * * *	* * *

Dated: December 22, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–122 Filed 1–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for TRINADA, Inc.

EFFECTIVE DATE: January 4, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: TRINADA, Inc., P.O. Box 129, Lewisburg, OH 45338, has informed FDA that it has changed its address to One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the sponsor address for ''TRINADA, Inc.,'' and in the table in paragraph (c)(2) in the entry for ''058690'' by revising the sponsor address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	* * *
TRINADA, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024	058690
* * * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
058690	TRINADA, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
* * *	* * * *

Dated: December 22, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–121 Filed 1–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

New Animal Drugs and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Fort Dodge Laboratories to Wildlife Laboratories, Inc.

EFFECTIVE DATE: January 4, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, Fort Dodge, IA 50501, has informed FDA that it has transferred ownership of, and all rights and interests in approved NADA 47–870 (Etorphine hydrochloride injection) to Wildlife Laboratories, Inc., 1401 Duff Dr., suite 600, Fort Collins, CO 80524. This NADA was originally owned by American Cyanamid Co. and transferred to Fort Dodge Laboratories but was inadvertently not codified in the regulations. Accordingly, FDA is amending the regulations in 21 CFR 522.883 to reflect the change of sponsor.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.883 [Amended]

2. Section 522.883 *Etorphine hydrochloride injection* is amended in paragraph (c) by removing ''010042'' and adding in its place ''053923''.

Dated: December 22, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–123 Filed 1–3–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301, and 602

[TD 8651]

RIN 1545–AS05

Automatic Extension of Time for Filing Individual Income Tax Returns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that reflect new simpler procedures for an individual to obtain an automatic extension of time to file an individual income tax return. The text of the temporary regulations also serves as the text of the cross reference notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the Federal Register.

DATES: These regulations are effective January 4, 1996.

For dates of applicability, see § 1.6081–4T and § 301.6651–1T.

FOR FURTHER INFORMATION CONTACT: Margaret A. Owens, (202) 622–6232 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–1479. Responses to this collection of information are required to obtain a benefit (an automatic 4-month extension of time to file an individual income tax return).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

For further information concerning the collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the Federal Register.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document amends the Income Tax Regulations (26 CFR Part 1) under section 6081 of the Internal Revenue Code of 1986 to implement Notice 93–22 (1993–1 C.B. 305). Notice 93–22, released April 7, 1993, grants relief to individuals who want an automatic 4-month extension of time to file an individual income tax return but who are unable to pay by the due date for the return the tax properly estimated to be due. The notice allows these individuals to obtain an automatic 4-month extension of time to file their individual

income tax returns for taxable years ending on or after December 31, 1992, by filing Form 4868, Application for Automatic Extension of Time to File U.S. Individual Income Tax Return, without an accompanying remittance. Individuals may rely on Notice 93–22 for taxable years ending on or after December 31, 1992 and before December 31, 1995. Notice 93–22 also advised taxpayers that the regulations under section 6081 will be amended to reflect this change in the procedure for an individual to obtain an automatic 4-month extension of time to file. In addition, this document amends the Regulations on Procedure and Administration (26 CFR Part 301) (relating to an automatic extension of time for filing an individual income tax return).

Explanation of Provisions

Under § 1.6081–4, an individual required to file an income tax return is allowed an automatic 4-month extension of time to file if (a) an application is prepared on Form 4868, (b) the application is signed by the individual or a person duly authorized by the individual, (c) the application is filed on or before the date the return is due, (d) the application shows the full amount properly estimated as tax, and (e) the application is accompanied by full remittance of the amount properly estimated as tax that is unpaid as of the date prescribed for the filing of the return.

These temporary regulations provide that individuals may obtain an automatic 4-month extension of time to file an individual income tax return without remitting the unpaid amount of any tax properly estimated to be due with the application for extension of time to file. Under these temporary regulations, an individual's inability to pay is not a condition for obtaining an automatic 4-month extension. However, taxpayers are encouraged to make payments, as large as possible, in order to reduce interest and penalties required by law.

In addition, these temporary regulations provide that the IRS may prescribe other manners for submitting an application in lieu of a paper application on Form 4868.

The temporary regulations remove the regulatory requirement that applications for an automatic 4-month extension be signed. Thus, notwithstanding the 1995 Form 4868 instructions, an unsigned application will be processed. In addition, the Commissioner may prescribe additional methods of obtaining an extension of time to file that do not require a signature.

Special Analyses

It has been determined that these temporary regulations are not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, a copy of these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information. The principal author of these regulations is Margaret A. Owens, Office of the Assistant Chief Counsel (Income Tax & Accounting), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1, 301, and 602 are amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805. * * *

Par. 2. Section 1.6081–4 is amended by revising paragraph (a) to read as follows:

§ 1.6081–4 Automatic extension of time for filing individual income tax returns.

(a) [Reserved] For further guidance see § 1.6081–4T(a).

* * * * *

Par. 3. Section 1.6081–4T is added to read as follows:

§ 1.6081–4T Automatic extension of time for filing individual income tax returns—taxable years ending on or after December 31, 1995 (temporary).

(a) *In general*—(1) *Period of extension*. An individual who is required to file an individual income tax return for any taxable year ending on or after December 31, 1995, will be allowed an automatic 4-month extension of time to file the return after the date prescribed for filing the return provided the requirements contained in paragraphs (a)(2), (3), and (4) of this section are met. In the case of an individual described in § 1.6081–5(a)(5) or (6), the automatic 4-month extension will run concurrently with the extension of time to file granted pursuant to § 1.6081–5.

(2) *Manner for submitting an application*. An application must be submitted—

(i) On Form 4868, Application for Automatic Extension of Time to File U.S. Individual Income Tax Return; or

(ii) In any other manner as may be prescribed by the Commissioner.

(3) *Time and place for filing application*. Except in the case of an individual described in § 1.6081–5(a)(5) or (6), the application must be filed on or before the date prescribed for filing the individual income tax return. In the case of an individual described in § 1.6081–5(a)(5) or (6), the application must be filed on or before the expiration of the extension of time to file granted pursuant to § 1.6081–5. The application must be filed with the IRS office designated in the application's instructions.

(4) *Proper estimate of tax*. An application for extension must show the full amount properly estimated as tax for the taxable year.

(5) *Allowance of extension*. Upon properly preparing and timely filing an application, the 4-month extension will be considered as allowed. Except in undue hardship cases, no extension of time for filing an individual income tax return will be granted under § 1.6081–1 until an automatic extension has been allowed pursuant to the provisions of this paragraph (a).

(b) and (c) [Reserved].

(d) *Penalties*. See section 6651 and the regulations under that section for the additions to tax for failure to file an individual income tax return or failure to pay the amount shown as tax on the return. In particular, see § 301.6651–1(c)(3) of this chapter (relating to a presumption of reasonable cause in certain circumstances involving an automatic extension of time for filing an individual income tax return).

PART 301—PROCEDURE AND ADMINISTRATION

Par. 4. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 5. Section 301.6651–1 is amended by revising paragraph (c)(3) to read as follows:

§ 301.6651–1 Failure to file tax return or to pay tax.

* * * * *

(c)(3) [Reserved] For further guidance see § 301.6651–1T(c)(3).

* * * * *

Par. 6. Section 301.6651–1T is added to read as follows:

§ 301.6651–1T Failure to file tax return or to pay tax—taxable years ending on or after December 31, 1995 (temporary).

(a) through (c)(2) [Reserved].

(c)(3) If, for a taxable year ending on or after December 31, 1995, an individual taxpayer satisfies the requirements of § 1.6081–4T(a) of this chapter (relating to an automatic extension of time for filing an individual income tax return), reasonable cause shall be presumed, for the period of the extension of time to file, with respect to any underpayment of tax if—

(i) The excess of the amount of tax shown on the individual income tax return over the amount of tax paid on or before the regular due date of the return (by virtue of taxes withheld by the employer, estimated tax payments, and any payment with an application for extension of time to file pursuant to § 1.6081–4T of this chapter) is no greater than 10 percent of the amount of tax shown on the individual income tax return; and

(ii) Any balance due shown on the individual income tax return is remitted with the return.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 7. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 8. In § 602.101, paragraph (c) is amended by adding an entry in numerical order to the table to read ''1.6081–4T. . . .1545–1479''.

Margaret Milner Richardson,
Commissioner of Internal Revenue.

Approved: December 20, 1995.

Leslie Samuels,
Assistant Secretary of the Treasury.

[FR Doc. 96–114 Filed 1–3–96; 8:45 am]

BILLING CODE 4830–01–U

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26 CFR Parts 1 and 602

[TD 8654]

RIN 1545–AS21

Information Reporting for Discharges of Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the information reporting requirements of applicable financial entities for discharges of indebtedness. The final regulations reflect changes to the Internal Revenue Code of 1986 (Code) made by section 13252 of the Omnibus Budget Reconciliation Act of 1993 (the Act). The final regulations affect certain financial institutions and federal executive agencies.

DATES: These regulations are effective December 22, 1996.

For dates of applicability, see § 1.6050P–1(h).

FOR FURTHER INFORMATION CONTACT: Sharon L. Hall (timing and amount of discharge) at (202) 622–4930 or Michael F. Schmit (other issues) at (202) 622–4960, both of the Office of Assistant Chief Counsel (Income Tax and Accounting). Neither telephone number is toll-free.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1419. Responses to this collection of information are required for the IRS to monitor whether discharged debtors are properly complying with tax laws respecting cancellations of indebtedness.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The time estimates for the reporting requirements contained in these final regulations are reflected in the burden estimates for Form 1099–C.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax information are confidential, as required by 26 U.S.C. 6103.

Background

Section 6050P was added to the Code by section 13252 of the Act. Section 6050P requires certain financial entities to report discharges of indebtedness of $600 or more during any calendar year, and requires reporting entities to make a return at such time and in such form as the Secretary may by regulations prescribe.

On December 27, 1993, temporary regulations (TD 8506) relating to the reporting of discharge of indebtedness under section 6050P were published in the Federal Register (58 FR 68301). A notice of proposed rulemaking (IA–63–93) cross-referencing the temporary regulations was published in the Federal Register for the same day (58 FR 68337).

Written comments were received in response to the notice of proposed rulemaking. Fourteen speakers provided testimony at a public hearing held on March 30, 1994. In response to the comments and testimony, the IRS and Treasury issued Notice 94–73 (1994–2 C.B. 553), providing interim relief from penalties for failure to comply with certain of the reporting requirements of the temporary regulations. The Notice provided that, with respect to a discharge of indebtedness occurring before the later of January 1, 1995, or the effective date of the final regulations under section 6050P, no penalties would be imposed for the failure to report a discharge of indebtedness:

(a) Under title 11 of the United States Code;

(b) Resulting from the expiration of the statute of limitations for collection of an indebtedness;

(c) For an amount other than principal in the case of indebtedness arising in

connection with a lending transaction; or

(d) For a person other than the primary (or first-named) debtor in the case of indebtedness incurred before January 1, 1995, that involves multiple debtors.

After consideration of all the comments, the proposed regulations under section 6050P are adopted, as revised by this Treasury decision, effective for discharges of indebtedness occurring after December 21, 1996. The temporary regulations and interim relief from penalties provided in Notice 94–73 remain in effect through December 21, 1996, at which time the temporary regulations are removed. However, no penalties will be imposed for the failure to report a discharge of indebtedness occurring after December 21, 1996, and before January 1, 1997, if the failure to report would have qualified for penalty relief under Notice 94–73 had the discharge occurred prior to December 22, 1996. Additionally, the final regulations provide that a financial entity subject to section 6050P may, at its discretion, apply any of the provisions of the final regulations to any discharge of indebtedness occurring on or after January 1, 1996, and before December 22, 1996. The comments and revisions to the proposed regulations are discussed below.

At the request of commentators, the IRS and Treasury are considering the issuance of guidance providing uniform procedures for requesting extensions of time within which to file information returns with the IRS and related statements to taxpayers. This guidance, if issued, would apply to the information reporting requirements set forth in this Treasury decision.

Explanation of Revisions and Summary of Comments

1. Identifiable Events

Comments were received relating to the issue of when an indebtedness is discharged for purposes of section 6050P. Under the temporary and proposed regulations, indebtedness is considered discharged, and reporting is required, upon the occurrence of an identifiable event indicating that the indebtedness will never have to be repaid by the debtor, taking into account all of the facts and circumstances. The temporary and proposed regulations list three identifiable events, but make clear that the three items do not represent an exclusive list of events requiring reporting.

Commentators objected to this facts and circumstances test, and stated that the final regulations should instead provide an exclusive list of reporting events. The comments indicated that creditors do not have the resources to weigh all the facts and circumstances in order to determine whether a debt will never have to be repaid by the debtor.

In response to these comments, the final regulations provide that, for purposes of section 6050P, indebtedness is considered discharged, and reporting is required, only upon the occurrence of certain identifiable events. The regulations contain an exclusive list of eight identifiable events, and provide that, in the absence of the occurrence of one of these events, a Form 1099–C is not required to be filed.

A. Discharges of Indebtedness in Bankruptcy

Commentators objected to the requirement in the temporary and proposed regulations relating to the reporting of a discharge of indebtedness in bankruptcy. The commentators stated that the obligation to report debts discharged in bankruptcy was extremely burdensome due to the large number of information returns that these bankruptcies would generate. These commentators also stated that some lenders do not receive information regarding a debtor's bankruptcy discharge in the normal course of business.

Commentators also objected to the requirement to report debts discharged in bankruptcy because income from a discharge in bankruptcy is excludable under section 108(a)(1)(A). Additionally, while acknowledging that section 108(b) generally requires the reduction of tax attributes for amounts of cancellation of indebtedness income excluded under section 108(a), these commentators indicated that the majority of bankruptcies involve consumer debt, the discharge of which is unlikely to give rise to attribute reduction. Thus, they contended that the reporting of consumer debts discharged in bankruptcy will not further the purposes of section 6050P.

Finally, based on language in section 6050P, commentators contended that the IRS and Treasury lacked authority to require reporting in bankruptcy. Under section 6050P(a), ''any applicable financial entity which discharges . . . the indebtedness of any person'' is subject to the rules of section 6050P. Commentators argued that creditors should not be subject to the rules of section 6050P for debts discharged in bankruptcy because it is the bankruptcy court, not the creditor, that discharges the debt.

In promulgating the temporary regulations, the IRS and Treasury fully considered the issue of whether bankruptcy discharges could be excluded from the reporting requirement. The legislative history to section 6050P states that ''information returns are required regardless of whether the debtor is subject to tax on the discharged debt. For example, Congress does not expect reporting financial institutions and agencies to determine whether the debtor qualifies for an exclusion under section 108.'' H.R. Conf. Rep. No. 213, 103d Cong., 1st Sess. 1, 671 (1993). This language indicates that Congress intended that discharges resulting in excluded income (such as bankruptcy discharges) be reported.

Accordingly, the IRS and Treasury do not believe that a requirement to report debts discharged in bankruptcy is outside the scope of section 6050P. In enacting section 6050P, Congress intended to increase debtor compliance in reporting discharges of indebtedness. With respect to the tax consequences to the debtor, it generally makes no difference whether the debt is voluntarily discharged by the financial entity, or discharged by a court order. Further, the creditor is receiving an amount that is less than the amount of the outstanding indebtedness whether the debt is voluntarily discharged or ordered to be discharged by a court. Thus, the language ''any applicable financial entity which discharges . . . indebtedness'' should not be narrowly construed to exclude instances in which a debt is ordered to be discharged or is discharged by operation of law.

The IRS and Treasury believe that an objective of the legislative history quoted above is that information reporting under section 6050P not impose an undue burden on filers by requiring determinations regarding whether discharges result in income to debtors. However, the legislative history does not preclude an exception for certain discharges in appropriate circumstances. Accordingly, in response to the above concerns of the commentators, the final regulations provide an exception from reporting in the case of certain bankruptcy discharges. Under the final regulations, indebtedness discharged in bankruptcy is required to be reported only if the creditor knows that the debtor incurred the indebtedness for business or investment purposes. Therefore, reporting is not required for consumer debts discharged in bankruptcy or in cases in which the creditor is not aware of the purpose for the borrowing or that purpose is not clear. Information relating to whether a debt was incurred for business or investment purposes will

be available to a creditor in some cases, such as those in which loan documents require the borrower to state the purpose of the loan. This limited reporting of debts discharged in bankruptcy will exclude information returns relating to consumer debt, while retaining reporting for those discharges most likely to involve the reduction of tax attributes under section 108(b). Pursuant to Notice 94–73, no penalties will be imposed for the failure to report any indebtedness discharged before December 22, 1996, in bankruptcy. Additionally, no penalties will be imposed for the failure to report any indebtedness discharged after December 21, 1996, and before January 1, 1997, in bankruptcy, since the failure to report would have qualified for penalty relief under Notice 94–73 had the discharge occurred prior to December 22, 1996.

B. Expiration of Statute of Limitations for Collection

Under the temporary and proposed regulations, an identifiable event includes a cancellation or extinguishment by operation of law that renders a debt unenforceable, such as the expiration of the statute of limitations for collection of an indebtedness.

Comments were received relating to the requirement to report indebtedness discharged as a result of the expiration of the statute of limitations. Commentators argued that expiration of the statute of limitations should not be an identifiable event because of the recordkeeping and other administrative burdens that are created by such a rule. Commentators noted that the statute of limitations for collection of debt varies from state to state, and that debtors may relocate and be subject to the rules of multiple jurisdictions. Further, they contended, an isolated payment by a debtor will frequently restart the running of the statute of limitations. According to the commentators, making lenders track the expiration of the statute of limitations for reporting purposes would require special computer applications not needed for any other creditor function, require legal expertise in the collection department, and be very costly.

As a legal matter, commentators argued that the statute of limitations is an affirmative defense, and affects only judicial enforceability of the obligation. Most commentators indicated that collection activity routinely continues after the expiration of the statute of limitations. The temporary and proposed regulations list collection activity on the part of the creditor as a factor to be considered in determining whether debt has been discharged. Thus, even under the temporary and proposed regulations, expiration of the statute of limitations would rarely mark the date on which debt is considered discharged, because collection activity routinely continues after that date.

In response to these comments, the final regulations provide that expiration of the statute of limitations for collection of an indebtedness is an identifiable event for which a Form 1099–C is required to be filed only if, and at such time as, a debtor's affirmative defense of the expiration of the statute of limitations is upheld in a final judgment or decision of a judicial proceeding, and the period for appealing the judgment or decision has expired.

C. Other Discharges by Operation of Law

As stated above, the temporary and proposed regulations provide that an identifiable event includes a cancellation or extinguishment by operation of law that renders a debt unenforceable (such as the expiration of the statute of limitations for collection of the indebtedness). The temporary and proposed regulations do not specify all of the circumstances requiring reporting under this identifiable event.

In order to further the goal of providing an exclusive list of reporting events, the final regulations specify those discharges occurring by operation of law that are required to be reported under section 6050P. In addition to the statute of limitations identifiable event previously discussed, the events relating to operation of law that must be reported are (i) a cancellation or extinguishment of an indebtedness that renders a debt unenforceable in a receivership, foreclosure, or similar proceeding in a federal or State court, as described in section 368(a)(3)(A)(ii); (ii) a cancellation or extinguishment of an indebtedness upon the expiration of a statutory period for filing a claim or commencing a deficiency judgment proceeding; (iii) a cancellation or extinguishment of an indebtedness that renders a debt unenforceable pursuant to a probate or similar proceeding; and (iv) a cancellation or extinguishment of an indebtedness pursuant to an election of foreclosure remedies by a creditor that statutorily extinguishes or bars the creditor's right to pursue collection of the indebtedness. This final event relating to an election of foreclosure remedies will require reporting only where a mortgage lender or holder is barred by local law from pursuing a deficiency judgment or note collection proceeding following exercise of a power of sale contained in a mortgage or deed of trust.

A discharge of indebtedness occurring by operation of law not enumerated above is not required to be reported under the final regulations.

D. Collection Activity

Commentators indicated that the temporary and proposed regulations were unclear regarding the effect of continuing collection activity on the requirement to report under section 6050P. The temporary and proposed regulations provide that collection activity is one of the facts and circumstances to be taken into account in determining whether a discharge of indebtedness has occurred. The commentators argued that the final regulations should clarify that reporting is not required prior to termination of collection efforts on the part of the creditor.

In response to these comments, the final regulations address the effect of collection efforts on the requirement to report under section 6050P. Under the final regulations, an identifiable event occurs and reporting is required upon a decision by the creditor, or the application of a defined policy of the creditor, to discontinue collection activity and discharge indebtedness. For this purpose, a defined policy may be either a written policy or a creditor's established business practice.

Additionally, under the final regulations, there is a rebuttable presumption that an identifiable event has occurred during a calendar year if a creditor has not received a payment on an indebtedness at any time during a 36-month testing period ending at the close of the year. This presumption is rebutted by the creditor if the creditor (or a third-party collection agency on behalf of the creditor) has engaged in significant, bona fide collection activity at any time during the 12-month period ending at the close of the calendar year, or if facts and circumstances existing as of January 31 of the calendar year following expiration of the 36-month testing period indicate that the indebtedness has not been discharged. Under the final regulations, significant, bona fide collection activity does not include merely nominal or ministerial collection action, such as an automated mailing. Further, facts and circumstances indicating that an indebtedness has not been discharged include the existence of a lien relating to the indebtedness against the debtor (to the extent of the value of the security), or the sale or packaging for sale of the indebtedness by the creditor.

E. Other Reportable Discharges

Under the temporary and proposed regulations, an identifiable event includes an agreement between the applicable financial entity and the debtor to discharge an indebtedness, provided that the last event necessary to effectuate the discharge has occurred. The final regulations retain this reporting requirement, restating that an identifiable event includes a discharge of indebtedness pursuant to an agreement between an applicable financial entity and a debtor to discharge indebtedness at less than full consideration. As under the temporary regulations, this identifiable event will not occur until the last event necessary to effectuate the discharge has occurred.

The final regulations also provide that a discharge of indebtedness occurring before the date on which an identifiable event occurs may, at the creditor's discretion, be reported under section 6050P.

2. Definition of Indebtedness

Commentators objected to the broad definition of indebtedness provided in the temporary and proposed regulations. The temporary and proposed regulations provide that, for purposes of reporting the amount of indebtedness discharged, an indebtedness is any amount owed to the creditor including principal, interest, penalties, fees, administrative costs, and fines, to the extent the amount constitutes an indebtedness under section 61(a)(12). Commentators argued that this definition is overly broad and should be amended to include principal only (or the primary indebtedness in the case of a non-lending transaction). In response to these comments, the final regulations provide certain exceptions relating to the reporting of amounts other than stated principal.

A. Reporting of Interest

Commentators offered two main objections to the reporting of interest. First, commentators stated that reporting interest was burdensome because interest is not tracked by lenders once indebtedness is written off or placed on nonaccrual status on the lender's books. Second, commentators suggested that reporting of interest would be of marginal benefit to the IRS because in many cases discharged interest may be excluded from gross income under sections 108(e)(2) and 111.

In response to these comments, and in an effort to reduce the information reporting burden on affected filers, the final regulations do not require the reporting of amounts of discharged interest (whether or not arising in connection with a lending transaction), despite the fact that some discharged interest will give rise to gross income. However, at the option of the applicable financial entity, interest may be included in the amount reported. Additionally, as provided in Notice 94–73, in the case of a discharge of indebtedness before December 22, 1996, no penalties will be imposed for failure to report an amount other than principal in the case of indebtedness arising in connection with a lending transaction.

B. Penalties, Fees, Administrative Costs, and Fines

Commentators also argued that, like interest, penalties, fees, administrative costs, and fines are not tracked by lenders once an indebtedness is written off on the books of the lender. Thus, they contended, tracking these amounts would require additional computer programming and recordkeeping, and would be very costly. With respect to lending transactions, the IRS and Treasury have concluded that the benefits that would be derived from requiring the reporting of penalties, fees, administrative costs, and fines are outweighed by the burden associated with the requirement. Accordingly, the final regulations provide that, in the case of a lending transaction, only discharged amounts of stated principal are required to be reported. In the case of non-lending transactions, the amount owed, such as a fee, fine, or penalty, is reportable if discharged.

3. Reporting for Multiple Debtors

Commentators recommended that the multiple debtor rules of the temporary and proposed regulations be amended so that reporting is required only with respect to the primary or first-named debtor on the lender's account. The rationale for this approach is that, in general, lenders track loans involving multiple debtors only by the name of the borrower of record, and thus, the information required to be reported under section 6050P (e.g., the name, address, and taxpayer identification number (TIN)) for debtors other than the primary debtor is generally not available to lenders. In addition, the commentators pointed out that most other information return regulations require reporting only with respect to a single taxpayer (e.g., § 1.6050H–1 requires reporting only with respect to one designated interest payor even if multiple debtors are liable on a mortgage). Finally, these commentators stated that the majority of multiple debtor situations involve a husband and wife who will likely file a joint return, and therefore, requiring reporting for each debtor is not necessary.

The IRS and Treasury believe, however, that requiring reporting for multiple debtors is consistent with section 6050P(a)(1), which provides that the reporting of a name, address, and TIN is required for *each person whose indebtedness was discharged*. Further, while reporting with respect to only one taxpayer is required under many information reporting sections of the Code, section 6050J, which is comparable to section 6050P in that it relates to the reporting of acquisitions and abandonments of property securing indebtedness, requires reporting for each person who is a borrower with respect to the secured indebtedness. Moreover, in Notice 94–73, the IRS addressed the concerns of commentators by providing that no penalties would be imposed for failure to report a discharge of indebtedness for other than the primary (or first-named) debtor in the case of indebtedness incurred before January 1, 1995, thus allowing creditors time to begin collecting the necessary information for all debtors in the case of indebtedness incurred after December 31, 1994. The final regulations incorporate this relief.

In order to reduce the information reporting burden on applicable financial entities, the final regulations contain two exceptions relating to multiple debtor reporting. In the case of indebtedness of less than $10,000 incurred on or after January 1, 1995, that involves multiple debtors, reporting is required only for the primary (or first-named) debtor. Additionally, to avoid duplication, the final regulations provide a husband/wife exception to the requirement for reporting in the case of multiple debtors. Under this exception, only one Form 1099–C must be prepared if the creditor knows, or has reason to know, that the co-obligors were husband and wife living at the same address when the indebtedness was incurred, and does not know or have reason to know that such circumstances have changed at the time of the discharge. These two exceptions apply to discharges of indebtedness after December 31, 1994.

The final regulations retain the rule of the temporary and proposed regulations relating to the amount to be reported with respect to each joint and several debtor.

4. Multiple Creditors/Lending Pools/REMICs

Commentators indicated that further guidance should be provided in the final regulations regarding section

6050P reporting obligations in the case of participation loans, lending pools, and other multiple-creditor situations. In response to these comments, the final regulations provide a general rule that, in the case of an indebtedness owned (or treated as owned for federal income tax purposes) by more than one creditor, each creditor that is an applicable financial entity must comply with the reporting requirements of this section with respect to any discharge of indebtedness of $600 or more allocable to such creditor. A creditor will be considered to have complied with the requirements of this section if a lead bank or other designee of the creditor complies on its behalf.

Comments were received advocating an exception from reporting for discharges of certain widely-owned securitized indebtedness. The commentators reasoned that the owners of widely-held securitized indebtedness will generally have no knowledge regarding when a discharge occurs, or the amount of discharged debt allocable to each owner. Further, commentators suggested that it is likely that a significant portion of such securitized indebtedness may be owned by persons that are not applicable financial entities and, therefore, are not subject to section 6050P.

The IRS and Treasury believe, however, that it would be inconsistent with the purpose of section 6050P to provide a general exception from reporting for such securitized indebtedness. Section 6050P is intended to increase the likelihood that a debtor will comply with the tax laws relating to discharge of indebtedness by requiring the reporting of that event to the IRS. The fact that indebtedness has been securitized and sold to numerous owners generally does not affect the tax consequences to the debtor upon a discharge of that indebtedness. Thus, the IRS and Treasury do not believe that a discharge of indebtedness should be excepted from section 6050P reporting simply because that indebtedness was part of a securitization arrangement.

Commentators also argued that the discharge of an indebtedness held by a real estate mortgage investment conduit (REMIC) should not be required to be reported under section 6050P. Because a REMIC is not an applicable financial entity, commentators contended that section 6050P should not apply upon a discharge of indebtedness held by a REMIC.

However, section 860F(e) provides that, for purposes of subtitle F of the Code (Procedure and Administration, including section 6050P), a REMIC is treated as a partnership and holders of residual interests in the REMIC are treated as partners. Under the final regulations, indebtedness owned by a partnership is treated as owned by the partners. Thus, arguably a discharge of REMIC indebtedness should be treated similar to partnership indebtedness and thus should be reported to the extent the residual owners of the REMIC are applicable financial entities.

Because the IRS and Treasury believe that further study of these issues is warranted, the final regulations reserve on the application of section 6050P to discharges of indebtedness held (1) in a pass-through securitized indebtedness arrangement, or (2) by a REMIC. For this purpose, a pass-through securitized indebtedness arrangement is any arrangement whereby one or more debt obligations are pooled and held for twenty or more persons whose interests in the debt obligations are undivided co-ownership interests that are freely transferrable. Co-ownership interests that are actively traded personal property (as defined in § 1.1092(d)–1) are presumed to be freely transferrable and held by twenty or more persons. Pending issuance of further guidance, no penalties will be imposed for failure to report a discharge of indebtedness held under these circumstances. This relief from penalties does not extend to arrangements formed for a principal purpose of avoiding the reporting requirements of this section. The IRS and Treasury welcome comments regarding compliance with section 6050P in the case of pass-through securitized indebtedness arrangements and REMICs.

5. Coordination of Form 1099–A and Form 1099–C

The legislative history to section 6050P indicates that Congress intended that the IRS and Treasury coordinate reporting under section 6050P with the reporting required under section 6050J. Section 6050J requires information relating to foreclosures and abandonments of secured property to be reported on Form 1099–A.

The final regulations provide that if, in the same calendar year, a discharge of indebtedness reportable under section 6050P occurs in connection with a foreclosure or abandonment of secured property reportable under section 6050J, it is not necessary to file both a Form 1099–A and a Form 1099–C for the same debtor. Under the final regulations, the filing requirements of section 6050J will be satisfied with respect to a debtor if, in lieu of filing a Form 1099–A, a Form 1099–C is filed in accordance with the instructions for the filing of that form. This coordinated filing provision applies to discharges of indebtedness after December 31, 1994.

6. Direct or Indirect Subsidiary

Commentators requested that the final regulations include a definition of a direct or indirect subsidiary for purposes of section 6050P. Section 6050P(c)(1)(C) provides that the definition of applicable financial entity includes a direct or indirect subsidiary of an entity described in section 6050P(c)(1)(A). In response to these comments, the final regulations provide that, for purposes of section 6050P(c)(1)(C), the term direct or indirect subsidiary means a corporation in a chain of corporations beginning with the entity described in section 6050P(c)(1)(A), if at least 50 percent of the total combined voting power of all classes of stock entitled to vote, or at least 50 percent of the total value of all classes of stock, of such corporation is directly owned by the entity described in section 6050P(c)(1)(A), or by one or more other corporations in the chain.

7. Other Exceptions From Reporting

The IRS and Treasury received numerous comments advocating that the final regulations include exceptions from reporting with respect to certain discharges of indebtedness.

A. Reporting for Non-U.S. Debtors

Comments were received relating to the inclusion in final regulations of an exception for reporting discharges of indebtedness of certain foreign debtors. These comments noted that, in some cases, discharges of indebtedness that involve such debtors will not result in income that is taxable in the United States.

On the other hand, there clearly are cases in which a foreign person may be subject to U.S. tax with respect to a discharge of indebtedness. Because there is no clear guidance on which financial institutions may rely for purposes of determining whether a foreign person would be subject to U.S. tax with respect to cancellation of indebtedness income, it is not appropriate to provide a general exception for foreign persons. However, the IRS and Treasury are continuing to study the issue of whether reporting is necessary in the case of foreign debtors whose debt is discharged by foreign branches of U.S. financial institutions. Accordingly, pending the issuance of further guidance, no penalties will be imposed if an applicable financial entity fails to report a discharge of indebtedness of a foreign debtor by a foreign branch of the entity.

B. Reporting Where Debt Is Acquired by Related Persons

Comments were received requesting that the final regulations clarify whether reporting is required in circumstances in which there is a deemed discharge of indebtedness pursuant to the regulations under section 108(e)(4). Section 108(e)(4) and implementing regulations (see § 1.108–2) provide that the acquisition of outstanding indebtedness by a person related to the debtor from a person who is not related to the debtor is treated as if the debtor had acquired the indebtedness and may result in a realization by the debtor of income from discharge of indebtedness. Commentators indicated that applicable financial entities often will be unaware that the conditions of section 108(e)(4) have been satisfied and that the debtor's indebtedness is considered to have been discharged. In response to these comments, the final regulations provide that no reporting is required under section 6050P in the case of a discharge of indebtedness under section 108(e)(4) unless the disposition of the indebtedness by the creditor was made with a view to avoiding the reporting requirements of this section.

C. Reporting for Guarantors of Indebtedness

Commentators also requested guidance on whether, and under what circumstances, a Form 1099–C must be filed for a guarantor of an indebtedness when the underlying indebtedness is discharged. The final regulations provide that, in the case of guaranteed debt, a guarantor is not treated as a debtor for purposes of reporting under section 6050P. Thus, reporting for guarantors is not required.

D. Reporting for Non-lending Transactions

A number of comments were received advocating an exception in the final regulations for discharges of indebtedness where the indebtedness is incurred in a non-lending transaction. Advocates of this exception argued that the primary reason applicable financial entities, and not all trade or businesses, were made subject to section 6050P is that financial entities have extensive involvement in lending transactions where the majority of discharges of indebtedness will occur. Commentators argued that when an applicable financial entity is a creditor as a result of a non-lending transaction, it should be treated in the same manner as a non-applicable financial entity with respect to that indebtedness, and not be subject to section 6050P if a discharge occurs.

Neither the language of section 6050P nor its legislative history provides any indication that Congress intended for discharges of non-lending indebtedness to be excluded from reporting. Moreover, it makes no difference in determining whether a debtor has income under section 61(a)(12) that the indebtedness was incurred in a non-lending transaction. Accordingly, the final regulations do not adopt this suggestion.

E. Reporting of Disputed Liabilities

The temporary and proposed regulations do not address the reporting requirements under section 6050P in the case of the settlement of a disputed liability. The preamble to the temporary regulations solicited public comment relating to this issue. Several commentators urged that the final regulations include an exception from reporting for settlements of bona fide disputed liabilities.

The determination regarding whether the settlement of a disputed liability results in discharge of indebtedness income under section 61(a)(12) is inherently factual. Thus, it continues to be the position of the IRS and Treasury that this issue should be addressed on a case-by-case basis, rather than by these final regulations. Therefore, the final regulations do not provide an exception from reporting for disputed liabilities. Instead, resolution of the question of whether there may have been a discharge of indebtedness reportable under this section remains the obligation of the applicable financial entity. The IRS and Treasury recognize that a creditor and debtor may take inconsistent positions on this issue. The IRS does not intend to impose penalties for good faith failures to report settlements that constitute discharges of indebtedness.

8. Miscellaneous Comments

Comments were also received relating to whether applicable financial entities have any information reporting obligations in instances where payments are received on previously discharged debts. In response to those inquiries, the final regulations clarify that no additional reporting or Form 1099–C correction is required if a creditor receives a payment of all or a portion of a discharged debt that has been reported to the IRS for a prior calendar year.

Comments were received respecting the TIN solicitation requirements of the temporary and proposed regulations. In response to those comments, the final regulations provide that a reasonable effort (rather than all reasonable efforts) must be made to obtain the correct name/TIN combination of the person whose indebtedness is discharged.

The IRS and Treasury received a number of other comments in addition to those summarized above. Some of the suggestions contained in the comments have been adopted in the final regulations. Other suggested changes were not adopted primarily because those suggestions were inconsistent with the purpose of the statute and its legislative history.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Sharon L. Hall and Michael F. Schmit, Office of the Assistant Chief Counsel (Income Tax and Accounting), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for § 1.6050P–1T and adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805. * * *

Section 1.6050P–1 also issued under 26 U.S.C. 6050P. * * *

Par. 2. Sections 1.6050P–0 and 1.6050P–1 are added to read as follows:

§ 1.6050P–0 Table of contents.

This section lists the major captions that appear in § 1.6050P–1.

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(2) Earlier application.

§ 1.6050P–1 Information reporting for discharges of indebtedness by certain financial entities.

(a) *Reporting requirement*—(1) *In general.* Except as provided in paragraph (d) of this section, any applicable financial entity (as defined in section 6050P(c)(1)) that discharges an indebtedness of any person (within the meaning of section 7701(a)(1)) of at least $600 during a calendar year must file an information return on Form 1099–C with the Internal Revenue Service. Solely for purposes of the reporting requirements of section 6050P and this section, a discharge of indebtedness is deemed to have occurred, except as provided in paragraph (b)(3) of this section, if and only if there has occurred an identifiable event described in paragraph (b)(2) of this section, whether or not an actual discharge of indebtedness has occurred on or before the date on which the identifiable event has occurred. The return must include the following information—

(i) The name, address, and taxpayer identification number (TIN), as defined in section 7701(a)(41), of each person for which there was an identifiable event during the calendar year;

(ii) The date on which the identifiable event occurred, as described in paragraph (b) of this section;

(iii) The amount of indebtedness discharged, as described in paragraph (c) of this section;

(iv) An indication whether the identifiable event was a discharge of indebtedness in a bankruptcy, if known; and

(v) Any other information required by Form 1099–C or its instructions, or current revenue procedures.

(2) *No aggregation.* For purposes of reporting under this section, multiple discharges of indebtedness of less than $600 are not required to be aggregated unless such separate discharges are pursuant to a plan to evade the reporting requirements of this section.

(3) *Amounts not includible in income.* Except as otherwise provided in this section, discharged indebtedness must be reported regardless of whether the debtor is subject to tax on the discharged debt under sections 61 and 108 or otherwise by applicable law.

(4) *Time and place for reporting*—(i) *In general.* Except as provided in paragraph (a)(4)(ii) of this section, returns required by this section must be filed with the Internal Revenue Service office designated in the instructions for Form 1099–C on or before February 28 of the year following the calendar year in which the identifiable event occurs.

(ii) *Indebtedness discharged in bankruptcy.* Indebtedness discharged in bankruptcy that is required to be reported under this section must be reported for the later of the calendar year in which the amount of discharged indebtedness first becomes ascertainable, or the calendar year in which the identifiable event occurs.

(b) *Date of discharge*—(1) *In general.* Solely for purposes of this section, except as provided in paragraph (b)(3) of this section, indebtedness is discharged on the date of the occurrence of an identifiable event specified in paragraph (b)(2) of this section.

(2) *Identifiable events*—(i) *In general.* An identifiable event is—

(A) A discharge of indebtedness under title 11 of the United States Code (bankruptcy);

(B) A cancellation or extinguishment of an indebtedness that renders a debt unenforceable in a receivership, foreclosure, or similar proceeding in a federal or State court, as described in section 368(a)(3)(A)(ii) (other than a discharge described in paragraph (b)(2)(i)(A) of this section);

(C) A cancellation or extinguishment of an indebtedness upon the expiration of the statute of limitations for collection of an indebtedness, subject to the limitations described in paragraph (b)(2)(ii) of this section, or upon the expiration of a statutory period for filing a claim or commencing a deficiency judgment proceeding;

(D) A cancellation or extinguishment of an indebtedness pursuant to an election of foreclosure remedies by a creditor that statutorily extinguishes or bars the creditor's right to pursue collection of the indebtedness;

(E) A cancellation or extinguishment of an indebtedness that renders a debt unenforceable pursuant to a probate or similar proceeding;

(F) A discharge of indebtedness pursuant to an agreement between an applicable financial entity and a debtor to discharge indebtedness at less than full consideration;

(G) A discharge of indebtedness pursuant to a decision by the creditor, or the application of a defined policy of the creditor, to discontinue collection activity and discharge debt; or

(H) The expiration of the non-payment testing period, as described in paragraph (b)(2)(iv) of this section.

(ii) *Statute of limitations.* In the case of an expiration of the statute of limitations for collection of an indebtedness, an identifiable event occurs under paragraph (b)(2)(i)(C) of this section only if, and at such time as, a debtor's affirmative statute of limitations defense is upheld in a final judgment or decision of a judicial proceeding, and the period for

appealing the judgment or decision has expired.

(iii) *Decision to discontinue collection activity; creditor's defined policy*. For purposes of the identifiable event described in paragraph (b)(2)(i)(G) of this section, a creditor's defined policy includes both a written policy of the creditor and the creditor's established business practice. Thus, for example, a creditor's established practice to discontinue collection activity and abandon debts upon expiration of a particular non-payment period is considered a defined policy for purposes of paragraph (b)(2)(i)(G) of this section.

(iv) *Expiration of non-payment testing period*. There is a rebuttable presumption that an identifiable event under paragraph (b)(2)(i)(H) of this section has occurred during a calendar year if a creditor has not received a payment on an indebtedness at any time during a testing period (as defined in this paragraph (b)(2)(iv)) ending at the close of the year. The testing period is a 36-month period increased by the number of calendar months during all or part of which the creditor was precluded from engaging in collection activity by a stay in bankruptcy or similar bar under state or local law. The presumption that an identifiable event has occurred may be rebutted by the creditor if the creditor (or a third-party collection agency on behalf of the creditor) has engaged in significant, bona fide collection activity at any time during the 12-month period ending at the close of the calendar year, or if facts and circumstances existing as of January 31 of the calendar year following expiration of the 36-month period indicate that the indebtedness has not been discharged. For purposes of this paragraph (b)(2)(iv)—

(A) Significant, bona fide collection activity does not include merely nominal or ministerial collection action, such as an automated mailing;

(B) Facts and circumstances indicating that an indebtedness has not been discharged include the existence of a lien relating to the indebtedness against the debtor (to the extent of the value of the security), or the sale or packaging for sale of the indebtedness by the creditor; and

(C) In no event will an identifiable event described in paragraph (b)(2)(i)(H) of this section occur prior to December 31, 1997.

(3) *Permitted reporting*. If a discharge of indebtedness occurs before the date on which an identifiable event occurs, the discharge may, at the creditor's discretion, be reported under this section.

(c) *Indebtedness*. For purposes of this section, indebtedness means any amount owed to an applicable financial entity, including stated principal, fees, stated interest, penalties, administrative costs and fines. The amount of indebtedness discharged may represent all, or only a part, of the total amount owed to the applicable financial entity.

(d) *Exceptions from reporting requirement*—(1) *Certain bankruptcy discharges*—(i) *In general*. Reporting is required under this section in the case of a discharge of indebtedness in bankruptcy only if the creditor knows from information included in the reporting entity's books and records pertaining to the indebtedness that the debt was incurred for business or investment purposes as defined in paragraph (d)(1)(ii) of this section.

(ii) *Business or investment debt*. Indebtedness is considered incurred for business purposes if it is incurred in connection with the conduct of any trade or business other than the trade or business of performing services as an employee. Indebtedness is considered incurred for investment purposes if it is incurred to purchase property held for investment, as defined in section 163(d)(5).

(2) *Interest*. The discharge of an amount of indebtedness that is interest is not required to be reported under this section.

(3) *Non-principal amounts in lending transactions*. In the case of a lending transaction, the discharge of an amount other than stated principal is not required to be reported under this section. For this purpose, a lending transaction is any transaction in which a lender loans money to, or makes advances on behalf of, a borrower (including revolving credits and lines of credit).

(4) *Indebtedness of foreign debtors held by foreign branches of U.S. financial institutions*—(i) *Reporting requirements*. [Reserved]

(ii) *Definition*. An indebtedness held by a foreign branch of a U.S. financial institution is described in this paragraph (d)(4) only if—

(A) The financial institution is engaged through a branch or office in the active conduct of a banking or similar business outside the United States;

(B) The branch or office is a permanent place of business that is regularly maintained, occupied, and used to carry on a banking or similar financial business;

(C) The business is conducted by at least one employee of the branch or office who is regularly in attendance at such place of business during normal working hours;

(D) The indebtedness is extended outside of the United States by the branch or office in connection with that trade or business; and

(E) The financial institution does not know or have reason to know that the debtor is a United States person.

(5) *Acquisition of indebtedness by related party*. No reporting is required under this section in the case of a deemed discharge of indebtedness under section 108(e)(4) (relating to the acquisition of an indebtedness by a person related to the debtor), unless the disposition of the indebtedness by the creditor was made with a view to avoiding the reporting requirements of this section.

(6) *Releases*. The release of a co-obligor is not required to be reported under this section if the remaining debtors remain liable for the full amount of any unpaid indebtedness.

(7) *Guarantors and sureties*. Solely for purposes of the reporting requirements of this section, a guarantor is not a debtor. Thus, in the case of guaranteed indebtedness, reporting under this section is not required with respect to a guarantor, whether or not there has been a default and demand for payment made upon the guarantor.

(e) *Additional rules*—(1) *Multiple debtors*—(i) *In general*. In the case of indebtedness of $10,000 or more incurred on or after January 1, 1995, that involves more than one debtor, a reporting entity is subject to the requirements of paragraph (a) of this section for each debtor discharged from such indebtedness. In the case of indebtedness incurred prior to January 1, 1995, and indebtedness of less than $10,000 incurred on or after January 1, 1995, involving multiple debtors, reporting under this section is required only with respect to the primary (or first-named) debtor. Additionally, only one return of information is required under this section if the reporting entity knows, or has reason to know, that co-obligors were husband and wife living at the same address when an indebtedness was incurred, and does not know or have reason to know that such circumstances have changed at the date of a discharge of the indebtedness. This paragraph (e)(1) applies to discharges of indebtedness after December 31, 1994.

(ii) *Amount to be reported*. In the case of multiple debtors jointly and severally liable on an indebtedness, the amount of discharged indebtedness required to be reported under this section with respect to each debtor is the total amount of indebtedness discharged. For this

purpose, multiple debtors are presumed to be jointly and severally liable on an indebtedness in the absence of clear and convincing evidence to the contrary.

(2) *Multiple creditors*—(i) *In general.* Except as otherwise provided in this paragraph (e)(2), if indebtedness is owned (or treated as owned for federal income tax purposes) by more than one creditor, each creditor that is an applicable financial entity must comply with the reporting requirements of this section with respect to any discharge of indebtedness of $600 or more allocable to such creditor. A creditor will be considered to have complied with the requirements of this section if a lead bank, fund administrator, or other designee of the creditor complies on its behalf in any reasonable manner, such as by filing a single return reporting the aggregate amount of indebtedness discharged, or by filing a return with respect to the portion of the discharged indebtedness allocable to the creditor. For purposes of this paragraph (e)(2)(i), any reasonable method may be used to determine the portion of discharged indebtedness allocable to each creditor.

(ii) *Partnerships.* For purposes of paragraph (e)(2)(i) of this section, indebtedness owned by a partnership is treated as owned by the partners.

(iii) *Pass-through securitized indebtedness arrangement*—(A) *Reporting requirements.* [Reserved]

(B) *Definition.* For purposes of this paragraph (e)(2)(iii), a pass-through securitized indebtedness arrangement is any arrangement whereby one or more debt obligations are pooled and held for twenty or more persons whose interests in the debt obligations are undivided co-ownership interests that are freely transferrable. Co-ownership interests that are actively traded personal property (as defined in § 1.1092(d)–1) are presumed to be freely transferrable and held by twenty or more persons.

(iv) *REMICs.* [Reserved]

(3) *Coordination with reporting under section 6050J.* If, in the same calendar year, a discharge of indebtedness reportable under section 6050P occurs in connection with a transaction also reportable under section 6050J (relating to foreclosures and abandonments of secured property), an applicable financial entity need not file both a Form 1099–A and a Form 1099–C with respect to the same debtor. The filing requirements of section 6050J will be satisfied with respect to a borrower if, in lieu of filing Form 1099–A, a Form 1099–C is filed in accordance with the instructions for the filing of that form. This paragraph (e)(3) applies to discharges of indebtedness after December 31, 1994.

(4) *Direct or indirect subsidiary.* For purposes of section 6050P(c)(1)(C), the term direct or indirect subsidiary means a corporation in a chain of corporations beginning with an entity described in section 6050P(c)(1)(A), if at least 50 percent of the total combined voting power of all classes of stock entitled to vote, or at least 50 percent of the total value of all classes of stock, of such corporation is directly owned by the entity described in section 6050P(c)(1)(A), or by one or more other corporations in the chain.

(5) *Use of magnetic media.* Any return required under this section must be filed on magnetic media to the extent required by section 6011(e) and the regulations thereunder. A failure to file on magnetic media when required constitutes a failure to file an information return under section 6721. Any person not required by section 6011(e) to file returns on magnetic media may request permission to do so under applicable regulations and revenue procedures.

(6) *TIN solicitation requirement*—(i) *In general.* For purposes of reporting under this section, a reasonable effort must be made to obtain the correct name/taxpayer identification number (TIN) combination of a person whose indebtedness is discharged. A TIN obtained at the time an indebtedness is incurred satisfies the requirement of this section, unless the entity required to file knows that such TIN is incorrect. If the TIN is not obtained prior to the occurrence of an identifiable event, it must be requested of the debtor for purposes of satisfying the requirement of this paragraph (e)(6).

(ii) *Manner of soliciting TIN.* Solicitations made in the manner described in § 301.6724–1(e)(1)(i) and (2) of this chapter will be deemed to have satisfied the reasonable effort requirement set forth in paragraph (e)(6)(i) of this section. A TIN solicitation made after the occurrence of an identifiable event must clearly notify the debtor that the Internal Revenue Service requires the debtor to furnish its TIN, and that failure to furnish such TIN may subject the debtor to a $50 penalty imposed by the Internal Revenue Service. A TIN provided under this section is not required to be certified under penalties of perjury.

(7) *Recordkeeping requirements.* Any applicable financial entity required to file a return with the Internal Revenue Service under this section must also retain a copy of the return, or have the ability to reconstruct the data required to be included on the return under paragraph (a)(1) of this section, for at least four years from the date such return is required to be filed under paragraph (a)(4) of this section.

(8) *No multiple reporting.* If discharged indebtedness is reported under this section, no further reporting under this section is required for the amount so reported, notwithstanding that a subsequent identifiable event occurs with respect to the same amount. Further, no additional reporting or Form 1099–C correction is required if a creditor receives a payment of all or a portion of a discharged indebtedness reported under this section for a prior calendar year.

(f) *Requirement to furnish statement*—(1) *In general.* Any applicable financial entity required to file a return under this section must furnish to each person whose name is shown on such return a written statement that includes the following information—

(i) The information required by paragraph (a)(1) of this section;

(ii) The name, address, and TIN of the applicable financial entity required to file a return under paragraph (a) of this section;

(iii) A legend identifying the statement as important tax information that is being furnished to the Internal Revenue Service; and

(iv) Any other information required by Form 1099–C or its instructions, or current revenue procedures.

(2) *Furnishing copy of Form 1099–C.* The requirement to provide a statement to the debtor will be satisfied if the applicable financial entity furnishes copy B of the Form 1099–C or a substitute statement that complies with the requirements of the current revenue procedure for substitute Forms 1099.

(3) *Time and place for furnishing statement.* The statement required by this paragraph (f) must be furnished to the debtor on or before January 31 of the year following the calendar year in which the identifiable event occurs. The statement will be considered furnished to the debtor if it is mailed to the debtor's last known address.

(g) *Penalties.* For penalties for failure to comply with the requirements of this section, see sections 6721 through 6724.

(h) *Effective dates*—(1) *In general.* The rules in this section apply to discharges of indebtedness after December 21, 1996, except paragraphs (e)(1) and (e)(3) of this section, which apply to discharges of indebtedness after December 31, 1994.

(2) *Earlier application.* Notwithstanding the provisions of paragraph (h)(1) of this section, an applicable financial entity may, at its discretion, apply any of the provisions of this section to any discharge of indebtedness occurring on or after

January 1, 1996, and before December 22, 1996.

§§ 1.6050P–0T and 1.6050P–1T [Removed]

Par. 3. Sections 1.6050P–0T and 1.6050P–1T are removed.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 5. In § 602.101, paragraph (c) is amended by removing the entry for 1.6050P–1T and adding an entry in numerical order in the table to read ''1.6050P–1.....1545–1419''.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

Approved: December 12, 1995.

Leslie Samuels,

Assistant Secretary of the Treasury.

[FR Doc. 96–131 Filed 1–3–96; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 69

[DoD Instruction 1342.jj]

School Boards for Department of Defense Domestic Dependent Elementary and Secondary Schools

AGENCY: Office of the Secretary, DoD.

ACTION: Interim final rule.

SUMMARY: This interim final rule provides guidance to the Department of Defense (DoD) Domestic Dependent Elementary and Secondary Schools (DDESS) implementing the National Defense Authorization Act in Fiscal Year 1995, which provides for elected School Boards in DoD DDESS. Pursuant to this legislation, school boards in DoD DDESS may participate in the development and oversight of fiscal, personnel, and educational policies, procedures, and programs for these schools. This interim final rule provides guidance outlining the responsibilities, operating procedures, composition, electorate and election procedures for the DoD DDESS school boards.

DATES: This part is effective January 4, 1996. Written comments on this interim final rule must be received by March 4, 1996.

ADDRESSES: Forward comments to the Office of the Director, DoD Domestic Dependent Elementary and Secondary Schools, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

FOR FURTHER INFORMATION CONTACT: Dr. Hector O. Nevarez at (703) 696–4373/4354.

SUPPLEMENTARY INFORMATION: Because of the importance of providing guidance for elected school boards, this interim final rule is being issued. The public's comments are welcomed and will be carefully considered in the issuance of a final rule. The Office of Management and Budget has determined that this is a significant regulatory action. However, since this rule is not ''economically significant'' as defined in Executive Order 12866, the extensive analysis report is not required, and the rule complies with the requirements of the Executive Order. It has been determined that this rule is not subject to Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The primary effect of this rule will be a reduction in administrative costs and other burdens resulting from the simplification and clarification of policies. It has been determined that Public Law 109–13, ''Paperwork Reduction Act of 1995,'' (44 U.S.C. Chapter 35) does not apply because the rule does not impose any reporting or recordkeeping requirements on persons or entities outside the Federal Government.

List of Subjects in 32 CFR Part 69

Elementary and secondary education, Government employees, Military personnel.

Accordingly, Title 32, Chapter I, Subchapter C is amended to add Part 69 to read as follows:

PART 69—SCHOOL BOARDS FOR THE DEPARTMENT OF DEFENSE DOMESTIC DEPENDENT ELEMENTARY AND SECONDARY SCHOOLS

Sec.
69.1 Purpose.
69.2 Applicability and scope.
69.3 Definitions.
69.4 Policy.
69.5 Responsibilities.
69.6 Procedures.

Authority: 10 U.S.C. 2164.

§ 69.1 Purpose.

This part prescribes policies and procedures for the establishment and operation of elected School Boards for schools operated by the Department of Defense (DoD) under 10 U.S.C. 2164 and 32 CFR part 345.

§ 69.2 Applicability and scope.

This part applies to:

(a) The Office of the Secretary of Defense (OSD), the Military Departments, the Coast Guard when operating as a service of the Department of the Navy or by agreement between DoD and the Department of Transportation, the Chairman of the Joint Chiefs of Staff, the Unified and Specified Combatant Commands, the Inspector General of the Department of Defense, the Uniformed Services University of the Health Sciences, the Defense Agencies, and the DoD Field Activities.

(b) The schools (pre-kindergarten through grade 12) operated by the DoD under 10 U.S.C. 2164 and 32 CFR part 345 within the Continental United States, Alaska, Hawaii, Puerto Rico, Wake Island, Guam, American Samoa, the Northern Mariana Islands, and the Virgin Islands, known as DoD DDESS Arrangements.

(c) This part does not apply to elected school boards established under State or local law for DoD DDESS special arrangements.

§ 69.3 Definitions.

(a) *Arrangements.* Actions taken by the Secretary of Defense to provide a free public education to dependent children under 10 U.S.C. 2164 through DoD DDESS arrangements or DoD DDESS special arrangements:

(1) *DDESS arrangement.* A school operated by the Department of Defense under 10 U.S.C. 2164 and 32 CFR 345 to provide a free public education for eligible children.

(2) *DDESS special arrangement.* An agreement, under 10 U.S.C. 2164, between the Secretary of Defense, or designee, and a local public education agency whereby a school or a school system operated by the local public education agency provides educational services to eligible dependent children of U.S. military personnel and federally employed civilian personnel. Arrangements result in partial or total Federal funding to the local public education agency for the educational services provided.

(b) *Parent.* The biological father or mother of a child when parental rights have not been legally terminated; a person who, by order of a court of competent jurisdiction, has been declared the father or mother of a child by adoption; the legal guardian of a child; or a person in whose household a child resides, provided that such person stands in loco parentis to that child and contributes at least one-half of the child's support.

§ 69.4 Policy.

(a) Each DoD DDESS arrangement shall have an elected school board, established and operated in accordance with this part and other pertinent guidance.

(b) Because members of DoD DDESS elected school boards are not officers or employees of the United States appointed under the Appointments Clause of the United States Constitution (Art. II, Sec. 2, Cl. 2), they may not exercise discretionary governmental authority, such as the taking of personnel actions or the establishment of governmental policies. This Instruction clarifies the role of school boards in the development and oversight of fiscal, personnel, and educational policies, procedures, and programs for DoD DDESS arrangements, subject to these constitutional limitations.

(c) The DoD DDESS chain of command for matters relating to school arrangements operated under 10 U.S.C. 2164 and 32 CFR 345 shall be from the Director, DoD DDESS, to the Superintendent of each school arrangement. The Superintendent will inform the school board of all matters affecting the operation of the local school arrangement. Direct liaison among the school board, the Director, and the Superintendent is authorized for all matters pertaining to the local school arrangement.

§ 69.5 Responsibilities.

The Assistant Secretary of Defense for Force Management Policy (ASD(FMP)), under the Under Secretary of Defense for Personnel and Readiness, shall:

(a) Make the final decision on all formal appeals to directives and other guidance submitted by the school board or Superintendent.

(b) Ensure the Director, DoD DDESS, shall:

(1) Ensure the establishment of elected school boards in DoD DDESS arrangements.

(2) Monitor compliance by the Superintendents and school boards with applicable statutory and regulatory requirements, and this Instruction. In the event of suspected noncompliance, the Director, DoD DDESS, shall take appropriate action, which will include notification of the Superintendent and the school board president of the affected DoD DDESS arrangement.

(3) Determine when the actions of a school board conflict with an applicable statute, regulation, or other guidance or when there is a conflict in the views of the school board and the Superintendent. When such conflicts occur, the Director, DoD DDESS, shall assist the Superintendent and the school board in resolving them or direct that such actions be discontinued. Such disapprovals must be in writing to the school board and the Superintendent concerned and shall state the specific supporting reason or reasons.

(c) Ensure the school board for DoD DDESS arrangements shall:

(1) Participate in the development and oversight of fiscal, personnel, and educational policies, procedures, and programs for the DoD DDESS arrangement concerned, consistent with this part.

(2) Approve agendas and prepare minutes for school board meetings. A copy of the approved minutes of school board meetings shall be forwarded to the Director, DoD DDESS, within 10 working days after the date the minutes are approved.

(3) Provide to the Director, DoD DDESS, names of applicants for a vacancy in the Superintendent's position after a recruitment has been accomplished. The school board shall submit to the Director, DoD DDESS, a list of all applicants based on its review of the applications and interviews (either in person or telephonically) of the applicants. The list of applicants will be accompanied by the recommended choice of the school board. The Director will select the Superintendent and will submit written notice with justification to the school board if the recommendation of the school board is not followed.

(4) Prepare an annual written on-site review of the Superintendent's performance for consideration by the Director, DoD DDESS. The written review shall be based on critical elements recommended by the school board and Superintendent and approved by the Director, DoD DDESS. The school board's review will be an official attachment to the Superintendent's appraisal.

(5) Participate in the development of the school system's budget for submission to the Director, DoD DDESS, for his or her approval as endorsed by the school board; and participate in the oversight of the approved budget, in conjunction with the Superintendent, as appropriate for operation of the school arrangement.

(6) Invite the Superintendent or designee to attend all school board meetings.

(7) Provide counsel to the Superintendent on the operation of the school and the implementation of the approved budget.

(8) Channel communications with school employees to the DoD DDESS Superintendent. Refer all applications, complaints, and other communications, oral or written, to the DoD DDESS Arrangement Superintendent.

(9) Participate in the development of school policies, rules, and regulations, in conjunction with the Superintendent, and recommend which policies shall be reflected in the School Policy Manual. At a minimum, the Policy Manual, which shall be issued by the Superintendent, shall include the following:

(i) A statement of the school philosophy.

(ii) The role and responsibilities of school administrative and educational personnel.

(iii) Provisions for promulgation of an annual school calendar.

(iv) Provisions on instructional services, including policies for development and adoption of curriculum and textbooks.

(v) Regulations affecting students, including attendance, grading, promotion, retention, and graduation criteria, and the student code of rights, responsibilities, and conduct.

(vi) School policy on community relations and noninstructional services, including maintenance and custodial services, food services, and student transportation.

(vii) School policy and legal limits on financial operations, including accounting, disbursing, contracting, and procurement; personnel operations, including conditions of employment, and labor management regulations; and the processing of, and response to, complaints.

(viii) Procedures providing for new school board member orientation.

(ix) Any other matters determined by the school board and the superintendent to be necessary.

(10) Under 10 U.S.C. 2164(b)(4)(B), prepare and submit formal appeals to directives and other guidance that in the view of the school board adversely impact the operation of the school system either through the operation and management of DoD DDESS or a specific DoD DDESS arrangement. Written formal appeals with justification and supporting documentation shall be submitted by the school board or Superintendent to ASD(FMP). The ASD(FMP) shall make the final decision on all formal appeals. The Director, DoD DDESS, will provide the appealing body written review of the findings relating to the merits of the appeal. Formal appeals will be handled expeditiously by all parties to minimize any adverse impact on the operation of the DoD DDESS system.

(d) Ensure school board operating procedures are as follows:

(1) The school board shall operate from a written agenda at all meetings. Matters not placed on the agenda before the start of the meeting, but approved by a majority of the school board present, may be considered at the ongoing meeting and added to the agenda at that time.

(2) A majority of the total number of school board members authorized shall constitute a quorum.

(3) School board meetings shall be conducted a minimum of 9 times a year. The school board President or designee will provide school board members timely notice of all meetings. All regularly scheduled school board meetings will be open to the public. Executive session meetings may be closed under 10 U.S.C. 2164(d)(6).

(4) The school board shall not be bound in any way be any action or statement of an individual member or group of members of the board, except when such action or statement is approved by a majority of the school board members during a school board meeting.

(5) School board members are eligible for reimbursement for official travel in accordance with the DoD Joint Travel Regulations and guidance issued by the Director, DoD DDESS.

(6) School board members may be removed by the ASD(FMP), or designee (who may not be below the level of a Deputy Assistant Secretary of Defense) for dereliction of duty, malfeasance, or other grounds for cause shown. The school board concerned may recommend such removal with a two-thirds majority vote. Before a member may be removed, the member shall be afforded due process, to include written notification of the basis for the action, review of the evidence or documentation considered by the school board, and an opportunity to respond to the allegations.

§ 69.6 Procedures.

(a) *Composition of school board.* (1) The school board shall recommend to the Director, DoD DDESS, the number of elected school board voting members, which shall be no fewer than 3 and no more than 9, depending upon local needs. The members of the school board shall select by majority vote of the total number of school board members authorized at the beginning of each official school board term, one member to act as President and another to act as Vice President. The President and Vice President shall each serve for one year. The President shall preside over school board meetings and provide leadership for related activities and functions. The Vice President shall serve in the absence of the President. If the position of President is vacated for any reason, the Vice President shall be the President until the next regularly scheduled school board election. The resulting vacancy in the position of the Vice President shall be filled by the majority vote of all members of the incumbent board.

(2) The DoD DDESS Arrangement Superintendent, or designee, shall serve as a non-voting observer to all school board meetings. The Installation Commander, or designee, shall serve as a non-voting observer to the school board. The Installation Commander, or designee, shall convey command concerns to the school board and the Superintendent and keep the school board and the Superintendent informed of changes and other matters within the host installation that affect school expenditures or operations.

(3) The Antilles Consolidated School System (ACSS) School Board shall be made up of representatives of the Ramey School, the schools on the Roosevelt Roads Naval Station, and the schools on Fort Buchanan.

(4) School board members may not receive compensation for their service on the school board.

(5) Members of the school board may not have any financial interest in any company or organization doing business with the school system. Waivers to this restriction may be granted on a case-by-case basis by the Director, DoD DDESS, in coordination with the Office of General Counsel of the Department of Defense.

(b) *Electorate of the school board.* The electorate for each school board seat shall be composed of parents of the students attending the school. Each member of the electorate shall have one vote.

(c) *Election of school board members.* (1) To be elected as a member of the school board, an individual must be a resident of the military installation in which the DoD DDESS arrangement is located, and in the case of candidates for the ACSS School Board, satisfy the requirements in paragraph (a)(3), of this section. Personnel employed by a DoD DDESS arrangement may not serve as school board members.

(2) The term of office for elected members shall be 3 years, with a maximum of 2 consecutive terms. The beginning of the term shall coincide with local elections.

(3) When there is a sufficient number of school board vacancies that result in not having a quorum, which is defined as a majority of seats authorized, a special election shall be called by the DoD DDESS Arrangement Superintendent or designee. A special election is an election that is held between the regularly scheduled annual school board election. The nomination and election procedures for a special election shall be the same as those of regularly scheduled school board elections. Individuals elected by special election shall serve until the next regularly scheduled school board election. Vacancies may occur due to the resignation, death, removal for cause, transfer, or disenrollment of a school board member's child(ren) from the DoD DDESS arrangement.

(4) Regularly scheduled school board elections shall be conducted to coincide with local elections. Parents shall have adequate notice of the time and place of the election. The election shall be by secret ballot. All votes must be cast in person at the time and place of the election. The candidate(s) receiving the greatest number of votes shall be elected as school board member(s).

(5) Each candidate for school board membership must be nominated in writing by at least one member of the electorate to be represented by the candidate. Votes may be cast at the time of election for write-in candidates who have not filed a nomination petition if the write-in candidates otherwise are qualified to serve in the positions sought.

(6) The election process shall provide staggered terms for board members, e.g., on the last day of the last month of each year, the term for some board members will expire.

(7) The DoD DDESS Superintendent, in consultation with the school board, shall be responsible for developing the plans for nominating school board members and conducting the school board election and the special election process. The DoD DDESS Superintendent shall announce election results within 7 working days of the election.

Dated: December 27, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–67 Filed 1–3–96; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF TRANSPORTATION

48 CFR Parts 1215, 1252, and 1253

RIN 2105–AC–32

Revision of Department of Transportation Acquisition Regulation

AGENCY: Transportation.

ACTION: Final rule.

SUMMARY: This final rule completes the rulemaking necessary to issue revisions to the Transportation Acquisition Regulation (TAR) which were published in the November 3, 1995 Federal Register (60 FR 55801) as an interim final rule with a request for comments.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Elaine Wheeler, Office of Acquisition and Grant Management, M–61, 400 Seventh Street, SW., Washington, DC 20590: (202) 366–4272.

SUPPLEMENTARY INFORMATION:

A. Background

On November 3, 1995, revisions to the TAR were published in the Federal Register (60 FR 55801) as an interim final rule. Comments were solicited from interested parties, including the public and other Federal agencies and none were received. The interim final rule established a public comment period which closed on December 4, 1995. This notice finalizes that rulemaking.

B. Regulatory Analyses and Notices

The Department has determined that this action will not have a significant economic impact on a substantial number of small entities because the basic policies remain unchanged and only editorial corrections or administrative changes are being made.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the TAR do not impose additional record keeping information collection requirements, or additional collections of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects in 48 CFR Parts 1215, 1252, and 1253

Government procurement.

The interim final rule amending 12 CFR parts 1215, 1252, and 1253 which was published at 60 FR 55801 on November 3, 1995, is adopted as a final rule without change.

This final rule is issued under delegated authority under 49 CFR part 1.59(q). This authority has been redelegated to the Senior Procurement Executive.

Issued this 22nd day of December 1995, at Washington, DC.

David J. Litman,

Senior Procurement Executive.

[FR Doc. 96–105 Filed 1–3–96; 8:45 am]

BILLING CODE 4910–62–P

National Highway Traffic Safety Administration

49 CFR Parts 573, 576, and 577

[Docket No. 93–68; Notice 8]

RIN 2127–AG15

Defect and Noncompliance Reports; Record Retention; and Defect and Noncompliance Notification

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant in part and denial in part of petitions for reconsideration.

SUMMARY: In this document, the National Highway Traffic Safety Administration (NHTSA) is granting in part petitions for reconsideration of an April 5, 1995 final rule that, among other things, amended 49 CFR Parts 573, 576, and 577 (60 FR 17254). On reconsideration, the agency is amending provisions of that final rule concerning submission by manufacturers of schedules for recall campaigns, recordkeeping regarding recalls of leased vehicles, record retention period, and notification to lessees of recall campaigns. NHTSA has concluded that these changes will reduce manufacturer burdens without adversely affecting the agency's recall program.

DATES: Effective date: The amendments made by this final rule are effective on January 4, 1996.

Any petitions for reconsideration must be received by NHTSA no later than February 5, 1996.

ADDRESSES: Any petitions for reconsideration should refer to the docket and notice number of this notice and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590. (Docket Room hours are 9:30 a.m. to 4 p.m., Monday through Friday.)

FOR FURTHER INFORMATION CONTACT: Jonathan D. White, Office of Defects Investigation, National Highway Traffic Safety Administration, 400 Seventh Street SW., Room 5319, Washington, DC 20590; (202) 366–5227.

SUPPLEMENTARY INFORMATION:

Background

This final rule amends several sections of 49 CFR Parts 573, 576, and 577, as those parts were recently amended on April 5, 1995. These changes are being adopted by NHTSA in response to four petitions for reconsideration of the April 5 final rule that were submitted by the Association of International Automobile Manufacturers (AIAM), Chrysler Corporation (Chrysler), Ford Motor Company (Ford), and General Motors Corporation (GM).

In addition to seeking substantive changes, the petitions asked for an extension of the original May 5, 1995 effective date of the April 5 amendments on the ground that it would be difficult to achieve compliance by that date. On May 16, 1995, the agency published a notice in the Federal Register setting a new effective date of July 7, 1995 for the April 5 amendments. 60 FR 26002. Subsequently, on July 7, 1995, NHTSA suspended until further notice the effective date of four of the provisions for which the petitioners had sought reconsideration. 60 FR 35458. That notice also confirmed that all other provisions of the April 5 final rule would go into effect on July 7, 1995.

In September 1995, the Office of the Federal Register informed NHTSA that it could not leave the effective date of a regulation indefinite, as it had done in the July 7 Federal Register notice. Accordingly, NHTSA published another notice setting January 2, 1996, as the effective date of those four provisions, pending the decision on reconsideration. 60 FR 50476 (Sept. 29, 1995).

Based on its review of the petitions for reconsideration, NHTSA also decided that it would be advisable to obtain further information from the public on four of the issues raised in the petitions. Accordingly, the agency announced that it would hold a public meeting in Detroit, Michigan to receive oral presentations on those issues and to ask questions of those present, and that it would also receive written comments on those issues. 60 FR 35459 (July 7, 1995).

The following five entities made presentations at the Detroit meeting, which took place on July 24, 1995: AIAM, Chrysler, Ford, GM, and the R. L. Polk Company (Polk). The following ten entities submitted written comments to the public docket: Advocates for Highway and Auto Safety (Advocates), American Automotive Leasing Association (AALA), American Honda Motor Company, Inc. (Honda), Association of Consumer Vehicle Lessors (ACVL), Ford, GM, Institute of International Container Lessors (IICL), National Automobile Dealers Association (NADA), National Vehicle Leasing Association (NVLA), and Truck Renting and Leasing Association (TRALA). In addition, NHTSA placed a written transcript of the Detroit meeting in the public docket for this rulemaking.

The notice published today grants the petitions for reconsideration with respect to the four provisions specified above and denies the petitions insofar as they sought amendments to other provisions of the April 5 final rule. The four provisions pertain to the enforcement of the provisions of Chapter 301 of Title 49 of the United States Code (49 U.S.C. § § 30101–30169) that set forth the obligations of manufacturers of motor vehicles and motor vehicle equipment to provide notification that motor vehicles or items of motor vehicle equipment contain a safety-related defect or do not comply with a Federal motor vehicle safety standard and to remedy the defect or noncompliance without charge. 49 U.S.C. 30116–30121. The provisions of the final rule regarding notification of defects and noncompliances in leased vehicles implement a provision of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) that requires vehicle lessors to send their lessees a copy of notifications received from manufacturers regarding a safety-related defect or noncompliance in the lessees' vehicles. 49 U.S.C. 30119(f).

Amendments to Part 573—Defect and Noncompliance Reports

NHTSA is amending two sections of 49 CFR Part 573, one that sets forth requirements regarding the submittal by manufacturers of schedules for owner notification and remedy campaigns (recalls) under certain circumstances (section 573.5(c)(8)), and one that specifies recordkeeping requirements for manufacturers in connection with recalls of leased vehicles (section 573.7(d) and (e)).

Schedule for Recall Campaigns

In order to address an increase in the number of recalls in which there has been a significant delay between the manufacturer's decision that a defect or noncompliance exists and the commencement and conclusion of the manufacturer's recall campaign, NHTSA included in the April 5 final rule a requirement that manufacturers include in their defect/noncompliance reports submitted to NHTSA pursuant to 49 U.S.C. 30119 and 49 CFR Part 573 (Part 573 Report) a detailed schedule for those notification campaigns that would not begin within thirty days of the Part 573 Report or end within 75 days of that Report. Several petitioners objected to this requirement as unnecessary and unduly burdensome. In oral statements at the public meeting and in their written comments, manufacturers indicated that the time periods specified in the final rule would mean that detailed schedules would be required in most recalls, because most notification campaigns are either begun more than 30 days after the Part 573 Report or not completed within 75 days of that Report. In addition, they asserted that the need to file detailed scheduling information with NHTSA at the outset of most recalls would have the effect of delaying implementation of recalls, because personnel and resources would have to be taken away from other aspects of recall implementation to ensure compliance with the added reporting requirements.

Pursuant to 49 U.S.C. 30119(c), manufacturers must notify owners, purchasers, and dealers of safety defects and noncompliances ''within a reasonable time'' after the decision that the defect or noncompliance exists. NHTSA continues to believe strongly that safety recalls should be implemented as soon as reasonably possible. However, it also recognizes that the concerns raised by the manufacturers are serious and need to be considered.

In order to make the rule more responsive both to the manufacturers' concerns and to the public safety interest in prompt notification of safety-related defects and noncompliances, NHTSA has decided to modify the burdensome aspects of the recall schedule provisions of the April 5 final rule. Thus, the agency is deleting the requirement that extensive scheduling information and explanatory material be provided in the manufacturer's Part 573 Report in instances where notification would begin more than 30 days after the Part 573 Report is submitted or end more than 75 days after the Report. Instead, under the rule adopted today, manufacturers will only be required to include in their Part 573 Reports the estimated date when owners will first be notified that a remedy for the defect or noncompliance is available and the estimated date when all owners will have been so notified.

No additional scheduling information will be required under the regulation. In those relatively rare instances where the agency wishes to further examine whether the manufacturer's time frame for the recall is reasonable under the circumstances, it may request more detailed information from the manufacturer on a case-by-case basis.

As NHTSA noted in the preamble to the April 5 final rule, in most cases, manufacturers develop a recall implementation schedule for their own internal use at the time they decide that a defect or noncompliance exists, or promptly thereafter. The final rule adopted today simply requires manufacturers to provide the agency with the two most basic elements of this scheduling information when they file their Part 573 Reports. Under this revision, manufacturers will have flexibility to tailor the recall notification schedule to the circumstances of the particular recall, with far less of a reporting burden, while NHTSA will retain the ability, on a case-by-case basis, to ensure that the timing of recall notification is reasonable. The agency is retaining its authority, as set forth in new section 577.7(a)(1), to order a manufacturer to notify owners on a specific date when it finds, after consideration of available information and the views of the manufacturer, that such notification is in the public interest.

NHTSA recognizes that in some cases a manufacturer may not have any scheduling information at the time it submits its Part 573 Report (e.g., where the remedy has not been developed or tested, or where the scope of the recall is uncertain). In such instances, the manufacturer should indicate in the Report that the information is not available. Thereafter, in accordance with section 573.5(b), the required information ''shall be submitted as it becomes available.''

On reconsideration, NHTSA has also decided to rescind new section 573.5(c)(8)(iii), which would have required a manufacturer to describe all factors that it anticipated could interfere with its ability to adhere to the proposed recall schedule and to describe with specificity the likely effect of each of those factors. The agency believes that the burden of requiring advance information about events which might never actually have any effect on the recall significantly outweighs whatever safety benefit might be derived from it. In addition, the agency believes that the purpose of that requirement can as readily be served by the requirement, retained in today's final rule, that a manufacturer must promptly advise NHTSA if circumstances arise that can result in unanticipated delays of two weeks or more in recall campaign implementation. This requirement, formerly included in section 573.5(c)(8)(iv), is now renumbered as § 573.5(c)(8)(ii).

This final rule renumbers sections 573.5(c)(8) (v) and (vi) as sections 573.5(c)(8) (iii) and (iv), respectively, and makes minor changes in those paragraphs to reflect the changes to this section described above, but makes no substantive changes. These provisions are concerned with the effect on the requirement to file a notification

schedule of a manufacturer's intent to submit a petition for an exemption from the recall requirements of the statute on the ground that the defect or noncompliance is inconsequential.

Recordkeeping Regarding Recalls of Leased Vehicles

After reviewing the petitions for reconsideration and the oral and written comments, NHTSA has decided to revise 49 CFR § 573.7 (d) and (e), which imposed requirements on manufacturers and lessors to maintain lists of the names and addresses of ''known'' lessees of vehicles covered by recall campaigns.

All of the manufactures that participated in the reconsideration process stated that the divisions of the company that deal with recalls and maintain owner lists do not know whether a particular vehicle is leased. However, the manufacturers were concerned that they could be held responsible under the rule for ''knowing'' that a vehicle was leased because that information is contained in records maintained elsewhere in the organization, such as corporate offices or subsidiaries involved with fleet operations or consumer credit matters.

These manufacturers stated that it would be extremely costly and time-consuming to integrate their leased vehicle records with the vehicle owner lists prepared in connection with recall campaigns. Such records are generally maintained in separate databases in separate parts of the company and integrating the databases and reprogramming the systems to generate the information in the manner required by section 573.7(d) would require many months of work and substantial additional financial cost. Similarly, Polk, which is the principal source of vehicle registration information used by manufacturers in recall mailings, stated at the public meeting that it could not specifically identify for their manufacturer clients which vehicles on a given list of registered vehicles were leased. Finally, even apart from cost considerations, the manufacturers contended that they should not have to bear the burden of maintaining records reflecting lessee notification, since that should be the responsibility of the vehicle lessors.

On the basis of the foregoing information, NHTSA has concluded that any benefit to be gained by requiring manufacturers to identify those vehicles on its recall notification lists that are leased and the person or entity to whom notification was sent as the lessor or lessee is far outweighed by the cost and time burdens that manufacturers would incur to implement such a system. Moreover, the agency agrees that it is not appropriate to require manufacturers to bear the burdens associated with keeping records regarding the notification of lessees, when Congress imposed the responsibility for such notification on the lessors.

Accordingly, NHTSA has decided to rescind in its entirety section 573.7(d) of the April 5 final rule. The agency will monitor lessor compliance with notification requirements of section 30119(f) through direct contact with lessors rather than by reviewing manufacturer records. To identify such lessors, NHTSA plans to obtain information from manufacturers and lessor organizations.

For similar reasons, the agency is also amending section 573.7(e), which primarily sets forth recordkeeping requirements applicable to lessors, by deleting language in the last two sentences that are applicable to record retention by manufacturers who send out recall notifications directly to lessees pursuant to agreements with lessors. Such lessees are, in effect, being notified as if they were owners, without any lessor involvement, so there is no need to apply additional recordkeeping burdens on the manufacturers to assure compliance requirements of section 30119(f).

Two commenters, AALA and TRALA, representing lessors, contended that the recordkeeping requirements for lessors set forth in section 573.7(e) are overly burdensome and time consuming because they require them to establish new systems for keeping these records. In addition, AALA questioned the utility of requiring lessors to maintain these records in light of the fact that, once the lease has expired, the vehicle generally undergoes one or more rapid changes of ownership. AALA questioned the purpose behind the requirement to maintain records on ''vehicles whose future ownership the lessor would be unable to verify.''

The purpose of this recordkeeping requirement is not to verify ''future ownership'' of vehicles; it is to give NHTSA a means of verifying that lessors are complying with their duty to provide their lessees with copies of safety recall notifications. This is analogous to the requirement that manufacturers must keep a record of recall notifications sent to registered owners.

The agency has made every effort to ensure that the recordkeeping requirements impose as little burden as possible on lessors. The information required is minimal (less than what is required of manufacturers), and it should not entail great expenditure of resources to develop and maintain a record retention system. For these reasons, NHTSA is retaining the substantive requirements of section 573.7(e) as they apply to the lists that must be maintained by lessors.

Amendments to Part 576—Record Retention

Prior to the April 5 final rule, 49 CFR § 576.5 required vehicle manufacturers to retain relevant records for five years from the date they are generated or acquired. The April 5 rule amended section 576.5 to require such records to be maintained for eight years from the last date of the model year in which the vehicle to which the records relate was produced. After considering the petitions for reconsiderations and the oral and written comments submitted on this subject, NHTSA has decided to rescind the amendment to section 576.5 and reinstate the preexisting requirement.

The primary reason for this decision is the time and cost burdens that the amendment would have placed upon vehicle manufacturers. Several manufacturers stated that it would be highly costly and extremely time consuming to change their computerized record keeping systems to comply with the new record retention requirements. The agency has concluded that the safety benefit that would be derived from revising the record retention period requirements would be far outweighed by costs and other burdens on resources that would be incurred by manufacturers in order to make the change.

The agency is also making a technical amendment to 49 CFR § 576.6, which defines the records that must be retained by manufacturers under Part 576. Ford pointed out that in the text of the April 5 amendment, the word ''such'' does not appear as a modifier to the term ''malfunctions'' the second time that word appears (in the second sentence of the section). Ford expressed concern that the removal of the word ''such'' could be construed to broaden the scope of the section to cover additional types of records beyond those related to motor vehicle safety.

The agency does not agree that the slight change in the wording of this phrase would have had a substantive affect on the record retention requirements, since the revised language specified that the requirement only applied to records of ''malfunctions that may be related to motor vehicle safety.'' Nevertheless, to prevent any possible misunderstanding, NHTSA is making a

technical amendment to this section to reinstate the preexisting wording. The agency wishes to emphasize that the April 5 amendment to section 576.6 that clarified that the record retention requirements apply to records made on electronic media has not changed, and remains in effect.

Amendments to Part 577—Defect and Noncompliance Notification

In its September 1993 notice of proposed rulemaking (NPRM) to implement the ISTEA requirement that vehicle lessors furnish their lessees with copies of notifications of safety-related defects and noncompliances in leased vehicles, NHTSA proposed to require manufacturers to include language in all recall notification letters to lessors that would remind them of their statutory obligations. Several comments submitted in response to the NPRM pointed out that it would be very difficult for manufacturers to identify which owners were lessors. On the basis of those comments, the April 5 final rule added a new section 577.5(h), which required manufacturers to include language describing a lessor's obligation to notify lessees of safety recalls in *all* owner notification letters.

During the reconsideration process, this requirement was vigorously challenged. Most commenters stated that the inclusion of lessor/lessee language in all owner notification letters would add clutter to the letter and could confuse the recipients of the owner notification letter who are not lessors/lessees. In addition, commenters representing various elements of the leased vehicle industry generally expressed the view that requiring manufacturers to notify lessors of their obligations is unnecessary for several alternative reasons: (1) Many lessors have an arrangement with manufacturers in which the latter mails recall letters directly to individuals on a list furnished by the lessor; (2) many individual lessees receive notification letters directly from manufacturers because the name of the lessee appears on the title as the owner; and (3) many lessors are already aware of their obligations and are complying with them.

These commenters also argued that the rule as written failed to take into account several features of the leased vehicle market: e.g., the fact that in consumer leasing, the lessee is likely to be the driver, whereas in commercial leasing, the vehicles will be driven by individuals who are not the lessee of record; and the fact that some lessors regard their lists of lessees as trade secrets and do not disclose them to manufacturers (which are often perceived as competitors).

On reconsideration, the agency has concluded that section 577.5(h) should be rescinded. The likely confusion resulting from the inclusion of this information in all owner notification letters will outweigh any potential safety benefit associated with reminding lessors of their obligations, particularly since there is reason to believe that most lessors are already aware of those obligations. However, since it is likely that not all lessors are aware of the duty to notify their lessees of recalls, the agency believes that further steps are appropriate to maximize the number of lessors that are informed of their obligations under the statute and regulations. To that end, NHTSA plans to send a notice to vehicle lessors informing them of their statutory and regulatory obligations with respect to recall notification of their lessees. The agency will also monitor the performance of such lessors through periodic compliance reviews. The agency plans to identify vehicle lessors from several sources, including manufacturers, lessor associations, and commercial publications.

Other Issues

The agency has also considered issues raised by petitioners and commenters concerning other aspects of the April 5 final rule. Several entities asserted that NHTSA should have allowed more time to comply with the April 5 amendments. The agency recognized that the original 30-day period may not have allowed sufficient time for those affected by the changes to come into compliance. However, NHTSA remains convinced that the extension of the effective date for the provisions not affected by the petitions for reconsideration to July 7 (providing a total of over 90 days) was sufficient.

Most of the concerns about the time centered on the provisions regarding manufacturer recordkeeping for leased car notifications (section 573.7) and the changes in the duration of the record retention requirements of section 576.5. However, those concerns are now moot due to the substantive changes made to those sections on reconsideration.

The other issues raised by the petitions for reconsideration were essentially restatements of arguments made during the comment period prior to issuance of the final rule. The agency has concluded that no change of those provisions is warranted.

Advocates objected to the fact that NHTSA postponed the effective date of several provisions of the final rule while it was considering the merits of the petitions for reconsideration. It noted that the agency had recently failed to stay a regulatory action when Advocates filed a petition for reconsideration.

Under 49 CFR § 553.35(d), a petition for reconsideration does not stay the effectiveness of a rule ''unless the Administrator so provides.'' Thus, a decision whether or not to stay the effective date of a rule pending consideration of petitions for reconsideration is within the discretion of the Administrator.

In the Federal Register notice that first extended the effective date of all provisions of the April 5 rule from May 5 to July 7, 1995 (60 FR 26002), the agency noted, ''The [petitioners] have presented NHTSA with information that makes a credible showing that they are not able to achieve compliance with at least some provisions of the final rule by May 5, and that it will be some months before they are able to do so.'' In addition, NHTSA noted that the short time between the filing of the petitions for reconsideration and original effective date precluded it from sorting through all of the provisions of this multifaceted rule and the arguments in the petitions in order to identify particular provisions whose effective date should have been extended. *Id.*

The agency extended the effective date of four specified provisions of the final rule beyond July 7, because it had decided that it needed to gather further information on those issues. See 60 FR 35458 (July 7, 1995). The agency believes that this decision was reasonable under the circumstances, and was adequately explained at the time.

The fact that the agency did not stay a rule for which Advocates sought reconsideration is not material. Unlike the manufacturers, Advocates did not risk noncompliance with Federal law if the agency had not stayed its action.

Advocates also contended that NHTSA should not have considered the merits of the arguments raised in the petitions for reconsideration because the manufacturers did not present any new information that could not have been presented prior to the issuance of the final rule. While it may be true that the information was previously available, there were relatively significant changes made to each of the four provisions between the NPRM and the April 5 final rule. The manufacturers could not have known exactly what the agency would require in those provisions. Thus, it was appropriate to consider the additional information and arguments presented in the reconsideration petitions and in the subsequent comments.

Rule Making Analyses and Notices

1. Executive Order 12866 (Federal Regulations) and DOT Regulatory Policies and Procedures

NHTSA has analyzed the changes made by this revised final rule and determined that it is not ''significant'' within the meaning of the Department of Transportation regulatory policies and procedures. OMB has also determined that it is not significant within the meaning of Executive Order 12866. These changes will not impose any costs on the regulated parties and are likely to reduce such costs.

2. Regulatory Flexibility Act

The agency has also considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). I certify that this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

3. National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, the agency has analyzed the environmental impacts of this rulemaking action and determined that implementation of this action will not have a significant impact on the quality of the human environment.

4. Paperwork Reduction Act

The amendments made by this final rule on reconsideration will not impose any new recordkeeping burdens and are likely to reduce such burdens.

5. Executive Order 12612 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rule making does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

6. Civil Justice Reform Act

This final rule does not have a retroactive or preemptive effect. Judicial review of this rule may be obtained pursuant to 5 U.S.C. section 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

List of Subjects

49 CFR Part 573

Imports; Motor vehicle safety; Motor vehicles; Reporting and record keeping requirements; Tires.

49 CFR Part 576

Motor vehicle safety; Reporting and recordkeeping requirements.

49 CFR Part 577

Motor vehicle safety.

In consideration of the foregoing, Parts 573, 576, and 577 of Title 49 of the Code of Federal Regulations are amended as follows:

PART 573—DEFECT AND NONCOMPLIANCE REPORTS

1. The authority citation for part 573 continues to read as follows:

Authority: 49 U.S.C. 30102–30103, 30112, 30117–30121, 30166–30167; delegation of authority at 49 CFR 1.50

2. Section 573.5 is amended by removing paragraphs (c)(8) (ii), (iii), and (iv), redesignating paragraphs (c)(8) (v) and (vi) as paragraphs (c)(8) (iii) and (iv) and revising them, and by adding a new paragraph (c)(8)(ii) to read as follows:

§ 573.5 Defect and noncompliance information report.

* * * * *

(c) * * *

(8) * * *

(ii) The estimated date on which it will begin sending notifications to owners that there is a safety-related defect or noncompliance and that a remedy without charge will be available, and the estimated date on which it will have completed such notification. If a manufacturer subsequently becomes aware that either the beginning or the completion date reported to the agency will be delayed by more than two weeks, it shall promptly advise the agency of the delay and the reasons therefor, and furnish a revised estimate.

(iii) If a manufacturer intends to file a petition for an exemption from the recall requirements of the Act on the basis that a defect or noncompliance is inconsequential as it relates to motor vehicle safety, it shall notify NHTSA of that intention in its report to NHTSA of the defect or noncompliance under this section. If such a petition is filed and subsequently denied, the manufacturer shall provide the information required by paragraph (c)(8)(ii) of this section within five Federal government business days from the date the petition denial is published in the Federal Register.

(iv) If a manufacturer advises NHTSA that it intends to file such a petition for exemption from the notification and remedy requirements on the grounds that the defect or noncompliance is inconsequential as it relates to motor vehicle safety, and does not do so within the 30-day period established by 49 CFR 556.4(c), the manufacturer must submit the information required by paragraph (c)(8)(ii) of this section no later than the end of that 30-day period.

3. Section 573.7 is amended by removing paragraph (d), redesignating paragraph (e) as paragraph (d), and revising new paragraph (d) to read as follows:

§ 573.7 Lists of purchasers, owners, lessors and lessees.

* * * * *

(d) Each lessor of leased motor vehicles that receives a notification from the manufacturer of such vehicles that the vehicle contains a safety-related defect or fails to comply with a Federal motor vehicle safety standard shall maintain, in a form suitable for inspection, such as computer information storage devices or card files, a list of the names and addresses of all lessees to which the lessor has provided notification of a defect or noncompliance pursuant to 49 CFR 577.5(h). The list shall also include the make, model, model year, and vehicle identification number of each such leased vehicle, and the date on which the lessor mailed notification of the defect or noncompliance to the lessee. The information required by this paragraph must be retained by the lessor for one calendar year from the date the vehicle lease expires.

PART 576—RECORD RETENTION

4. The authority citation for part 576 continues to read as follows:

Authority: 49 U.S.C. 30112, 30115, 30117–30121, 30166–30167; delegation of authority at 49 CFR 1.50.

5. Section 576.5 is revised to read as follows:

§ 576.5 Basic requirements.

Each manufacturer of motor vehicles shall retain as specified in § 576.7 all records described in § 576.6 for a period of five years from the date on which they were generated or acquired by the manufacturer.

6. Section 576.6 is revised to read as follows:

§ 576.6 Records.

Records to be retained by manufacturers under this part include all documentary materials, films, tapes, and other information-storing media that contain information concerning malfunctions that may be related to motor vehicle safety. Such records include, but are not limited to, communications from vehicle users and memoranda of user complaints; reports and other documents, including material generated or communicated by computer, telefax or other electronic means, that are related to work

performed under, or claims made under, warranties; service reports or similar documents, including electronic transmissions, from dealers or manufacturer's field personnel; and any lists, compilations, analyses, or discussions of such malfunctions contained in internal or external correspondence of the manufacturer, including communications transmitted electronically.

PART 577—DEFECT AND NONCOMPLIANCE NOTIFICATION

7. The authority citation for part 577 continues to read as follows:

Authority: 49 U.S.C. 30102–30103, 30112, 30115, 30117–30121, 30166–30167; delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.

§ 577.5 [Amended]

8. Section 577.5 is amended by removing paragraph (h) and redesignating paragraph (i) as paragraph (h).

Issued on: December 21, 1995.

Ricardo Martinez,

Administrator.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611 and 663

[Docket No. 951227306–5306–01; I.D. 121295C]

Foreign Fishing; Pacific Coast Groundfish Fishery; Annual Specifications and Management Measures

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

ACTION: 1996 groundfish fishery specifications and management measures; 1996 preliminary fishery specifications for Pacific whiting; receipt of applications for experimental fishing permits; request for comments.

SUMMARY: NMFS announces the 1996 fishery specifications and management measures for groundfish taken in the U.S. exclusive economic zone (EEZ) and state waters off the coasts of Washington, Oregon, and California as authorized by the Pacific Coast Groundfish Fishery Management Plan (FMP). The specifications include the level of the acceptable biological catch (ABC) and harvest guidelines including the distribution between domestic and foreign fishing operations. The harvest guidelines are allocated between the limited entry and open access fisheries. The management measures for 1996 are designed to keep landings within the harvest guidelines, for those species for which there are harvest guidelines, and to achieve the goals and objectives of the FMP and its implementing regulations. The intended effect of these actions is to establish allowable harvest levels of Pacific Coast groundfish and to implement management measures designed to achieve but not exceed those harvest levels, while extending fishing and processing opportunities as long as possible during the year.

DATES: Effective 0001 hours (local time) January 1, 1996, until the 1997 annual specifications and management measures are effective, unless modified, superseded, or rescinded. The 1997 annual specifications and management measures will be published in the Federal Register. Comments will be accepted until February 5, 1996.

ADDRESSES: Comments on these specifications should be sent to Mr. William Stelle, Jr., Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way N.E., BIN C15700, Bldg. 1, Seattle, WA 98115–0070; or Ms. Hilda Diaz-Soltero, Director, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213. Information relevant to these specifications and management measures, including the stock assessment and fishery evaluation (SAFE) report, has been compiled in aggregate form and is available for public review during business hours at the office of the Director, Northwest Region, NMFS (Regional Director), or may be obtained from the Pacific Fishery Management Council (Council), by writing the Council at 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: William L. Robinson (Northwest Region, NMFS) 206–526–6140; or Rodney R. McInnis (Southwest Region, NMFS) 310–980–4040.

SUPPLEMENTARY INFORMATION: The FMP requires that fishery specifications for groundfish be evaluated each calendar year, that harvest guidelines or quotas be specified for species or species groups in need of additional protection, and that management measures designed to achieve the harvest guidelines or quotas be published in the Federal Register and made effective by January 1, the beginning of the fishing year. This action announces and makes effective the final 1996 fishery specifications and the management measures designed to achieve them. These specifications and measures were considered by the Council at two meetings and were recommended to NMFS by the Council at its October 1995 meeting.

I. Final Specifications: ABCs and Harvest Guidelines; Apportionments to Foreign and Joint Venture Fisheries; Open Access and Limited Entry Allocations

The fishery specifications include ABCs, the designation of harvest guidelines or quotas for species that need individual management, the apportionment of the harvest guidelines or quotas between domestic and foreign fisheries, and allocation between the open access and limited entry segments of the domestic fishery.

The final 1996 specifications for ABCs, harvest guidelines, and limited entry and open access allocations are listed in Table 1, followed by a discussion of each 1996 specification that differs from 1995. The apportionment between foreign and domestic fisheries is explained separately at the end of this section. As in the past, the specifications include fish caught in state ocean waters (0–3 nautical miles (nm) offshore) as well as fish caught in the EEZ (3–200 nm offshore).

TABLE 1.—1996 SPECIFICATIONS OF ACCEPTABLE BIOLOGICAL CATCH (ABC), HARVEST GUIDELINES, AND LIMITED ENTRY AND OPEN ACCESS ALLOCATIONS, BY INTERNATIONAL NORTH PACIFIC FISHERIES COMMISSION (INPFC) SUBAREAS

Species	Acceptable biological catch (ABC) (x 1,000 mt)						Harvest guideline (x 1,000 mt)	Allocations (x 1,000 mt)			
								Limited entry		Open access	
	Vancouver [a]	Columbia	Eureka	Monterey	Conception	Total ABC		1000 mt	Percent	1000 mt	Percent
Roundfish:											
Lingcod [b]	1.3		0.3	0.7	0.1	2.4	2.4	1.21	80.9	0.29	19.1
Pacific cod	3.2		(c)		(c)	3.2		.....	.....	.....	.....
Pacific whiting [d]		Preliminary 123.0				123.0	98.4	.....	.....	.....	.....
Sablefish [e f]		8.7			0.425	9.1	7.8	6.557	93.4	0.463	6.6
Jack mackerel [g]		52.6			.....	52.6	52.6	.....	.....	.....	.....
Rockfish:											
POP [h]	0.0	0.0	(c)	(c)	(c)	0.0	0.75	.....	.....	.....	.....
Shortbelly			23.5			23.5	23.5	.....	.....	.....	.....
Widow [i]			7.7			7.7	6.5	6.26	96.3	0.24	3.7
Thornyheads:		8.0			.....	8.0		.....	.....	0.00	.....
Shortspine [e j]		1.0			.....	1.0	1.5	1.496	99.75	0.004	0.25
Longspine [e j]		7.0			.....	7.0	6.0	.....	.....	.....	.....
Sebastes complex: [k]	11.9			13.2		11.9 N	11.2 N	10.12	90.4	1.08	9.6
						13.2 S	13.2 S	8.76	67.4	4.24	32.6
Bocaccio [l]	(G5c)	(c)		1.7		1.7	1.7	1.01	67.4	0.49	32.6
Canary [m]	1.0		0.25	(c)	(c)	1.25	0.85	0.78	91.2	0.07	8.8
Chilipepper	(c)	(c)		4.0		4.0		.....	.....	.....	.....
Yellowtail [n]	1.19	2.9	2.58	(c)	(c)	6.74	3.59 N	3.25	90.4	0.35	9.6
		7	.....	.....	.....		2.58 S	2.33	90.4	0.25	9.6
Remaining rockfish	0.8	3.7		7.0		11.5		.....	.....	.....	.....
Flatfish:											
Dover sole [e o]	0.82–1.57	3.0	2.9	3.16–4.36	1.0	10.88–12.83	11.05 WOC 2.85 Col	.....	.....	.....	.....
English sole	2.0			1.1		3.1		.....	.....	.....	.....
Petrale sole	1.2		0.5	0.8	0.2	2.7		.....	.....	.....	.....
Arrowtooth flounder			5.8			5.8		.....	.....	.....	.....
Other flatfish	0.7	3.0	1.7	1.8	0.5	7.7		.....	.....	.....	.....
Other fish [p]	2.5	7.0	1.2	2.0	2.0	14.7		.....	.....	.....	.....

[a] U.S. Vancouver only, except for Pacific whiting.

[b] The lingcod stock assessment covers the entire Vancouver INPFC area, including Canada, and the Columbia subarea north of Cape Falcon. The U.S. ABC is based on 50 percent of the ABC for this assessment area plus 400 mt for the Columbia subarea south of Cape Falcon. The coastwide harvest guideline equals the sum of the ABCs and includes a recreational harvest of 900 mt. The limited entry and open-access percents are applied only to the commercial portion of the harvest guideline, which is 1,500 mt (the 2,400 mt harvest guideline minus 900 mt for estimated recreational harvest).

[c] These species are not common nor important in the areas footnoted. Accordingly, for convenience, Pacific cod is included in the ''other fish'' category for the areas footnoted, and rockfish species are included in the ''remaining rockfish'' category for the areas footnoted only.

[d] Whiting specifications are preliminary. The ABC is coastwide, including Canadian waters. The U.S. harvest guideline is preliminarily set at 80 percent of the U.S./Canada ABC. The allocation to Washington coastal treaty tribes will be determined in a separate rulemaking. The 40 percent reserve for shore-based processing will be based on the commercial portion of the harvest guideline (the U.S. harvest guideline minus the tribal allocation).

[e] Dover sole, thornyheads, and trawl-caught sablefish are managed together as the ''DTS complex'' (formerly called the deepwater complex). There is no harvest guideline for the DTS complex.

[f] The 7,800 mt sablefish harvest guideline is the 8,700 mt ABC north of the Conception subarea (north of 36° N. latitude) reduced by 900 mt for estimated discards. The 7,800-mt harvest guideline is reduced by 780 mt for the treaty tribes before dividing the remaining 7,020 mt between the limited entry (6,557 mt) and open-access (463 mt) fisheries. The limited entry allocation is further allocated 58 percent (3,803 mt) to the trawl fishery, and 42 percent (2,754 mt) to the nontrawl fishery, both of which are harvest guidelines.

[g] Only jack mackerel north of 39°00′ N. latitude are managed by the FMP. The ABC and harvest guideline include area beyond 200 nm.

[h] The POP harvest guideline for landed catch applies to the Vancouver/Columbia subareas combined.

[i] The 6,500 mt harvest guideline for widow rockfish is derived by subtracting 16 percent for estimated discards (1,200 mt) from the ABC (7,700 mt).

[j] The thornyhead ABCs and harvest guidelines apply north of Point Conception, CA. The harvest guideline represents landed catch. Limited entry and open-access allocations are set for the first time for shortspine thornyheads because open-access harvest has exceeded traditional levels during the 1984–1988 window period.

[k] The *Sebastes*-North harvest guideline (11,200 mt) applies to the Vancouver and Columbia subareas and equals the sum of the ABCs as follows: canary (1,000 mt), yellowtail rockfish (6,740 mt coastwide minus 300 mt for the Eureka subarea), and remaining rockfish (4,500 mt), minus 720 mt for estimated discards (150 mt for canary rockfish and 570 mt for yellowtail rockfish north of Cape Lookout). Within the *Sebastes*-North harvest guideline are two small harvest guidelines for commercial harvest of black rockfish by the Makah, Quileute, Hoh, and Quinault Indian tribes: 20,000 pounds (9,072 kg) for the EEZ north of Cape Alava (48°09′30″ N. latitude) and 10,000 pounds (4,536 kg) between Destruction Island (47°40′00″ N. latitude) and Leadbetter Point 46°38′10″ N. latitude). The *Sebastes*-South harvest guideline is the sum of the ABCs for the species in the Eureka/Monterey/Conception subareas: bocaccio (1,700 mt), canary (250 mt), chilipepper (4,000 mt), yellowtail rockfish (300 mt), and remaining rockfish (7,000 mt).

[l] The bocaccio harvest guideline applies to the Eureka, Monterey, and Conception subareas; as trip-limit induced discards are believed to be minimal, there is no deduction for discards. The open-access and limited entry allocation percentages for bocaccio are applied only to the commercial portion of the harvest guideline, which is 1,500 mt in 1995 (1,700 mt harvest guideline minus 200 mt estimated recreational harvest).

[m] The canary rockfish harvest guideline for the Vancouver/Columbia area is the sum of the ABCs minus 150 mt for estimated discards.

[n] The 1993 yellowtail rockfish assessment addressed three separate areas: U.S. Vancouver; Columbia north of Cape Falcon; and Columbia south of Cape Falcon plus Eureka. For this table, the 2,970 mt Columbia ABC is for north Columbia only, and the Eureka ABC is for the Eureka subarea plus south Columbia. The total ABC for yellowtail rockfish is divided into two harvest guidelines: 3,600 mt for the northern area (4,160 mt for Vancouver plus Columbia north of Cape Lookout, close to Cape Falcon minus 570 mt for discards) and 2,580 mt for the southern area (Eureka plus Columbia area south of Cape Lookout). The harvest guidelines for the *Sebastes* complex apply to different areas, north and south of the Columbia/Eureka border at 43°00′00″ N. latitude. For calculating the *Sebastes* complex harvest guidelines, 300 mt of yellowtail rockfish is estimated for the Eureka subarea. Therefore, 300 mt of the yellowtail rockfish southern harvest guideline is included in the southern *Sebastes* complex harvest guideline, and the remainder of the yellowtail rockfish southern harvest guideline is included in the northern *Sebastes* complex harvest guideline.)

[o] The 11,050 mt coastwide harvest guideline for Dover sole (the upper end of the ABC range for the Vancouver subarea and the lower end of the ABC for the Monterey subarea (which are the recent average catches in those two subareas), plus the ABCs for the Columbia, Eureka and Conception subareas, minus 580 mt for estimated discards. The coastwide harvest guideline includes a 2,850 mt harvest guideline for the Columbia subarea (3,000 mt ABC minus 150 mt estimated discards).

[p] Includes sharks, skates, rays, ratfish, morids, grenadiers, and other groundfish species noted above in footnote c.

Changes to the ABCs and Harvest Guidelines

The ABCs represent the total catch—amounts that are discarded as well as retained. Information considered in determining the ABCs is available from the Council and was made available to the public, before the Council's October 1995 meeting, in the Council's SAFE document (see **ADDRESSES**). The 1996 final ABCs are changed from the 1995 ABCs only for Dover sole, as explained below. The preliminary whiting ABC for 1996 also differs from the 1995 ABC. These changes are based on the best available scientific information. Changes that result only from rounding are not explained.

Those species or species groups managed with harvest guidelines in 1995 will continue to be managed with harvest guidelines in 1996. As in 1995, no quotas are established. The 1996 harvest guidelines differ from those in 1995 for: Pacific ocean perch (POP), the *Sebastes* complex in the Vancouver/Columbia subareas (north of 43°00′ N. lat.), yellowtail rockfish north of Cape Lookout (45°20′15″ N. lat.), and Dover sole coastwide. The preliminary harvest guideline for Pacific whiting (whiting) in 1996 also differs from the 1995 harvest guideline. Where information is available, a discard factor is subtracted from the ABC to determine the harvest guideline. Therefore, except for whiting, the 1996 harvest guidelines represent only that portion of the catch that is landed.

The changes to the ABCs and harvest guidelines are described briefly below. All other ABC and annual harvest guideline specifications announced for 1995 (Table 1 at 60 FR 2331, January 9, 1995) will apply again in 1996 and are included in Table 1. More detailed information appears in the Council's SAFE document (September 1995), the ''Final Groundfish Management Team Acceptable Biological Catch and Harvest Guideline Recommendations for 1996'' (GMT Report C.1.) from the October 1995 Council meeting, and the Council's newsletters for its August and October 1995 meetings (see **ADDRESSES**).

POP

Since 1981, POP has been managed under a schedule intended to rebuild POP to a level that would annually support removals of 1,000 metric tons (mt). Landings were higher than this as recently as 1993. To achieve an annual harvest of about 1,000 mt while maintaining a biologically sound harvest rate, the current biomass would have to double. This would be a slow process unless there is a fortuitous sequence of large recruitments. The harvest guideline for POP is meant to accommodate only small, incidental catches and, therefore, is not a target to be achieved deliberately. Trip limits for POP will not be increased to achieve the harvest guideline, and may be reduced if landings are too high. The harvest guideline for POP is reduced from 1,300 mt in 1995 to 750 mt in 1996, close to the projected landings in 1995.

Yellowtail Rockfish—North

The 1996 harvest guideline for yellowtail rockfish north of Cape Lookout is reduced by 570 mt, from 4,160 mt in 1995 to 3,590 mt in 1996, to account for trip-limit induced discards in that area. The harvest guideline in 1996 represents landings rather than total catch. Before 1996, the harvest guideline represented total catch, and estimates of discards were added to landings during the season.

Sebastes Complex—North

The harvest guideline for the Sebastes complex in the Vancouver and Columbia subareas, which consists of the sum of the ABCs of the different species that make up the complex minus estimated discards, is reduced by 570 mt, from 11,800 mt in 1995 to 11,200 mt in 1996 (rounded to the nearest hundred mt). This amount represents the difference after subtracting the estimate of discards for yellowtail rockfish.

As in 1995, the 1996 ABCs and harvest guidelines for the *Sebastes* complex and yellowtail rockfish apply to different areas due to differences in stock assessment areas. The ABCs and harvest guidelines for the *Sebastes* complex apply north and south of 43°00′00″ N. lat. (the Columbia/Eureka subarea boundary). The yellowtail rockfish ABCs in the Columbia area are divided at Cape Falcon (45°46′00″ N. lat.), which is the boundary used in the stock assessment, and the harvest guidelines are divided at Cape Lookout (45°20′15″ N. lat.), about 26 nm to the south, for management purposes.

Dover Sole

New stock assessments were conducted for Dover sole in the Vancouver and Monterey subareas. However, uncertainty in the stock assessments and the surveys on which they are based prompted the Council to recommend ranges of ABCs for these two subareas in 1996. In the Vancouver subarea, the lower end of the ABC range (820 mt) is the ABC recommended in the recent stock assessment, and the upper end (1,570 mt) is based on the 1990–94 average landings. In the Monterey subarea, the lower end of the ABC range (3,160 mt) is based on the 1990–94 average landings and the upper end (4,360 mt) is the level proposed in the recent stock assessment. The 1996 coastwide ABC is the sum of the area ABCs, which ranges from 10,880 mt to 12,830 mt.

The 1996 coastwide harvest guideline for Dover sole is based on the recent average catch in the Vancouver and Monterey subareas (the upper end of the Vancouver ABC range and the lower end of the Monterey ABC range), plus the ABCs for the Columbia, Eureka, and Conception subareas, which are the same as in 1995. The total is then reduced by 5 percent (580 mt) for expected discards. The 1996 coastwide harvest guideline is 11,050 mt, which is reduced from 13,600 mt in 1995. The harvest guideline for Dover sole in the Columbia subarea is the same as in 1995.

Whiting—Preliminary

In order to consider the results of a new stock assessment, the Council has recommended only the preliminary whiting ABC and harvest guideline at this time, and will recommend the final ABC and harvest guideline in March 1996.

In 1994, the ABC for whiting was substantially higher than in previous years, primarily because it was based on data from the 1992 hydroacoustic survey that utilized new, more sensitive equipment, and extended farther offshore and farther north to encompass the species' range. To provide for cautious exploitation until the 1992 survey results could be confirmed, a conservative harvest rate policy was adopted in 1994 and 1995 to minimize the risk to the resource if the ABC were later found to be too high. The most recent stock assessment, prepared in 1995, supported resumption of the moderate exploitation rate, and the Council recommended a preliminary 1996 whiting ABC (for the U.S. and Canada combined) of 123,000 mt, assuming large recruitment from the 1994 year class. This continues the decline in ABC from 325,000 mt in 1994 and 223,000 mt in 1995, as the strong 1980 and 1984 year classes become less abundant. As in recent years, the preliminary U.S. harvest guideline is 80 percent of the U.S.-Canada ABC (98,400 mt). An update to the 1995 stock assessment based on the results of the summer/fall 1995 hydroacoustic survey is expected to be completed early in 1996. The Council will review the results of the new stock assessment at its March 1996 meeting and will recommend the final ABC and harvest

guideline at that time. The final ABC may be higher or lower than the preliminary ABC.

The recent overages have not caused a biological problem, particularly given the large increase in the ABC in 1994 and use of a conservative exploitation rate in 1994 and 1995. Even though the preliminary ABC and harvest guideline return to a higher, moderate exploitation rate, the total harvest in 1996 is expected to be lower than the overfishing level. Bilateral discussions with Canada are expected to continue.

The regulations at 50 CFR 663.23(b)(4) set aside 40 percent of the U.S. harvest guideline in 1994–96 for priority use by vessels delivering whiting to shoreside processors. The amount available for this shoreside reserve in 1996 depends on the level of the final U.S. harvest guideline and the amount set aside for tribal fisheries, which are not yet determined.

Setting Harvest Guidelines Greater Than ABC

In most cases, harvest guidelines are less than or equal to the ABCs, or prorated ABCs, for specific areas. However, for 1996 as in 1995, the Council recommended harvest guidelines that exceed the ABCs for two species, POP and shortspine thornyheads. The FMP requires that the Council consider certain factors when setting a harvest guideline above an ABC. These factors were analyzed by the Council's groundfish management team (GMT) and considered at the Council's October 1995 meeting before the Council recommended the 1996 harvest guidelines. These factors also were considered when establishing the 20-year rebuilding schedule for POP in the 1981 FMP, in the most recent stock assessments for POP (in the September 1995 SAFE document) and shortspine thornyheads (in the October 1994 SAFE document), and in the GMT's recommendations for 1996 (GMT Report C.1., October 1995).

Overfishing

The FMP defines ''overfishing'' as a fishing mortality rate that would, in the long term, reduce the spawning biomass per recruit below 20 percent of what it would have been if the stock had never been exploited (unless the species is above the level that would produce maximum sustainable yield (MSY)). The rate is defined in terms of the percentage of the stock removed per year.

Therefore, high catch rates can cause overfishing at any stock abundance level. Conversely, overfishing does not necessarily occur for stocks at low abundance levels if the catch can be kept to a sufficiently small fraction of that stock level. The target rate of exploitation for Pacific Coast groundfish typically is the rate that would reduce spawning biomass per recruit to 35 percent of its unfished level. This desired rate of fishing will always be less than the overfishing rate, so there is a buffer between the management target and the level that could harm the stock's long-term potential productivity. If the overfishing level is reached, the Guidelines for Fishery Management Plans at 50 CFR part 602 require the Council to identify actions to be undertaken to alleviate overfishing.

None of the ABCs for 1996 reaches or exceeds the level of overfishing. However, for those species whose harvest guidelines exceed ABC (POP and shortspine thornyheads), the harvest guideline approaches the overfishing level. In addition, the overfishing level for POP and shortspine thornyheads was projected to be reached in 1995. Landings of POP were projected at 857 mt in 1995, very close to the 852 mt overfishing level for landed catch. Landings of shortspine thornyheads were projected at about 1,800 mt through November 1995, but total catch may have exceeded the 1,757 mt overfishing level (for total catch) by as much as 170 mt (10 percent), depending on assumptions made about the level of trip-limit induced discards. Further discussion appears in the GMT Supplemental Report C.1. (October 1995). Overfishing in 1996 will be avoided by establishment or reduction of harvest guidelines and by more restrictive management of the fisheries for these species.

Discards

In 1996, the ABCs represent total catch, and the harvest guidelines, except for whiting, represent only that portion of the catch that is landed. Stock assessments and inseason catch monitoring are designed to account for all fishing mortality, including that resulting from fish discarded at sea. Discards of rockfish and sablefish in the fishery for whiting are well monitored and are accounted for inseason as they occur. In the other fisheries, discards caused by trip limits have not been monitored, so discard factors have been developed to account for this extra catch. A level previously measured for widow rockfish (about 16 percent of the total catch) in a scientific study is assumed to be appropriate for the commercial fisheries for widow rockfish, yellowtail rockfish (in the northern area), canary rockfish, and POP. A discard level of 8 percent is used for the deepwater thornyhead fishery, 5 percent for Dover sole, and 20 percent for sablefish. The discard factors are typically applied by setting the harvest guideline for landed catch at a level that is equal to the ABC minus expected discard. More detailed information is found in the Council's SAFE document.

Foreign and Joint Venture Fisheries

For those species needing individual management that will not be fully utilized by domestic processors or harvesters, and that can be caught without severely affecting species that are fully utilized by domestic processors or harvesters, foreign or joint venture operations may occur. A joint venture occurs when U.S. vessels deliver their catch to foreign processing vessels in the EEZ. The harvest guidelines or quotas for these species may be apportioned to domestic annual harvest (DAH, which includes domestic annual processing (DAP) and joint venture processing (JVP)) and to the total allowable level of foreign fishing (TALFF). In January 1996, no surplus groundfish are available for joint venture or foreign fishing operations. Consequently, all the harvest guidelines in 1996 are designated entirely for DAP (which also equals DAH), and JVP and TALFF are set at zero.

In the unlikely event that fish are reallocated inseason and a foreign or joint venture fishery should occur, the incidental catch levels would be as follows: For a whiting fishery, the same as announced at Table 2, footnote 1 of 58 FR 2990 (January 7, 1993); for a jack mackerel joint venture, initially the same as those suggested in section 12.5.2 of the FMP but subject to change during the year.

II. The Limited Entry Program

Amendment 6 to the FMP established a limited entry program that, on January 1, 1994, divided the commercial groundfish fishery into two components, the limited entry fishery and the open access fishery, each of which has its own allocations and management measures. The limited entry and open access allocations are calculated according to a formula specified at section II.E. of the appendix to 50 CFR part 663, which takes into account the relative amounts of a species taken by each component of the fishery during the 1984–88 limited entry window period. At its October 1995 meeting, the Council recommended the species and areas subject to open access and limited entry allocations in 1996, and the Regional Director calculated the amounts of the allocations that are

presented in Table 1. Unless otherwise specified, the limited entry and open access allocations are treated as harvest guidelines in 1996.

Open Access Allocations

The open access fishery is composed of vessels using (1) exempt gear, or (2) longline or pot (trap) gear used pursuant to the harvest guidelines, quotas, and other management measures governing the open access fishery. Exempt gear means all types of legal groundfish fishing gear except groundfish trawl, longline, and pots. (Exempt gear includes trawls used to harvest pink shrimp or spot or ridgeback prawns (shrimp trawls), and, south of Point Arena, CA (38°57′30″ N. lat.), California halibut or sea cucumbers.)

The open access allocation is derived by applying the open access allocation percentage to the annual harvest guideline or quota after subtracting any set-asides for recreational fishing or treaty Indians (see sections II.E.(b) and (c) of the Appendix to 50 CFR part 663). For those species in which the open access share would have been less than 1 percent, no open access allocation is specified unless significant open access effort is anticipated. At the time the calculations were made, the status of some vessels (whether they would receive a limited entry permit) was not certain. These amounts are minor and would not affect the level of trip limits for the limited entry or open access fisheries.

At its October 1995 meeting, the Council learned that the harvest of shortspine thornyheads in 1995 had increased from the level of harvest during the 1984–88 limited entry window period. More than 150 mt of shortspine thornyheads were landed in California alone in 1995, whereas the coastwide harvest by open access gear during the 1984–88 window period was less than one percent (15 mt) of the harvest guideline. Consequently, the Council recommended that an open access allocation for shortspine thornyheads be set in 1996 and that management measures be implemented to keep landings within that harvest guideline. The open access allocation percentage for shortspine thornyheads subsequently was determined to be 0.25 percent of the harvest guideline, which is 4 mt in 1996.

Limited Entry Allocations

The limited entry fishery means the fishery composed of vessels using limited entry gear fished pursuant to the harvest guidelines, quotas, and other management measures governing the limited entry fishery. Limited entry gear means longline, pot, or groundfish trawl gear used under the authority of a valid limited entry permit, issued under 50 CFR part 663, affixed with an endorsement for that gear. (Groundfish trawl gear excludes shrimp trawls used to harvest pink shrimp, spot prawns, or ridgeback prawns, and other trawls used to fish for California halibut or sea cucumbers south of Point Arena, CA.)

The limited entry allocation is the allowable catch (harvest guideline or quota) reduced by: (1) Set-asides, if any, for treaty Indian fisheries or recreational fisheries; and (2) the open access allocation.

Recreational Harvest

Before calculating limited entry and open access allocations, estimates of recreational fishing currently are subtracted for two species, 200 mt for bocaccio (which also is reflected in the allocations for the *Sebastes* complex in the Eureka, Monterey, and Conception subareas), and 900 mt for lingcod.

Washington Coastal Tribal Fisheries

The treaty Indian fisheries will be managed by the tribes. The treaty Indian fisheries for sablefish and whiting are not governed by the limited entry or open access regulations or allocations.

Sablefish

From 1991 through 1994, the Washington Coastal Treaty Tribes conducted a tribal sablefish fishery of 300 mt that was recognized in these annual management measures. In 1994, the U.S. Government formally recognized the treaty right to fish for groundfish of the four Washington Coastal Treaty Tribes (the Makah, Hoh, Quileute, and Quinault) and concluded that, in general terms, the quantification of the right is 50 percent of the harvestable surplus of groundfish available in the tribes' usual and accustomed fishing areas (marine waters under U.S. jurisdiction north of 46°53′18″ N. lat. and east of 125°44′00″ W. long.). For 1996 as in 1995, the tribes' treaty right to sablefish is 10 percent of the sablefish harvest guideline, or 780 mt in 1996.

Whiting

The Washington Coastal Treaty Tribes have requested that whiting be set aside for tribal fishing in 1996. The amount of the tribal allocation for 1996 has not yet been determined, and will be announced in a separate rulemaking that will provide a procedure for implementing tribal treaty rights for groundfish.

Rockfish

The tribes continue to have a small harvest guideline, the same as in 1995, for black rockfish off Washington State, to which the non-tribal trip limits do not apply (50 CFR 663.23(b)). For other rockfish, the open access trip limits will apply for fixed gear. The limited entry trip limits will apply for trawl-caught rockfish, and this will be implemented with a separate rule governing tribal groundfish.

III. 1996 Management Measures

Projections of landings in 1995 are based on the information available to the Council at its October 1995 meeting (GMT Supplemental Report C.3.a., October 1995).

A. Limited Entry Fishery

The following management measures apply to vessels operating in the limited entry fishery after January 1, 1996, and are designed to keep landings within the harvest guidelines or limited entry allocations. Cumulative trip limits continue to be used for most of the limited entry fishery, which allows fishers to accumulate fish over a period of time without limit on the number of landings. However, in response to the industry's concerns about discards and the difficulty of accurately weighing small amounts of fish at sea to assure compliance with trip limits, 2-month rather than 1-month cumulative limits will be used for the limited entry fishery in 1996. However, no more than 60 percent of the 2-month limit may be taken in either calendar month, resulting in a variable monthly trip limit within the 2-month limit. This enables the limited entry fleet to maintain its current monthly fishing pattern, target on 50 percent of the 2-month cumulative limit in a month, and have the protection of a buffer equivalent to 10 percent of the 2-month cumulative limit to account for inaccuracies in weighing fish at sea or for small amounts caught above the target level. The 2-month periods are: January-February, March-April, May-June, July-August, September-October, November-December.

Widow rockfish

In 1995, the cumulative trip limit for widow rockfish continued at 30,000 lb (13,608 kg) per month until July 14, when it was increased to 45,000 lb (20,412 kg) per month. Landings are projected to exceed the 6,500-mt harvest guideline by about 1 percent in 1995. In 1996, a 2-month cumulative limit of 70,000 lb (31,752 kg) will be implemented, which is intended to

reduce the need for abrupt adjustment during the year.

The Sebastes complex (including yellowtail rockfish, canary rockfish, and bocaccio). In 1995, three different cumulative monthly trip limits were set for the *Sebastes* complex, which continued throughout the year: 35,000 lb (15,876 kg) north of Cape Lookout, 50,000 lb (22,680 kg) between Cape Lookout and Cape Mendocino, and 100,000 lb (45,359 kg) south of Cape Mendocino. The monthly cumulative trip limit for yellowtail rockfish was 18,000 lb (8,165 kg) north of Cape Lookout and 30,000 lb (13,608 kg) between Cape Lookout and Cape Mendocino until May 1, when it was increased to 18,000 lb (8,165 kg) north of Cape Lookout and 40,000 lb (18,144 kg) between Cape Lookout and Cape Mendocino. The cumulative monthly trip limit for canary rockfish was 6,000 lb (2,722 kg) coastwide until August 1, when it was increased to 9,000 lb (4,082 kg). By the end of 1995, landings are projected as follows: *Sebastes* complex in the Vancouver/Columbia subarea—6,825 mt (30 percent below the harvest guideline); yellowtail rockfish north of Cape Lookout—3,416 mt (5 percent over the harvest guideline); yellowtail rockfish south of Cape Lookout—1,489 mt (27 percent below the harvest guideline); canary rockfish—627 mt (26 percent below the harvest guideline); and bocaccio—741 mt (39 percent below the harvest guideline).

In January 1996, the 2-month cumulative trip limits for the *Sebastes* complex will be: 70,000 lb (31,752 kg) north of Cape Lookout, 100,000 lb (45,359 kg) between Cape Lookout and Cape Mendocino, and 200,000 lb (90,719 kg) south of Cape Mendocino. Two-month cumulative limits also apply to yellowtail rockfish, canary rockfish and bocaccio, which also count toward the limits for the *Sebastes* complex. These 2-month cumulative limits are: Yellowtail rockfish—32,000 lb (14,515 kg) north of Cape Lookout or 70,000 lb (31,752 kg) between Cape Lookout and Cape Mendocino; canary rockfish—18,000 lb (8,165 kg); bocaccio south of Cape Mendocino—60,000 lb (27,216 kg).

The declaration procedures implemented by the States of Washington and Oregon for vessels operating north and south of Cape Lookout remain in effect for the *Sebastes* complex and yellowtail rockfish. The declarations enable a vessel to operate both north and south of Cape Lookout during the trip limit period, and to take and retain the more liberal, southern limits of the *Sebastes* complex and yellowtail rockfish, but only if the appropriate state is notified, as required by state law. In 1996, the trip limit period is changed to 2 months for most limited entry fisheries, and remains at 1 month for most open access fisheries.

POP

In 1995, the cumulative trip limit for POP of 6,000 lb (2,722 kg) per month continued throughout the year. Landings were projected to be 785 mt at the end of 1995, 36 percent below the harvest guideline. The 1996 harvest guideline was reduced close to the level of 1995 landings, and the cumulative trip limit is changed to 10,000 lb (4,536 kg) per 2-month period. POP is managed to achieve a rebuilding schedule, so trip limits will not be increased to achieve the harvest guideline.

Sablefish

The sablefish harvest guideline is subdivided among several fisheries. The tribal fishery allocation is set aside prior to dividing the balance of the harvest guideline between the commercial limited entry and open access fisheries. These three fisheries are managed differently. The limited entry allocation is further subdivided into trawl (58 percent) and nontrawl (42 percent) allocations. Trawl-caught sablefish are managed together with Dover sole and thornyheads as the DTS complex because they often are caught together. Landings of sablefish are expected to be close to the 7,800 mt harvest guideline in 1995.

DTS complex (Dover sole, thornyheads, and trawl-caught sablefish). In 1995, the two cumulative monthly trip limits for the DTS complex remained in effect until December 1: 35,000 lb (15,876 kg) north of Cape Mendocino and 50,000 lb (22,680 kg) south of Cape Mendocino. This differential trip limit was intended to provide additional protection for shortspine thornyheads, the most valuable and least abundant species in the DTS complex, while encouraging the harvest of Dover sole in more southern areas. In 1996, the trip limit will be doubled to accommodate the 2-month periods: 70,000 lb (31,752 kg) north of Cape Mendocino, and 100,000 lb (45,359 kg) south of Cape Mendocino.

Further protection for shortspine thornyheads was provided by managing the two thornyhead species separately in 1995. On January 1, a cumulative trip limit was set for shortspine and longspine thornyheads combined of 20,000 lb (9,072 kg) per month, containing no more than 4,000 lb (1,814 kg) of shortspine thornyheads. On April 1, the monthly cumulative limit was reduced to 15,000 lb (6,804 kg) of thornyheads, containing no more than 3,000 lb (1,361 kg) of shortspine thornyheads. On September 1, the cumulative monthly limit was reduced further to 8,000 lb (3,629 kg) of thornyheads, of which no more than 1,500 lb (680 kg) could be shortspines. Even so, landings of shortspine thornyheads reached the harvest guideline on September 20, and are projected to exceed the overfishing level by as much as 170 mt, even with the fishery closure in December. Landings of longspine thornyheads are projected to be about 5,800 mt in 1995, 200 mt below its harvest guideline. Landings of both thornyhead species were prohibited on December 1, since the two species often are caught together. In January 1996, the trip limits for thornyheads are half the amount of limits in effect at the beginning of 1995: 20,000 lb (9,072 kg) of thornyheads in a 2-month period, of which no more than 4,000 lb (1,814 kg) may be shortspine thornyheads.

The monthly cumulative trip limit for trawl-caught sablefish remained at 6,000 lb (2,722 kg) cumulative per month from July 1994 until it was raised to 7,000 lb (3,175 kg) on May 1, 1995. The ''per trip'' limit for sablefish smaller than 22 inches (56 cm) remained at 500 lb (227 kg). Landings of trawl-caught sablefish were projected to exceed the limited entry trawl allocation by the end of 1995. Therefore, to keep landings within the trawl allocation, and because shortspine thornyheads often are caught with sablefish, the trawl fishery for sablefish also was closed on December 1. In 1995, landings are projected to be very close to the limited entry trawl allocation of 3,803 mt. In 1996, the cumulative trip limit is doubled to 12,000 lb (5,443 kg) to accommodate the new, 2-month cumulative trip limit period. The 500-lb (227-kg) per-trip limit for sablefish smaller than 22 inches (56 cm) remains in effect.

Dover sole were managed somewhat indirectly in 1995, as in previous years. Until December 1, the amount of the DTS limit that was not comprised of thornyheads or trawl-caught sablefish could be Dover sole. A ''per trip'' limit of 3,000 lb (1,361 kg) was implemented on December 1, concurrent with the closure of the limited entry and open access fisheries for thornyheads and trawl-caught sablefish, to accommodate bycatch in the petrale sole fishery. Landings of Dover sole are expected to be far below its harvest guidelines in 1995 (projected at 42 percent below the coastwide harvest guideline and 30 percent below the Columbia subarea harvest guideline, even before the

reduction to 3,000 lb (1,361 kg) cumulative in December 1995). These ''underages'' were not addressed by increasing the trip limits in 1995 because of the close association of Dover sole, sablefish, and thornyheads, and new information supporting more cautious management of Dover sole. In 1996, Dover sole will be managed the same as in 1995; the trip limit will be the amount of the DTS limit remaining after subtracting landings of sablefish and thornyheads.

Nontrawl sablefish

Small daily trip limits were applied to the nontrawl fishery again in 1995 before and after the August 6–13, 1995, ''regular'' and September 1–31, 1995, ''mop-up'' seasons. A 300-lb (136-kg) daily trip limit was applied only north of the Conception subarea (36°00′00″ N. lat.), the same area covered by the harvest guideline. In the Conception area, where there is no harvest guideline and landings had been below the 425-mt ABC, the daily trip limit was 350 lb (159 kg) to accommodate most landings without encouraging excessive effort shifts into that area. The trip limit for sablefish smaller than 22 inches (56 cm) of 1,500 lb (680 kg) or 3 percent of all legal sablefish on board, whichever is greater, remained in effect during the regular and mop-up seasons. In 1995, the regular (derby) season was preceded by a 72-hour closure for all limited entry and open access fixed gear used to take and retain groundfish, with one exception. Pot gear could be set 24 hours before the regular season because this gear takes longer to deploy. Landings in 1995 are expected to be just below the limited entry nontrawl allocation for sablefish of 2,754 mt.

In 1996, the same daily trip limits for the limited entry fishery will apply outside the regular and mop-up seasons and any closure. The ''per trip'' limit for nontrawl sablefish smaller than 22 inches (56 cm) will remain in effect during the regular and mop-up fisheries, but, for ease of calculation, the percentage is modified to apply only to legal sablefish 22 inches (56 cm) or larger (total length). The Council recommended that the date of the regular season be changed to September 1 in 1996. This change has not yet been approved by NMFS. The Council also is considering different management strategies for 1997 and beyond, but has not yet submitted a recommendation to NMFS.

Whiting

Approximately 176,600 mt of whiting was harvested in 1995, 74,000 mt by the shore-based fleet and 102,600 mt by the at-sea processing sector (which includes deliveries to motherships). The 10,000-lb (4,536-kg) trip limit for whiting taken before and after the regular whiting season and inside the 100-fathom (183-m) contour in the Eureka subarea (40°30′00″-43°00′00″ N. lat.) continues in effect in 1996. Additional regulations, including the allocation of whiting to vessels that deliver shoreside and those that deliver at-sea, are found at 50 CFR 663.23(b) (3) and (4). The Council has recommended that the start of the regular season north of 42° N. lat. be changed from April 15 to May 15, but this recommendation has not yet been approved by NMFS.

Lingcod

Throughout 1995, lingcod was managed under a monthly cumulative trip limit of 20,000 lb (9,072 kg). Lingcod smaller than 22 inches (56 cm) could not be landed in the commercial or recreational fisheries until August 1, 1995, when a 100-lb (45-kg) per trip exception was made for trawl-caught lingcod. Landings of lingcod are projected at 1,431 mt in 1995, 3 percent below the harvest guideline. To maintain similar landing rates in 1996, the cumulative limit is doubled to 40,000 lb (18,144 kg) per 2-month period.

Black Rockfish

Black rockfish off the State of Washington continue to be managed under the regulations at 50 CFR 663.23(b). The State of Oregon implements trip limits for black rockfish off the Oregon coast. The Council has considered trip limits off Oregon but has not yet submitted its recommendation to NMFS for review.

B. Open Access Fishery

The trip limits for the open access fishery are designed to keep landings within the open access allocation, while allowing the fisheries to operate for as long as possible during the year. The overall open access limits for rockfish, sablefish and ''all groundfish'' in 1996 are the same as in 1995 with several exceptions, explained below.

(1) As in 1995, any more restrictive limits imposed on limited entry vessels also apply to open access vessels. However, in 1996, a vessel operating in the open access fishery may not, in any calendar month, exceed 50 percent of any 2-month cumulative trip limit in the limited entry fishery. This is intended to maintain a relatively consistent pattern of landings and to discourage new entry into the open access fishery.

(2) A daily trip limit is added for thornyheads to keep landings within the new open access allocation (4 mt in 1996). Landings of shortspine thornyheads by open access vessels are estimated at over 150 mt in 1995, much higher than landings during the 1984–88 window period. The best available information at the October 1995 Council meeting indicated that a trip limit of 50 lb (23 kg) per day would accommodate most open access trips, but still may be too liberal to keep landings within the open access allocation in 1996. After the Council made its recommendation, some members of the industry stated that 50 lb (23 kg) per day was too low to sustain current fisheries south of Point Conception CA (34°27′ N. lat.). Historical landings by open access vessels were less than 1 percent coastwide during the window period, so they were even smaller south of Pt. Conception, suggesting this is new effort in the area which the FMP seeks to discourage. Nonetheless, the Council may reconsider this issue in the future.

(3) The open access trip limits in 1995 applied to all shrimp and prawn gear. In 1996, they will apply only to shrimp/prawn trawl gear because the open access trip limits for pots already accommodate shrimp gear that conforms with the Federal requirements for groundfish pots: To have biodegradable escape panels constructed with #21 or smaller untreated cotton twine in such a manner that an opening at least 8 inches (20.5 cm) in diameter results when the twine deteriorates (50 CFR 663.22(e)).

C. Operating in Both Limited Entry and Open Access Fisheries

Vessels using open access gear are subject to the management measures for the open access fishery, whether or not the vessel has a valid limited entry permit endorsed for any other gear. In addition, a vessel operating in the open access fishery must not exceed any trip limit, frequency limit, and/or size limit for the same gear and/or subarea in the limited entry fishery (as announced in this Federal Register document in paragraphs titled ''limited entry''). A vessel that operates in both the open access and limited entry fisheries is not entitled to two separate trip limits for the same species. Fish caught with open access gear will also be counted toward the limited entry trip limit. For example: In one month, a trawl vessel catches 6,000 lb (2,722 kg) of sablefish in the limited entry fishery, and in the same month catches 1,500 lb (680 kg) of sablefish with shrimp trawl (open access) gear, for a total of 7,500 lb (3,402 kg) of sablefish. Because the open access landings are counted toward the limited entry limit, the vessel would have

exceeded its limited entry, cumulative limit of 7,200 lb (3,266 kg) (60 percent of the 12,000-lb (5,443-kg) 2-month cumulative limit for the limited entry fishery).

D. Operating in Areas with Different Trip Limits

Trip limits may differ for a species or species complex at different locations on the coast. Unless otherwise stated (as for yellowtail rockfish, black rockfish, and the *Sebastes complex*), the same cross-over provisions utilized in 1995 will apply.

E. Changes to Trip Limits; Closures

Unless otherwise stated, a vessel must have initiated offloading its catch before the fishery is closed or before a more restrictive trip limit becomes effective. As in the past, all fish on board the vessel when offloading begins are counted toward the landing limits (See 50 CFR 663.2, the definition of ''landing'').

F. Designated Species B Permits

Designated species B permits may be issued if the limited entry fleet will not fully utilize the harvest guideline for Pacific whiting, shortbelly rockfish, or jack mackerel. However, the limited entry fleet has requested the full use of these species in 1996, so issuance of designated species B permits is not expected. If designated species B permits for jack mackerel are issued, the bycatch limits announced in the 1995 annual management measures (60 FR 2331, January 9, 1995) may be used or modified.

G. Recreational Fishing

Bag limits in the 1996 recreational fishery remain the same as in 1995.

IV. NMFS Actions

For the reasons stated above, the Assistant Administrator for Fisheries, NOAA (Assistant Administrator), concurs with the Council's recommendations and announces the following management actions for 1996, including those that are the same as in 1995.

A. General Definitions and Provisions

The following definitions and provisions apply to the 1996 management measures, unless otherwise specified in a subsequent notice:

(1) *Trip limits.* Trip limits are used in the commercial fishery to specify the amount of fish that may legally be taken and retained, possessed, or landed, per vessel, per fishing trip, or cumulatively per unit of time, or the number of landings that may be made from a vessel in a given period of time, as explained below.

(a) *A trip limit* is the total allowable amount of a groundfish species or species complex, by weight, or by percentage of fish on board, that may be taken and retained, possessed, or landed per vessel from a single fishing trip.

(b) *A daily trip limit* is the maximum amount that may be taken and retained, possessed, or landed per vessel in 24 consecutive hours, starting at 0001 hours local time. Only one landing of groundfish may be made in that 24-hour period. Daily trip limits may not be accumulated during multiple day trips.

(c) *A cumulative trip limit* is the maximum amount that may be taken and retained, possessed, or landed per vessel in a specified period of time, without a limit on the number of landings or trips.

(i) *Limited entry fishery.* Unless otherwise specified, cumulative trip limits in the limited entry fishery apply to 2-month periods. No more than 60 percent of the applicable 2-month cumulative limit may be taken and retained, possessed or landed in either month of a 2-month period; this is called the ''60-percent monthly limit.'' The 2-month periods are: January–February, March–April, May–June, July–August, September–October, November–December.

(ii) *Open access fishery.* Unless otherwise specified, cumulative trip limits apply to 1-month periods in the open access fishery. Within these limits, in any calendar month, no more than 50 percent of the applicable 2-month cumulative limit for the limited entry fishery may be taken and retained, possessed, or landed from a vessel in the open access fishery; this is called the ''50-percent monthly limit.''

(2) Unless the fishery is closed, a vessel that has landed its cumulative or daily limit may continue to fish on the limit for the next legal period, so long as no fish (including but not limited to groundfish with no trip limits, shrimp, prawns, or other nongroundfish species or shellfish) are landed (offloaded) until the next legal period. As stated in the regulations at 50 CFR 663.2, once offloading of any species begins, all fish aboard the vessel are counted as part of the landing.

(3) All weights are round weights or round-weight equivalents.

(4) Percentages are based on round weights, and, unless otherwise specified, apply only to legal fish on board.

(5) ''Legal fish'' means fish legally taken and retained, possessed, or landed in accordance with the provisions of 50 CFR part 663, the Magnuson Fishery Conservation and Management Act (Magnuson Act), any notice issued under subpart B of part 663, and any other regulation promulgated or permit issued under the Magnuson Act.

(6) *Size limits and length measurement.* Unless otherwise specified, size limits in the commercial and recreational groundfish fisheries apply to the longest measurement of the fish without mutilation of the fish or the use of force to extend the length of the fish. No fish with a size limit may be retained if it is in such condition that its length has been extended or cannot be determined by these methods.

(a) For a whole fish, total length will be measured from the tip of the snout (mouth closed) to the tip of the tail in a natural, relaxed position.

(b) For a fish with the head removed (''headed''), the length will be measured from the origin of the first dorsal fin (where the front dorsal fin meets the dorsal surface of the body closest to the head) to the tip of the upper lobe of the tail; the dorsal fin and tail must be left intact.

(7) ''Closure,'' when referring to closure of a fishery, means that taking and retaining, possessing, or landing the particular species or species group is prohibited. (See the regulations at 50 CFR 663.2.) Unless otherwise announced in the Federal Register, offloading must begin before the time the fishery closes.

(8) The fishery management area for these species is the EEZ off the coasts of Washington, Oregon, and California between 3 and 200 nm offshore, bounded on the north by the Provisional International Boundary between the United States and Canada, and bounded on the south by the International Boundary between the United States and Mexico. All groundfish possessed between 0–200 nm offshore, or landed in, Washington, Oregon, or California are presumed to have been taken and retained from the fishery management area, unless otherwise demonstrated by the person in possession of those fish.

(9) Inseason changes to trip limits are announced in the Federal Register. Most trip and bag limits in the groundfish fishery have been designated ''routine,'' which means they may be changed rapidly after a single Council meeting. Information concerning changes to trip limits is available from the NMFS Northwest and Southwest Regional Offices (see **ADDRESSES**). Changes to trip limits are effective at the times stated in the Federal Register. Once a change is effective, it is illegal to take and retain, possess, or land more fish than allowed under the new trip limit. This means, unless otherwise

announced in the Federal Register, offloading must begin before the time a fishery closes or a more restrictive trip limit takes effect.

(10) It is unlawful for any person to take and retain, possess, or land groundfish in excess of the landing limit for the open access fishery without having a valid limited entry permit for the vessel affixed with a gear endorsement for the gear used to catch the fish (50 CFR 663.7(t)).

(11) *Operating in both limited entry and open access fisheries.* The open access trip limit applies to any fishing conducted with open access gear, even if the vessel has a valid limited entry permit with an endorsement for another type of gear. A vessel that operates in both the open access and limited entry fisheries is not entitled to two separate trip limits for the same species. Fish caught with open access gear will also be counted toward the limited entry trip limit.

(12) *Operating in areas with different trip limits.* Trip limits for a species or species complex may differ in different geographic areas along the coast. The following ''crossover'' provisions apply to vessels operating in different geographical areas that have different cumulative or ''per trip'' trip limits for the same species or species complex. They do not apply to species that are only subject to daily trip limits, or to the trip limits for black rockfish off the State of Washington (see 50 CFR 663.23(b)). They also do not apply to the trip limits for yellowtail rockfish and the *Sebastes* complex when the vessel is in compliance with paragraph IV.C.(2)(c) below.

If a vessel fishes, for any species, in an area where a more restrictive trip limit applies, then that vessel is subject to the more restrictive trip limit for the entire period to which that trip limit applies, no matter where the fish are taken and retained, possessed, or landed. Similarly, if a vessel takes and retains a species (or species complex) in an area where a higher trip limit (or no trip limit) applies, and possesses or lands that species (or species complex) in an area where a more restrictive trip limit applies, then that vessel is subject to the more restrictive trip limit for that trip limit period.

In 1996, the trip limit period for cumulative trip limits is 2 months for the limited entry fishery and 1 month for the open access fishery, unless otherwise specified.

(13) *Sorting.* Regulations at 50 CFR 663.7(l) make it unlawful for any person to ''fail to sort, prior to the first weighing after offloading, those groundfish species or species groups for which there is a trip limit, if the weight of the total delivery exceeds 3,000 lb (1,361 kg) (round weight or round weight equivalent).'' This provision applies to both the limited entry and open access fisheries.

[Note: The Council has recommended that this regulation be changed to require all species or species groups with a trip limit, harvest guideline, or quota to be sorted. There would be no exception for landings under 3,000 lb (1,361 kg). The States of Washington and Oregon already have the same or similar requirements. If approved, the regulation is expected to be implemented in 1996, after publication in the Federal Register.]

(14) *Experimental fisheries.* U.S. vessels operating under an experimental fishing permit issued under 50 CFR 663.10 also are subject to these restrictions, unless otherwise provided in the permit.

(15) Paragraphs IV.B. through IV.I. below pertain to the commercial groundfish fishery. The provisions in paragraphs IV.B. through IV.I. that are not covered under the headings ''limited entry'' or ''open access'' apply to all vessels in the commercial fishery that take and retain groundfish, unless otherwise stated. Paragraph IV.J. pertains to the recreational fishery.

(16) *Commonly used geographical coordinates.*

(a) Cape Falcon, OR—45°46′ N. lat.

(b) Cape Lookout, OR—45°20′15″ N. lat.

(c) Cape Mendocino, CA—40°30′ N. lat.

(d) Point Conception, CA—34°27′ N. lat.

(e) International North Pacific Fisheries Commission (INPFC) subareas (for more precise coordinates for the Canadian and Mexican boundaries, see 50 CFR 663.5):

(i) Vancouver—U.S.- Canada border to 47°30′ N. lat.

(ii) Columbia—47°30′ to 43°00′ N. lat.

(iii) Eureka—43°00′ to 40°30′ N. lat.

(iv) Monterey—40°30′ to 36°00′ N. lat.

(v) Conception—36°00′ N. lat. to the U.S.-Mexico border.

B. Widow Rockfish (Widow rockfish are commonly called brownies)

(1) *Limited entry fishery.* The cumulative trip limit for widow rockfish is 70,000 lb (31,752 kg) per vessel per 2-month period. The 60-percent monthly limit is 42,000 lb (19,051 kg).

(2) *Open access fishery.* Within the limits at paragraph IV.I. below, the 50-percent monthly limit for widow rockfish is 35,000 lb (15,876 kg).

C. Sebastes Complex (including Bocaccio, Yellowtail, and Canary Rockfish)

(1) *General. Sebastes* complex means all rockfish managed by the FMP except Pacific ocean perch (*Sebastes alutus*), widow rockfish (*S. entomelas*), shortbelly rockfish (*S. jordani*), and *Sebastolobus* spp. (also called thornyheads, idiots, or channel rockfish). Yellowtail rockfish (*S. flavidus*) are commonly called greenies. Bocaccio (*S. paucispinis*) are commonly called rock salmon. Canary rockfish (*S. pinniger*) are commonly called orange rockfish.

(2) *Limited entry fishery*

(a) *Cumulative trip limits*

(i) *North of Cape Lookout.* The cumulative trip limit for the *Sebastes* complex taken and retained north of Cape Lookout is 70,000 lb (31,752 kg) per vessel per 2-month period. Within this cumulative trip limit for the *Sebastes* complex, no more than 32,000 lb (14,515 kg) may be yellowtail rockfish taken and retained north of Cape Lookout, and no more than 18,000 lb (8,165 kg) may be canary rockfish.

(ii) *Cape Lookout to Cape Mendocino.* The cumulative trip limit for the *Sebastes* complex taken and retained between Cape Lookout and Cape Mendocino is 100,000 lb (45,359 kg) per vessel per 2-month period. Within this cumulative trip limit for the *Sebastes* complex, no more than 70,000 lb (31,752 kg) may be yellowtail rockfish taken and retained between Cape Lookout and Cape Mendocino, and no more than 18,000 lb (8,165 kg) may be canary rockfish.

(iii) *South of Cape Mendocino.* The cumulative trip limit for the *Sebastes* complex taken and retained south of Cape Mendocino is 200,000 lb (90,719 kg) per vessel per 2-month period. Within this cumulative trip limit for the *Sebastes* complex, no more than 60,000 lb (27,216 kg) may be bocaccio taken and retained south of Cape Mendocino, and no more than 18,000 lb (8,165 kg) may be canary rockfish.

(iv) The 60-percent monthly limits are: For the *Sebastes complex, 42,000 lb (19,051 kg) north of Cape Lookout, 60,000 lb (27,216 kg) between Cape Lookout and Cape Mendocino, and 120,000 lb (54,431 kg) south of Cape Mendocino; for yellowtail rockfish, 19,200 lb (8,709 kg) north of Cape Lookout, and 42,000 lb (19,051 kg) between Cape Lookout and Cape Mendocino; for bocaccio, 36,000 lb (16,329 kg) south of Cape Mendocino; and, for canary rockfish, 10,800 lb (4,899 kg) coastwide.*

(b) For operating in areas with different trip limits for the same species, see paragraph IV.A.(12) above.

(c) *State declarations.* The provisions of paragraph IV.A.(12) do not apply to vessels fishing in conformance with this paragraph. The States of Oregon and Washington are implementing declaration procedures that enable a vessel that fishes or transits both north and south of Cape Lookout during a trip limit period (2 months for the limited entry fishery, 1 month for the open access fishery) to retain the larger cumulative limit for the *Sebastes* complex and yellowtail rockfish taken and retained south of Cape Lookout. Declarations must be made, according to state law, to the state where the fish will be landed. To make a declaration or for further information, contact: Washington Department of Fish and Wildlife, Montesano, WA, at 206–249–4628; or Oregon Department of Fish and Wildlife, Newport, OR, at 503–867–4741 or 503–867–0300.

(3) *Open access fishery.*

(a) The state declaration procedures are available to all vessels, whether in the limited entry or open access fishery.

(b) Within the limits at paragraph IV.I. below, the 50-percent monthly limits are: For the *Sebastes* complex, 35,000 lb (15,876 kg) north of Cape Lookout, 50,000 lb (22,680 kg) between Cape Lookout and Cape Mendocino, and 100,000 lb (45,359 kg) south of Cape Mendocino; for yellowtail rockfish, 16,000 lb (7,258 kg) north of Cape Lookout, and 35,000 lb (15,876 kg) between Cape Lookout and Cape Mendocino; for bocaccio, 30,000 lb (13,608 kg) south of Cape Mendocino; and, for canary rockfish, 9,000 lb (4,082 kg) coastwide.

D. POP

(1) *Limited entry fishery.* The cumulative trip limit for POP is 10,000 lb (4,536 kg) per vessel per 2-month period. The 60-percent monthly limit is 6,000 lb (2,722 kg).

(2) *Open access fishery.* Within the limits at paragraph IV.I. below, the 50-percent monthly limit for POP is 5,000 lb (2,268 kg).

E. Sablefish and the DTS Complex (Dover Sole, Thornyheads, and Trawl-Caught Sablefish)

(1) *1996 Management goal.* The sablefish fishery will be managed to achieve the 7,800-mt harvest guideline in 1996.

(2) *Washington coastal tribal fisheries.* The U.S. Government recognizes that the Makah, Hoh, Quileute, and Quinault tribes have treaty rights to fish for groundfish. Each tribe has such right in its usual and accustomed fishing grounds. The tribal treaty allocation for sablefish for 1996 is 780 mt. The tribes will regulate their fisheries so as not to exceed this allocation.

(3) *Limited entry fishery*

(a) *Gear allocations.* After subtracting the tribal-imposed catch limit and the open access allocation from the harvest guideline for sablefish, the remainder is allocated 58 percent to the trawl fishery and 42 percent to the nontrawl fishery.

[Note: The 1996 harvest guideline for sablefish north of 36° N. lat. is 7,800 mt. The 780-mt tribal allocation is subtracted, and the limited entry and open access allocations are based on the remaining 7,020 mt. The limited entry allocation of 6,557 mt for 1996 is allocated 3,803 mt (58 percent) to the trawl fishery and 2,754 mt (42 percent) to the nontrawl fishery. The trawl and nontrawl gear allocations are harvest guidelines in 1996, which means the fishery will be managed not to exceed the harvest guidelines, but will not necessarily be closed if they are reached.]

(b) *Limited entry trip and size limits for the DTS complex.* These provisions apply to Dover sole and thornyheads caught with any limited entry gear and to sablefish caught with limited entry trawl gear. ''DTS complex'' means Dover sole (*Microstomus pacificus*), thornyheads (*Sebastolobus* spp.), and trawl-caught sablefish (*Anoplopoma fimbria*). Sablefish are also called blackcod. Thornyheads, also called idiots, channel rockfish, or hardheads, include two species, shortspine thornyheads (*S. alascanus*) and longspine thornyheads (*S. altivelis*).

(i) *North of Cape Mendocino.* The cumulative trip limit for the DTS complex taken and retained north of Cape Mendocino is 70,000 lb (31,752 kg) per vessel per 2-month period. Within this cumulative trip limit, no more than 12,000 lb (5,443 kg) may be sablefish, and no more than 20,000 lb (9,072 kg) may be thornyheads. No more than 4,000 lb (1,814 kg) of the thornyheads may be shortspine thornyheads.

(ii) *South of Cape Mendocino.* The cumulative trip limit for the DTS complex taken and retained south of Cape Mendocino is 100,000 lb (45,359 kg) per vessel per 2-month period. Within this cumulative trip limit, no more than 12,000 lb (5,443 kg) may be sablefish, and no more than 20,000 lb (9,072 kg) may be thornyheads. No more than 4,000 lb (1,814 kg) of the thornyheads may be shortspine thornyheads.

(iii) The 60-percent monthly limits are: For the DTS complex, 42,000 lb (19,051 kg) north of Cape Mendocino, and 60,000 lb (27,216 kg) south of Cape Mendocino; for trawl-caught sablefish, 7,200 lb (3,266 kg); for both species of thornyheads combined, 12,000 lb (5,443 kg); and for shortspine thornyheads, 2,400 lb (1,089 kg).

(iv) In any trip, no more than 500 lb (227 kg) may be trawl-caught sablefish smaller than 22 inches (56 cm) total length. (See paragraph IV.A.(6) regarding length measurement.)

(v) For operating in areas with different trip limits for the same species, see paragraph IV. A.(12) above.

(c) *Limited entry trip and size limits for nontrawl sablefish.* These daily trip limits, which apply to sablefish of any size, apply until the closed period before the start of the regular season (as specified at 50 CFR 663.23(b)(2)), between the end of the regular season and the beginning of the mop-up season, and after the mop-up season.

[Note: The Council recommended that the regular season be delayed until September 1, 1996. Before this change can be made effective, it must be approved by NMFS and then implemented by a regulation published in the Federal Register.]

(i) *North of 36°00′ N. lat.* The daily trip limit for sablefish taken and retained with nontrawl gear north of 36°00′ N. lat. is 300 lb (136 kg).

(ii) *South of 36°00′ N. lat.* The daily trip limit for sablefish taken and retained with nontrawl gear south of 36°00′ N. lat. is 350 lb (159 kg).

(iii) During the ''regular'' or ''mop-up'' seasons, the only trip limit in effect applies to sablefish smaller than 22 inches (56 cm) total length, which may comprise no more than 1,500 lb (680 kg) or 3 percent of all legal sablefish 22 inches (56 cm) (total length) or larger, whichever is greater. (See paragraph IV.A.(6) regarding length measurement.)

(d) For headed and gutted sablefish:

(i) The minimum size limit for headed sablefish, which corresponds to 22 inches (56 cm) total length for whole fish, is 15.5 inches (39 cm).

(ii) The conversion factor established by the state where the fish is or will be landed will be used to convert the processed weight to round weight for purposes of applying the trip limit. (The conversion factor currently is 1.6 in Washington, Oregon, and California. However, the state conversion factors may differ; fishermen should contact fishery enforcement officials in the state where the fish will be landed to determine that state's official conversion factor.)

(4) *Open access fishery.* Within the limits in paragraph IV.I. below, a vessel using exempt trawl gear in the open access fishery is subject to the 50-

percent monthly limits, which are as follows: For the DTS complex, 35,000 lb (15,876 kg) north of Cape Mendocino, and 50,000 lb (22,680 kg) south of Cape Mendocino; for trawl-caught sablefish, 6,000 lb (2,722 kg); for both species of thornyheads combined, 10,000 lb (4,536 kg); and for shortspine thornyheads, 2,000 lb (907 kg).

F. Whiting

(1) *Limited entry fishery.* Additional regulations that apply to the whiting fishery are found at 50 CFR 663.7 and 663.23(b)(3) and (4).

(a) No more than 10,000 lb (4,536 kg) of whiting may be taken and retained, possessed, or landed, per vessel per fishing trip before the regular season for whiting begins, as specified at 50 CFR 663.23(b)(3). This includes any whiting caught shoreward of 100 fathoms (183 m) in the Eureka subarea (see paragraph IV.F.(1)(b)).

(b) No more than 10,000 lb (4,536 kg) of whiting may be taken and retained, possessed, or landed by a vessel that, at any time during a fishing trip, fished in the fishery management area shoreward of the 100-fathom (183-m) contour (as shown on NOAA Charts 18580, 18600, and 18620) in the Eureka subarea.

(2) *Open access fishery.* See paragraph IV.I. below.

G. Lingcod

(1) *Limited entry fishery.* The cumulative trip limit for lingcod is 40,000 lb (18,144 kg) per vessel per 2-month period. The 60-percent monthly limit is 24,000 lb (10,886 kg). No lingcod may be smaller than 22 inches (56 cm) total length, except for a 100-lb (45-kg) trip limit for trawl-caught lingcod smaller than 22 inches (56 cm). Length measurement is explained at paragraph IV.A.(6)

(2) *Open access fishery.* Within the limits in paragraph IV.I. below, the 50-percent monthly limit for lingcod is 20,000 lb (9,072 kg).

(3) *Conversions*

(a) *Size conversion.* For lingcod with the head removed, the minimum size limit, which corresponds to 22 inches (56 cm) total length for whole fish, is 18 inches (46 cm).

(b) *Weight conversion.* The conversion factor established by the state where the fish is or will be landed will be used to convert the processed weight to round weight for purposes of applying the trip limit. (The states' conversion factors may differ and fishers should contact fishery enforcement officials in the state where the fish will be landed to determine that state's official conversion factor.) If a state does not have a conversion factor for lingcod that is headed and gutted, or only gutted, the following conversion factors will be used. To determine the round weight, multiply the processed weight times the conversion factor.

(i) *Headed and gutted.* The conversion factor for headed and gutted lingcod is 1.5. (The State of Washington currently uses a conversion factor of 1.5.)

(ii) *Gutted, with the head on.* The conversion factor for lingcod that has only been eviscerated is 1.1.

H. Black Rockfish

The regulations currently at 50 CFR 663.23(b)(1)(iii) state: ''The trip limit for black rockfish (*Sebastes melanops*) for commercial fishing vessels using hook-and-line gear between the U.S.-Canada border and Cape Alava (48°09′30″ N. lat.), and between Destruction Island (47°40′00″ N. lat.) and Leadbetter Point (46°38′10″ N. lat.), is 100 lb or 30 percent by weight of all fish on board, whichever is greater, per vessel per fishing trip. This trip limit does not apply to coastal treaty Indian fishermen operating under harvest guidelines established under paragraph (b)(1)(ii) of this section [§ 663.23].'' The provisions at paragraphs IV.A.(12) and IV.C.(2)(c) do not apply.

I. Trip Limits in the Open Access Fishery

A vessel operating in the open access fishery must not exceed any trip limit, frequency limit, and/or size limit for the open access fishery; or for the same gear and/or subarea in the limited entry fishery; or, in any calendar month, 50 percent of any 2-month cumulative trip limit for the same gear and/or subarea in the limited entry fishery, called the ''50-percent monthly limit.'' For purposes of this paragraph, exempted trawl gear (that is used to harvest shrimp, prawns, California halibut or sea cucumbers as provided in this paragraph I.) may not exceed any limit for the limited entry trawl fishery, or 50 percent of any 2-month cumulative limit that applies to limited entry trawl gear. No groundfish landing by shrimp or prawn pot (trap) gear may be in excess of the limited entry trip limit for nontrawl gear. The cross-over provisions at paragraph IV.A.(12) that apply to the limited entry fishery apply to the open access fishery as well.

(1) *Rockfish.* Rockfish means all rockfish as defined at 50 CFR 663.2, which includes the *Sebastes* complex (including yellowtail rockfish, bocaccio, and canary rockfish), shortbelly rockfish, widow rockfish, POP, and thornyheads.

(a) *North of Cape Lookout.* The cumulative monthly trip limit for rockfish taken and retained north of Cape Lookout is 35,000 lb (15,876 kg) per vessel per month.

(b) *South of Cape Lookout.* The cumulative monthly trip limit for rockfish taken and retained south of Cape Lookout is 40,000 lb (18,144 kg) per vessel per month.

(c) *Coastwide.* The following trip limits also apply and are counted toward the cumulative monthly limit for rockfish:

(i) 10,000-lb (4,536-kg) of rockfish per vessel per fishing trip, except for vessels using setnet or trammel net gear; and,

(ii) A daily trip limit of 50 lb (23 kg) of thornyheads.

(d) For operating in areas with different trip limits for the same species, see paragraph IV.A.(12) above.

(2) *Sablefish.* [*Note*: Under current regulations, the closure prior to the ''regular season'' for the limited entry fishery also applies to the open access fishery.]

(a) *North of 36°00′ N. lat.* The daily trip limit for sablefish taken and retained north of 36°00′ N. lat. is 300 lb (136 kg).

(b) *South of 36°00′ N. lat.* The daily trip limit for sablefish taken and retained south of 36°00′ N. lat. is 350 lb (159 kg).

(3) *Groundfish taken by shrimp or prawn trawl*

(a) *Pink shrimp.* The trip limit for a vessel engaged in fishing for pink shrimp is 1,500 lb (680 kg) (multiplied by the number of days of the fishing trip) of groundfish.

(b) *Spot and ridgeback prawns.* The trip limit for a vessel engaged in fishing for spot or ridgeback prawns is 1,000 lb (454 kg) of groundfish species per fishing trip.

(c) This rule is not intended to supersede any more restrictive state law relating to the retention of groundfish taken in shrimp or prawn pots or traps.

(4) *Groundfish taken by California halibut or sea cucumber trawl.* The trip limit for a vessel participating in the California halibut fishery or in the sea cucumber fishery south of Point Arena, CA (38°57′30″ N. lat.) is 500 lb (227 kg) of groundfish per vessel per fishing trip.

(a) A trawl vessel will be considered participating in the California halibut fishery if:

(i) It is not fishing under a valid limited entry permit issued under 50 CFR part 663 for trawl gear;

(ii) All fishing on the trip takes place south of Point Arena; and

(iii) The landing includes California halibut of a size required by California Fish and Game Code section 8392(a),

which states: ''No California halibut may be taken, possessed or sold which measures less than 22 inches in total length, unless it weighs four pounds or more in the round, three and one-half pounds or more dressed with the head on, or three pounds or more dressed with the head off. Total length means the shortest distance between the tip of the jaw or snout, whichever extends farthest while the mouth is closed, and the tip of the longest lobe of the tail, measured while the halibut is lying flat in natural repose, without resort to any force other than the swinging or fanning of the tail.''

(b) A trawl vessel will be considered participating in the sea cucumber fishery if:

(i) It is not fishing under a valid limited entry permit issued under 50 CFR part 663 for trawl gear;

(ii) All fishing on the trip takes place south of Point Arena; and

(iii) The landing includes sea cucumbers taken in accordance with California Fish and Game Code section 8396, which requires a permit issued by the State of California.

J. Recreational Fishery

(1) *California.* The bag limits for each person engaged in recreational fishing seaward of the State of California are: five lingcod per day, which may be no smaller than 22 inches (56 cm) total length; and 15 rockfish per day. Multi-day limits are authorized by a valid permit issued by the State of California and must not exceed the daily limit multiplied by the number of days in the fishing trip.

(2) *Oregon.* The bag limits for each person engaged in recreational fishing seaward of the State of Oregon are: Three lingcod per day, which may be no smaller than 22 inches (56 cm) total length; and 15 rockfish per day, of which no more than 10 may be black rockfish (*Sebastes melanops*).

(3) *Washington.* The bag limits for each person engaged in recreational fishing seaward of the State of Washington are: three lingcod per day no smaller than 22 inches (56 cm) total length, and either 15 rockfish per day south of Leadbetter Point (46°38′10″ N. lat.) or 12 rockfish per day north of Leadbetter Point.

V. Issuance of Experimental Fishing Permits (EFPs) in 1995

In 1995, applications were received and approved for three different types of experimental fishing permits (50 CFR 663.10).

(1) The first was from the State of Oregon (representing Washington and California as well) for the purpose of renewing the EFP to monitor the bycatch of salmon in the shore-based whiting fishery. Under this permit, 35 vessels were issued EFPs that required all salmon caught incidentally in the whiting fishery to be landed shoreside. Almost 15 percent of the shore-based landings were observed, higher than the 10 percent goal.

(2) The second application was a variation of the whiting EFP. The State of California requested that, in addition to the terms and conditions governing the whiting EFP, a small number of fishers be allowed to fish for whiting inside of the 100-fathom (183-m) contour in the Eureka subarea, which currently is prohibited. The purpose was to see if the bycatch rate of salmon could be kept at acceptable levels by this small, shore-based sector of the fleet delivering to Eureka and Crescent City, CA. However, whiting did not appear in fishable concentrations in 1995, so even though this experimental fishery was approved, the EFPs were not issued.

(3) The third application was for a new, enhanced data collection program that applied to other groundfish fisheries. This application was submitted by the State of Oregon, but could include involvement by the States of Washington and California as well. The purpose of the experiment was to monitor trip-limit-induced discards and the bycatch of salmon and non-target species in the groundfish trawl fishery. All participating vessels will be required to land salmon caught incidentally in groundfish trawl gear and to keep enhanced logbooks required by the State of Oregon. Some vessels will carry at-sea observers to monitor trip-limit induced discards, and some vessels will be required to bring virtually their entire catch to shore for additional monitoring. This is intended to be the first of a multi-year cooperative data collection program with the industry and state and Federal governments. This fishery started later than expected. Three EFPs have been issued since early November 1995. The EFP program may continue through 1996.

VI. Applications for Experimental Fishing Permits in 1996

Three applications also were received for experimental fishing permits in 1996. Two, the whiting EFPs described in paragraphs (1) and (2) of paragraph V. above, had been approved for 1995. The scope of the experiment and level of participation would be the same as requested for 1995. The third is for a new experiment to obtain biological information on sablefish to confirm or improve data used in the stock assessment for this species. This experiment would allow one vessel to retain 500 lb (227 kg) in excess of the trawl trip limit for sablefish, and is not expected to exceed 5 mt per year. A state or Federal scientist would be aboard every trip to gather the biological data. These applications were presented at the Council's October 1995 meeting. The Council recommended issuance of all three in 1996. (In addition, the enhanced data collection program discussed as number (3) in the previous paragraph continues in 1996.) Comments on the three applications for 1996 are invited. If approved, the whiting EFPs would be issued by March 1 for vessels delivering in the State of California, and mid-April for vessels delivering in Washington and Oregon; and the EFP for sablefish would be issued early in 1996. The decision on whether to issue EFPs and determinations on appropriate permit conditions will be based on a number of considerations, including the Council's recommendation and comments received from the public.

Classification

The final specifications and management measures for 1996 are issued under the authority of and are in accordance with 50 CFR parts 611 and 663, the regulations implementing the FMP.

Much of the data necessary for these specifications and management measures came from the current fishing year. Because of the timing of the receipt, development, review, and analysis of the fishery information necessary for setting the initial specifications and management measures, and the need to have these specifications and management measures in effect at the beginning of the 1996 fishing year, there is good cause under 5 U.S.C. 553(b)(B) to waive prior notice and opportunity for public comment for the specifications and management measures. Amendment 4 to the FMP, implemented on January 1, 1991, recognized these timeliness considerations, and set up a system by which the interested public is notified, through Federal Register publication and Council mailings, of meetings and of the development of these measures, and is provided the opportunity to comment during the Council process. The public participated in GMT, Groundfish Advisory Subpanel, Scientific and Statistical Committee, and Council meetings in August and October 1995 where these recommendations were formulated. Additional public comments will be accepted for 30 days after publication of

this document in the Federal Register. The Assistant Administrator will consider all comments made during the public comment period and may propose modifications as appropriate.

Because prior notice and opportunity for public comment is not required under 5 U.S.C. 553, or under any other public law, preparation of a Regulatory Flexibility Analysis under 5 U.S.C. 603(a) and 604(a) is not required and none has been prepared.

The Administrative Procedure Act requires that publication of an action be made not less than 30 days before its effective date unless the Assistant Administrator finds and publishes with the rule good cause for an earlier effective date (5 U.S.C. 553(d)(3)). These specifications announce the harvest goals and the management measures designed to achieve those harvest goals in 1996. A delay in implementation could compromise the management strategies that are based on the projected landings from these trip limits. Therefore, a delay in effectiveness is contrary to the public interest and these actions are effective on January 1, 1996.

Dated: December 28, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 95–31580 Filed 12–29–95; 11:57 am]

BILLING CODE 3510–22–P

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50 CFR Part 625

[Docket No. 951116270–5308–02; I.D. 110195B]

Summer Flounder Fishery; Final Specifications for 1996; Technical Amendment

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

ACTION: Final specifications for the 1996 summer flounder fishery; final rule, technical amendment.

SUMMARY: NMFS issues the final specifications for the 1996 summer flounder fishery, which include commercial catch quotas and mesh size requirements, and revises the applicable regulations to accurately reflect the intent of the Mid-Atlantic Fishery Management Council regarding the ''cap'' on the harvest limit. The intent of this document is to comply with implementing regulations for the fishery that require NMFS to publish measures for the upcoming fishing year that will prevent overfishing of the summer flounder resource, and to modify the language specifying the ''cap'' on the annual harvest limit.

EFFECTIVE DATE: December 29, 1995.

ADDRESSES: Copies of the Environmental Assessment and supporting documents used by the Monitoring Committee are available from: Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 S. New Street, Dover, DE 19901–6790.

FOR FURTHER INFORMATION CONTACT: Regina Spallone, Fishery Policy Analyst, 508–281–9221.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for the Summer Flounder Fishery (FMP) was developed jointly by the Atlantic States Marine Fisheries Commission (ASMFC) and the Mid-Atlantic Fishery Management Council (Council) in consultation with the New England and South Atlantic Fishery Management Councils. The management unit for the FMP is summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina northward to the Canadian border. Implementing regulations for the fishery are found at 50 CFR part 625.

Section 625.20 of Title 50, Code of Federal Regulations implementing the Fishery Management Plan for the Summer Flounder Fishery (FMP) specifies the process for setting annual management measures in order to achieve the fishing mortality (F) rates specified in the FMP. Under Amendment 7 to the FMP, the schedule of F rates established sets a target fishing mortality rate of 0.41 in 1996, 0.3 in 1997, and 0.23 (F_{max}) in 1998 and thereafter, provided the allowable levels of fishing in 1996 and 1997 may not exceed a ''cap'' of 18.51 million lb (8.4 million kg), unless such fishing levels had an associated F of 0.23. This ''cap'' reflected a rounding of the actual poundage. The Council felt that such a rounding, while convenient for the reader, did not accurately reflect the true intent, which was 18,518,830 lb (8,400 mt). Therefore, this action modifies the ''cap'' to reflect the Council's intent that the maximum allowable harvest level associated with this ''cap'' is 18,518,830 lb (8,400 mt). This clarification is outlined in the section below, which specifies changes from the proposed specifications.

Pursuant to § 625.20, the Director, Northeast Region, NMFS, implements certain measures for the fishing year to ensure achievement of the appropriate fishing mortality rate. The measures include those that are changed, and those that are not changed, from the proposed 1996 specifications that were published in the Federal Register on November 28, 1995 (60 FR 58593). The unchanged measures include: (1) A minimum commercial fish size of 13 inches (33 cm); and (2) a minimum mesh size restriction of 5.5-inch (14.0-cm) diamond or 6-inch (15.2-cm) square. The changed measures include: (1) A coastwide harvest limit of 18,518,830 lb (8.40 million kg); (2) a coastwide commercial quota of 11,111,298 lb (5.04 million kg); and (3) a coastwide recreational harvest limit of 7,407,532 lb (3.36 million kg).

Commercial Quota

The coastwide commercial quota is allocated among the states based on historic catch shares specified in the regulations. Table 1 presents the 1996 commercial quota (11,111,298 lb; 5,040,000 kg) apportioned among the states according to the percentage shares specified in § 625.20(d)(1). These state allocations do not reflect the adjustments required under § 625.20, if 1995 landings exceed the 1995 quota for any state. A notification of allocation adjustment will be published in the Federal Register if such an adjustment is necessary.

TABLE 1.—1996 STATE COMMERCIAL QUOTAS

State	Share (%)	1996 quota (lb)	1996 quota (kg)
ME	0.04756	5,284	2,397
NH	0.00046	51	23
MA	6.82046	757,841	343,751
RI	15.68298	1,742,583	790,422
CT	2.25708	250,791	113,757
NY	7.64699	849,680	385,408
NJ	16.72499	1,858,363	842,939

TABLE 1.—1996 STATE COMMERCIAL QUOTAS—Continued

State	Share (%)	1996 quota (lb)	1996 quota (kg)
DE	0.01779	1,977	897
MD	2.03910	226,570	102,770
VA	21.31676	2,368,569	1,074,365
NC	27.44584	3,049,589	1,383,270

Recreational catch data for 1995 are not yet available. The Council and ASMFC will consider modifications to the recreational possession limit and recreational season after a review of that information.

Final Rule, Technical Amendment and Changes From Proposed Specifications to Final Specifications

This document modifies the language specified in § 625.20(a) established by the final rule for Amendment 7 to the FMP that set the harvest limit ''cap'' at 18.51 million lb (8,396 mt). The final rule, technical amendment contained in this action changes the harvest limit ''cap'' to be 18,518,830 lb (8,400 mt), making the ''cap'' consistent with Council intent as stated in the comment submitted by the Council and addressed below. The value of 8,400 mt is contained in Amendment 7 and that value is equivalent to 18,518,830 lb, which is 8,830 lb greater than the rounded off value of 18.51 million lb. As a result, the state allocations of commercial quota have been altered slightly relative to the proposed specifications.

Comments and Responses

One comment was received regarding the 1996 summer flounder specifications from the Council.

Comment: The Council checked the administrative record and acknowledged an error in the publication of the harvest limit ''cap'', as published in Amendment 7 to the FMP. The Council wishes to correct the specifications to reflect accurately their intent regarding the total harvest limit and subsequent specifications for the commercial and recreational fisheries. Specifically, the Council intended the total harvest limit to equal 18,518,830 lb (8,400 mt), rather than 18.51 million lb which actually equals 8,396 mt. The value of 18,518,830 lb would result in an allocation of 11,111,298 lb (5,040,000 kg) to the commercial sector, and 7,407,532 lb (3,360,000 kg) to the recreational sector.

Response: NMFS agrees. The administrative record shows that, for the purpose of reading ease, the numbers for pounds were rounded during publication. However, this rounding resulted in a loss of the original intent of the Council. To modify the regulations to reflect more accurately the record, a technical amendment to the final rule for Amendment 7 is necessary. That action accompanies the publication of these final specifications.

Classification

This action is authorized by 50 CFR part 625 and complies with the National Environmental Policy Act.

These final specifications are exempt from review under E.O. 12866.

For the technical regulatory change, NMFS finds good cause to waive prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B). The technical change corrects the regulation's codification of the quota cap in Amendment 7 to reflect accurately the language adopted by the Council. As such, NMFS finds that prior notice and comment are unnecessary. Further, there is no requirement to delay the effective date of this technical change as it is not a substantive rule.

List of Subjects in 50 CFR Part 625

Fisheries, Reporting and recordkeeping requirements.

Dated: December 28, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 625 is amended as follows:

PART 625—SUMMER FLOUNDER FISHERY

1. The authority citation for part 625 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 625.20, paragraph (a) introductory text is revised to read as follows:

§ 625.20 Catch quotas and other restrictions.

(a) *Annual review.* The Summer Flounder Monitoring Committee will review the following data on or before August 15 of each year to determine the allowable levels of fishing and other restrictions necessary to achieve a fishing mortality rate (F) of 0.53 in 1993 through 1995, 0.41 in 1996, 0.30 in 1997, and 0.23 in 1998 and thereafter, provided the allowable levels of fishing in 1996 and 1997 may not exceed 18,518,830 lb (8,400 mt), unless such fishing levels have an associated F of 0.23:

* * * * *

[FR Doc. 95–31584 Filed 12–29–95; 12:22 pm]

BILLING CODE 3510–22–P

50 CFR Part 625

[I.D. 122895A]

Summer Flounder Fishery; Commercial Quota Transfer

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

ACTION: Notification of commercial quota transfer.

SUMMARY: NMFS announces that the State of New Jersey is transferring 138,000 lb (62,596 kg) of commercial summer flounder quota to the Commonwealth of Massachusetts. NMFS adjusted the quotas and announces the revised commercial quota for each state involved.

EFFECTIVE DATE: December 31, 1995.

FOR FURTHER INFORMATION CONTACT: Regina L. Spallone, Fishery Policy Analyst, (508) 281–9221.

SUPPLEMENTARY INFORMATION: Regulations implementing Amendment 2 to the Fishery Management Plan for the Summer Flounder Fishery are found at 50 CFR part 625. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state is described in § 625.20.

The commercial quota for summer flounder for the 1995 calendar year was set equal to 14,690,407 lb (6,663,569 kg), and the allocations to each state were published February 16, 1995 (60 FR 8958). At that time, New Jersey was

allocated a quota of 2,456,969 lb (1,114,462 kg), and Massachusetts was allocated a quota of 1,001,953 lb (454,478 kg). The 1995 quotas for several states were adjusted for overages occurring in 1994, as required under § 625.20(d)(2), on May 26, 1994 (60 FR 27906). The Commonwealth of Massachusetts' quota after the adjustment for overages was 984,246 lb (446,446 kg). Since New Jersey's quota was not exceeded in 1994, its 1995 quota was unaffected by this adjustment.

On August 30, 1995, the State of North Carolina transferred 7,229 lb (3,279 kg) of commercial quota to the State of New Jersey (60 FR 45107). As a result of that transfer, the revised quota for New Jersey was 2,464,198 lb (1,117,741 kg). On December 26, 1995, New Jersey transferred 20,000 lb (9,072 kg) of its commercial quota to the State of New York. As a result of that transfer, the revised quota for New Jersey was 2,444,198 lb (1,108,670 kg).

The final rule implementing Amendment 5 to the FMP was published December 17, 1993 (58 FR 65936), and allows two or more states, under mutual agreement and with the concurrence of the Director, Northeast Region, NMFS (Regional Director) to transfer or combine summer flounder commercial quota. The Regional Director is required to consider the criteria set forth in § 625.20(f)(1), in the evaluation of requests for quota transfers or combinations.

New Jersey has agreed to transfer 138,000 lb (62,596 kg) of its commercial quota to Massachusetts. The Regional Director has determined that the criteria set forth in § 625.20(f)(1) have been met, and publishes this notification of quota transfer. The revised quotas for the calendar year 1995 are: New Jersey, 2,306,198 lb (1,046,074 kg); and Massachusetts, 1,122,246 lb (509,042 kg).

This action does not alter any of the conclusions reached in the environmental impact statement prepared for Amendment 2 to the FMP regarding the effects of summer flounder fishing activity on the human environment. Amendment 2 established procedures for setting an annual coastwide commercial quota for summer flounder and a formula for determining commercial quotas for each state. The quota transfer provision was established by Amendment 5 to the FMP and the environmental assessment prepared for Amendment 5 found that the action had no significant impact on the environment. Under section 6.02b.3(b)(i)(aa) of NOAA Administrative Order 216–6, this action is categorically excluded from the requirement to prepare additional environmental analyses. This is a routine administrative action that reallocates commercial quota within the scope of previously published environmental analyses.

Classification

This action is taken under 50 CFR part 625 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 28, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 95–31579 Filed 12–29–95; 11:10 am]

BILLING CODE 3510–22–P

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50 CFR Part 652

[Docket No. 951017252–5307–02; I.D. 101695C]

Atlantic Surf Clam and Ocean Quahog Fisheries; 1996 Fishing Quotas

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

ACTION: Final 1996 fishing quotas for surf clams and ocean quahogs.

SUMMARY: NMFS issues final quotas for the Atlantic surf clam and ocean quahog fisheries for 1996. These quotas are selected from a range defined as optimum yield (OY) for each fishery. The intent of this action is to establish allowable harvests of surf clams and ocean quahogs from the exclusive economic zone in 1996.

EFFECTIVE DATES: Effective January 1, 1996, through December 31, 1996.

ADDRESSES: Copies of the Mid-Atlantic Fishery Management Council's analysis and recommendations and environmental assessment are available from David R. Keifer, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19901–6790.

FOR FURTHER INFORMATION CONTACT: Myles Raizin (Resource Policy Analyst) 508–281–9104.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for the Atlantic Surf Clam and Ocean Quahog Fisheries (FMP) directs NMFS, acting on behalf of the Secretary of Commerce (Secretary) and in consultation with the Mid-Atlantic Fishery Management Council (Council), to specify quotas for surf clams and ocean quahogs on an annual basis from a range defined by the FMP as the OY for each fishery. Further, the Council follows the policy that the quotas selected should allow fishing to continue at that level for at least 10 years for surf clams and 30 years for ocean quahogs. While staying within these constraints, the quotas are also to be set at a level that would meet the estimated annual demand.

For surf clams, the quota must fall within the OY range of 1.85 million bushels (mil. bu.) (652 thousand hectoliters (hL)) to 3.40 mil. bu. (1.2 mil. hL). For ocean quahogs, the quota must fall within the OY range of 4.00 mil. bu. (1.4 mil. hL) to 6.00 mil. bu. (2.1 mil. hL). These ranges are specified in 50 CFR 652.21 (a) and (b).

During its discussions of the 1996 quota recommendations, the Council began developing new overfishing definitions for both species managed under the FMP. Overfishing is presently defined for both species in terms of actual yield levels in excess of the specified quota levels. These definitions do not incorporate biological considerations to protect against overfishing. Although preferred alternatives for overfishing definitions have not yet been chosen for each species, NMFS believes that none of the alternatives being considered by the Council for each species, if adopted, would necessitate any revision of the 1996 quotas contained in this action.

This action establishes a surf clam quota of 2.565 mil. bu. (1.36 mil. hL) and an ocean quahog quota of 4.45 mil. bu. (2.36 mil. hL) for the 1996 fisheries. The 1996 surf clam quota is identical to the 1995 quota, and the 1996 ocean quahog quota represents a 9 percent reduction from the 1995 quota. These quotas established by NMFS on behalf of the Secretary are unchanged from the proposed quotas published in the Federal Register on October 23, 1995 (60 FR 54330).

FINAL 1996 SURF CLAM/OCEAN QUAHOG QUOTAS

Fishery	mil. bu.	mil. hL
Surf clam	2,565,000	1,362,000
Ocean quahog	4,450,000	2,363,000

Comments and Responses

Three comments were received during the public comment period. A consulting firm involved in the industry commented in support of the proposed quotas. The National Fisheries Institute and an attorney involved in the industry opposed the proposed quotas.

Comment: The consulting firm commented that the proposed 1996 surf

clam quota is very liberal and should be set 8 percent below the proposed quota of 2.565 mil. bu. (1.36 mil. hL) because of declining landings per unit of effort.

Response: This level of surf clam quota was recommended by the Scientific and Statistical Committee of the Council and meets the Council policy of leaving 10 years of supply available. NMFS believes a reduction of 8 percent would be overly conservative and is not justified based on the most recent stock assessment.

Comment: The opponents of the proposed quotas commented that NMFS should reevaluate the assumptions, conclusions, and recommendations of the 19th Stock Assessment Workshop (19th SAW), upon which these quotas are based, to incorporate what they believe is new information that was revealed during testimony in their lawsuit against the agency concerning the 1995 quota levels. Both accuse NMFS scientists of withholding critical information from the Council and industry.

Response: The Council and NMFS have accepted the advice of the 19th SAW and consider it to be the best scientific information available. No new information that would require NMFS to reevaluate the conclusions of the 19th SAW was presented at the hearing held in the lawsuit referred to by the commenters. The only additional information was speculation that the dredge may have traveled farther than believed during the 1994 survey. However, the dredging distance could not account for the three-fold increase in the catch experienced during the 1994 survey.

The quota setting process, including the Stock Assessment Workshop that occurred in January 1995, is a very open and participatory process. The scientists provided the Council with all of the information relative to the surf clam and ocean quahog resource that was available at that time. The scientists still have not been able to determine the reason for the statistical anomalies contained in the 1994 survey and did not speculate as to their cause. However, even if the scientists had speculated on the reasons for the anomalies, the Council is still required to base its quota recommendation on the best scientific information available, especially any recommendations of the SAW. The scientists still have not been able to determine the reason for the statistical anomalies contained in the 1994 survey. When a reasonable explanation is determined, the Council will be informed.

Comment: At a minimum, NMFS should maintain the 1995 quota levels for both species until affected industry participants have an opportunity to evaluate the assumptions and conclusions of the 19th SAW with the assistance of scientific advisers from outside NMFS.

Response: NMFS sees no scientific basis for maintaining the 1995 quota levels for other than surf clams. The best scientific information available supports a reduction in the ocean quahog quota by 9 percent. NMFS further points out that independent scientific advisers were involved in the 19th SAW and that industry advisers were actively encouraged to participate in that process.

Classification

This action is authorized by 50 CFR part 652 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 28, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 95–31578 Filed 12–29–95; 11:01 am]

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Proposed Rules

Federal Register
Vol. 61, No. 3
Thursday, January 4, 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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 40 and 70

Public Workshop on the Regulation of Radioactive Devices

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The NRC will hold a public workshop in Rockville, Maryland to review the regulatory program for devices containing radioactive materials licensed under 10 CFR Parts 30, 31, 32, 40 and 70. Interested members of the public are welcome to attend the meeting, however, for efficient conduct of the workshop, participation will be in the format of a round table discussion among invited representatives of potentially affected parties. The NRC has prepared a workshop agenda. This and related documents are available for review prior to the workshop and interested parties are encouraged to review this information. The NRC will accept and consider written comments from interested parties on this regulatory issue.

DATES: The workshop will be held on January 18, 1996 from 9:00 am to 5:00 pm. The workshop will continue, if necessary, on January 19, 1996 from 9:00 am to 12 noon. Comments on this regulatory issue should be received no later than January 31, 1996.

ADDRESSES: The public workshop will be held in the NRC auditorium at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. Visitor parking around the NRC building is limited, however, the workshop site is adjacent to the White Flint station on the Metro Red Line. Written comments can be provided at the workshop or by January 31, 1996 to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of the agenda and related documents can be obtained from the NRC's Public Document Room, 2120 L Street NW, Washington DC 20037; Phone: 202–634–3273; Fax: 202–634–3343.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Mail Stop O–15B18, U.S. Nuclear Regulatory Commission, Washington, DC 20555; Phone: 301–415–1642; Fax: 301–415–3200; INTERNET:FXC@NRC.GOV.

SUPPLEMENTARY INFORMATION: Inadequate control of radioactive devices by licensees has lead to radioactive materials being included in metal scrap intended for recycling (see J. Lubenau & J. Yusko, ''Radioactive materials in Recycled Metals,'' *Health Physics*, 68:4, April, 1995). Radioactive sources have been accidentally smelted in metal mills resulting in radioactive contamination of mills, metal products and mill byproducts. In the U.S., costs attributable to decontamination, waste disposal and temporary mill closures following a smelting of a radioactive source have been as much as $23,000,000 per event. There is a risk of radiation exposure to unsuspecting workers and members of the public. In 1990, the Commission determined that the problem needed to be addressed and directed a rulemaking to improve oversight of generally licensed devices. The proposed rule was published for public comment in 1991 (56 FR 67011, 26 December 1991). In 1993, however, finalization of the rule was deferred because of resource constraints. Instead, the Commission directed the staff to pursue alternatives. In 1995, the Commission approved formation of a joint Agreement State—Nuclear Regulatory Commission (NRC) Working Group to review the regulation of *all* devices containing licensed radioactive materials to assess the current regulatory program for these devices and provide recommendations to the Commission.

The Working Group held its initial meeting October 24–25, 1995, and a second meeting on December 19–20, 1995, in Rockville, Maryland. The Working Group members are Robert Free, Texas and Joel Lubenau, NRC, Co-chairs; Robin Haden, North Carolina, Martha Dibblee, Oregon; Rita Aldrich, New York (alternate); Lloyd Bolling, NRC and John Telford, NRC. James Yusko, Pennsylvania, is serving as liaison to the Working Group for the Conference of Radiation Control Program Directors. James Richardson, NRC Nuclear Safety Attache in Vienna, Austria is serving as liaison for the International Atomic Energy Agency. At its initial meeting, in addition to the Working Group members, 28 representatives of the metal recycling and steel manufacturing industries, devices vendors and users, health physics consultants and government agencies attended. Minutes of the first and second meetings of the Working Group and other background information are available for public inspection and copying for a fee at the NRC Public Document Room, under the file, ''Review Group—Radioactive Devices.''

The public workshop is intended to provide an opportunity for stakeholders to have an input into the Working Group assessment of the need for regulatory changes and development of recommendations, as needed, for regulatory options to improve controls of licensed devices and assure their proper disposal. A target date of May 1996 has been set for the Working Group to develop and finalize its recommendations.

For efficient conduct of the workshop, the meeting format will be a round table discussion among invited representatives from affected interests, e.g., the metal recycling industry and recycled metal consumers, device vendors and users, Federal and state regulators and citizen groups. The workshop will be open to the public, and the public will be provided opportunities throughout the workshop to comment on the issues presented for discussion.

If the Working Group recommends changes in NRC regulations and the Commission agrees, such changes would be proposed through a subsequent NRC public rulemaking process.

Dated at Rockville, Maryland, this 28th day of December 1995.

For the Nuclear Regulatory Commission.

Malcolm R. Knapp,

Deputy Director, Office of Nuclear Materials Safety and Safeguards.

[FR Doc. 96–108 Filed 1–3–96; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95P–0197]

RIN 0910–AA19

Food Labeling: Health Claims; Oats and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use, on food labels and in food labeling, of health claims on the association between oat products, i.e., oat bran and oatmeal, and reduced risk of coronary heart disease (CHD). FDA is proposing this action in response to a petition filed by the Quaker Oats Co. (the petitioner). The agency has tentatively concluded that, based on the totality of publicly available scientific evidence, diets high in oatmeal and oat bran and low in saturated fat and cholesterol may reduce the risk of CHD.

DATES: Written comments by April 3, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective upon its publication in the Federal Register.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they confirmed FDA's authority to regulate health claims on food labels and in food labeling. As amended by the 1990 amendments, section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations adopted by FDA.

Under section 403(r)(3)(B)(i) of the act, the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations authorizing such claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Sections 403(r)(3)(B)(ii) and (r)(3)(B)(iii) of the act describe the information that must be included in any claim authorized under the act. The act provides that the claim shall be an accurate representation of the significance of the substance in affecting the disease or health-related condition, and that it shall enable the public to comprehend the information and understand its significance in the context of the total daily diet. Finally, section 403(r)(4)(A)(i) of the act provides that any person may petition FDA to issue a regulation authorizing a health claim.

The 1990 amendments, in addition to amending the act, directed FDA to consider 10 substance-disease relationships as possible subjects of health claims. One of the 10 substance-disease relationships was the relationship between dietary fiber and cardiovascular disease (CVD) (58 FR 2552, January 6, 1993) (hereinafter referred to as the 1993 dietary fiber and CVD final rule).

B. FDA's Response

In the Federal Register of January 6, 1993 (58 FR 2478), FDA adopted a final rule that implemented the health claim provisions of the act (hereinafter referred to as the 1993 health claims final rule). In that final rule, FDA adopted § 101.14 (21 CFR 101.14), which sets out the circumstances in which a substance is eligible to be the subject of a health claim (§ 101.14(b)), adopts the standard in section 403(r)(3)(B)(i) of the act as the standard that the agency will apply in deciding whether to authorize a claim about a substance-disease relationship (§ 101.14(c)), sets forth general rules on how authorized claims are to be made in food labeling (§ 101.14(d)), and establishes limitations on the circumstances in which claims can be made (§ 101.14(e)). The agency also adopted § 101.70 (21 CFR 101.70), which establishes a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(d)). These regulations became effective on May 8, 1993.

In addition, FDA conducted an extensive review of the evidence on the 10 substance-disease relationships listed in the 1990 amendments. As a result of its review, FDA has authorized claims that relate to 8 of these 10 relationships. While the agency denied the use on food labeling of health claims relating dietary fiber to reduced risk of CVD (58 FR 2552), it authorized a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber (particularly soluble fiber) to a reduced risk of CHD, the most common, most frequently reported, and most serious form of CVD.

In denying the dietary fiber and CVD health claim, the agency stated that a problem in determining whether there is a relationship between dietary fiber and heart disease is presented by the fact that dietary fiber is a diverse group of chemical substances that may be associated with different physiological functions (58 FR 2552 at 2572). Chemically and physiologically, cellulose, lignin, hemicellulose, pectin, and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. The agency also noted that it is very difficult to chemically analyze dietary fiber components, and that it is consequently hard to correlate the role of specific fiber components to health effects.

Based on its review of numerous authoritative documents, including Federal government reports and recent research on dietary fiber and CHD, and on its consideration of comments received in response to its ''Health Claims; Dietary Fiber and Cardiovascular Disease'' proposed rule (56 FR 60582, November 27, 1991) (hereinafter referred to as the 1991 dietary fiber and CVD proposal), FDA concluded that the publicly available scientific evidence supports an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods that are low in saturated fat and cholesterol and that are good sources of dietary fiber, and reduced risk of heart disease (58 FR 2552 at 2572). The

agency further stated that, although the specific roles of the numerous potentially protective substances in such plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of heart disease. The agency noted, however, that there was no scientific agreement as to whether the observed protective effects against heart disease are the result of a combination of nutrient components of the foods, including soluble fiber; of the other components of soluble fiber-rich diets (for example, potassium and magnesium); of the displacement of saturated fat and cholesterol from the diet; or of non-nutritive substances in these foods. For all these reasons, the agency stated that the fact that these foods contain dietary fiber, particularly soluble fiber, can serve as a useful marker for identifying those fruits, vegetables, and grain products that, when added to diets low in saturated fat and cholesterol, may help in reducing blood LDL-cholesterol levels (58 FR 2552 at 2572). Thus, the agency authorized a health claim in § 101.77 (21 CFR 101.77) on the association between diets low in saturated fat and cholesterol and high in vegetables, fruit, and grain products that contain soluble fiber and a reduced risk of heart disease.

In the 1993 dietary fiber and CVD final rule, in response to a comment regarding the apparent hypocholesterolemic properties of specific food fibers, e.g., oats, FDA agreed that the effectiveness of naturally occurring fibers in foods may be documented for specific food products (e.g., oat brans meeting specified parameters) (58 FR 2552 at 2567). Further, the agency stated that if manufacturers can document, through appropriate studies, that dietary consumption of the soluble fiber in their particular food has the effect of lowering low density lipoprotein cholesterol (LDL)-cholesterol, and has no adverse effects on other heart disease risk factors (e.g., high density lipoprotein (HDL)-cholesterol), they should petition for a health claim for their particular product.

The present rulemaking is in response to a manufacturer's health claim petition on the relationship between a specific fiber-containing food, oats, and heart disease.

II. Petition for Oat Products and Reduced Risk of CHD

A. Background

On March 22, 1995, the Quaker Oats Co. submitted a health claim petition to FDA requesting that the agency authorize a health claim on the relationship between consumption of oat products and the risk of CHD (Ref. 1). On June 29, 1995, the agency sent the petitioners a letter stating that it had completed its initial review of the petition, and that the petition would be filed in accordance with section 403(r)(4) of the act (Ref. 2). In this document, the agency will consider whether a health claim on this food-disease relationship is justified under the standard in section 403(r)(3)(B)(i) of the act and § 101.14(c) of FDA's regulations. The following is a review of the health claim petition.

B. Preliminary Requirements

1. The Substances Are Associated With a Disease for Which the U.S. Population Is at Risk

CHD remains a major public health problem and the number one cause of death in the United States. Despite the decline in deaths from CHD over the past 30 years, this disease is still exacting a tremendous toll in morbidity and mortality (Refs. 3 and 4). There are more than 500,000 deaths each year for which CHD is an underlying cause, and another 250,000 deaths for which CHD is a contributing cause. About 20 percent of adults (male and female; black and white) ages 20 to 74 years have blood total cholesterol (or serum cholesterol) levels in the ''high risk'' category (total cholesterol greater than (>) 240 milligrams (mg) per (/) deciliter (dL) and LDL-cholesterol greater than 160 mg/dL) (Ref. 47). Another 31 percent have ''borderline high'' cholesterol levels (total cholesterol between 200 and 239 mg/dL and LDL-cholesterol between 130 and 159 mg/dL) in combination with two or more risk factors.

CHD has a significant effect on health-care costs. In 1985, total direct costs related to CHD were estimated at $13 billion, and indirect costs from loss of productivity due to illness, disability, and premature deaths from this disease were an estimated $36 billion (Ref. 3).

Based on these facts, FDA concludes that, as required in § 101.14(b)(1), CHD is a disease for which the U.S. population is at risk.

2. The Substances Are Food

Oatmeal and oat bran are foods and are used as ingredients in other foods. These oat products contribute taste, aroma, or nutritive value that are retained when consumed at levels necessary to justify the petitioned claim.

Therefore, FDA tentatively concludes that these substances satisfy the preliminary requirements of § 101.14(b)(3)(i).

3. The Substances Are Safe

Oatmeal and oat bran are safe and lawful under the act. Both substances have a long history of use as food and food ingredients and are generally recognized as safe under § 170.30(d) (21 CFR 170.30(d)).

Thus, FDA tentatively concludes that the petitioner has satisfied the requirement of § 101.14(b)(3)(ii).

III. Review of Scientific Evidence

A. Basis for Evaluating the Relationship Between Oats and CHD

In the 1991 dietary fiber and CVD proposal, the agency set forth the basis of the relationship between dietary fiber and CVD (56 FR 60582 at 60583). In that document, the agency stated that there are many risk factors that contribute to the development of CVD, and specifically CHD, the most serious form of CVD and the leading cause of disability. The agency also stated that there is general agreement that elevated blood cholesterol levels are one of the major ''modifiable'' risk factors in the development of CVD and, more specifically, CHD. The Federal government and other reviews have concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total cholesterol and LDL-cholesterol are a cause of atherosclerosis (inadequate circulation of blood to the heart due to narrowing of the arteries) and represent major contributors to CHD (56 FR 60727 at 60728, November 27, 1991; Refs. 3 through 6). Factors that decrease total cholesterol and LDL-cholesterol will also tend to decrease the risk of CHD. High intakes of saturated fat and, to a lesser degree, of dietary cholesterol are associated with elevated blood total and LDL-cholesterol levels (56 FR 60727 at 60728). Thus, it is generally accepted that total cholesterol and LDL-cholesterol levels can predict the risk of developing CHD, and that dietary factors affecting blood total cholesterol levels affect the risk of CHD (Refs. 3 through 6).

When considering the effect that the diet or components of the diet have on blood (or serum) lipids, it is also important to consider the effect that these factors may have on blood levels of HDL-cholesterol. Evidence from epidemiologic studies show that elevated levels of HDL-cholesterol are inversely related to the incidence of atherosclerosis and thus CHD (Ref. 3). HDL- cholesterol is involved in the regulation of cholesterol transport out of

cells and to the liver from which it is ultimately excreted (Refs. 3 and 48). Therefore, HDL-cholesterol has a protective effect in the body by helping to lower total cholesterol. Dietary factors that help to significantly lower total cholesterol should, themselves, not have an adverse affect on the level of HDL-cholesterol.

For these reasons, FDA limited its review of the relationship between oatmeal and oat bran and CHD to effects of these food components on blood lipid levels and on the risk of developing CHD. The agency based its evaluation of this relationship on changes in total blood and LDL-cholesterol from dietary intervention with oatmeal and oat bran and with oat- containing products. This focus is consistent with that used by the agency in response to the 1990 amendments in deciding on the dietary saturated fat and cholesterol and CHD health claim (§ 101.75) (56 FR 60727 and 58 FR 2739, January 6, 1993) and the fruits, vegetables, and grain products and CHD claim (§ 101.77) (56 FR 60582 and 58 FR 2552).

B. Review of Scientific Evidence

1. Evidence Considered in Reaching the Decision

The petitioner submitted scientific studies evaluating the relationship between oat bran and oatmeal, consumed as foods and as ingredients in foods, and serum lipid levels (Ref. 1). These studies were conducted between 1980 and 1995. The petition included a review of these studies and a summary of the evidence. Most of the studies that were published before 1993 had been reviewed by the agency in the proposed and final rules on dietary fiber and CVD (56 FR 60582 at 60596 and 58 FR 2552 at 2581). A review of the studies evaluating the effect of oat products on blood lipids submitted by the petitioner, including those previously reviewed by the agency, is provided in Table 1. In addition, in its review of the petition, the agency considered the conclusions of the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) (Ref. 7) relative to studies involving oats.

2. Criteria for Selection of Human Studies

The criteria that the agency used to select pertinent studies were that the studies: (1) Present data and adequate descriptions of the study design and methods; (2) be available in English; (3) include estimates, or enough information to estimate, soluble dietary fiber intakes; (4) include direct measurement of blood total cholesterol and other blood lipids related to CHD; and (5) be conducted in persons who represent the general U.S. population (adults with blood total cholesterol levels less than (<) 300 mg/dL).

In selecting human for review, the agency excluded studies that were published in abstract form because they lacked sufficient detail on study design and methodologies, and because they lacked necessary primary data. Studies using special population groups, such as insulin-dependent diabetics, individuals with very high serum cholesterol (mean greater than 300 mg/dL), children with hypercholesterolemia, and persons who had already experienced a myocardial infarction, were also generally not weighed heavily because of questions about their relevance to the general healthy U.S. population.

3. Criteria for Evaluating the Relationship Between Oat Products and CHD

FDA applied the same criteria in evaluating the relationship between oat products and CHD that it did in evaluating the relationship between dietary fiber and CVD in the 1991 dietary fiber and cardiovascular disease proposal (56 FR 60582 at 60587). The criteria that the agency used in evaluating these studies included: (1) Reliability and accuracy of the methods used in nutrient intake analysis, including measurements of total dietary soluble fiber and total dietary fiber; (2) available information on the soluble fiber or beta-glucan (β-glucan, the predominant soluble fiber in oats) content of the oat products and control food; (3) measurement of study endpoints (i.e., total cholesterol, LDL-cholesterol, and HDL-cholesterol); and (4) general study design characteristics. The characteristics of general study design included randomization of subjects, appropriateness of controls, selection criteria for subjects, attrition rates (including reasons for attrition), potential for misclassification of individuals with regard to dietary intakes, presence of recall bias and interviewer bias, recognition and control of confounding factors (for example, intake of saturated fat and other nutrients, monitoring body weight, and control of weight loss), appropriateness of statistical tests and comparisons, and statistical power of the studies. The agency considered whether the intervention studies that it evaluated had been of long enough duration to reasonably ensure stabilization of blood lipids (greater than or equal to 3 weeks duration). Finally, the agency considered it highly desirable if the available information on a study included information on the total dietary fiber and total dietary soluble fiber content of baseline, treatment, and control diets and on the nutrient intakes of the subjects during the course of the study.

As stated above, dietary saturated fat and cholesterol affect blood lipid levels (Refs. 4 through 6). Previous reviewers have generally concluded that, in persons with relatively higher baseline levels of blood cholesterol, responses to treatment tend to be of a larger magnitude than is seen in persons with more normal blood cholesterol levels (56 FR 60582 at 60587 and Refs. 4 through 6). To take into account these factors, FDA separately evaluated studies on mildly to moderately hypercholesterolemic individuals (persons with elevated blood total cholesterol levels of 200 to 300 mg/dL) and studies on normocholesterolemic individuals (persons with normal blood total cholesterol levels (< 200 mg/dL)). FDA also separately evaluated studies in which oat products' effects were evaluated as part of a ''typical'' American diet (approximately 37 percent of calories from fat, 13 percent of calories from saturated fat, and more than 300 mg of cholesterol daily) and studies in which the test protocols incorporated a Step I or similar (e.g., American Heart Association (AHA)) dietary regimen (less than 30 percent of calories from fat, less than 10 percent of calories from saturated fat, and less than 300 mg of cholesterol daily). Moreover, to ensure that results were not reflective of transient changes, such as failure of blood cholesterol levels to stabilize to the dramatic changes in dietary patterns that occur with the introduction of large amounts of test substances, FDA gave less weight to studies with treatment periods of less than 3 weeks than it gave to studies of longer duration.

C. Summary of Human Studies

FDA's review of the 37 human studies on oat bran and oatmeal and serum cholesterol (Refs. 8 through 32, 34 through 39, and 41 through 46) that were submitted with the petition is summarized in detail in Table 1. The results of a metaanalysis (Ref. 33) that included a number of the oat studies is discussed in section III.C.5. of this document.

1. Hypercholesterolemics: ''Typical'' or ''Usual'' Diets

Eight of the studies (Refs. 8, 12, 20, 21, 25, 35, 44, and 45) show a relationship between consumption of oat products and reduced serum

cholesterol in hypercholesterolemic subjects consuming a typical American diet. Anderson et al. (Ref. 8) in a metabolic ward study reported significantly lower total (12.8 percent) and LDL-cholesterol (12.1 percent) in male subjects consuming 110 grams (g) (7.6 g soluble fiber, 13.4 g total dietary soluble fiber) oat bran for 21 days (d). A wheat group, which consumed 40 g of wheat bran (1.3 g soluble fiber, 7.8 g total dietary soluble fiber), experienced nonsignificant decreases in total (4.4 percent) and LDL-cholesterol (5.5 percent). There was no significant change in HDL-cholesterol in either group. Both groups experienced a significant decrease in weight (1 kilogram (kg)) compared to their mean baseline weight values. There was no difference in weight loss between the oat and wheat groups.

Braaten et al. (Ref. 12) evaluated the effects on blood cholesterol levels of instant oat gum (7.2 g; 5.8 g β-glucan), an extract of oat bran comprised of almost entirely β-glucan soluble fiber plus some trace elements, or a placebo (maltodextrin) when mixed with a noncarbonated diet fruit drink (250 milliliters (mL)) and consumed twice a day at each main meal for 4 weeks by hypercholesterolemic subjects. Results showed significantly lower total cholesterol by 9.2 percent ($p<0.0001$) and LDL-cholesterol by 10 percent ($p<0.001$) in the oat gum group compared to baseline.

Hegsted et al. (Ref. 20) evaluated the hypocholesterolemic properties of rice bran and oat bran in hypercholesterolemic subjects. Using a cross-over design, subjects consumed treatment diets providing 100 g/d of rice bran and oat bran for 3-week periods each. A control diet, which consisted of the treatment diet but with wheat flour and no bran, was consumed for 2 weeks before each bran period. The results showed significant reductions in total cholesterol with both the rice and oat bran diets compared to the control diet ($p<0.001$). During the two oat test periods, serum cholesterol was reduced about 10 percent (phase 1) and 4 percent (phase 2) compared to serum cholesterol values during the control period. Oat bran intervention also resulted in significant reductions (about 13 percent in phase 1 and about 7 percent in phase 2) in LDL-cholesterol. Rice bran was as effective in lowering serum cholesterol as oat bran.

Kahn et al. (Ref. 21) evaluated the hypocholesterolemic properties of four oat bran muffins/d (80 g total daily oat bran) in hypercholesterolemic subjects randomized into immediate oat bran intervention and delayed oat bran intervention groups. The delayed oat bran intervention group served as the control group. After correcting for the time delay of the study, the results showed that oat bran dietary intervention significantly reduced total cholesterol by almost 8 percent ($p<0.02$), LDL-cholesterol by about 10 percent ($p<0.02$), and HDL-cholesterol by almost 1 percent ($p<0.03$) from baseline.

Kestin et al. (Ref. 25) reported decreased levels of total cholesterol (4.9 percent) and LDL-cholesterol (6.8 percent) in hypercholesterolemic subjects consuming 95 g/d (5.8 g soluble fiber) oat bran. These values were significantly lower than those observed in subjects consuming rice bran ($p<0.01$) and wheat bran ($p<0.001$). HDL-cholesterol increased in all groups. The oat bran was incorporated into bread and muffins.

Spiller et al. (Ref. 35) reported significantly lower total cholesterol (3.7 percent) and LDL-cholesterol (6.6 percent), and a nonsignificant increase in HDL-cholesterol (1 percent), in hypercholesterolemic subjects consuming 77 g/d (5 g soluble fiber) oat bran. Changes in total cholesterol were experienced within the first 14 days with no significant changes occurring between days 14 and 21 of the study. The oat bran was mixed with water and consumed before meals. The calories provided by the oat bran replaced about an equal amount of carbohydrate calories in the subjects' diets.

Whyte et al. (Ref. 45) reported decreases in total cholesterol of 3.1 percent ($p<0.01$) and LDL-cholesterol of 5.7 percent ($p<0.01$) compared to baseline values after hypercholesterolemic subjects consumed 123 g (10.3 g soluble fiber) oat bran/day for 4 weeks. The oat bran was consumed as a breakfast cereal. Consumption of total fat and saturated fat remained the same during the test period.

Van Horn et al. (Ref. 44) reported reductions in total cholesterol (about 6.2 percent) and LDL-cholesterol (9.2 percent) levels, compared to a control group, in subjects consuming 57 g of instant oats daily for 8 weeks. The control group experienced decreases in total cholesterol and LDL-cholesterol of 1.4 percent and 3.7 percent, respectively. The differences between the oat and control groups were significant ($p<0.05$). The authors reported greater reductions in total cholesterol in those individuals who had a baseline cholesterol level above the baseline median cholesterol level of 243 mg/dL. The authors also reported significantly different dietary intakes after 4 weeks of intervention for a number of nutrients in the oat group's diet compared to that of the control group. After 4 weeks of intervention, the oat group had higher intakes of soluble and total fiber and lower intakes of saturated fat and cholesterol. A metaanalysis conducted by Ripsin et al. (Ref. 33), which is discussed in section III.C.5. of this document, evidences that the changes in dietary fats and cholesterol intake in this study did not appear to be responsible for the drop in serum cholesterol levels, thus suggesting that oat bran and oatmeal were responsible for the observed effect.

Results of four studies (Refs. 18, 26, 34, and 38) were inconclusive regarding the relationship between oat bran or oatmeal consumption and reduced serum lipids. Gormley et al. (Ref. 18) reported no effect of oatmeal porridge on serum cholesterol or HDL-cholesterol in hypercholesterolemic men and normocholesterolemic women. The authors stated that dietary intakes were monitored, but the subjects' dietary intakes were not reported. The amount of total dietary fiber and soluble fiber in the total diet and oatmeal porridge were not provided. Insufficient dietary controls make the results of this study difficult to interpret.

Leadbetter et al. (Ref. 26) reported no significant effect of increasing intakes of β–glucan from oat bran on serum cholesterol in 40 hypercholesterolemic men and women. Subjects consumed 0, 30, 60, or 90 g oat bran/day for 1-month intervals. The authors stated that the New Zealand oats used in this study were lower in soluble fiber (3.7 to 4.2 percent β–glucan) than oat bran used in studies that showed a significant lowering of serum cholesterol with oat bran supplementation.

Saudia et al. (Ref. 34) reported no significant difference in serum cholesterol levels in hypercholesterolemic subjects consuming oat bran daily for 93 days. The subjects consumed 3 ounces (oz) (about 84 g) of oat bran daily with their usual diet for 3 months. The subjects' total dietary intake, including their intake of total and saturated fat and cholesterol, before and during the trial were not reported. The authors stated that the subjects may have changed their diets during the test period because the study took place over summer months and because of an increased awareness by the subjects of risk-reducing behavior and lifestyles. The study also lacked a control group, thus making the results of this study difficult to interpret.

Törrönen et al. (Ref. 38) showed small reductions in serum cholesterol, LDL-, and HDL-cholesterol in an oat bran

group compared to baseline, but these reductions were not statistically significant. An oat bran concentrate was prepared and incorporated into a loaf of bread (11.2 g β-glucan per loaf). A control bread was made with wheat flour. The use of oat bran concentrate in this study does not provide evidence for an effect of oat bran per se on serum cholesterol because the authors state that the method of concentrating and processing the oat bran and β-glucan may have affected the effectiveness of the β-glucan in lowering serum cholesterol. Animal studies by these authors confirmed that the method of producing the oat bran concentrate produced significantly weaker hypocholesterolemic responses than untreated oat bran or concentrates with higher viscosities.

One study (Ref. 32) showed equivocal results in reducing total cholesterol. Poulter and coworkers reported small but significant reductions in serum cholesterol and LDL-cholesterol in hypercholesterolemic subjects consuming 50 g of oat cereal compared to subjects consuming the same amount of cereal without oats. Subjects with baseline cholesterol values greater than 231 mg/dL experienced the most significant reduction in serum cholesterol. However, the results of this study are difficult to interpret because some subjects made changes in their diets after starting the trial. There was a significant reduction in total energy from fat compared to baseline intakes. Similarly, the ratio of polyunsaturated fat to saturated fat in the subjects' diet also fell significantly during the oat period.

2. Hypercholesterolemics: Low Fat Diets

Results of six studies (Refs. 11, 15, 23, 24, 39, and 43) showed a cholesterol reducing effect of oatmeal or oat bran in hypercholesterolemic subjects who consumed the oat products as part of a low fat diet. Beling et al. (Ref. 11) divided the subjects into 3 groups. Group 1 consumed their regular (not fat modified) diet. Groups 2 and 3 consumed an AHA fat modified diet. There were significantly lower total and LDL-cholesterol levels after 4 weeks in groups 2 and 3. In groups 2 and 3, total cholesterol decreased by 10 percent and 11.8 percent, and LDL-cholesterol decreased by 11.5 percent and 11.8 percent, respectively. From weeks 5 to 8, group 2 continued on the AHA diet, while group 3 consumed the AHA diet plus 56 g oat bran cereal/day. At the end of week 8, total cholesterol had decreased by 2.3 percent, 8.4 percent, and 12.2 percent from baseline levels for groups 1, 2, and 3, respectively. The mean total cholesterol level of the oat group was significantly different from the control group and the group that consumed only the AHA diet ($p<0.05$). At week 8, LDL-cholesterol levels were 10.1 percent below baseline for group 2 and 14.9 percent below baseline for group 3 ($p<0.05$). HDL-cholesterol decreased 1 percent, 3 percent, and 8 percent in groups 1, 2, and 3, respectively, at 8 weeks. The differences in HDL-cholesterol between the 3 groups were not significant. The differences in HDL-cholesterol in groups 2 and 3 were significantly different from the control ($p<.05$). Groups 2 and 3 experienced weight loss, but the differences between these groups were not significant.

Davidson et al. (Ref. 15) evaluated the hypocholesterolemic effects of increasing amounts of β-glucan from oat bran and oatmeal in hypercholesterolemic subjects consuming a Step 1 diet. The results showed that groups consuming diets containing 3 g/d or more of β-glucan experienced significant declines in blood total cholesterol (7 to 10 percent) and LDL-cholesterol (10 to 16 percent) compared to baseline. Blood total cholesterol levels of groups consuming diets containing 1 to 2.4 g daily of β-glucan did not differ significantly from baseline.

Turnbull and Leeds (Ref. 39) evaluated the effects of oats and wheat on total cholesterol in hypercholesterolemic subjects consuming a low fat diet. During a 1-month run-in period (baseline), the subjects consumed the low fat diet alone and experienced a 7.6 percent (not significant) reduction in total cholesterol. The subjects were then randomized to receive 150 g/d of oats or wheat while consuming the low fat diet for another month. At the end of the month, subjects crossed over to the other grain supplement. The results of this study showed that during the oat period, subjects experienced significant reductions in total cholesterol ($p<0.03$) and LDL-cholesterol ($p<0.002$) compared to baseline despite an increase in energy and total fat intake. There were no significant changes in total cholesterol and LDL-cholesterol when subjects consumed the wheat diet. HDL-cholesterol showed a nonsignificant increase from baseline during the oat period and no change during the wheat period.

In a large, controlled clinical trial, Van Horn et al. (Ref. 43) instructed moderately hypercholesterolemic subjects (mean total cholesterol of 208 mg/dL) on the AHA low fat diet. The subjects consumed the AHA diet alone for 6 weeks, during which time they experienced significantly reduced total cholesterol compared to baseline. The subjects were then randomized to one of 3 groups: two oat groups (2 oz of oat bran or oatmeal daily) or the control group (AHA diet only) for another 6 weeks. At the end of the intervention period, subjects consuming 56 g of oat bran and oatmeal had total cholesterol values 8 percent and 9.3 percent lower than baseline, respectively. The control group experienced a 4.5 percent reduction in serum cholesterol. At the end of the study, the differences in total cholesterol levels for all three groups compared to baseline levels were statistically significant ($p<0.05$), but there was no significant difference between the oat groups and the control. Both the oat bran and the oatmeal groups experienced a modest (3 percent) reduction in serum cholesterol beyond that achieved by the low fat diet alone.

The modest effect of oat bran and oatmeal on serum cholesterol in this study may have been affected by the subjects' cholesterol levels before dietary intervention. The subjects' mean cholesterol level was 208.4 mg/dL. After dietary intervention, the mean cholesterol levels were 201 mg/dL (control), 196.4 mg/dL (oat bran group), and 195.2 mg/dL (oatmeal group). Studies have shown that subjects with higher initial blood cholesterol levels usually experience the most reduction in total cholesterol from oat intervention (Refs. 6 and 33). Thus, because of the subjects' relatively low cholesterol levels at the initiation of the oats intervention period, the differences among the groups may have been minimized.

Keenan et al. (Ref. 23) reported variable responses in serum lipids depending on the order of feeding of the diets supplemented with 56 g of oat bran or wheat cereal during an 18-week double-blind study with crossover. Subjects consumed a Step 1 diet during the first period (6 weeks) and then were randomized to 1 of 3 groups. The control group consumed a Step 1 diet for another 12 weeks. The two test groups consumed wheat cereal or oat cereal for 6 weeks before crossover to the other test cereal for another 6 weeks. Interpretation of results was complicated by the fact that the control group showed an initial decline in blood cholesterol levels followed by a return to baseline at the end of the study. Only the oat groups maintained reduced serum cholesterol and LDL-cholesterol throughout the test periods. When compared to the control and wheat groups, these reductions were significant ($p<.01$).

Kelley et al. (Ref. 24) reported significantly reduced serum cholesterol ($p<0.04$) and LDL-cholesterol ($p<0.05$) at the end of 4 weeks in subjects who were participating in a program of supervised aerobic exercises. The subjects consumed about 94 g of oat bran daily as part of their usual low fat, low saturated fat diets. This study lacked an appropriate placebo control.

Six studies (Refs. 13, 16, 27, 28, 36, and 41) gave inconclusive results regarding the relationship between oat consumption and reduced serum lipids in hypercholesterolemic subjects consuming low fat diets. In a study by Bremer et al. (Ref. 13), subjects consumed either oat or wheat bread (about 8 slices/day) in place of other carbohydrate foods as part of their AHA phase II diet (total fat 25 to 30 percent of energy, saturated fat <8 percent of energy, polyunsaturated fat 5 to 10 percent of energy, cholesterol <250 mg/day). Subjects had a mean intake of 44.6 g/day of oat bran (range of 34.2 to 68.4 g/day). The study showed no significant differences in total serum cholesterol or LDL-cholesterol between the period in which the subjects consumed oat bread and the period in which they consumed wheat bread. However, the lack of an observed effect on serum cholesterol from oat bran could be attributable to the lower soluble fiber content of the New Zealand oat bran used in this study compared to oat bran used in other studies.

Demark-Wahnefried et al. (Ref. 16) evaluated the hypocholesterolemic properties of oat bran in hypercholesterolemic subjects following one of four dietary protocols for 12 weeks: Step 1 diet alone, Step 1 diet plus added soluble fiber from 50 g of oat bran, regular diet plus 50 g of oat bran, and regular diet plus 42 g of processed oat bran. The results of this study showed significant reductions ($p<0.05$) in serum cholesterol in all diet groups. The serum cholesterol levels of groups consuming diets containing the higher soluble fiber (approximately 4 g added soluble fiber daily) did not differ from groups on a dietary regimen modified only in fat and cholesterol content. Variable weight loss was reported among the groups, and dietary changes in all groups confound the results of this study.

In a study by Lepre and Crane (Ref. 27), subjects received a prescribed low fat diet for 8 weeks before being randomly assigned to either the oat or wheat group. Subjects consumed 2 oat bran muffins (60 g of oat bran, 3.2 g soluble fiber) or 2 wheat bran muffins (60 g wheat bran) daily for 8 weeks. At the end of the first 8-week test period, subjects crossed over to the other test group for another 8 weeks. The results showed small, nonsignificant reductions in serum cholesterol (2.2 percent) and LDL-cholesterol (3.1 percent) and a nonsignificant increase in HDL-cholesterol (3.0 percent) during the oat bran period compared to diet only period. During the wheat bran period, there was a nonsignificant increase in total cholesterol, LDL-cholesterol, and the ratio of LDL- to HDL-cholesterol (LDL:HDL) and a nonsignificant decrease in HDL-cholesterol. The results of this study were confounded because subjects made significant dietary changes during the diet only and the oat bran periods. The subjects were aware of their hyperlipidemias and were already on a low fat diet before the start of this study. They also knew in advance which days they were required to record their dietary intake. The intakes of dietary cholesterol and saturated fat were significantly less, and dietary fiber intake was significantly more, during the oat bran period compared to the diet only period. The results of this study, therefore, are inconclusive for an effect of oat bran on serum cholesterol.

Mackay and Ball (Ref. 28) evaluated the hypocholesterolemic properties of 55 g each of low-fiber and high-fiber oat bran (New Zealand cultivars) and of beans in hypercholesterolemic subjects consuming a moderately low fat diet. The oat bran used in this study was specially formulated to provide specific amounts of β-glucan. The low-fiber oat bran provided 1.9 g β-glucan, and the high-fiber oat bran provided about 3 g β-glucan. The results of this study showed no significant changes in serum cholesterol or LDL-cholesterol from any of the test substances. HDL-cholesterol, however, increased in all groups compared to baseline values, and these increases were statistically significant ($p<0.05$). The energy intake on the high-fiber oat bran diet was significantly higher than that of the low-fat diet alone; however, there was no reported change in body weights. This study lacked a placebo control which makes the study difficult to interpret. Also, the source of this oat bran, a New Zealand cultivar, may have contributed to the lack of a hypocholesterolemic response to oat bran in this study (see Refs. 13 and 26).

Stewart et al. (Ref. 36) reported no significant differences in serum cholesterol, LDL-, or HDL-cholesterol in subjects consuming an oat-free, low fat diet or a low fat diet with 50 g/d of oat bran for 6 weeks each. However, the subjects' compliance with the required dietary protocol in this study was poor. The authors reported a wide variability among the subjects' diets at baseline as well as a variability in the intake of oat bran. Moreover, both processed and unprocessed New Zealand oat brans were used in this study. As stated in the previous paragraph, the type of oat bran cultivar used, and the method of processing the oat bran, may have affected the results of this study.

Uusitupa et al. (Ref. 41) evaluated the hypocholesterolemic effects of a β-glucan-enriched oat bran and regular wheat bran in hypercholesterolemic subjects consuming an AHA Step 1 diet. Baseline serum cholesterol values were determined during a 4-week run-in period when the subjects consumed the AHA Step 1 diet with no bran. The subjects were then randomized into two groups to receive the β-glucan-enriched oat bran or regular wheat bran for an 8-week test period. The brans were provided in sachets (62 g/sachet), and the subjects instructed to increase their daily consumption of bran in a step-wise approach until they consumed the entire contents of the sachet or until they reached the highest tolerable amount. The mean intake of oat bran during the test period was 50 g. At the end of 4 weeks of bran intervention, there was a significant reduction in serum cholesterol in the oat bran group compared to baseline. By the end of 8 weeks, however, the differences were no longer significant. There was no change in LDL-cholesterol in the oat bran group after 4 weeks, but a small, nonsignificant reduction (about 3 percent) after 8 weeks. There was a small, nonsignificant increase in serum cholesterol in the wheat bran group. The results of this study were difficult to interpret because subjects did not adhere to the reduced fat diet and failed to consume the required amount of bran.

Two studies (Refs. 10 and 46) showed equivocal results in reducing total cholesterol. Bartram et al. (Ref. 10) evaluated the effect of oat bran muesli cereal on serum cholesterol in 13 men and women who had been on a low cholesterol diet for 6 months. The subjects consumed 60 g of oat muesli (made with lowfat milk and 120 g of bananas, grapes, and apples) for 3 weeks. The results of this study showed a significant reduction in serum cholesterol (8–10 percent) ($p<0.01$) and LDL-cholesterol ($p<0.05$) during the oat cereal period. However, the results are difficult to interpret because the fruits consumed with the muesli cereal may have contributed to the observed reduction in serum cholesterol.

Zhang et al. (Ref. 46) compared the hypocholesterolemic properties of oat

bran (118 g) with wheat flour using a crossover design. The subjects consumed one of the test substances as part of a low fiber base diet for 3 weeks before crossover to the other test substance. During the oat period, serum cholesterol was significantly lower than during the wheat flour period. The results of this study are difficult to interpret because all subjects had ileostomies (i.e., an opening from the ileum through the abdominal wall, permitting drainage of the contents of the small intestine) and the mechanism by which oat bran lowers serum lipids in this group may not apply to the general population.

3. Normocholesterolemics: ''Typical'' or ''Usual'' Diets

The results of two studies (Refs. 17 and 29) support a cholesterol lowering effect of oat bran or oatmeal in subjects with normal serum cholesterol values. A third study (Ref. 14) showed evidence of the cholesterol-lowering effects of oat bran postprandially.

Gold and Davidson (Ref. 17) reported a significant ($p<0.05$) reduction in total cholesterol (5.3 percent) and LDL-cholesterol (8.7 percent) compared to baseline measures in normocholesterolemic subjects consuming 2 oat bran muffins/d for 4 weeks. The oat bran muffins provided a total of 34 g oat bran. There were no data given on the subjects' dietary intake before or during the test period.

Marlett et al. (Ref. 29) studied the mechanism of serum cholesterol reduction by oat bran using a single isotope to determine bile acid kinetics. During the first month, normo-cholesterolemic subjects consumed a low fiber control diet provided in a metabolic unit. During the second month, this same diet was supplemented with 100 g of oat bran. The results showed significantly lowered serum cholesterol compared to baseline values during both periods. Serum cholesterol on the low fiber diet was reduced 14 percent ($p<0.01$) and on the oat bran diet 22 percent ($p<0.01$) compared to baseline values. Serum cholesterol during the high fiber period was also significantly lower than that of the low fiber period (an additional decrease of 9 percent).

Cara et al. (Ref. 14) evaluated the effects of oat bran and other high fiber-containing foods on postprandial lipemia in 6 normocholesterolemic men. The subjects consumed, on separate days, a low fiber (control) meal or a high fiber test meal enriched with 10 g of oat bran, rice bran, wheat fiber, or wheat germ. The results of this study showed that the oat bran test meal produced the greatest reduction in serum cholesterol compared to the other fibers tested. The differences between serum cholesterol levels in the oat bran test and those in the control test remained significant ($p<0.05$) 7 hours postprandial. The results of this study support a significant short term effect on serum cholesterol, but they do not address long term effectiveness of oat bran in maintaining reduced serum cholesterol levels.

The results of one study (Ref. 31) was inconclusive for an effect of oatmeal on serum cholesterol in normo-cholesterolemic subjects. O'Kell and Duston (Ref. 31) reported no significant differences in serum cholesterol and HDL-cholesterol in subjects consuming 1/2 to 3/4-cup of oatmeal daily for a series of 3-month test periods over the course of a year. After each 3-month oatmeal period, the subjects consumed their usual diets without oatmeal for 3 months. The results of this study were difficult to interpret because the subjects' dietary intakes before and during the study were not reported, and subject compliance was not adequately addressed.

One study (Ref. 37) showed equivocal results in reducing total cholesterol. Swain et al. evaluated the hypocholesterolemic effects of oat bran and wheat bran in a group of young females with normal serum cholesterol (mean total cholesterol of 185 mg/dL) using a double-blind, cross-over study design. The subjects consumed an average of 87 g oat bran and 93 g wheat bran/day during each 6-week test period. The authors reported statistically significant reductions from baseline levels in total cholesterol ($p<0.05$) and LDL-cholesterol ($p<0.05$) in both bran test periods. The differences between the oat bran and wheat bran groups were not significant. The results of this study are difficult to interpret because of dietary changes during the oat bran period. The subjects significantly increased their intake of total calories from fat and saturated fat compared to the wheat period. Mean body weight was unchanged over the short test period suggesting that there was a substitution effect with the diet. Young premenopausal women with low serum cholesterol levels do not represent a population at risk for CHD. Therefore, the benefits of oat bran may not be reflected in this group.

4. Normocholesterolemics: Low Fat Diets

One study (Ref. 42) reported significantly lower total cholesterol, compared to a control group, after 4-weeks of oat intervention in subjects with normal to mildly elevated total cholesterol. The oat group consumed a Phase II AHA diet (low fat, low saturated fat, low cholesterol) plus 56 g of oatmeal daily compared to a control group that consumed only the Phase II diet. Over the next 4 weeks, however, serum cholesterol levels increased slightly in the oat group and decreased slightly in the control group. After 8 weeks, serum cholesterol was reduced 3.1 percent in the oat group and 1.4 percent in the control group. There were no significant differences in total serum cholesterol levels between the groups. Subgroup analysis of the data showed greater reductions in serum cholesterol among those subjects in the oat group who had the highest baseline cholesterol levels. The results of this study suggest a modest benefit of oatmeal in lowering serum cholesterol in subjects with normal cholesterol levels.

One survey (Ref. 19) showed equivocal results for an effect of oat bran or oatmeal on serum cholesterol. He et al. (Ref. 19) evaluated the relationship between the intakes of oats and buckwheat and serum cholesterol in a population of Chinese by conducting a survey of their dietary habits. This particular population group consumed a high energy, low fat, and high fiber diet, and had active working lifestyles. The results of this study showed that the groups consuming greater than 25 g of oats a day had significantly lower serum cholesterol than those who ate less than 25 g of oats a day or no oats. All baseline serum cholesterol values, however, were under 160 mg/dL. The results of this study were difficult to interpret because this population group is one whose diets and lifestyles do not reflect that of the general American population. The results of this study are also confounded because of the questionable assessment of dietary intake of oat bran and oatmeal and the absence of any controls.

5. Other Studies

Evidence for the cholesterol-lowering effect of soluble fiber from oatmeal and oat bran was evaluated using a metaanalysis (Ref. 33). In this study, after pooling the raw data from 13 studies (Refs. 11, 15 through 17, 23, 25, 30, 37, 39, 40, and 42 through 44) that reported on the effect of consumption of oatmeal and oat bran on total cholesterol, a modest reduction (average decrease of 5 to 6 mg/dL) on blood total cholesterol levels was found.

To assess whether other dietary factors, i.e., substitution of oats for dietary fats and cholesterol, might have been responsible for the drop in blood

total cholesterol levels, Ripsin and coworkers used the experimentally derived, predictive equation of Keys to see whether dietary changes in fat components of the test diets could account for the observed decreases in serum cholesterol (Ref. 33). The results of their analysis showed that reduction in fat and cholesterol intake attributable to substituting oat bran or oatmeal for these food components did not account for all of the blood cholesterol reduction observed. Oat bran and oatmeal apparently had some effect beyond that of simply replacing fat and cholesterol in the diet. The authors concluded, therefore, that incorporation of oat products into diets causes a modest decrease in average blood cholesterol.

The authors also suggested that there was a dose-response relationship between the amount of soluble fiber from oat bran or oatmeal and the reduction in blood cholesterol levels, with intakes of soluble fiber from oats above 3 g/day showing more effect than lower intakes. They stated that there is significant evidence of an interaction between dose and initial cholesterol levels. The trials that used subjects with initial serum cholesterol levels of 229 mg/dL or higher demonstrated fivefold greater reductions in total cholesterol with 3 g/d or more of soluble fiber from oat bran or oatmeal than trials whose subjects had lower initial cholesterol levels. Additionally, the authors noted that other components in oats may play a role in the observed cholesterol reduction and suggested the need for long-term clinical trials (6 months or more) with multiple doses to verify their conclusions from the metaanalysis.

LSRO, in its 1987 report entitled ''Physiological Effects and Health Consequences of Dietary Fiber,'' stated that oat bran has been shown to exert a substantial cholesterol-lowering effect in patients with hypercholesterolemia (Ref. 7). It noted that the effects of oat bran are not as pronounced in subjects with normal serum cholesterol as they are in subjects with elevated serum lipid levels.

6. Summary

Of the 37 studies that FDA reviewed, 4 studies (Refs. 9, 14, 22, and 30) had short test periods, ranging from 7 hours to 18 days and, thus, did not meet the agency's criteria for selecting pertinent studies with respect to study duration (i.e., intervention test period of no less than 3 weeks).

Seventeen studies (Refs. 8, 11, 12, 15, 17, 20, 21, 23, 24, 25, 29, 35, 39, 42 through 45) demonstrated a positive effect of oat bran or oatmeal on total and LDL-cholesterol. The majority of these studies showed statistically significant reductions in total and LDL-cholesterol in hypercholesterolemic subjects consuming either a typical American diet (Refs. 8, 12, 20, 21, 25, 35, 44, and 45) or a low fat diet (Refs. 11, 15, 23, 24, 39, 42, and 43). The results of three studies showed a statistically significant effect of oat bran or oatmeal in subjects with normal serum cholesterol consuming either a typical American diet (Refs. 17 and 29) or a low fat diet (Ref. 42). The amount of oat bran or oatmeal consumed daily to lower total and LDL-cholesterol in the above studies ranged from 34 g (2.5 g soluble fiber) (Ref. 17) to 123 g (10.3 g soluble fiber) (Ref. 45). In those studies that evaluated HDL-cholesterol responses to oat intervention, three reported a slight, nonsignificant decrease in HDL-cholesterol (Refs. 8, 11, and 21); four reported no change (Refs. 12, 20, 23, and 35); and five reported a slight increase in HDL- cholesterol as a result of oat intervention (Refs. 24, 25, 39, 42, and 45).

Five studies (Refs. 10, 19, 32, 37, and 46) showed equivocal results in reducing serum cholesterol. The results by Bartram et al. (Ref. 10) were difficult to interpret because fruits were included in the oat bran cereal. The soluble fiber of the fruit may have had an independent effect on serum lipid levels. The questionable assessment of dietary intake and the lack of temporal sequence in an uncontrolled, cross-sectional survey conducted by He et al. (Ref. 19) make the beneficial results of this study difficult to interpret. In addition, the population group used in this study (i.e., Chinese farmers and migrants) do not reflect the general population in the United States. The agency also questioned the appropriateness of the population groups used in two other studies (Refs. 37 and 46). Zhang et al. (Ref. 46) showed significant reductions in total cholesterol in subjects who had ileostomies. The mechanism by which oat bran or oatmeal help lower serum lipids in this population may not reflect the general population in the United States. Swain and coworkers (Ref. 37) evaluated the cholesterol-lowering properties of oat bran and wheat in a group of young pre-menopausal women with low serum cholesterol levels, a group who does not represent a population at risk for CHD. Dietary changes were reported during the oat period which also make interpretation of the results difficult.

Significant dietary changes during the oat intervention period made it difficult to interpret the results of another study (Ref. 32). Poulter et al. (Ref. 32) reported significant reductions in total and LDL-cholesterol in subjects consuming 56 g of oat cereal. There were no significant changes in total and LDL-cholesterol when the subjects consumed their usual (control) cereal. However, an analysis of the nutrient data revealed a significant reduction in total energy from fat and in the ratio of polyunsaturated to saturated fat (P:S) during the oat period.

In the 11 studies in which no effect on serum lipid levels were found (Refs. 13, 16, 18, 26 through 28, 31, 34, 36, 38, and 41), a number of reasons were advanced for the lack of a positive finding. A lack of compliance and changes in dietary intakes by the subjects plagued a number of these studies (Refs. 18, 27, 31, 34, and 41). The source of the oat cultivars allegedly contributed to the lack of an effect of oat bran or oatmeal on serum lipids in four others (Refs. 13, 26, 28, and 36). The authors of these studies noted that New Zealand oat cultivars tend to have lower levels of soluble fiber than oat cultivars used in studies showing cholesterol-lowering properties.

The processing of oats allegedly caused a loss of effectiveness in another study (Ref. 38). Törrönen and coworkers found that wet milling Finnish oats to produce an oat bran concentrate negatively affected the hypocholesterolemic properties of oat β-glucan.

The results of the study by Demark-Wahnefried et al. (Ref. 16) suffered from a lack of statistical power to detect changes between groups, variable weight loss among the groups, and significant dietary changes during the course of the study.

IV. Decision To Propose a Health Claim Relating Oat Products to Reduction in Risk of CHD

The petition set out the conclusions reached by the Federal government and other recognized scientific bodies, as well as those reached in review articles and in pertinent human studies published since 1987. FDA reviewed this information as well as those studies that evaluated the effects on serum cholesterol and LDL-cholesterol levels from dietary intervention with oat bran or oatmeal in subjects with normal to elevated serum cholesterol levels.

FDA tentatively concludes that, based on the totality of publicly available scientific evidence, there is significant scientific agreement to support the relationship between consumption of oat bran or oatmeal as foods, or as ingredients in foods, and the risk of CHD. The strongest evidence for the effect of oat bran or oatmeal on the risk of CHD is provided by studies that

measured the effect of dietary oat consumption on the two major risk factors for CHD, total and LDL-cholesterol. FDA is aware of five studies of that effect in which problems associated with subject compliance and weight loss were avoided and in which appropriate controls were used (Refs. 12, 25, 29, 39, and 45). All of these studies showed a significant relationship between oat consumption and lowered serum total and LDL-cholesterol levels and no adverse effect on other CHD risk factors, such as significantly lowering HDL-cholesterol. The daily oat intake ranged from an estimated 70 g oat bran (Ref. 12) to 150 g oat bran (Ref. 39). Four of these studies (Refs. 12, 25, 39, and 45) were conducted in subjects with mild to moderately elevated levels of serum cholesterol. One study (Ref. 29) used subjects with normal serum cholesterol levels.

Braaten et al. (Ref. 12) showed that when subjects consumed an amount of purified oat gum (containing 80 percent β-glucan) equivalent to consuming 70 g oat bran daily, total and LDL-cholesterol were significantly reduced, and HDL-cholesterol remained unchanged. The oat gum was consumed with a typical American diet.

Kestin et al. (Ref. 25) showed significant reductions in total and LDL-cholesterol, compared to blood lipid levels during wheat and rice bran periods, in subjects who consumed 95 g oat bran/day for 4 weeks (Ref. 25). HDL-cholesterol showed slight, nonsignificant increases compared to baseline in all diet periods. The subjects consumed the test foods as part of their usual diet.

Subjects with moderate hypercholesterolemia showed significant reductions in total and LDL-cholesterol after they consumed 150 g oats/day for 4 weeks compared to baseline lipid levels (Ref. 39). These same subjects experienced small increases in total and LDL-cholesterol (not significant) after consuming wheat products. Blood levels of HDL-cholesterol increased slightly (not significant) during the oat period but remained the same during the wheat period. All subjects consumed a low fat diet in this study.

Whyte et al. (Ref. 45) reported significant reductions in total and LDL-cholesterol in subjects who consumed 123 g oat bran/day for 4 weeks as part of their usual diets. The subjects experienced a slight increase in total cholesterol and no change in LDL-cholesterol after consuming wheat bran. HDL-cholesterol increased slightly (not significant) during both bran periods.

In a study designed to assess the mechanism by which oat bran lowers total cholesterol, Marlett et al. (Ref. 29) reported significant reductions in total cholesterol in the period in which subjects consumed oat bran compared to a wheat control period. The subjects consumed 100 g oat bran/day for 4 weeks during the high fiber period and wheat gluten during the low fiber, control period, with their usual diets.

The results of 12 other studies (Refs. 8, 11, 15, 17, 20, 21, 23, 24, 35, and 42 through 44) also support the relationship between oat consumption and reduction in total and LDL-cholesterol. Six studies (Refs. 8, 17, 20, 21, 35, and 44) showed the benefits of oat intervention in reducing serum total and LDL-cholesterol in subjects consuming a typical American diet. HDL-cholesterol showed no significant change in four of these studies (Refs. 8, 20, 21, and 35) and a significant reduction in one study (Ref. 21). The amount of oat bran or oatmeal consumed in these studies ranged from 34 g/day (Ref. 17) to 110 g/d (Ref. 8).

Three studies (Refs. 15, 23, and 24) showed a significant effect of oat bran or oatmeal on total and LDL-cholesterol that was beyond that of a Step 1 diet alone. The results of the three other studies (Refs. 11, 42, and 43) showed lower, nonsignificant, total and LDL-cholesterol in subjects who consumed oat bran or oatmeal compared to the group who consumed the Step 1 or Step 2 diets alone. In two of these studies (Refs. 42 and 43), the subjects' lipid values after a run-in period on the low fat diet ranged from a mean of 193 to 197 mg/dL. The lack of significant difference between the diet only and the oat groups in these studies may be overshadowed by the effect of the diet alone on subjects who had initially low total and LDL-cholesterol levels. There were no significant changes in HDL-cholesterol from the consumption of a low fat diet plus oats. The range of oat intake in these studies ranged from 35 g (Ref. 43) to 100 g/day (Ref. 24).

Two studies (Ref. 20 and 23) used wheat as a placebo control. The results of these studies showed significantly lower total and LDL-cholesterol in subjects who consumed oat bran compared to those who consumed wheat.

A metaanalysis (Ref. 33) using pooled, raw data from a number of oat studies (Refs. 11, 15 through 17, 23, 25, 30, 37, 39, 40, and 42 through 44) found that an intake of 3 g soluble fiber (used as a marker for oat bran and oatmeal) or more produced modest reductions (average decrease of 5 to 6 mg/dL) of serum total cholesterol levels. The decrease in total cholesterol was largest in those trials with subjects that initially had high total cholesterol levels.

As stated in section III.A. of this document, Federal government and other reviews have concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total cholesterol and LDL-cholesterol represent major contributors to CHD (56 FR 60727 at 60728, and Refs. 3 through 5). Dietary factors that decrease total cholesterol and LDL-cholesterol will affect the risk of CHD (Refs. 3 through 6). Based on the scientific evidence presented in the petition, the agency tentatively concludes that there is significant scientific evidence to show that oat bran and oatmeal will help reduce serum lipids, and that such reductions may reduce the risk of CHD. In the majority of clinical studies evaluating oat products, total and LDL-cholesterol fractions were shown to be the most affected by oat intervention. Regular consumption of oat bran or oatmeal, in an amount to provide 3 g or more of oat β-glucan soluble fiber, resulted in reduced total and LDL-cholesterol levels in subjects with normal and elevated serum cholesterol levels.

Changes in HDL-cholesterol levels as a result of oat intervention were generally absent or not significant (Refs. 8, 11 through 13, 18, 20, 23 through 28, 32, 35 through 39, 41, 42, and 45). A tendency toward an increase in HDL-cholesterol was shown in nine studies (Refs. 13, 24, 25, 27, 28, 32, 39, 42, and 45); no change was shown in nine studies (Refs. 8, 12, 18, 20, 23, 24, 35, 36, and 41); and a nonsignificant decrease in HDL-cholesterol was shown in three studies (Ref. 11, 26, and 38). Although HDL-cholesterol was reduced 0.9 percent ($p<0.03$) in the study by Kahn et al. (Ref. 21), the HDL:LDL and HDL:total cholesterol ratios were improved, compared to baseline, because of significant reductions in total cholesterol (8 percent) and LDL-cholesterol (10 percent).

Oat bran and oatmeal were tested in a variety of food forms but produced fairly consistent results, showing that the way in which these foods are consumed does not alter their effect on serum lipids. They were consumed as hot and cold cereals or used in a variety of other foods, such as muffins, breads, shakes, and entrees.

The eleven studies that did not show reduced total and LDL-cholesterol from the consumption of oat bran or oatmeal (Refs. 13, 16, 18, 26 through 28, 31, 34, 36, 38, and 41) do not detract from the agency's tentative conclusion about this relationship or that the claim is valid.

The lack of result in five of these studies (Refs. 13, 26, 28, 36, and 38) was apparently attributed to the oat source, i.e., New Zealand cultivars, or to the method of processing oat bran. The results of the remaining six studies were associated with a lack of subject compliance and significant changes in dietary intake during the test periods, or to problems in study design, i.e., a lack of statistical power to detect changes between groups.

Given all of this evidence, the agency is proposing a health claim on the relationship between oat bran and oatmeal and reduced risk of CHD.

V. Description and Rationale for Components of Health Claim

A. Relationship Between Oatmeal and Oat Bran and CHD and the Significance of the Relationship

Proposed § 101.81(a) describes the relationship between diets high in oat bran or oatmeal and the risk of CHD. In proposed § 101.81(a)(1), the agency recounts that CHD is the most common and serious form of CVD, and that CHD refers to diseases of the heart muscle and supporting blood vessels. The regulation also notes that high blood total and LDL-cholesterol levels are associated with increased risk of developing CHD. The regulation identifies the levels of total cholesterol and LDL-cholesterol that would put an individual at high risk of developing CHD and those serum lipid levels that are associated with borderline high risk. The intent is to provide consumers with information to help them understand the seriousness of CHD.

In proposed § 101.81(a)(2), the agency recounts that populations with a low incidence of CHD tend to have low blood total and LDL-cholesterol levels. It states that these populations also tend to have dietary patterns that are low in total fat, saturated fat, and cholesterol and high in fruits, vegetables, and grain products, such as oatmeal and oat bran. This information is consistent with that provided in the authorized health claim for fruits, vegetables, and grain products and CHD (§ 101.77). The agency tentatively finds that this information provides a basis for a better understanding of the numerous factors that contribute to the risk of CHD and the relationship between oat bran and oatmeal and a low fat diet.

Proposed § 101.81(a)(3) describes the relationship between oat bran and oatmeal, foods low in saturated fat and cholesterol, and reduction in the CHD risk factors. The paragraph states that several studies have shown that diets high in oatmeal or oat bran are associated with reduced blood lipid levels. This information encapsulates the scientific evidence about how oatmeal and oat bran can contribute to reduction in heart disease risk factors.

Proposed § 101.81(b) describes the significance of the diet-disease relationship. In proposed § 101.81(b)(1), the agency recounts that CHD remains a major public health concern in the United States because the disease accounts for more deaths than any other disease or group of diseases. The claim states that early management of modifiable risk factors for CHD is a major public health goal that can assist in reducing the risk of CHD. This information is consistent with the evidence that lowering blood total and LDL-cholesterol levels reduces the risk of CHD (56 FR 60727, 58 FR 2739, and Refs. 3 through 6 and 47).

In proposed § 101.81(b)(2), the significance of the relationship between oatmeal and oat bran and CHD risk factors in context of the total diet is discussed. The agency recounts that many Americans' intakes of saturated fat and cholesterol exceed recommended levels, and it summarizes public health recommendations for the diet (56 FR 60727 at 60738 and § 101.75(b)(3)). This paragraph also states that scientific evidence demonstrates that diets high in oatmeal and oat bran and low in saturated fat and cholesterol are associated with reduced blood lipids. FDA tentatively concludes that the latter statement is scientifically valid based on the evidence that it has reviewed on this nutrient-disease relationship.

B. Nature of the Claim

In § 101.81(c)(1) (21 CFR 101.81(c)(1)), FDA is proposing to require that all of the general requirements for health claims set out in § 101.14 be met. This provision is consistent with the provisions of the other specific health claim regulations in part 101, subpart E, of the Code of Federal Regulations (CFR) (21 CFR part 101, subpart E).

In § 101.81(c)(2)(i), FDA is proposing to authorize a health claim on the relationship between diets high in oat bran or oatmeal and the risk of CHD. The agency is proposing to do so based on its review of the scientific evidence on this nutrient-disease relationship which shows that diets that are high in oat bran or oatmeal help to reduce total and LDL-cholesterol levels in individuals with normal to elevated blood total cholesterol (Refs. 8, 11, 12, 15, 17, 20, 21, 23 through 25, 29, 35, 39, 44, and 45). This result is significant for the risk of heart disease because elevated levels of total and LDL-cholesterol are associated with increased risk of CHD (Refs. 3 through 6).

In § 101.81(c)(2)(i)(A), the agency is proposing to require, consistent with other health claims, that the relationship be qualified with the terms ''may'' or ''might.'' These terms are used to make clear that not all persons can necessarily expect to benefit from these dietary changes (56 FR 60727 at 60740 and 58 FR 2552 at 2573).

In § 101.81(c)(2)(i)(B), the agency is proposing to require, consistent with other authorized health claims, that the terms ''coronary heart disease'' or ''heart disease'' be used in specifying the disease. These terms are commonly used in dietary guidance materials, and therefore they should be readily understandable to the consumer (56 FR 60727 at 60740 and 58 FR 2552 at 2573).

In § 101.81(c)(2)(i)(C)(*1*), the agency is proposing that the claim describe the relationship between diets high in oatmeal or oat bran and risk for CHD. Based on its review of the scientific evidence submitted with the petition, the agency tentatively concludes that there is significant scientific agreement that diets high in oat bran or oatmeal may help to reduce blood total and LDL-cholesterol levels, the major modifiable risk factors for CHD (Refs. 12, 17, 20, 21, 25, 29, 35, 44, and 45).

The petitioner stated in its petition that there is significant scientific evidence to show that the effect of oats on lowering serum lipids is independent of a diet low in saturated fat and cholesterol. In light of this evidence, the petitioner argued that any health claim that is authorized need not refer to such a diet. The petitioner explained that important public health policy objectives, as well as FDA's statutory mandate to authorize health claims supported by significant scientific agreement, mandate that FDA issue a regulation that requires only that claims describe the relationship between oat products and reduced risk of CHD (Ref. 1, p. 68).

The agency acknowledges that there were a number of studies that showed that high intakes of oat bran and oatmeal lowered blood total and LDL-cholesterol in subjects that otherwise consumed a typical American diet (Refs. 12, 17, 20, 21, 25, 29, 35, 44, and 45). However, as stated in section V.A. of this document, CHD is a major public health concern in the United States, and that the totality of the scientific evidence provides strong and consistent support that diets high in saturated fat and cholesterol are associated with elevated levels of blood total and LDL-cholesterol, and thus CHD (56 FR 60727

at 60737). Dietary estimates for American adults show that the average saturated fat intakes of American adults are about 13 percent of calories, total fat intakes are about 37 percent of calories, and average cholesterol intakes range from 300 to over 400 mg daily for adult men and women (56 FR 60727 at 60738). The current intakes of saturated fat and total fat are thus well in excess of recommended goals of less than 10 percent and 30 percent of calories. Dietary guidelines from both government and private-recognized scientific bodies conclude that the majority of the American population would benefit from decreased consumption of dietary saturated fat and cholesterol (Refs. 3 through 6).

The results of several studies showed that while daily consumption of oat bran or oatmeal lowered total cholesterol and LDL-cholesterol, the effects of dietary intake of oat bran or oatmeal were particularly evident when the diets were low in saturated fat and cholesterol (Refs. 11, 15, 24, 39, and 43). Thus, the agency tentatively finds that it will be more helpful to Americans' efforts to maintain healthy dietary practices if the effect of oats on serum lipids is described in context of a healthy diet. This information is extremely important to a full understanding of the significance of the claim.

The agency tentatively finds that for the public to understand fully, in the context of the total daily diet, the significance of consumption of oat bran and oatmeal on the risk of CHD (see section 403(r)(3)(B)(iii) of the act), information about the total diet needs to be included as part of the claim. Therefore, in § 101.81(c)(2)(i)(C)(*2*), the agency is proposing to require that the claim include the fact that the effect of dietary consumption of oatmeal or oat bran on the risk of CHD is particularly evident when these foods are consumed as part of a diet that is low in saturated fat and cholesterol. Based on its review of the scientific evidence submitted with the petition, the agency tentatively concludes that there is significant scientific agreement that diets high in oat bran or oatmeal and low in saturated fat and cholesterol are associated with reduced blood total and LDL-cholesterol levels (Refs. 11, 15, 23, 24, 39, 42, and 43).

FDA is proposing to require that this dietary information be included as part of the full health claim to ensure that people understand the significance of the information in the claim. A diet low in saturated fat and cholesterol is important because if intake of these dietary components are not controlled, then there is a significant question as to whether high fiber diets will have their full effect on blood total and LDL-cholesterol levels, and thus on the risk of heart disease. However, based on information supplied by the petitioner, FDA tentatively concludes that a claim that diets high in oat bran or oatmeal may reduce the risk of heart disease is truthful, not misleading, and scientifically valid without this additional information. Therefore, FDA tentatively finds that it is appropriate to require that a label that bears an oat bran or oatmeal health claim disclose the fact that a diet should be high in oat bran and oatmeal and low in saturated fat and cholesterol, but that it is not necessary to require that the latter dietary information be disclosed in immediate proximity of the oat bran or oatmeal claim each time the claim appears on the label or in labeling (see the discussion of § 101.81(c)(2)(ii) below). FDA is proposing to require only that the full statement of the claim disclose the fact that the effect of the dietary intake of oat bran or oatmeal is particularly evident when the diet is low in saturated fat and cholesterol.

Proposed § 101.81(c)(2)(i)(D), consistent with other authorized health claims, requires that the claim not attribute any degree of risk reduction of CHD to consumption of oat products. None of the studies that the agency reviewed provide a basis for determining the percent reduction in risk of CHD likely from consuming diets high in oat products.

The agency considered proposing to require that the claim state that the development of CHD depends on many factors. This statement has been required in the two authorized heart disease health claims (§§ 101.75 and 101.77) (although the agency has recently proposed to delete this requirement in a document that published in the Federal Register of December 21, 1995 (60 FR 66206) (hereinafter referred to as the 1995 proposal). The petitioner requested that the statement regarding the multifactorial nature of CHD be listed under optional requirements for the health claim (Ref. 1, p. 68). The petitioner stated that based on an ever increasing background of health information made available through various media, consumers already understand that foods are not drugs, and that health enhancement depends not only on consumption of a particular food but also on other dietary practices, exercise, heredity, lifestyle, and a host of other factors. The petitioner did not provide any data to support this observation. The petition stated that the ''depends on many factors'' language makes the health claim cumbersome, unnecessarily long, and detracts from its central and critical consumer message. The petition stated that using the required statement ''may help'' (i.e., ''may help reduce the risk of heart disease'') more simply, directly, and succinctly indicates to consumers that oatmeal and oat bran are not magic bullets, and that other factors are associated with CHD risk.

The agency agrees with the petitioner that the requirement that the claim use the term ''may'' or ''might'' to relate the ability of oat bran or oatmeal to reduce the risk of heart disease is intended to reflect the multifactorial nature of the disease. In response to comments on the scientific standard proposed for health claims, the agency stated in the 1993 health claims final rule (58 FR 2478 at 2505):

> * * * Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term ''may'' with respect to the potential to reduce the risk of disease. * * *

The agency notes that FDA has been asked in a petition from the National Food Processors Association (NFPA) (Docket No. 94P–0390) to reevaluate the required elements of the health claim and to consider a number of options including the option of using an abbreviated health claim and eliminating the multifactorial element of the health claim requirements. In the 1995 proposal, the agency initiated rulemaking that, in part, proposed to eliminate or make optional some of the required elements. More specifically, the agency proposed to make optional the statement ''a disease caused by many factors'' (see section IV.E. of the 1995 proposal), and to permit the use of certain abbreviated health claims on the label or labeling of a product (see section IV.C. of the 1995 proposal) (60 FR 66206). In this proposed rule on oat bran and oatmeal and CHD, the agency is proposing to make the phrase ''depends on many factors'' optional information. In place of the requirement for stating the multifactorial nature of

the disease, the agency is proposing § 101.81(c)(2)(i)(E) to require that the claim not imply that the consumption of oat bran and oatmeal is the only recognized means of achieving a reduced risk of CHD. Thus, the agency tentatively concludes that the concept of the multifactorial nature of CHD will be preserved without adding additional words to the claim. The agency requests comment on whether consumers will be misled to believe that reduction of risk will be achieved if the multifactorial nature of CHD is not stated on the claim. This proposed rule would also permit use of a shortened version of the claim in conjunction with the full claim (see section IV.C. of the 1995 proposal).

C. Presentation of the Claim

In proposed § 101.81(c)(2)(ii), the agency is providing for how the health claim is to be presented on the label or labeling. This paragraph states that all of the elements listed in § 101.81(c)(2)(i) must be included in one presentation of the claim on the label or labeling. As discussed in sections V.A. and B. of this document, the scientific evidence provides strong and consistent support that diets high in saturated fat and cholesterol are associated with elevated levels of blood total and LDL-cholesterol, the major modifiable risk factors for CHD. Because the typical American diet tends to be high in saturated fat and cholesterol, dietary guidelines recommend that Americans modify their intakes of food that contain significant levels of saturated fat and cholesterol. From a public health standpoint, it is important for the public to comprehend the significance of the relationship between diets high in oat bran or oatmeal and CHD risk in context of a diet low in saturated fat and cholesterol. This relationship is supported by significant scientific evidence as discussed above.

However, the 1995 proposal permits a short, simple statement of certain health claims that is truthful, not misleading, and scientifically valid, which may be used on the principal display panel, as long as the full claim appears on the particular label or in the particular labeling in which the short statement appears, and there is a referral statement from the shortened to the full claim (60 FR 66206). In recognition of this fact, FDA is providing in proposed § 101.81(c)(2)(ii) that if a full statement of the claim appears on a label or in a piece of labeling, other presentations of the claim may appear on the label or in labeling that do not include the information required in proposed § 101.81(c)(2)(i)(C)(*2*) so long as there is a referral statement to the full statement of the claim in immediate proximity with the shortened statement. FDA has explained above the basis for its tentative conclusion that the shortened claim need not include the information in paragraph (c)(2)(i)(C)(*2*) regarding the importance of low saturated fat and cholesterol diet.

The referral statement that FDA is proposing accompany the shortened claim is consistent with that provided for in the general requirements for nutrient content claims (§ 101.13) and health claims (§ 101.14(d)(2)(iv)). This referral statement is short and thus consistent with the use of an abbreviated claim. It is important, however, because the agency tentatively finds that it is essential that the consumer be directed to the full claim. Specifically drawing the consumer's attention to the full claim will help to ensure that he or she is able to comprehend the information that is being presented in the context of the total daily diet.

In its 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). The agency was concerned that an abbreviated claim would not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet. The agency was concerned that confusion is possible whenever the full health claim information appears in a location different from that of the reference statement and is especially likely to occur when a multiplicity of labeling is associated with a product.

The agency has tentatively concluded that this proposed rule addresses these concerns. It is providing for an abbreviated statement that reflects the facts that are material under section 201(n) of the act (21 U.S.C. 321(n)) and that are necessary to ensure that the claim is scientifically valid. It is also providing for an accompanying referral statement to additional information that is necessary for a full understanding of the claim. The agency is concerned, however, about the possibility that consumers may not read the complete claim, and thus that they will not have all of the facts necessary to fully understand the significance of the claim being made and to comprehend the claim in the context of the daily diet. For this reason, the agency is asking for data to demonstrate that permitting a shortened claim in this manner will not significantly decrease the likelihood that consumers will read the full claim so long as it appears prominently on the label or in the piece of labeling.

In new § 101.81 (c)(2)(ii)(A) and (c)(2)(ii)(B), the agency is proposing, consistent with requirements for nutrient content claims in § 101.13 (g)(1) and (g)(2), requirements for the typesize and location of the referral statement.

FDA has long held that accompanying information should be in a size reasonably related to that of the information that it modifies. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. Section 403(r)(2)(B) of the act requires that a referral statement for nutrient content claims appear prominently, although it does not specify specific requirements such as to typesize or style. For nutrient content claims, FDA established type size requirements for referral and disclosure statements related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. The proportionality between the size of the referral statement and the size of the label ensures that the referral statement is presented with appropriate prominence. However, when the claim is less than twice what the minimum size of the referral statement would be given the size of the label and § 101.105(i) (21 CFR 101.105(i)) the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. This approach to the type size requirement for the referral statement provides flexibility to firms in utilizing label space but still ensures adequate prominence for this statement. Because health claim referral statements are used similarly to those that accompany nutrient content claims and are likely to appear on the principal display panel, the agency tentatively concludes that a health claim referral statement should have the same type size requirements as those for nutrient content claims. Therefore, the agency tentatively concludes that the requirements for the referral statement set forth in § 101.105 (c)(2)(ii)(A) and (c)(2)(ii)(B) are appropriate when a shortened health claim is used and is including them in this proposed rule.

D. Nature of the Food

Proposed § 101.81(c)(2)(iii)(A) requires that the food bearing the health claim contain 13 g of oat bran or 20 g

oatmeal, and that the oat bran or oatmeal contain, without fortification, at least 1.0 g of β-glucan soluble fiber. The paragraph states that oat β-glucan be determined by the Association of Official Analytical Chemists (AOAC) official method (i.e., method 992.28), per reference amount customarily consumed (RACC).

The requirement that the food contain oat bran or oatmeal is consistent with the scientific evidence that shows that oat bran or oatmeal, when consumed as a food or as an ingredient in food, helps to lower total and LDL-cholesterol.

The agency is not proposing to permit a claim for oat gums or oat fibers, substances that may be manufactured by different methods and are not well defined chemically or physically. These substances, like all food fibers, are a complex matrix and factors, such as the fermentability; particle size; molecular weight; chemical structure; water holding capacity; nonfiber components; net charge; viscosity; and cation-exchange capacity, binding, and chelation, may affect their physiological properties (Ref. 7).

The effects of processing on the physiological properties of oat bran were evidenced in three studies. In a study by Törrönen et al. (Ref. 38), a specially processed oat bran concentrate incorporated into bread to provide 11.2 g/d β-glucan showed no effect on lowering serum lipids in a controlled study with hypercholesterolemic subjects. Two other studies testing a specially processed oat fiber source providing 3.3 g/d β-glucan soluble fiber (Ref. 35) and oat gum providing 5.8 g/d β-glucan soluble fiber (Ref. 12) showed significant reductions in blood total and LDL-cholesterol levels. The latter two studies showing a cholesterol-lowering response did not adequately characterize the material being tested to permit their (oat fiber source and oat gum) inclusion in the regulations, however. If manufacturers can document, through appropriate studies, that dietary consumption of a well-characterized oat product, e.g., purified extracts of oat gum or modified oat fiber isolates, has the effect of lowering total and LDL-cholesterol levels, and has no adverse effects on other heart disease risk factors (e.g., HDL-cholesterol), they should submit that information in comments or petition FDA to amend § 101.81 to cover the substance.

Because the subject of this health claim petition is the effect of oatmeal or oat bran on the risk of CHD, it is appropriate to consider the levels of oat bran and of oatmeal intake that have been shown to have significant effects on the levels of serum total and LDL-cholesterol in establishing qualifying levels for foods to bear an oatmeal or oat bran and CHD health claim. In the clinical studies that showed that consumption of oatmeal or oat bran lowered total and LDL-cholesterol, daily consumption ranged from 35 g (Ref. 43) to 84 g (Ref. 15) of oat bran and 34 g (Ref. 17) to 150 g (Ref. 39) of oatmeal. Based on values provided in the petition, 35 g of oatmeal would provide about 1.75 g of β-glucan soluble fiber, and 34 g of oat bran would provide about 2.5 g of β-glucan soluble fiber (Ref. 1, p. 66). The higher the daily intake of oatmeal and oat bran, the higher the intake of β-glucan soluble fiber and the better the response in lowering serum lipids. This observation is supported by the metaanalysis of oat products by Ripsin et al. (Ref. 33) and is consistent with the agency's comments on the Davidson et al. study (Ref. 15) in the preamble to the 1993 dietary fiber and CVD final rule (58 FR 2552 at 2568):

> * * *[B]ased on the results of this study, an intake of soluble fiber (in this case, β-glucan from oats) of about 3 g per day or more was beneficial in that it resulted in a significant lowering of serum cholesterol in persons consuming a low-fat diet.

An intake of 3 g of β-glucan soluble fiber is equivalent to approximately 60 g of oatmeal or 40 g of oat bran (dry weight) (Ref. 1, p. 67), the approximate midpoints of the consumption ranges of oat bran and oatmeal that had an effect on blood lipids. The petitioner suggested that 40 g of oat bran, 60 g of oatmeal, and 3 g β-glucan soluble fiber be considered as the standard for determining the qualifying levels of oat bran and oatmeal for this health claim. Applying a regression analysis to the results of Davidson et al. (Ref. 15), and using β-glucan soluble fiber as a marker for oat bran and oatmeal, the petitioner determined that 3 g β-glucan would be required to achieve a 5 percent reduction in serum cholesterol (Ref. 1, p. 22–27). The petition stated that a 5 percent reduction in serum cholesterol is a desirable goal because that is the level that was achieved as a result of a dietary fat and cholesterol focused intervention in the Multiple Risk Factor Intervention Trial (MRFIT) and Lipid Research Council (LRC) clinical trials (Refs. 1 and 40).

The petitioner stated that while current research may not demonstrate that β-glucan is the only component of oats that affects blood lipids, it does suggest that it is an excellent marker for cholesterol reduction potential (Ref. 1, p. 64). The petitioner stated that the amount of β-glucan also serves as a marker for the content of oat bran and oatmeal in foods. Using 40 g of oat bran, 60 g of oatmeal, and 3 g β-glucan as the qualifying amounts for a CHD claim, the petitioner suggested that a single serving of an oat-containing product (i.e., 1 RACC) should provide ⅓ of this amount (based on 3 servings a day). Thus, an oat bran-containing product would have to contain at least 13 g oat bran (⅓ × 40 g) that provides 1 g β-glucan (⅓ × 3 g) soluble fiber per RACC. An oatmeal-containing product would have to contain no less than 20 g oatmeal (⅓ × 60) that provides 1 g β-glucan soluble fiber. The petitioner stated that this approach is reasonable because it would permit a wide variety of low fat, oat-containing products, e.g., muffins, cereals, and breads, to qualify for this health claim. The petitioner provided several examples of meals, developed on the basis of U.S. Dietary Guidelines, that demonstrated how 40 g of oat bran and 60 g of oatmeal, providing 3 g of β-glucan soluble fiber, could be incorporated into a diet that is consistent with dietary guidelines (Ref. 1, pp. 43–54).

The agency agrees that, based on Davidson et al. (Ref. 15), the metaanalysis (Ref. 33), and other studies that reported the amount of β-glucan soluble fiber in oat products, 3 or more grams of oat β-glucan soluble fiber were associated with significant reductions in serum cholesterol. The agency also agrees that not all oat bran or oatmeal-containing products that might otherwise qualify for this claim contain that amount per RACC of oat product. Based on nutrient composition data presented in the petition (Ref. 1, pp. 38–39), only oat bran hot and cold cereals contain 3 g β-glucan soluble fiber would qualify for this proposed health claim. Thus, limiting eligibility for the claim to products with 3 g β-glucan soluble fiber would have the unintended effect of eliminating a number of low fat, oat-containing products, e.g., oatmeal cereals, oatmeal waffles, oat bran muffins, and oatmeal breads, from bearing an oatmeal or oat bran and CHD health claim.

The petition states that the most common oat food forms are oat bran and oatmeal consumed as hot cereals (Ref. 1, p.33). The mean daily dietary intake by oat consumers of oatmeal and oat bran hot cereals is 43.3 g (dry weight basis) and the median intake is 40.1 g (Ref. 1, p. 33). The petition states that the 90th and 95th percentiles of intake are 71.3 and 84.2 g (dry weight basis) per day, respectively. Therefore, it is reasonable to assume that a person could consume a total of, or more than, 40 g oat bran, 60 g oatmeal, or a combination of the

two that provides 3 g β-glucan soluble fiber if the oat products are consumed over the course of a day.

The agency has generally made the assumption that a daily food consumption pattern includes three meals and a snack (see 58 FR 2302 at 2379, January 6, 1993). Therefore, one approach to determining the qualifying levels of oat bran, oatmeal, and oat β-glucan soluble fiber for a CHD health claim is to divide the effective levels of these substances by four eating occasions per day. Using this approach, an oat bran product would have to provide at least 10 g of oat bran and 0.75 g β-glucan soluble fiber, and an oatmeal product would have to provide at least 15 g of oatmeal and 0.75 g β-glucan soluble fiber per RACC in order to qualify to bear an oat and CHD health claim. However, considering that the mean daily dietary intake of oatmeal and oat bran is 43 g, and that that amount is consumed mostly in the form of hot cereal, and considering the nature of this food, it is not expected that people will consume oat-containing products 4 times a day. The agency is persuaded by the petitioner's argument that oat products can reasonably be expected to be consumed 3 times a day, being incorporated into a variety of products. Thus, an oat bran-containing product would have to provide no less than 13 g oat bran and 1 g β-glucan soluble fiber per RACC, and an oatmeal-containing product would have to provide no less than 20 g oatmeal and 1 g β-glucan soluble fiber. Therefore, the agency tentatively finds that use of 13 g oat bran and 20 g oatmeal that provide 1 g β-glucan soluble fiber as the qualifying criteria for this proposed rule is appropriate and is proposing these levels in this document.

The proposed qualifying requirement of 1 g β-glucan soluble fiber per RACC of oat bran or oatmeal-containing product is higher than the amount of soluble fiber that is required for a food to qualify to bear the fruits, vegetables, and grain products and CHD health claim (§ 101.77). Under § 101.77(c)(ii)(C), a food need only contain, without fortification, 0.6 g soluble fiber per RACC. In the preamble to the 1993 dietary fiber and CVD final rule, the agency explained that the 0.6 g of soluble fiber was based in part on the recommendation by the LSRO expert panel that 25 percent of the recommended daily intake of fiber be soluble fiber (58 FR 2552 at 2573 and 2574). The agency also stated that the 0.6 g soluble fiber is consistent with the definition of a ''good source'' of a nutrient (i.e., 10 percent of the daily reference value (DRV)). The agency explained that the 10 percent level is deemed useful and appropriate because very few foods could naturally meet the requirement for a ''high'' source of soluble fiber. The current dietary guidance recommendations of five or more servings of fruits and vegetables and six or more servings of grain products daily, if followed, would likely result in intakes of soluble fiber close to or exceeding the recommended daily intake of 6 g (58 FR 2552 at 2574). Thus, the 0.6 g of soluble fiber was intended to allow a number of fruits, vegetables, and grain products to qualify. The agency stated that without this alternate level very few fruits, vegetables, and grain products would qualify for the health claim (58 FR 2552 at 2574).

Based on the scientific evidence reviewed in this document, higher daily intakes of oat bran and oatmeal (about 40 g and 60 g, respectively) that provided 3 g/d or more of β-glucan soluble fiber were associated with significant cholesterol-lowering benefits (Refs. 15 and 33). As discussed above, it is reasonable to assume that oat bran and oatmeal would likely not be consumed in more than three eating occasions per day. Therefore, the agency tentatively finds that the proposed criterion that the oat bran or oatmeal provide 1 g β-glucan soluble fiber per RACC is appropriate for this health claim. The agency is asking for comments on this tentative determination.

In § 101.81(c)(2)(iii)(B), the agency is proposing, consistent with other authorized heart disease health claims, that foods bearing the health claim meet requirements for ''low saturated fat,'' ''low cholesterol,'' and ''low fat.'' In the preamble to the final rule on fruits, vegetables, and grain products and heart disease (§ 101.77, 58 FR 2552 at 2572), the agency stated that populations with diets rich in these low saturated fat and low cholesterol foods experience many health advantages, including lower rates of heart disease. In the preamble to the proposed rule on dietary lipids and heart disease (56 FR 60727 at 60739), the agency stated that while total fat is not directly linked to increased risk of CHD, it may have significant indirect effects. Foods that are low in total fat facilitate reductions in intakes of saturated fat and cholesterol to recommended levels. Therefore, the agency tentatively concludes that proposed § 101.81(c)(2)(iii)(B) sets forth an appropriate requirement for food to be eligible to bear the oatmeal and oat bran/CHD claim.

E. Optional Information

FDA is proposing in § 101.81(d)(1) that the claim may state that the development of heart disease depends on many factors and, consistent with authorized CHD health claims, may list the risk factors for heart disease that are listed in §§ 101.75(d)(1) and 101.77(d)(1). The agency is also proposing, in response to the petition, that the claim may provide additional information about the benefits of exercise and body weight management. This additional information can provide a context that is useful for an understanding of the relationship between oat bran and oatmeal and heart disease, but manufacturers should be cautioned that it should not be presented in a way that is misleading to the consumer.

In proposed § 101.81(d)(2), consistent with §§ 101.75(d)(2) and 101.77(d)(2), FDA is providing that the claim may state that the relationship between a diet high in oat bran or oatmeal and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total cholesterol'' and ''LDL-cholesterol.'' The relationship between oat bran or oatmeal and reduced blood total cholesterol and LDL-cholesterol is supported by the scientific evidence presented in this proposal.

In § 101.81(d)(3), the agency is proposing that, consistent with §§ 101.75(d)(3) and 101.77(d)(3), the claim may include information from § 101.81(a) and (b). These paragraphs summarize information regarding the relationship between diets high in oat bran or oatmeal and the risk of CHD and about the significance of that relationship. This information helps to convey the seriousness of CHD and the role that a diet high in oat bran and oatmeal can play to help reduce the risk of CHD.

In § 101.81(d)(4), the agency is proposing that the claim may state that oat bran or oatmeal are good sources of dietary fiber, particularly soluble fiber. In referring to the fiber components the claim may use the terms ''fiber,'' ''dietary fiber,'' and ''soluble fiber.'' If the term ''soluble fiber'' is used in the claim, the declaration of soluble fiber content is required. This proposed provision is consistent with § 101.9(c)(6)(i)(A), which states that the declaration of soluble fiber on the nutrition label is voluntary, except that when a claim is made on the label or in labeling about soluble fiber, label declaration is required.

The agency is proposing that the claim may include any of the optional information authorized to be included

in §§ 101.75(d)(5), (d)(6), and (d)(7) and 101.77(d)(5), (d)(6), and (d)(7). The health claim may state that diets high in oat bran or oatmeal and low in saturated fat and cholesterol are part of a dietary pattern that is consistent with dietary guidelines for Americans. The claim may state that individuals with elevated serum lipids should consult their physicians for medical advice and treatment and may include information on the prevalence of CHD in the United States. The intent of this information is to provide consumers with information that will help them understand the seriousness of CHD in the United States and to help them understand that diets high in oat bran or oatmeal are consistent with dietary guidelines.

In proposed § 101.81(d)(8), in response to the petition, the claim may provide information about the amount of food, such as bowls, servings or slices, to be consumed daily. This information may give the consumer a better perspective on how much oat bran and oatmeal is needed to help lower serum cholesterol levels.

F. Model Health Claims

In proposed § 101.81(e), FDA is providing model health claims to illustrate the requirements of new § 101.81. FDA emphasizes that these model health claims are illustrative only. These model claims illustrate the required, and some of the optional, elements of the proposed rule. If the agency authorizes a claim about the relationship between oat products and CHD, manufacturers will be free to design their own claim so long as it is consistent with § 101.81(c).

In § 101.81(e)(1), the model claim illustrates all of the required elements of the proposed health claim. The claim states ''Diets high in [oat bran or oatmeal] and low in saturated fat and cholesterol may reduce the risk of heart disease.''

In § 101.81(e)(2), the model claims provide examples of a shortened claim with the required referral statement.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

This proposed rule will not result in significant costs to industry. Some oat manufacturers are currently using FDA's approved health claim regarding the benefits of fruits, vegetables, and grain products. This proposed health claim will allow them to specifically highlight the benefits of oat bran and oatmeal. Consumers will benefit from the additional information regarding the relationship of oat products and CHD.

VIII. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements; thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule to permit health claims on the association between oat products (i.e., oat bran and oatmeal) and reduced risk of CHD imposes any paperwork burden.

IX. Effective Date

FDA is proposing to make these regulations effective upon publication in the Federal Register of a final rule based upon this proposal.

X. Comments

Interested persons may, on or before April 3, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. New § 101.81 is added to subpart E to read as follows:

§ 101.81 Health claims: Oat products and risk of coronary heart disease.

(a) *Relationship between diets high in oatmeal and oat bran and the risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease.

(2) Populations with a low incidence of coronary heart disease tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat, and cholesterol but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as oatmeal and oat bran.

(3) Oat bran and oatmeal are low in saturated fat and cholesterol and a good source of soluble fiber. Scientific evidence demonstrates that diets high in these oat products are associated with reduced blood total and LDL-cholesterol levels.

(b) *Significance of the relationship between diets high in oatmeal and oat bran and the risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing the risk of coronary heart disease. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets high in oat bran and oatmeal and low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets high in oatmeal or oat bran with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that oatmeal or oat bran ''may'' or ''might'' reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease.''

(C) The claim states that:

(*1*) Diets high in oatmeal or oat bran may reduce the risk of coronary heart disease; and

(*2*) The effect of dietary intake of oatmeal or oat bran on the risk of coronary heart disease is particularly evident when these foods are consumed as part of a diet that is low in saturated fat and cholesterol.

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets high in oat bran or oatmeal and low in saturated fat and cholesterol.

(E) The claim does not imply that consumption of oat bran or oatmeal is the only recognized means of achieving a reduced risk of coronary heart disease.

(ii) *Presentation of the claim.* All of the elements listed in paragraph (c)(2)(i) of this section must be included in one presentation of the claim displayed prominently on the label or in the labeling on which the claim appears. Other presentations of the claim on that label or labeling, including on the principal display panel, need not include the information in paragraph (c)(2)(i)(C)(*2*) of this section provided that, displayed prominently and in immediate proximity to a shortened statement of the claim, the following referral statement is used: ''See _____ for more information'' with the blank filled in with the identity of the panel on which is presented the statement of the claim that includes all of the elements in paragraph (c)(2)(i) of this section.

(A) The referral statement ''See [appropriate panel] for more information'' shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than 2 times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(B) The referral statement shall be immediately adjacent to any presentation of the health claim that does not include all of the elements in paragraph (c)(2)(i) of this section, and there may be no intervening material between the claim and the referral statement. If the abbreviated health claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the full health claim, where it may be omitted.

(iii) *Nature of the food.* (A) The food shall contain no less than 20 g oatmeal or 13 g oat bran that provides, without fortification, at least 1 g of β-glucan soluble fiber per reference amount customarily consumed. Beta-glucan will be determined by method No. 992.28 from the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th ed. (1993), which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC;

(B) The food shall meet the nutrient content requirements in § 101.62 for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food.

(d) *Optional information*. (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of oat bran and oatmeal and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total- and LDL-cholesterol.''

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between oat bran or oatmeal and coronary heart disease and the significance of the relationship.

(4) The claim may state that oat bran and oatmeal are good sources of dietary fiber, particularly soluble fiber. In referring to the oat fiber component, the claim may use the terms ''fiber,'' ''dietary fiber,'' or ''soluble fiber.'' If the claim uses the term soluble fiber, the total soluble fiber content shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(5) The claim may state that a diet low in saturated fat and cholesterol and high oatmeal or oat bran is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or ''Nutrition and Your Health: Dietary Guidelines for Americans,'' USDA and DHHS, GPO;

(8) The claim may provide information about the amounts of oat-containing food, e.g., bowls, servings, slices, to be consumed in a day.

(e) *Model health claim*. The following model health claims may be used in food labeling to describe the relationship between oat bran and oatmeal and reduced risk of heart disease:

(1) The following is an example of a full claim: Diets high in [oat bran/oatmeal] and low in saturated fat and cholesterol may reduce the risk of heart disease.

(2) The following are examples of a shortened claim:

(A) [Front panel] Diets high in [oat bran or oatmeal] may reduce the risk of heart disease

See [side/back] panel for more information

(B) [Front panel] Eating [oat bran or oatmeal] daily may reduce heart disease risk

See [side/back] panel for more information

Dated: December 22, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

Note: The following tables will not appear in the Code of Federal Regulations.

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Table 1. Oats and Coronary Heart Disease

Study	Study Design, Subjects	Methods	Results	Comments
Anderson et al., 1991 (Ref. 8)	Clinical study, randomized, controlled, metabolic ward study 21 men*, ages 38-73 years (yrs); hypercholesterolemic (TC: 190 to 347 mg/dL). Body mass indices less than 28.7; no medication for hypercholesterolemia. 1 subject failed to complete study. *14 men had hypertension, CHD, or CVD	Subjects (Ss) consumed "typical" American diet for 7 d as a baseline control (C), then randomized to OB (110 g OB/d) or WB (40 g WB/d) diets for 21 d; C and treatment diet identical in energy content, and nutrients, differing only in SF (OB) and insoluble fiber (WB). Baseline diet: 41% of E from fat, 16% protein, 43% from carbohydrate, 450 mg CHOL, 14 g/d TDF, 3 g/d SF. Brans were incorporated into muffins and cereals. TDF / SF (bran) / TSF (diet) g/d Baseline diet 14 / 5.6 OB 34 / 7.4 / 13.4 WB 34 / 1.3 / 7.8	TC % / LDL % / HDL % OB ↓12.8* / ↓12.1* / ↓7.4 WB ↓4.4 / ↓5.5 / ↓3.1 *significant from baseline There was no change in the LDL-HDL ratio in OB group. No effect on HDL in either group.	Authors state the purpose of their study is to compare the effects of SF (from OB) and insoluble fiber (from WB) keeping TDF constant. Significant weight loss in both groups (about 1 kg from control values). The weight loss in the OB group was not significantly different to the weight loss in the WB group.
Anderson et al., 1990 (Ref. 9)	Clinical study, randomized, self-controlled, cross-over on metabolic ward 12 men; 46-70 yrs old; hypercholesterolemic (TC 210-326 mg/dL); body mass indices of less than 30; 5 subjects had evidence of CVD	Ss, randomized into 2 groups, consumed typical "American" diet for 2 weeks (wks) in addition to test or control cereal followed by cross-over to other cereal for 2 wks. Base diet provided 41% E as fat; 20% E as protein; 43% E as carbohydrate; 355 mg CHOL. One group started with addition of 56 g OB cereal to the diet; the other consumed 56 g of cornflakes (control). TDF / TSF OB cereal 21 g / 7.4 g Cornflakes 15 g / 4.5 g	OB diet: ↓ TC 5.4% (signif.) compared to the corn flakes diet. LDL was lowered by 8.5%, and HDL was not significantly lowered.	The intake of carbohydrates, protein, fat and cholesterol were nearly identical in the two groups. Total dietary fiber varied between the two diets. No change in body weight. Short duration of test (2 wks) is a major limitation with this study.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Bartram et al., 1992 (Ref. 10)	Clinical study, self-controlled 13 adults (4 male, 9 female), ages 21- 59 years, with hyperlipidemia type IIa (mean TC 284.9 mg/dL); all within desirable weight range.	All Ss had been on low CHOL diet for 6 months (mo). Individual dietary instruction given every 2 mo before the study. Serum lipids were measured 4 times during 3-wk baseline period. Dietary intake assessed by 3-d records. Each morning for 3 wks, Ss consumed OB cereal muesli (60 g OB cereals) made with 250 mL low-fat milk and 120 g soft fruits (bananas, grapes, apples) in the metabolic ward; otherwise Ss were free living but kept dietary records. Serum CHOL was measured weekly during test period and for 2 followup wks when Ss consumed pre-study diets without oat bran muesli. Comparison between study periods and baseline made by nonparametric Friedman's block test.	Dietary intakes: Energy (E), Cal/d: Pre 2230, Test 2133, Post 2316 Fat(% E): 33.7, 32.6, 42.2 Sat fat (% E): 9.1, 9.7, 14.0 Dietary CHOL, mg/d: 268, 244, 336 TDF, g/d: 21.9, 42.4, 22.0 Serum lipids: mean mg/dL Base: TC 284.9, LDL 194.9, HDL 64.1 Cereal Week 1: 253.6*, 182.6*, 58.7 Week 2: 260.9*, 173.3+, 60.2 Week 3: 257.1*, 174.5+, 57.5* Post Week 1: 263.2, 181.8, 58.7+ Week 2: 262.0, 179.1+, 57.9* * p<0.01; + p<0.05 -- p values are compared to baseline values	Authors reported no significant changes in Ss' body weight. Ss said to be on low fat diet but actual fat intake reported at >30% E and Sat Fat > 9%. Results of this study are confounded because the muesli cereal contained other sources (fruits) of dietary fiber and SF which can affect serum TC. The amount of SF from OB was not reported and the amount of total SF in daily diet was not reported. Although serum TC values remained elevated, Ss experienced a ↓ in TC of about 8 to 10%. No significant changes to HDL-TC until the 3d test week. No significant changes to HDL:LDL.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Beling et al., 1989 (Ref. 11)	Clinical trial, randomized, controlled 351 men and women, ages 20-60, hypercholesterolemic (TC between 200 and 300 mg/dL); not greater than 50% above ideal body weight. 433 enrolled; 351 completed; attrition rates for groups 1,2, & 3 were 17%, 15%, and 24%, respectively. Major reason for attrition was inability to attend classes.	This was an 8-wk study with 3 groups: Group 1: no dietary change Group 2: American Heart Association (AHA) Step I diet, which was introduced during the first 4 wks of the study and continued for 8 wks. Group 3: Step I diet for wks 1-4, followed by the addition of 2 oz (56 g) oat cereal for wks 5-8. Oatcor™, a concentrated OB cereal, was provided in 2 packets (1 oz each) to be consumed as a snack or cereal. The OB provided 10.6 g TDF/d; 4 g β-glucans. Group % E - Sat Fat: Base, Tx; % E - Fat: Base, Tx 1: 12, 10-11, 38, 34-36 2: 11, 6, 34, 23 3: 12, 7, 37, 25-26 TDF: baseline 9-12 g; Test: group 1 12-14 g; group 2 18-19 g; group 3 15-16 g. Sample size calculations based on a null hypothesis of no difference in TC between groups at end of 8 wks with a 5% chance of failing to reject this hypothesis and 90% chance of detecting at least 15 mg/dL CHOL reduction.	TC, mg/dL % = % change from baseline Group Base 4 wks % 8 wks % 1 238.7 233.9 2↓ 233.2 2↓ 2 242.9 218.5+ 10↓ 222.4* 8.4↓ 3 242.3 213.9+ 11.8↓ 212.5* 12.2↓ LDL-CHOL, mg/dL % = % change from baseline Base 4 wks % 8 wks % 1 165.6 161.0 3↓ 157.6 5↓ 2 165.7 147.4+ 11.5↓ 149.7* 10.1↓ 3 167.2 147.8+ 11.8↓ 142.5* 14.9↓ + p<0.05 compared with C * p<0.05 compared with C and other treatment group HDL % change from baseline Group 4 wks 8 wks 1 ↓ 1 ↓ 1 2 ↓ 6 ↓ 3 3 ↓ 8 ↓ 8	Variable weight loss by treatment: group 1: 2 lbs; group 2: 4 lbs, and group 3: 6 lbs. There was no significant difference in weight loss between groups 2 and 3. There was no data on SF in diets. Not everyone responded similarly; both positive and negative responders and variation in magnitude of effect within treatment groups. Oatcor group maintained about 12% reduction in TC and 15% reduction in LDL-CHOL at 8 wks. AHA group experienced a slight increase in TC and LDL to a final reduction of 8.4% for TC and 10.1% for LDL. Results of this study suggest a modest CHOL-lowering effect of oats beyond that of a low fat diet.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Braaten et al., 1994 (Ref. 12)	Clinical study, randomized, placebo controlled, crossover 19 adults (9 males, 10 females), ages 44-64 years, hypercholesterolemic (TC 220 to 308 mg/dL), free living, all with stable body mass	Study design: 1 to 3-wk pretest period, two 4-wk test periods with a 3 to 4 wk wash-out period between oat gum (OG) and placebo (P) test periods, and a 3-wk washout following the OG period when the OG was tested in the second 4-wk period. Ss randomized to OG or P groups. Test substance: purified OG (80% β glucan) blended with maltodextrin which was mixed with a noncarbonated diet drink or water. Each packet of OG contained 3.6 g OG, 2.9 g β-glucan, and 5.4 g maltodextrin. Ss consumed 2 packets a day with their regular meals. This was equivalent to a daily intake of 70 g OB. Ss were asked not to consume any oat products with diets. Placebo: 5.4 g packets maltodextrin. Ss consumed 2 packets daily with meals. 3-day food diary was kept. Analysis of variance (ANOVA) used to examine blood lipid and body weight data. Repeated measures ANOVA used with subject, treatment, week of treatment, and treatment X week interaction.	No significant differences in nutrient intake among various phases of study. Pre Test / OG / P / Wash out E, Cal: 2175 / 2072 / 2065 / 1967 Fat, % E: 31.0 / 31.3 / 30.6 / 30.7 Fat, g: 79.1 / 76.2 / 72.5 / 70.9 CHOL, mg: 220 / 187 / 214 / 193 Fiber, g: 21.6 / 18.7* / 19.2 / 18.1 *Does not include additional 5.8 g/d β-glucan fiber. TC / LDL / HDL (mg/dL) Oat gum Week 0: 261.8 / 178.6 / 49.9 Week 4: 237.8* / 160.9* / 49.1 * p<0.0001 compared to baseline HDL remained unchanged throughout study; no significant correlations between body weight or nutrient intake and blood lipid levels, or changes in these, during OG phase.	A well-controlled study. Results suggests that the OG used in this study lowers TC. Total dietary SF and CHOL were not reported. TC and LDL decreased 9% (p<0.0001) and 10% (p<0.001), respectively, during the 4-week gum phase. TC and LDL returned towards pre-treatment levels during wash-out period at end of study further supporting a true effect of OG. Authors reported that based on individual one-tailed 95% confidence intervals for LDL, 5 Ss were nonresponders and 14 were responders (LDL ↓ from baseline approximately 13%).

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Bremer et al., 1991 (Ref. 13)	Clinical study, randomized, single-blind, cross-over 12 hyperlipidemic men and women, mean age 53 yrs, mean TC 298 mg/dL, free living	Ss were stabilized on phase II AHA diet for 3 mo prior to study. Base diet: fat 25-30% E; Sat Fat <8%; PUFA 5-10%; mono-unsat. fat >10%; CHOL <250 mg/d; fiber >20 g/1000 Cal. Two-wk run-in with the addition of bread to the diet prior to test. Ss randomized to oat or wheat group for 4 wks, followed by 2-wk washout, then cross-over to other diet. Bread added to diet in place of other carbohydrate foods. Mean intake oat bread and wheat bread 7.8 slices/d. Dietary assessment by food records and bread charts. bread: TDF, g% — Oat bread 5.2, Wheat 6.1; IF, g% — Oat bread 4.0, Wheat 5.2; SF, g% — Oat bread 1.2, Wheat 0.9 OB intake: 34.2-68.4 g/d TDF intake: Oat period - 32.2 g; Wheat period - 34.1 g	At beginning of first study period, there was no significant difference between TC, LDL, and HDL between groups. At end of 4 wks, no significant difference between lipid parameters. TC, mg/dL: OB Wk 0 286, Wk 4 274, % change 4.1↓; WB Wk 0 297, Wk 4 286, 3.9↓ LDL, mg/dL: OB Wk 0 216.5, Wk 4 204.9, % Change 5.4↓; WB Wk 0 228.1, Wk 4 212.7, 6.8↓ HDL, mg/dL: OB Wk 0 37.5, Wk 4 41.1, % Change 10.3↑; WB Wk 0 40.2, Wk 4 43.7, 8.7↑ Mean body weights did not change during the oat period but decreased significantly during the wheat period.	Ss had very high mean TC values. At end of study, TC remained very high. There was no measure of dietary soluble fiber. Subjects increased consumption of PUFA and decreased intake of Sat Fat (all nonsignificant) during test period. Investigators accounted for ↑ in fat consumption as due to use of PUFA margarine with bread. Oat bran bread was no better than wheat bran bread on lowering serum TC when Ss were on AHA diet. Authors suggest the full lipid-lowering potential of the AHA diet had already been achieved prior to the bran intervention. They also noted that New Zealand oat bran may not be the same as oat brans used in other studies (difference may be in the SF portion of the oats). WB cannot be considered a placebo because Ss experienced decreased TC and LDL while consuming the wheat bread.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Cara et al., 1992 (Ref. 14)	Clinical study, randomized, double blind, self controlled; study to evaluate effects of dietary fibers on postprandial lipemia 6 males, ages 22-41 yrs, normocholesterolemic (TC 158.6 - 200.7 mg/dL), with stable body weights	Ss instructed not to deviate from regular habits and to avoid excess alcohol consumption and exercise. Their basal diets were monitored through a 7-d food recall. Ss consumed typical western diet: 2815 Cal/d; protein - 108 g; carbohydrates - 295 g/d; 134 g fat; dietary CHOL 492 mg/d; and low to moderate dietary fiber (range 15-24 g/d). Ss ingested on separate days a low-fiber test meal: protein, 12.7%; carbohydrate, 37.9%; fat, 49.4%; TDF, 2.8 g. On high fiber days, the low fiber test meal was enriched with 10 g TDF as oat bran, rice bran, or wheat fiber or 4.2 g as wheat germ. The fiber sources were ground fine and incorporated into tomato sauce. Soluble fiber: OB, 5.14 g; rice bran, 1.16 g; wheat fiber, 2 g; wheat germ, 0.50 g. The control low-fiber meal and the 4 test meals were presented in random order. The interval between two meals was 7-15 d. Ss ingested meals within 20 minutes (min), then blood samples were collected every 0.5 hour (hr) for 5 hr and then 6 and 7 hr later. ANOVA and Student's t-test used to compare baseline and test values.	Serum TC dropped rapidly and significantly after ingestion of the C meal and maintained a low constant value (-5.8 to -8.5 mg/dL) from 1.5 to 6 hours. 7 hr after the meal CHOL values increased to baseline. With the exception of rice bran, other fibers suppressed serum TC below that from C meal and remained significantly less ($p<0.05$) than baseline after 7 hours. The OB meal produced the greatest change in TC (maximum decrease of 15.5 mg/dL after 4 hr) compared to baseline and the C. The difference from baseline values averaged -84.5 mg/dL.	With C diet, serum TC ↓ to a maximum of -8.5 mg/dL within 2 hr, then ↑ gradually over the next 5 hr. OB produced a continuous ↓ in serum TC over 4 1/2 hr before beginning a gradual ↑. Results of this study support a significant short-term effect on lowering serum TC by OB; however, the results do not address long term effects of OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Davidson et al., 1991 (Ref. 15)	Clinical trial, randomized, single-blinded, controlled. 156 men and women (ages 30-65 yrs), 148 completed this study; free living hypercholesterolemic (230-319 mg/dL) with multiple risk factors. Data from only 140 were used, 8 dropped because of lack of compliance. Dropouts: placebo (3), OB-56 (2); OM-28(1); OM-84(1), and OB-84(1).	NCEP Step 1 diet given 8 wks before randomization to test diet and during the test period. 6 wks of intervention with OM or OB in 28 g, 56 g, or 84 g servings. 28 g farina as a control. After intervention, 6 wks of followup with no supplementation. Step 1 diet: fat: <30% E Sat Fat: <10% E Groups — TDF — TSF OM 28 g — 16 — 6 OB 28 g — 17 — 6 OM 56 g — 14 — 5 OB 56 g — 20 — 7 OM 84 g — 19 — 7 OB 84 g — 22 — 7 Farina 28 g — 15 — 0 4-d food records at baseline, wks 3, 6, and 12.	Group — g — β Glu — % TC — % LDL 1. OM 28 — 1.2 — 3.9↓ — 5.8↓ 2. OB 28 — 2.0 — 2.7↓ — 4.7↓ 3. OM 56 — 2.4 — 2.7↓ — 3.5↓ 4. OB 56 — 3.6 — 9.5↓* — 15.9↓* 5. OM 84 — 4.0 — 7.1↓* — 10.1↓* 6. OB 84 — 6.0 — 6.9↓* — 11.5↓* 7. FA 28 — 0.0 — 0.6↓ — 0.6↓ FA=farina Glu=glucan * Only these changes are significantly different from baseline. The groups showed a decrease in total- and LDL-CHOL at the higher levels of oat intake.	Lacked control group for each level of oats consumed. Body weights were stable. The wash-out period is not a true control, but considered with evidence from the intervention period, TC was reduced at higher β-glucan intakes. 3 g/d or more is beneficial with a low fat diet.
Demark-Wahnefried et al., 1990 (Ref. 16)	Clinical study, randomized 81 men and women, ages 20-65 yrs, hypercholesterolemic (mean of 271 mg/dL), free-living: 13 dropped out.	12 wks of intervention on OB or processed OB cereal. Individuals given OB supplements, OB cereal, and a recipe book for fat-modified diets. One group consumed regular diet and did not get recipes. 50 g OB/d (estimated 3.7 g SF) as add-on to test group. 50 g OB and 42.5 g processed cereal had same amount β-glucan. Diets: Group 1: low fat, low CHOL Group 2: low fat, low CHOL plus 50 g OB Group 3: Regular diet plus 50 g OB Group 4: Regular diet plus 42.5 g processed OB	Although there was a significant ↓ in TC with all groups, there was no significant difference in the final serum TC between any of the four groups. The low fat, low cholesterol C group had the most marked ↓ in TC (↓17%) from baseline. C group 1: TC ↓ 17% group 2: ↓ 13.1% group 3: ↓ 12.3% group 4: ↓ 10.1%	Drop out rate is very high (16%). The study size is small; power to detect changes between groups is limited. Variable weight loss among groups with the group consuming low fat diet plus OB experiencing the greatest weight loss (4-5%) and group 4 (processed OB) experienced the least (0-0.1%). E intake decreased in all groups from -10% to -28%. % changes from baseline in Sat Fat ranged from 22% for regular OB group to 51% for low fat, low CHOL OB group. Results of CHOL-lowering effect of low fat diet was not further enhanced by the addition of OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Gold and Davidson, 1988 (Ref. 17)	Clinical study, double blind 72 male and female medical students; 25-37 yrs old; free-living; TC - mean 178 mg/dL	This was a 4-wk intervention study. Ss consumed 2 muffins/d that contained test fibers (muffins were provided) along with their regular diet. 3-d food records were submitted. Ss randomized into 3 groups and received muffins made with either OB, WB, or a wheat/OB combination. SF and DF from muffins: (per muffin) Total Bran / SF* / DF (grams) O: 17.0 / 2.5 / 5.0 oat/wheat: 5.5/8.3 / 0.9 / 5.3 WB: 11.3 / 0.33 / 5.5 *estimated Intake of oat bran per day about 34 g.	OB: TC ↓5%* and LDL ↓9%* *significant from baseline, $p<0.05$ SF from combined oat/wheat and wheat: TC no change; LDL no significant decrease.	No assessment of the dietary intake before or during the test period. No data on total dietary fiber or total SF intakes in baseline and treatment diets.
Gormley et al., 1978 (Ref. 18)	Clinical study, randomized 58 males: hypercholesterolemic (TC about 240 mg/dL) 10 females: normocholesterolemic (TC about 190 mg/dL); mostly between ages 30-50, except 5 who were less than 30 and 2 who were over 50. 6 smoked cigarettes, 5 smoked cigars, 3 were pipe smokers. Free living	All Ss ate 43 g cornflakes daily for 20 days. Blood samples were taken and based on the values, Ss were paired on the basis of similar TC levels into 2 groups. Ss in each pair were randomly assigned to be in the C group (cornflakes) or the test group (oatmeal porridge). C group consumed 43 g cornflakes daily and the test group - 43 g oatmeal. No other dietary restrictions given. Ss consumed cereals for 1 1/2 months. Weekly dietary log maintained to show cereals were consumed. Paired t-test used to assess significance.	Results showed no effect of oatmeal porridge on TC and HDL.	Authors state that dietary intakes were monitored but nothing is reported in this study. Amounts of total dietary fiber, oatmeal total- and soluble fibers consumed were not reported. LDL was not reported. Authors do not account for the influence of smoking and other lifestyle habits on the results. Results of this study are hard to interpret. There is insufficient dietary control.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
He et al., 1995 (Ref. 19)	Survey 857 Chinese people (ages 15-77 yrs) (included farmers and migrants; people with almost no leisure time activity): at time of survey only 65 (15%) consumed oats and were included in this part of the survey. Normo-cholesterolemics	Age, sex, race, education level, smoking, medical history, and intakes of oats and buckwheat were obtained by local physicians. A 24-hr recall, administered on 3 consecutive days, was also used to get specific information on the diet. Authors stated that agreement between the estimates obtained by interview and 24-hr recall was moderate, with a correlation coefficient of 0.41 ($p<0.001$) for oats and 0.61 ($p<0.001$) for buckwheat. Ss divided into groups based on average daily intake of oats and buckwheat. Blood samples were taken in morning after 14-hr fast. Serum TC, HDL, and triglycerides were measured. 100 g oats: 10.2 TDF; 3.9 SF Differences in cardiovascular disease (CVD) risk factors and dietary nutrients among the oats and buckwheat intake groups were examined by ANOVA.	Dietary Intakes[1] Groups Oats 1 2 3 4 g/d: 0 <25 25-90 >90 E, Cal/d 3134 3233 3464 3120 Dietary Fat, % of E 24 24 16 12 P:S 1.37[2,5] 1.29[2,5] 2.14[3,4] 2.08[3,4] CHOL, mg/d 214[2,5] 186[2,5] 86[2,5] 186[2,5] Lipids Group mg/dL 1 2 3 4 TC 156[2,5] 154[2,5] 33[3,4] 139[3,4] LDL 71.4[5] 68.7[5] 59.4[3,4] 67.9 HDL 15.1 15.1 15.5 13.9 HDL:CHOL 0.39 0.30 0.40 0.36 [1] mean values [2] $p<0.05$, signif. from group 4 [3] $p<0.05$, signif. from group 1 [4] $p<0.05$, signif. from group 2 [5] $p<0.05$, signif. from group 3	Authors report that groups consuming ≥ 25 grams of oats per day had significantly lower TC than those who did not consume oats. Authors state that TDF and SF from oats were significantly and independently associated with lower TC concentrations. The overall effect of oats was more pronounced in group with higher initial TC concentration. This population group consumes a low fat and high fiber diet. Dietary intake of oats and buckwheat were not accurately assessed. This is a large population-based cross-sectional study with no controls. The lack of temporal sequence in a cross-sectional survey and the questionable assessment of dietary intake of oats makes support of a beneficial effect of oats on serum CHOL by this study trivial.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Hegsted et al., 1993 (Ref. 20)	Clinical study, randomized, cross-over, double blinded, controlled diets 11 subjects (10 males, 1 female), ages 19-57, with mild hypercholesterolemia (mean TC 233 mg/dL); free living subjects	10-wk study. Test diets contained 100 g/d stabilized rice bran (RB) (heat stabilized to inactivate lipase enzymes in the bran) or OB. Test periods: 3 wks each. Bran was used in muffins, cookies, crackers, breads and other foods. Ss consumed C diet containing wheat for 2 wks prior to phase 1 and between phases 1 and 2 (before cross-over). Control diets: C RB OB E, Cal/d 2746 2551 2608 Fat, % E 36 37 36 Sat fat, % 27.6 28.4 28.8 Dietary CHOL, mg 300 300 300 Fibers: RB OB Fat, % 21.9 9.6 Carbohydrate, % 47.2 57.1 Fiber, insol % 21.9 9.1 sol % 2.6 8.0 β glucan, % - 3.8 Comparison between RB and OB effects on CHOL were analyzed as a cross-over design. Changes between the C diet and bran diets were evaluated as a split plot design. Paired t-test used to test differences between means.	C Phase 1 C Phase 2 mg/dL TC OB 220.8 198.8* 224.7 214.6+ RB 234.7 210.8* 216.5 207.7+ LDL OB 160.6 139.0* 167.5 154.8+ RB 179.9 154.8* 151.0 140.9+ HDL OB 48.0 46.1** 37.9 39.1 RB 39.1 37.1** 48.0 47.2 * signif. different from previous diet by p<0.001 ** signif. different from previous diet by p<0.01 + signif. different from previous diet by p<0.05	During the first OB phase, TC ↓ 10% and in phase 2, it ↓ 5% (all signif.). LDL ↓ about 13% during phase 1 of OB and about 7% during phase 2 (all signif.). During phase 1, HDL ↓ significantly, but ↑ to 3.1% in phase 2. Small number of subjects.
Kahn et al., 1990 (Ref. 21)	Clinical study, randomized, controlled 16 men and women, age 51-54 yr, hypercholesterolemic (215-314 mg/dL); some were diabetic. Free living	One group began immediate intervention on OB for 3 wks; the other group was the untreated control for 3 wks, after which they started the intervention diet for 3 wks. This was followed by a 6-wk washout period during which blood samples were taken. Test Ss consumed 80 g/d OB (estimated 5 g SF), added to the diet as OB muffins (4/d). Each muffin provided 112 Cal and 20 g OB. Ss' usual diets were not assessed.	All groups, including the control group, had ↓ TC but there was no significant change in serum TC values when the immediate intervention test group was compared to the delayed intervention group (serving as a C). When the results were combined, the oat group showed a significant ↓ in TC by 8% (p<.02), LDL by 10% (p<.02), and HDL 0.9 % (p<.03) from baseline.	No dietary assessment before or during test. Subjects experienced some weight loss. The study design should have been modified to overcome the problem of time delay in comparing the groups. After correcting for the delay, results of this study show that OB significantly reduced TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Kashtan et al., 1992 (Ref. 22)	Clinical study, randomized, metabolically controlled, parallel, double-blind 44 men and women (31 men and 14 women), mean age of 61.3 yrs. Mean TC for group 1: 207 mg/dL; group 2: 227 mg/dL.	Ss randomly assigned to either the OB group or the WB (control) group. Ss consumed the bran products twice a day for 2 wks. All food was prepared and delivered to the Ss. E content of diet was one of 4 amounts: 1,600, 2,000, 2,400, and 2,800 Cal. Ss were fed the amount closest to their requirements based on the Lipid Research Clinic tables. Base diet: 37% E from fat; 16% protein; 47% carbohydrate; TDF 24 to 25 g/d. OB consumed as cereals: dry wt OB 88.4 g, estimated 5.5 g SF/d. WB consumed as Cream of Wheat: 73 g/d	Before / After mg/dL TC WB 207 198** OB 227* 203** LDL WB 129 125** OB 150* 131** * Significantly different from WB ** Significantly different from baseline	OB group experienced a TC decrease of 24.9 points (10.7%) from baseline ($p<0.001$); LDL decreased 18.7 points (12.5%) from baseline ($p<0.001$). HDL decreased 10% from baseline but the difference was not significant. Short term study (14 d) is a limitation.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Keenan et al., 1991 (Ref. 23)	Clinical trial, randomized, controlled, double blind with crossover 145 men and women, ages 20-70; free living; hypercholesterolemic (207-267 mg/dL). 15% dropout after randomization.	Study designed with 3 periods (6 wks each): period 1: step 1 diet (C); periods 2 & 3: test periods. Test products were provided. 3 groups: C, wheat, and oat. The C group consumed step 1 diet for entire study period. 2 groups randomized to consume oats or wheat during period 2, followed by cross-over after 6 wks to other diet (period 3). 4-d food records were collected in wk 5 of each period; baseline dietary intake taken by self-administered food frequency questionnaire. Step 1 diet: Fat, % E: <30%; Sat Fat, % E: <10%; CHOL: 240 mg/d Test products: 2 oz OB cereal and 2 oz of ready-to-eat wheat cereal. OB: (3 g SF/d); mean intake SF during OB period was 8 g. Wheat cereal: (1 g SF/d); mean intake SF during wheat period was 6 g. Group and period effect for lipids assessed using a 3(group) X 4(phase) repeated ANOVA.	TC and LDL decreased in all groups on step 1 diet (↓2.5-4%). Oat-wheat group had a further ↓ in TC of 2% (NS) on oat cereal, followed by a 6% ↑ in TC on wheat cereal. The wheat-oat group had a nonsignif. change in TC on wheat and a 3% ↓ on oats. The C group had significant ↑ in TC back to baseline during test periods. Women under 50 found resistant to OB intervention. TC, mg/dL Group / Base / End Step 1 / Period 1 / Period 2 Diet 238 228 236 242 W-O 237 231 231 225 O-W 239 229 224 239 LDL, mg/dL Group / Base / End Step 1 / Period 1 / Period 2 Diet 165 156 162 166 W-O 164 159 158 152 O-W 162 155 148 160 Lipid responses during cereal periods complicated by an order or period effect, which overlays the treatment effect.	Placebo was needed for diet only group. Control group initially dropped TC and then returned to baseline making it difficult to use as a control. A significant order or period effect was observed which overlaid the treatment results. Both the diet only and wheat group showed a tendency for TC and LDL to return to baseline. The oat groups maintained their original diet period improvement in lipids. Post hoc analysis demonstrated evidence of additional significant reductions in TC and LDL in the oat group when compared with diet only and wheat groups ($p<.01$). There was no significant change in HDL in any group.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Kelley et al., 1994 (Ref. 24)	Clinical study, self controlled, unblinded 13 Ss (7 men and 6 postmenopausal women), ages 50-84 yrs; all with fasting TC > 200 mg/dL. All Ss had been in a supervised program of exercise for at least 3 mo; free living	4 wk study. Ss continued their exercise program (40-60 minutes at 65% to 75% of maximum capacity) during the study. Ss consumed their usual low fat diet (without oats) for 2 wks prior to study. During baseline (last 3 d of 2d wk), Ss kept food records. Ss instructed to consume 100 g OB (7.1 g SF)/d for 4 wks. Oats were used in recipes and baked products. Total E and fat intakes were to remain stable. Ss recorded oat intake during 4-wk period. Dietary and plasma data analyzed by one way ANOVA with repeated measures. Fisher's least significant difference test used for post-hoc testing.	Daily Nutrient Intakes Base / Wk 2 / Wk 4 / Sig. E: 1,762 / 1,870 / 1,827 / NS Fat, % E: 24.2 / 24.8 / 25.5 / NS Sat Fat, % E: 6.5 / 6.9 / 6.4 / NS CHOL, mg: 166 / 179 / 232 / NS Fiber, g: 21.3 / 25.6 / 22.6 / NS Base / Wk 2 / Wk 4 / Sig. (mg/dL) TC: 226.2 / 212.3 / 207.7 / p<0.04 Change: 6.1%↓ / 8.2%↓ LDL: 155.2 / 140.5 / 139.7 / p<0.05 Change: 9.4%↓ / 9.9%↓ HDH: 46.4 / 47.6 / 46.8 / NS Change: 2.5%↑ / 1%↓	Study lacked an adequate placebo control. Authors reported mean daily intake of OB by 10 of 13 Ss was 94.07 g. Mean body weight was maintained in 11 of 13 Ss. Reduction in LDL significantly correlated with baseline LDL (p<0.04). Results suggest a benefit from OB intake beyond that of a low fat, low CHOL diet.
Kestin et al., 1990 (Ref. 25)	Clinical study, randomized, double blind, controlled with cross-over. 24 men, 29-61 yrs, mild to moderate hypercholesterolemia (186-293 mg/dL)	3-wk control period prior to test; 4 wks on each of 3 test diets; no washout. Test foods (OB, WB, rice bran (RB)) were provided as bread and muffins; control - low fiber white bread. Test foods were added to individual's normal diet. Test fibers: OB: 95 g/d; 5.8 g SF/d Rice bran: 60 g/d; 2.9 g SF/d WB: 35 g/d; 2.6 g SF/d Base diet: % fat cal: 31-37 % SFA cal: 12-13 CHOL: 250-300 mg/d TDF: Baseline: 11.2 g/day Test diet: 21 g/day SF: OB diet: 10.3 g/day RB diet: 7.2 g/day WB diet: 6.8 g/day Baseline: 5.7 g/day	TC / LDL / HDL (mg/dL) Baseline: 245.2 / 175.9 / 40.6 OB: 233.2 / 163.9 / 41.8 WB: 247.1* / 175.6* / 42.1 RB: 242.5+ / 173.6+ / 42.5 * Signif. from OB, p<0.001 + Signif. from OB, p<0.01	The amounts of SF and insoluble fiber in the three test diets were varied while total fiber was held constant. The OB diet had higher SF than the rice, wheat or baseline diets. OB lowered TC ↓ 5% and LDL 6.8% compared to baseline (significance to baseline not reported).

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Leadbetter et al., 1991 (Ref. 26)	Clinical study, randomized, not blinded. 4 x 4 Latin square with 3 levels of oat intake and a control. 40 men and women, ages 25-64 (TC 250-348 mg/dL), free-living	Ss randomized into one of 4 sequences: 0, 30, 60, or 90 g/d OB added to Ss' usual diet. Each period was 1 mo long. No washout between periods. OB was provided in weighed sachets and detailed advice and recipes were provided. 5-d food records were kept prior to study and single-day records were kept during study periods. Beta-glucan content of oat bran was 3.7-4.2%. Base diets (excluding OB): Group: 0 g, 30 g, 60 g, 90 g E: 1854, 1947, 2017, 2017 % Fat: 36.6, 34.7, 33.5, 34.8 % Sat Fat: 13.5, 13.0, 13.4, 14.0 Fiber, g: 27, 23, 26, 24 Starch, g: 64, 86, 93, 99	No significant effect of OB at any dose on TC or LDL; no dose-related trend and no correlation between bran dose and change in TC conc. OB Intake, g/d 0, 30, 60, 90 TC, mg/dL: 278, 284, 279, 273 LDL, mg/dL: 184.5, 179.8, 187.5, 177.1 HDL, mg/dL: 60.3, 57.2, 57.6, 54.9	Authors state that OB used in this study (New Zealand) may be lower in SF content than the OB used in studies showing ↓ TC with OB supplementation. Dietary CHOL intake not reported. No body weight data provided.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Lepre and Crane, 1992 (Ref. 27)	Clinical study, randomized, double blind, placebo controlled, cross-over 37 Ss (16 men, 21 women), mean age 51.9 yrs, TC 212-300 mg/dL, Ss already on low CHOL, low Sat Fat diet.	24-wk study: Ss received prescribed diet for 8 wks, then were randomly assigned to receive 2 muffins/d containing 60 g OB (4.6 g TDF and 1.6 g SF each) or WB (5.2 g TDF and 0.7 g SF each) for 8 wks. At end of 8 wks, Ss crossed over to other kind of muffin for another 8 wks. Diet during study contained less than 30% of total E as fat, less than 10% as sat fat, less than 300 mg dietary CHOL, and 21-27 g of TDF. Muffins were consumed with meals. Energy intake was adjusted to maintain body weight during first 8-wk (diet only) period. During muffin period, diets adjusted for energy, fat, and fiber content of muffins. Differences between periods in serum measures analyzed by repeated measures ANOVA followed by pairwise comparisons using 2-tailed t-test.	30 Ss completed study. Nutrient content test diets: Baseline / OB / WB E, Cal/d: 1434 / 1483 / 1546* Fat, % of E: 25.8 / 26.3 / 25.3 Sat Fat, % E: 8.4** / 7.4 / 6.9 CHOL, mg: 200+ / 169++ / 153 Fiber, g: 21.6# / 26.0 / 26.8 * p<0.001 compared to baseline ** p<0.01 and p<0.001 compared to OB and WB, respectively + p<0.05 compared to OB, p<0.001 compared to WB ++ p<0.05 compared to WB # p<0.001 compared to OB and WB Serum measures at end of test periods: Baseline / OB / WB TC, mg/dL: 264.8 / 259.0 / 266.3 LDL, mg/dL: 186.0 / 180.3 / 191.1* HDL, mg/dL: 51.3 / 52.9 / 50.9 LDL/HDL: 3.83 / 3.68 / 4.01** * p<0.01; ** p<0.001 (comparison of OB to WB periods)	WB cannot be considered a placebo because it caused ↑ in TC and LDL. Authors reported no signif. changes in Ss' body weights during test period. Signif. differences were reported between diet only phase and the test periods in dietary CHOL, sat fat, and dietary fiber. During the OB period, Ss consumed signif. less (p<0.01) sat fat and dietary cholesterol (p<0.05) compared to the diet only period. Dietary fiber was significantly less (p<0.001) during the diet only period. OB produced a nonsignif. ↓ in TC (2.2%), LDL (3.1%), LDL/HDL (3.9%) and a nonsignif. ↑ in HDL (3.0%) compared to baseline (diet only) measures. During WB period, there was a nonsignif. ↑ in TC, LDL, and LDL/HDL, and a nonsignif. ↓ in HDL. Authors reported that, using the Keys equation, a ↓ of 4.63 mg/dL in serum TC CHOL was expected based on the dietary intake in the OB period compared to diet only period. Authors state that the observed ↓ of 5.8 mg/dL in TC is likely due to the ↓ intake of dietary sat fat and not to the OB.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Mackay and Ball, 1992 (Ref. 28)	Clinical study, randomized, crossover 39 adults (22 males. 17 females), ages 28-66 years, hypercholesterolemic (mean TC 265 mg/dL), free living	Study consisted of 4-wk run-in period followed by 3 test periods of 6 wks each. During run-in, Ss consumed moderately low-fat diet (28-32% of E from fat and less than 10% E from sat fat). Ss divided into 2 groups based on TC (above or below 262.6 mg/dL) and randomized to one of 6 possible combinations of the order of the diets. Test substances in diets: 55 g low-fiber OB (LFOB) (3.5% β-glucan), 55 g high-fiber OB (HFOB) (5.4% β-glucan), or 80 g cooked beans (SF same as high fiber OB). Other high SF-containing foods were not allowed during test periods. Three-day dietary records kept during run-in and test periods. Statistical methods: one-way ANOVA using repeated measures to assess between stages and between diets. Paired t-tests were used to establish trends between plasma lipids at wks 3 and 4 of run-in and wks 5 and 6 of each diet. Repeated measures analysis using SPSS-X MANOVA used to test difference between order of diets, the difference between diets, and the interaction of both variables.	Nutrient intake: run-in / HFOB / Beans / LFOB E, Cal/d 1664 / 1876* / 1710 / 1817 % of E Fat 29 / 30 / 28 / 28 Sat fat 10 / 10 / 9 / 10 CHOL, mg 188 / 215 / 161 / 192 TDF, g 24 / 28* / 29* / 27 * signif. different (p<0.05) compared to run-in Serum Lipids: mg/dL / run-in / HFOB / Beans / LFOB TC 242.0 / 241.2 / 240.1 / 240.1 LDL 161.7 / 162.1 / 161.7 / 159.8 HDL 44.4 / 49.4* / 49.0* / 49.4* LDL/HDL 3.76 / 3.43* / 3.51* / 3.4* * signif. different (p<0.05) compared to run-in	There was no placebo control. Authors reported that the order of consumption made no significant difference on results. The interaction of order of diet was not significant for TC or LDL, but was significantly different for HDL whether the run-in was excluded or included. No change to TC or LDL from OB in this study. HDL ↑ significantly which improved the LDL/HDL ratio. This study does not support a beneficial effect of OB on TC. Results observed in this study may be related to the type of cultivar used (New Zealand source of oats) and the method for analyzing for SF.
Marlett et al., 1992 (Ref. 29)	Clinical study, metabolically controlled, single isotope used to determine bile acid kinetics 9 men, ages 20-28 yrs, normocholesterolemic (mean TC of 177 mg/dL)	A 2-mo study: period 1 was a low fiber C period and period 2, a high fiber period with OB. Base diets: Energy - 2,770, 3,000, 3,300, and 3,600 Cal/d with 35% fat, 15% protein, and 50% carbohydrate. Foods were consumed in a metabolic unit except an evening snack which could be taken home. OB: 100 g (16.1% TDF, 38% β-glucan, 46% SF) Wheat gluten: an amount comparable to protein in OB was included in low fiber foods.	SF intake: Low fiber period, 4 g High fiber period, 10.3 g Pre Study / Low fiber Period / High fiber Period mg/dL TC 177 / 152* / 138** * p<0.01 Signif. lower than prestudy period ** p<0.01 Signif. lower than low fiber period Total daily fecal bile acid excretion more than doubled when OB was incorporated into the metabolic diet.	There was no change in body weights. Small sample size. Authors state that the results of the bile acid study showed 2 mechanisms by which oat bran lowers TC: through increased bile acid synthesis and decreased bile acid adsorption. The lowered TC in the C group was in response to the lower fat diet given the Ss. Authors report prestudy fat intake at 40 to 45% of E.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
O'Brien et al., 1985 (Ref. 30)	Clinical study, randomized, controlled 45 adults (30 males, 15 females), mean age of 57±2 yr, hyper-cholesterolemic (TC >250 mg/dL), free living.	Pre test period - 3 d: Ss consumed a low CHOL diet of unprocessed foods (<10% E from fat, 13% protein, and remainder carbohydrate from whole wheat grains and bread, beans, fresh vegetables and fruits). TDF = 35-40 g/1000 Cal and <25 mg CHOL. Test period - 18 d: Ss divided into 3 groups: OB group (50 g/d OB: 15.2 g TDF, 7.6 g SF); WB group (50 g/d WB: 23 g TDF, 1.8 g SF); C group - diet only, no bran. The brans were provided in packets daily and the Ss instructed to add the bran to each of their 3 main meals. All variables analyzed using Hotelling's multivariate analysis and t-test comparison. Total CHOL data analyzed using univariate and multivariate analysis to test for significance between group differences.	TC / HDL / CHOL/HDL / Wt mg/dL / kg OB pre 276.0 / 43.0 / 6.8 / 82.4 test* 195.4 / 37.5 / 5.4 / 78.0 WB pre 272.9 / 44.0 / 7.0 / 88.2 test 203.0 / 40.8 / 5.1 / 84.2 C pre 290.1 / 56.2 / 5.3 / 77.3 test 214.0 / 45.3 / 5.0 / 74.4 * All test values significantly different from pre values, except the CHOL/HDL for the C group. No signif. difference between the groups. Significant loss of weight in all groups but differences among groups were not significant.	Short test period is a limitation. The diet high in fruits, vegetables, and grain products and low in fat and dietary CHOL was effective in lowering serum TC significantly. This diet, for all groups, was probably already high in SF. The addition of OB produced an additional ↓ in TC (about 3%) but the effect was not statistically significant. TC: ↓ 29% in OB group, ↓ 26% in WB group, and ↓ 26% in C group. Results also show HDL significantly lowered: ↓ 11 in OB group, ↓7% in WB group, and ↓ 19% in C group.
O'Kell and Duston, 1988 (Ref. 31)	Clinical study, randomized, self controlled 45 adults (21 males and 24 females), normal to moderately high cholesterol (TC from >180 to <211 mg/dL during non-OM mo), free living	Ss randomly divided to 2 groups. Ss instructed to include OM (women - 1/2 cup dry and men - 2/3 cup) in their usual diet for 5 of 7 d. Ss in OM group consumed oats for 3 mo followed by 3 mo with OM no more than once per wk. There were two 3-mo OM periods and two 3-mo non OM periods. When group 1 was consuming OM, group 2 was not. Repeated measures ANOVA used on data.	TC, mg/dL: Period: OM / Non-OM Group 1 189-213 / 175-194 Group 2 176-193 / 193-211 No signif. differences between OM and non-OM periods and no signif. differences in HDL values between periods.	Dietary intakes were not reported. TDF and SF were not reported. Authors state that the Ss' diets did not change during the study and no signif. change in body weights. LDL not reported. Results of this study suggests that an intake of 1/2-2/3 cup OM may not be beneficial in lowering TC in individuals with normal to moderately elevated TC values.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Poulter et al., 1993 (Ref. 32)	Clinical study, randomized, cross-over Ss recruited from hypertension clinic (n=44), their spouses (n=7), and hospital staff and their relatives (n=13); all cereal eaters. 74 participated, 59 (17 males, 42 females) completed study. Mean age range 52-59 yrs, TC 231 mg/dL, free living	Retrospective 48-hr recall used to assess baseline diets. Ss in oat group asked to consume 50 g oat cereal (4.5 g TDF, 2.6 g SF) daily for 4 wks. All Ss told not to change lifestyle or diets. Second group served as C and ate their usual cereal (without oats). Diet diaries were kept for last 2 days of 4-wk period. After 4 wks, Ss crossed over to other cereal type for another 4 wks. No washout Student's two-tailed t-test used to compare data.	Mean daily intake oats 56 g (2.24 g SF) Dietary intake: Baseln: Group 1 / 2; Fat, % 35.2 / 37.1; P:S 0.5 / 0.7; TDF, g 15.7 / 17.0 Usual Cereal: Group 1 / 2; Fat, % 32.1 / 31.9; P:S 0.5 / 0.7; TDF, g 17.5 / 18.7 Oat Cereal: Group 1 / 2; Fat, % 30.9 / 35.8; P:S 0.4 / 0.5; TDF, g 17.3 / 17.7 mg/dL TC: Baseln 231.6*; Usual Cereal 232.0; Oat Cereal 226.6*; % Diff 2.23 LDL: Baseln 151.3; Usual Cereal 145.9; Oat Cereal 139.0**; % Diff 4.55 HDL: Baseln 56.4; Usual Cereal 59.8; Oat Cereal 58.3; % Diff 2.69 LDL/HDL: Baseln 2.9; Usual Cereal 2.6; Oat Cereal 2.5; % Diff 8.8 * $p<0.04$ compared to value after usual cereal ** $p<0.05$ compared to value after usual cereal	C group permitted to consume any cereal as long as it didn't contain oats. No change in weights were reported. Small but significant ↓ in TC and LDL with oat cereal. Authors reported significant reductions in TC and LDL in 32 Ss with baseline TC of >231 mg/dL. There was a nonsignif. ↓ in HDL, so there was no improvement in the LDL/HDL ratio. Authors reported that 11 Ss reported making changes in their diets after starting the trial. Combined in-trial data compared with baseline nutrient intake data revealed a signif. reduction in total E consumed from fat ($p<0.05$). The P:S ratio fell significantly during oats consumption ($p<0.001$).
Saudia et al., 1992 (Ref. 34)	Prospective intervention study, unblinded, not controlled, not randomized 20 adults (11 males, 9 females), age range of 21-60 yrs, TC > 200 mg/dL	Ss completed dietary survey sheet to identify food groups and daily consumption of each. Ss were to consume their regular diets. All Ss consumed 3 oz (84 g) OB/d for 3 mo. TC was measured at the end of each month. Total study time = 93 d. A dietary intake sheet was completed at the end of the study. Repeated measures ANOVA	Results showed no signif. difference in TC levels over the 3 consecutive time periods using repeated measures ANOVA. ANOVA for polynomial trends revealed a signif. difference in TC levels over time ($p<0.007$). TC ↓ first month (day 31, mean of 239.4 mg/dL), but levels gradually returned to baseline (mean of 254.4) over next 2 mo (day 62, mean of 242.1 and day 93, mean of 250.7 mg/dL).	Actual data not given. Lacks a control group. Not a well controlled study. Diets not reported. Dietary intake not adequately assessed. Authors consider the possibility that Ss may have changed their diets for a period considering the clinical trial took place over summer months and the increased awareness of risk-reducing behavior and a healthy lifestyle.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Spiller et al., 1991 (Ref. 35)	Clinical study, randomized, cross-over 13 male and females, ages 62 ± 3.0 years, TC 204-276 mg/dL, free living.	3-d food record kept during 1-wk baseline period and during 3d wk of treatment. Each treatment dose was preweighed in pouches; 3-wk supply given to Ss at start of each test period. Both fibers were mixed with water or other fluid and consumed before each meal. Ss remained on usual diet whether it was fat modified or not. Test periods: 21 d then cross-over to other fiber for 21 d. Blood lipid values made on days 14 and 21 during treatment period and on days 14 and 16 after treatment stopped. Fiber sources: guar gum: 15 g/d providing 11 g/d dietary fiber and 10 g/d SF; oat fiber source: 77 g/d providing 11 g/d dietary fiber and 5 g/d SF, 3.3 g β-glucan.	TC / LDL / HDL (mg/dL) Baseline: 244 / 152 / 62 Guar day 14: 217 / 124 / 63 Guar day 21: 219* / 126* / 63 OB day 14: 235 / 142 / 62 OB day 21: 236* / 143* / 62 * Significant from baseline Oats: 3.7% ↓ TC 6.6% ↓ LDL	Study needs a low SF control. Changes in TC for both treatment groups took place within 14 d with no significant changes taking place between days 14 and 21. Limitations of study: No washout between test periods; baseline diets and dietary intake during treatment periods not reported; total dietary SF was not reported. Small sample size. No dietary data. No weight changes. Both guar and oat fibers consumed before meals--not typical dietary intake.
Stewart et al., 1992 (Ref. 36)	Clinical study, randomized, cross-over, self-controlled 24 adults (11 men and 13 women), ages 21-67 yrs, hypercholes-terolemic (TC 215.8 - 328 mg/dL) already prescribed a diet with <30% E from fat; free living	Ss consumed an oat-free, low fat diet (<30 of E from fat) diet for a 6-wk run-in period followed by a second 6-wk period on the diet as part of the trial (C1). Ss were then randomized to receive 50 g OB or to continue on the C diet (C2). After 6 wks, Ss crossed over to other diet for another 6 wks. A 3-d food diary was kept during wk 3 of each period. Two-tailed student t-tests used to assess differences between groups, the two C periods, and the second C period and the OB periods. Regression curves used to compare changes between C and OB, weight (basal metabolic index (BMI)), E intake, % fat intake, and OB consumption. Differences between wks 5 and 6 were analyzed with a repeatability coefficient. Paired samples used.	Baseline data: mean C1 / C2 / OB E, Cal: 1711 / 1680 / 1731 Fat, % E: 29.3 / 29.7 / 28.9 OB, g: - / - / 51.7 Weight, BMI: 23.3 / 23.3 / 23.4 No signif. differences found in the above data Serum Lipids: mean C1 / C2 / OB (mg/dL) TC: 259.0 / 260.6 / 258.2 LDL: 177.9 / 178.7 / 177.9 HDL: 56.7 / 55.2 / 55.2 No signif. differences found in the above data	Sat fat, SF, and TDF contents of diets were not reported. SF content of oats was not reported. New Zealand oats reportedly contain less SF than U.S. cultivars. Compliance with the dietary protocol in this study was not good. Authors reported wide variability in Ss' diets: at baseline total E intake ranged 928 Cal to 2,852 Cal; fat 20 to 44.1% (mean 29.3%) of E, and protein 13.3 to 32% (mean 17.8). The remaining balance of E was from alcohol. Mean OB intakes ranged from 29.2 g to 112.5 g. Changes in dietary components between C2 and OB periods and between C1 and C2 were small and not statistically significant.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Swain et al., 1990 (Ref. 37)	Clinical study, randomized, double blind, cross-over 4 male, 16 female hospital employees; 23-49 yrs old; free-living but foods prepared in metabolic kitchen and taken home; normal cholesterol: mean 185 mg/dL	1-wk baseline; 6-wk test period followed by a 2-wk washout, then cross-over to other diet for 6 wks. OB and WB were added to Ss' regular diets. Dietary intake assessed with food frequency questionnaire; 4-d food records kept during 5th wk of each test period. Test foods were prepared in a meta-bolic research kitchen and given to Ss to consume at home. OB: 87 g/d consumed (estimated SF about 5.65 g). OB provided in entrees (60 g) or muffins (20 g). Wheat: 93 g/d consumed (about 3.7 g SF). Wheat provided in Cream of Wheat cereal and refined white flour. Base diet: Fat 31% of E; high fiber period had 35% E as fat, which came from unsaturated fat in OB supplements.	Oat fiber: TC ↓7.5%*+ LDL ↓9.1%*+ Wheat fiber: TC ↓7.1%*+ LDL ↓6.4%*+ *significantly lower from baseline +no difference between groups	No placebo. Study results limited by small number of subjects. Total dietary soluble fiber was not reported. Dietary intake assessed by two different methods. Author proposes that substitution of either wheat or oat fiber for dietary saturated fat causes the decrease in TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Törrönen et al., 1992, (Ref. 38)	Clinical study, randomized, double blind, controlled 28 adult males, ages 25-52 yrs, mild to moderate hypercholesterolemic (TC 216.2 to 343.5 mg/dL for C group; 223.9 to 289.5 mg/dL for oat group), free living	A 12-wk study consisted of a 2-wk baseline period, an 8-wk test period, and a 2-wk followup period. An OB concentrate (with 2- to 3-fold concentration of both TDF and β-glucan) was made and incorporated into bread. The C group consumed bread containing wheat flour. Ss consumed regular diets during baseline and follow-up (post) periods. During first 2-wk of test period, Ss in oat group consumed 1/2 roll of oat bread (5.6 g β-glucan/d) and an entire roll of bread (11.2 g β-glucan) divided in two meals for the last 6 wk. No other dietary restrictions. 3-d food record kept during the last week of each period. Body weight was monitored. Data analyzed by one-factor ANOVA for repeated measures, followed by 2-tailed t-test for paired data.	Nutrient intake: Base / Test / Post / ANOVA E, Cal/d: C 2344.5 / 2368.4 / 2224.9 / NS; O 2210.0 / 2320.6 / 2201 / NS Fat, %: C 35.0 / 34.6 / 36.5 / NS; O 35.2 / 32.4 / 37.9 / NS Sat Fat % E: C 14 / 13 / 14.8 / NS; O 14 / 11.1* / 13.9 / p<0.05 Fiber g: C 26.8 / 23.1 / 25.1 / NS; O 28.3 / 39.7+ / 23.7 / p<0.001 * p<0.05, + p<0.001 }compared to base Lipid analysis: Time: 0 / 2 Wk / 4 Wk / 8 Wk / Post (mg/dL) TC: C 246.7 / 244.7 / 247.8 / 244.7 / 252.1; O 246.7 / 236.2 / 233.5 / 242.0 / 244.1 LDL: C 164.8 / 169.1 / 167.1 / 164.8 / 177.9; O 171.4 / 166.0 / 167.9 / 165.6 / 174.9 HDL: C 55.6 / 54.8 / 54.4 / 53.6 / 53.6; O 49.4 / 47.9 / 47.9 / 47.1 / 48.2	There were no statistically significant effects of the β-glucan concentrate-enriched bread on TC, LDL or HDL. Authors suggest that the reduced intake of Sat Fat (21% less) during the test period by the oat group may account for the slight reduction in TC observed. SF content of OB concentrate not provided. Results of this study do not provide evidence for a CHOL-lowering effect of concentrated β-glucan from OB. The authors suggest that the method of concentrating and processing the β-glucan may have affected the effectiveness of the β-glucan in lowering serum cholesterol. Authors state "a weak effect is to be expected due to poor solubility or due to enzymatic breakdown of β-glucan during the concentration or isolation processes * * *."
Turnbull and Leeds, 1987 (Ref. 39)	Clinical study, randomized, cross-over 9 men and 8 women, ages 23-59 yrs. Initial TC of about 255 mg/dL, free living	All Ss followed a low fat diet (≤ 35% E from fat) during a 1-mo run-in period. Ss randomly assigned to oat diet, 150 g/d (50 g/d oats at breakfast and 100 g oats as biscuits consumed over the course of a day) or a wheat diet (37 g/d wheat biscuits at breakfast and 100 g wheat as biscuits over the course of a day) for a 1-mo period before cross-over to the other diet. TC following the run-in period on the low fat diet was 232 mg/dL. Oats provided 5.4 g/d SF Wheat provided 3.1 g/d SF	Baseline / Final (mg/dL) Oats: TC 232 / 220*; LDL 167 / 143**; HDL 46 / 54 * p=0.02 compared to baseline ** p=0.003 compared to baseline Wheat: TC 228 / 232; LDL 159 / 163; HDL 50 / 50	Statistical methods not given. TC ↓ 5.2% and LDL 13.9%, compared to baseline, when Ss consumed the oat diet. Total fat and E intake ↑ during oat period and ↓ during wheat period. Mean body weight ↓ in some Ss on oat diet. These changes do not invalidate CHOL-lowering effect of oats. No sat fat or CHOL intake data provided. Authors state that no attempt was made to measure compliance, but subjectively it seemed that the Ss who achieved the greatest reduction in TC were those who were most compliant.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Uusitupa et al., 1992 (Ref. 41)	Clinical study, randomized, double blind 36 adults (20 males, 16 females), mild to moderate hypercholesterolemia (TC 212 to 328 mg/dL) on CHOL-lowering diets	4 wk run-in during which medical history was taken and Step 1 AHA diet was reenforced. 8-wk trial with Ss consuming OB or WB. OB (Finnish variety), enriched with β-glucan, contained 10.3 g fat, 48.1 g TDF (16.6 g β glucan) in 100 g dry material. The brans were provided in sachets and the Ss instructed to increase their daily dose stepwise until they consumed the entire sachet (estimated to have 62 g of bran) or the highest tolerable dose. Dietary records were kept during run-in and study period. Statistical analysis: multivariate ANOVA for repeated measures to find the differences between groups and changes within groups. All p values were two-sided.	Dietary intake: wk / OB / WB E, Cal/d: 0 1678.2 1796.6; 8 1665.8 1811.7 Fat, % E: 0 32.6 32.3; 8 32.8 33.9 Sat Fat, % E: 0 11.5 11.0; 8 11.7 11.8 CHOL, mg: 0 211 223; 8 198 224 Fiber, g: 0 22.7 24.4; 4 21.5 21.8; 8 20.9 19.0* Bran, g: 4 50.5 48.9; 8 49.7 48.9 * p<0.001 compared to baseline Serum lipids: wk / OB / WB (mg/dL) TC: 0 271.8 281.1; 4 259.9* 286.2; 8 266.4 282.3 LDL: 0 189.5 202.6; 4 178.3 207.3; 8 183.3 199.1 HDL: 0 54.5 50.7; 4 54.5 51.4; 8 54.9 53.7 * p=0.028 compared to baseline	Ss did not adhere to Step 1 diet. Fat calories ranged from 32% to 34% E, Sat fat 11-11.8%, and polyunsat fat 10.6 to 11% of E. Overall results of this study show no statistically signif. differences in TC between the OB and C groups. TC and LDL showed significant reductions at 4 wks (↓4.4%, p<.03; and ↓5.9%, p<0.04, respectively). There was incomplete adherence to the OB and WB dosages. Authors reported that an analysis of data showed that those who adhered to the diet instructions showed a decline in TC and LDL. 86% of Ss considered the daily dose to be too much. Authors reported significant decline in TDF intake in wheat bran group from baseline to 8 weeks. Results of this study suggest only a short term effect of OB on TC and LDL-cholesterol.
Van Horn et al., 1988 (Ref. 42)	Clinical trial, randomized 236 men and women, ages 30-65, free living; normo-cholesterolemic (163-247 mg/dL)	A 12-wk study: 4 wks on C diet and 8 wks on test diet. Both test and C groups consumed the Phase II AHA diet throughout the study. The test group consumed 56 g OM/d (2.3 g of SF) for 8 wks. Oatmeal was consumed as hot cereal and used in muffins and other foods. Phase II AHA diet: total fat: ≤ 30% Cal; equal distribution among saturated, mono-unsaturated, and polyunsaturated fats. Dietary CHOL: 250 mg/day.	Group / Base / AHA Diet / Intervention Wk 4 / Wk 8 TC mg/dL AHA only: 205.3 194.5 192.4 191.7 AHA+OM: 203.9 193.0 186.1* 187.0 * P=0.008 compared to AHA group At wk 8, the 3.1% ↓ in TC in OM group was not significantly different from the 1.4%↓ in the C group. Changes in LDL paralleled changes in TC. Similar and nonsignif. ↑ occurred in HDL in both groups. Subgroup analysis showed that Ss in test group with highest baseline TC had greater reductions in TC.	No significant benefit of oatmeal in lowering TC beyond that achieved with the AHA diet only after 8 wks. The low fat diet was effective in lowering TC.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Van Horn et al., 1986 (Ref. 43)	Clinical trial, randomized, controlled 208 men and women, ages 30-65 yrs, mean TC 208 mg/dL	12-wk study. Ss attended a series of 6 weekly nutrition education classes and were instructed on an AHA diet. No oat products were consumed during first 6-wk period. Intakes of fruits, vegetables, and grains were not altered during wks 7-12. Ss randomized to 1 of 3 groups at end of first 6 wks. Wks 7-12 groups 1 and 2 added 2 oz (56 g) OB (14 g SF/100 g) or OM (7.7 g SF/100 g) to the AHA diet, substituting for other carbohyrates. Recipes using OB or OM were provided. Group 3 was the control on AHA diet only. 3-d food records were kept. The null hypothesis was that no differences in TC reduction would occur between groups on AHA diets with or without oats. Sample size calculations were based on assumption that difference in TC between test and C groups would be at least 20 mg/dL.	Total Cholesterol Group / Base / End AHA Period / End Oat Period mg/dL C n=70: 209.3 / 201.0 / 199.7 1 OB n=69: 207.7 / 196.4 / 191.1 2 OM n=69: 208.2 / 195.2 / 188.8 Total n=208: 208.4 / 197.6 / 193.2 After 6 wks diet only, TC signif. reduced 5.2% ($p<0.001$) from baseline. Oat bran intake at 12 wks was 39 g/d (5.5 g SF) and OM intake was 35 g/d (2.7 g SF)	Although the OB and OM group experienced an additional reduction in TC of 2.7% and 3.3%, respectively, during the oat intervention period, there was no signif. difference in TC among the 3 groups at end of the study. Compared to baseline values, all groups were statistically significant ($p<0.05$). TC ↓ 8% in the OB group, 9.3% in the OM group, and 4.5% in the diet only control group.
Van Horn et al., 1991 (Ref. 44)	Clinical study, randomized, controlled 80 men and women, mild to moderate hypercholesterolemia (213-285 mg/dL)	Two groups: control group consumed regular diet; test group consumed regular diet plus instant oats (2 packets/d - 57 g). Baseline diets Test group / Control E, Cal: 1909.5 / 2007.4 Fat, % E: 36.8 / 37.0 Sat fat, % E: 12.6 / 12.6 TDF, g: 14.5 / 16.0 SF, g: 5.2 / 5.5 TDF / SF / IF OM: 5.6 g / 2.2 g / 3.4 g	Test group, while supplementing their diet with OM: TC ↓ 6.25% (signif.) Both LDL and the LDL/HDL ratio ↓ 9%. Control group: TC ↓ 1.4%; LDL ↓ 3.7%.	The study was not blinded; the test group reduced their intake of total fat, saturated fat and CHOL, and may have made other lifestyle changes. The C group increased their intake of total fat, sat fat, and CHOL.

Table 1. Oats and Coronary Heart Disease (continued)

Study	Study Design, Subjects	Methods	Results	Comments
Whyte et al., 1992 (Ref. 45)	Clinical study, randomized with cross-over 23 men, mean age 45 years, moderate hypercholesterolemia (TC 209 to 259 mg/dL), free living.	Ss randomly assigned to either the wheat cereal or the oat cereal group after a 3-wk baseline diet. During baseline, all Ss consumed wheat cereal. Preweighed packages of cereal were provided: 54 g of WB/d; 123 g OB/d. Base diet: typical Australian diet- approximately 30-34% of E as fat. Ss instructed on how to keep dietary records, measure and restrict fiber (so all Ss would have approximately same total fiber intake of less than 30 g/d). 2 servings/d cereal was consumed for 4 wks, then cross-over to other cereal for another 4 wks. Oat cereal: 10.3 g/d SF Wheat cereal: 3.4 g/d SF All diets: TDF approximately 27 g/d.	Data analysis showed no effect of treatment order. TC / LDL / HDL (mg/dL) Baseline 226 / 159 / 47.6 Oats 218* / 150* / 49.9 Wheat 228 / 159 / 51.0 * Significantly different ($p<0.01$) compared to both baseline and wheat period.	Consumption of total fat and Sat Fat during both test periods was about the same (35.5 g fat/1,000 Cal and 12.7 to 13 g Sat Fat/1,000 Cal). No significant changes in body weight. No dietary CHOL intake data provided.
Zhang et al., 1992 (Ref. 46)	Clinical study, randomized, controlled, cross-over. Ss studied on outpatient basis except on sampling days when they were admitted to research ward. 9 men and women, ages 45-67 yrs, with ileostomies. Mean TC 231 mg/dL	During each test period, Ss instructed to eat diets that were low in dietary fiber. Ss randomly assigned to either a high fiber diet group, in which an experimental bread made with OB was added to the low fiber base diet, or a low fiber diet group, in which Ss consumed their base diet with an experimental bread made with wheat flour. Test periods were 3 wks. Ss free living except on sampling days when they were given a diet with an average of 31% of E from fat. OB intake: 118 g; Bread had 29 g TDF Wheat bread: 4.9 g TDF	TC, mg/dL All Ss Wheat 214 Oat 194.5* * Significantly different from low fiber period	Total E, dietary fat, sat fat, SF, and CHOL of Ss diets on nonsampling days were not provided. All Ss had ileostomies. Conclusions about oat mechanisms in lowering serum lipids may not apply to general population.

Abbreviations:
CHOL = Cholesterol
TC = Total Serum Cholesterol
LDL = Low density lipoprotein cholesterol
HDL = High density lipoprotein cholesterol
P:S = Polyunsaturated to saturated fatty acid ratio
TDF = Total dietary fiber
IF = Insoluble fiber
SF = Soluble fiber
Sat Fat = Saturated Fat
E = Energy (Calories)
Cal = Calories
C = Control
OB = Oat bran
OM = Oatmeal
WB = Wheat bran
ANOVA = analysis of variance
NS = nonsignificant

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[IL–0075–92]

RIN 1545–AR31

Definition of Foreign Base Company Income and Foreign Personal Holding Company Income of a Controlled Foreign Corporation; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to the definition of subpart F income and foreign personal holding company income of a controlled foreign corporation and the allocation of deficits for purposes of computing the deemed-paid foreign tax credit.

DATES: The public hearing originally scheduled for Thursday, January 4, 1996, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7190, (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under sections 952, 954(c) and 960 of the Internal Revenue Code. A notice of proposed rulemaking and notice of public hearing appearing in the Federal Register for Thursday, September 7, 1995 (60 FR 46548), announced that the public hearing on proposed regulations under sections 952, 954(c) and 960 of the Internal Revenue Code would be held on Thursday, January 4, 1996, beginning at 10 a.m., in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, D.C.

The public hearing scheduled for Thursday, January 4, 1996, is cancelled.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 95–31581 Filed 12–29–95; 11:24 am]

BILLING CODE 4830–01–M

26 CFR Parts 1 and 301

[IA–41–93]

RIN 1545–AS04

Automatic Extension of Time for Filing Individual Income Tax Returns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross reference to temporary regulations and notice of public hearing.

SUMMARY: In the Rules and Regulations section of this issue of the Federal Register, the IRS is issuing temporary regulations that reflect the new procedures for obtaining an automatic extension of time to file an individual income tax return. The text of the temporary regulations also serves as the comment document for this notice of proposed rulemaking. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written comments must be received by April 1, 1996. Outlines of topics to be discussed at the public hearing scheduled for May 8, 1996, beginning at 10:00 a.m. must be received by April 1, 1996.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (IA–41–93), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (IA–41–93), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. The public hearing will be held in the IRS Auditorium.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Margaret A. Owens, 202–622–6232 (not a toll-free number). Concerning submissions and the public hearing, Michael Slaughter, 202–622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by March 4, 1996.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The collection of information is in § 1.6081–4T(a). This information is required by the IRS to monitor the filing of individual income tax returns. This information will be used to determine which individuals need automatic 4-month extensions of time to file. The likely respondents are individuals or households. Responses to this collection of information are required to obtain a benefit (an automatic 4-month extension of time to file an individual income tax return).

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Estimates of the reporting burden in this Notice of Proposed Rulemaking will be reflected in the burden of Form 4868.

Background

The temporary regulations published in the Rules and Regulations section of this issue of the Federal Register contain amendments to the Income Tax Regulations (26 CFR part 1) and the Regulations on Procedure and Administration (26 CFR part 301). The temporary regulations provide rules relating to obtaining an automatic 4-month extension of time to file an individual income tax return. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these rules, and therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, a copy of this notice of proposed rulemaking will be submitted to the Chief Counsel for

Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 8, 1996, at 10:00 a.m., at the IRS Auditorium. Because of access restrictions, visitors will not be admitted beyond the building lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who wish to present oral comments at the hearing must submit written comments by April 1, 1996, and submit an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by April 1, 1996.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving comments has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Margaret A. Owens, Office of the Assistant Chief Counsel (Income Tax & Accounting), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805. * * *

Par. 2. Section 1.6081–4 is amended by:

1. Revising paragraph (a).
2. Adding paragraph (d).

The revised and added provisions read as follows:

§ 1.6081–4 Automatic extension of time for filing individual income tax returns.

[The text of proposed paragraphs (a) and (d) are the same as the text of § 1.6081–4T (a) and (d) published elsewhere in this issue of the Federal Register].

PART 301—PROCEDURE AND ADMINISTRATION

Par. 3. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 4. In § 301.6651–1, paragraph (c)(3) is revised to read as follows:

§ 301.6651–1 Failure to file tax return or to pay tax.

* * * * *

(c)(3) [The text of this proposed paragraph (c)(3) is the same as the text of § 301.6651–1T(c)(3) published elsewhere in this issue of the Federal Register].

* * * * *

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 96–115 Filed 1–3–96; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Individual Case Management

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements provisions of the 1993 National Defense Authorization Act which allows the Secretary of Defense to establish a case management program for CHAMPUS beneficiaries with extraordinary medical or psychological disorders and to allow such beneficiaries medical or psychological services, supplies, or durable medical equipment excluded by law or regulation as a CHAMPUS benefit. Under this program, waiver of benefit limits to the Basic CHAMPUS program may be authorized for beneficiaries when the provision of such services or supplies is cost effective and clinically appropriate, as compared to historical or projected CHAMPUS/MTF utilization of health care services. It is designed to develop a cost-effective plan of care by targeting appropriate resources to meet the individual needs of the beneficiary.

DATES: Written public comments must be received on or before March 4, 1996.

FOR FURTHER INFORMATION CONTACT: CAPT Deborah Kamin, Office of the Assistant Secretary of Defense (Health Affairs), (703)–697–8975.

SUPPLEMENTARY INFORMATION: The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplements the availability of health care in military hospitals and clinics. Case management centering on a multidisciplinary treatment approach offers the beneficiary and provider assurance that specific services and supplies are allowable as CHAMPUS benefits and provides an opportunity to use those benefits efficiently.

Statutory Authority

The case management program is based on the authority of 10 U.S.C. 1079(a)(17), which provides:

> The Secretary of Defense may establish a program for the individual case management of a person covered by this section or section 1086 of this title who has extraordinary medical or psychological disorders and, under such a program, may waive benefit limitations contained in paragraphs (5) and (13) of this subsection or section 1077(b)(1) of this title and authorize the payment for comprehensive home health care services, supplies, and equipment if the Secretary determines that such a waiver is cost effective and appropriate.

Case Management

The CHAMPUS individual case management program seeks to achieve cost effective quality health care by considering alternatives to inpatient hospitalization and by recommending a waiver of the current CHAMPUS benefit limits that, when provided in lieu of inpatient care (or to prevent recurrent hospitalizations), are cost effective and clinically appropriate. Waivers of benefit limits must be approved and coordinated by the case manager and may include, but not be limited to services or supplies such as home health care, medical supplies, back-up durable medical equipment, extended skilled nursing care and home health aides. CHAMPUS case managers will be employees or contractors of the Department of Defense. We propose to add to section 199.4 authorization, as a case management related benefit and on a case-by-case basis, services or supplies that would otherwise be excluded as non-medical or duplicate durable

equipment, custodial care, or domiciliary care. We also propose to add definitions for waiver of benefit limits, case management, case manager, case management multidisciplinary team, extraordinary condition, and primary caregiver.

Eligibility

A beneficiary's eligibility for participation in the CHAMPUS case management program is dependent on: (1) The presence of an extraordinary medical or psychological condition which has resulted in high utilization of CHAMPUS/MTF resources in an inpatient setting, (2) the cost-effectiveness of providing services of supplies outside inpatient settings, and (3) the willingness of the beneficiary to participate, and (4) the presence of a primary caregiver in the home when the services provided include home health care.

Role/Purpose of a Primary Caregiver

Candidates for this program will require a level of support which cannot occur safely outside an inpatient setting unless there is a primary caregiver in the home. Therefore, the presence of a primary caregiver to provide services is a pre-condition of participation. We envision that, in most cases, the role of primary caregiver will fall to members of the beneficiary's family.

Covered Services

A list of services or supplies that may be covered as a waiver of benefit limits will not be established. Rather, we propose that, under the case management program, clinically appropriate services and/or supplies may be provided when those services or supplies are cost effective.

Custodial Care

The provision of custodial care as a waiver of benefit limits is proposed as a transitional benefit for patients and families facing extraordinary medical or psychological conditions. To qualify for this waiver of benefit limits, the following conditions must be met: (1) The patient must have been rehospitalized for exacerbations or complications of his/her custodial condition on a recurring basis in the prior year, (2) The proposed treatment must be cost effective when compared to alternative treatment which would otherwise occur, (3) The patient's condition at referral for case management is either acute or there are indicators of a rapidly approaching acute episode, and (4) There must be a primary caregiver.

We expect individual patients will require varying levels of support and time to stabilize in the home environment. We propose a maximum of 30 (thirty) days for custodial care under case management. However, this rule would allow case managers to extend the period of time beyond thirty days when it is considered cost effective to do so.

Prior Authorization

Prior authorization from case managers will be required before the delivery of any case managed benefits. Because eligibility for a waiver of benefit limits is based on an indepth assessment of medical needs, as well as the cost effectiveness and clinical appropriateness of alternate services, any services provided absent prior authorization will not be covered by CHAMPUS. Retrospective requests for coverage under this program will not be authorized.

Military Health Services System Resource Management

To ensure cost efficient as well as cost effective use of resources, the Department of Defense will include case management requirements, as described in this rule, in nationwide managed care support contracts now being procured. Managed care support contractors will be authorized to make available case management services to Military Medical Treatment Facilities. In areas where transition to managed care support contracts has not occurred, case management services will be provided through existing regional peer review organizations (Regional Review Centers, or RRCs). MTFs will be provided the opportunity to refer potential candidates to the appropriate CHAMPUS case manager. Where possible, Military Medical Treatment Facilities will provide care and services or supplies in support of regional case management programs.

Beneficiary Acknowledgment

Case management is a collaborative process among the case manager, beneficiary, primary caregiver, and professional health care providers. For case management to be successful, the beneficiary and primary caregiver must participate in the process and be aware of and agree with the requirements of the program. To document the understanding of their roles, rights and responsibilities, a standard acknowledgment, signed by the beneficiary (or representative) and the primary caregiver, will be required prior to the start of case management services.

CHAMPUS HHC/HHC–CM Demonstration

The 1986 Home Health Care and 1988 Home Health Care-Case Management Demonstration projects were developed to test whether case management, coupled with home health care benefits, could reduce medical costs and improve services to CHAMPUS beneficiaries. Under the 1986 demonstration, case management services were limited to beneficiaries who, in the absence of case managed home health care, would have remained hospitalized. The 1988 program was less restrictive and no longer required case management services only as a substitute for continued hospitalization. The effectiveness of methods for identifying potentially eligible beneficiaries and establishing the clinical appropriateness and cost-effectiveness of services provided was addressed by the General Accounting Office (GAO). In their report, ''DEFENSE HEALTH CARE: Further Testing and Evaluation of Case Management Home Care Is Needed,'' the GAO identified a need for stronger cost controls and improved targeting of potential candidates before implementation of a permanent case management program under CHAMPUS. While the GAO identified some weaknesses in both demonstrations, the more restrictive design of the 1986 program was seen as one which presented an acceptable level of risk to the government. With the GAO's recommendations and observations in mind, the Department is proposing a CHAMPUS case management program which is limited to beneficiaries who would remain hospitalized in the absence of such a program, or who have demonstrated a recent history of multiple inpatient episodes.

Regulatory Procedures

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one which would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This proposed rule is a significant regulatory action under EO 12866 and has been reviewed by the Office of

Management and Budget. In addition, we certify that this proposed rule will not significantly affect a substantial number of small entities.

Paperwork Reduction Act

This rule, as written, imposes no burden as defined by the Paperwork Reduction Act of 1995. If however, any program implemented under this rule causes such a burden to be imposed, approval therefore will be sought of the Office of Management and Budget in accordance with the Act, prior to implementation.

List of Subjects in 32 CFR Part 199

Claims, handicapped, health insurance, and military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.2(b) is amended by adding new definitions in alphabetical order:

§ 199.2 Definitions.

* * * * *

Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, using communication and available resources to promote quality, cost effective outcomes.

Case manager. A licensed register nurse or licensed social worker who has a minimum of two (2) years of case management experience.

* * * * *

Extraordinary condition. A complex clinical condition which resulted, or is expected to result, in inpatient CHAMPUS/MTF costs or utilization above a threshold established by the Director, OCHAMPUS, or designee.

* * * * *

Primary caregiver. An individual who renders to a beneficiary services to support the essentials of daily living (as defined in § 199.2) and specific services essential to the safe management of the beneficiary's condition.

* * * * *

Waiver of benefit limits. Coverage, under the Case Management Program, of medical care, services, and or equipment not otherwise a benefit under the Basis CHAMPUS program.

* * * * *

3. Section 199.4 is amended by adding new paragraphs (e)(20) and (i) as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) *Special benefit information.*

* * * * *

(20) *Case management services.* As part of case management for beneficiaries with complex medical or psychological conditions, payment for services or supplies not otherwise covered by the Basic CHAMPUS program may be authorized when they are provided in accordance with § 199.4(i). Waiver of benefit limits to the basic CHAMPUS program may be cost shared where it is demonstrated that the absence of such services would result in the exacerbation of an existing extraordinary condition, as defined in § 199.2, to the extent that frequent or extensive institutional services are required; and such services are a cost effective alternative to the Basic CHAMPUS program.

* * * * *

(i) *Case management program.*

(1) *In general.* Case management, as it applies to this program, provides a collaborative process among the case manager, beneficiary, primary caregiver, professional health care providers and funding sources to meet the medical needs of an individual with an extraordinary condition. It is designed to promote quality and cost-effective outcomes through assessment, planning, implementing, monitoring and evaluating the options and services required. Payment for services or supplies not otherwise covered by the basic CHAMPUS program may be authorized when they are provided in accordance with this paragraph (i). Waiver of benefit limits may be cost-shared where it is demonstrated that the absence of such services would result in the exacerbation of an existing extraordinary condition, as defined in § 199.2, to the extent that frequent or extensive hospitalizations are required; and such services are a cost-effective alternative to the Basic CHAMPUS program.

(2) *Applicability of case management program.* A CHAMPUS eligible beneficiary may participate in the case management program if he/she has an extraordinary condition which is disabling and requires inpatient care at a CHAMPUS-covered level-of-care. The medical or psychological condition must also:

(i) Be contained in the latest revision of the International Classification of Diseases Clinical Modification, or the Diagnostic and Statistical Manual of Mental Disorders;

(ii) Meet at least one of the following:

(A) Demonstrate a prior history of frequent, multiple inpatient admissions, generating high CHAMPUS costs in the year immediately preceding eligibility for the case management program; or

(B) Require clinically appropriate services or supplies from multiple providers to address an extraordinary condition; and

(iii) More cost effectively and in a more clinically appropriate manner be treated at a less resource intensive level of care.

(3) *Prior authorization required.* Services or supplies allowable as a benefit exception under this Section shall be cost-shared only when a beneficiary's entire treatment has received prior authorization through an individual case management program.

(4) *Cost effectiveness requirement.* Treatment cost effectiveness shall be calculated as the reduction in the cost to the Department of Defense for proposed treatment which substitutes individual case management services for more expensive care which would have otherwise been reimbursed under the basic program. Generally, cost effectiveness determinations will involve comparisons between treatments primarily using an inpatient setting and those primarily using an outpatient or in-home setting. Treatment must meet the requirements of appropriate medical care as defined in § 199.2.

(5) *Limited waiver of exclusions and limitations.* Limited waivers of exclusions and limitations normally applicable to the basic program may be granted for specific services or supplies only when a beneficiary's entire treatment has received prior authorization through the individual case management program described in this paragraph (i). The Director, OCHAMPUS may grant a patient-specific waiver of benefit limits for services or supplies in the following categories, subject to the waiver requirements of this section.

(i) *Durable equipment.* The cost of a device or apparatus which does not qualify as Durable Medical Equipment (as defined in § 199.2) or back-up durable medical equipment may be shared when determined by the Director, OCHAMPUS to be cost-effective and clinically appropriate.

(ii) *Custodial Care.* The cost of services or supplies rendered to a beneficiary that would otherwise be excluded as custodial care (as defined in § 199.2) may be cost-shared for a period of 30 (thirty) days when determined by

the Director, OCHAMPUS, to be cost effective and clinically appropriate. To qualify for a waiver of benefit limits of custodial care, the patient must meet all eligibility requirements of this paragraph (i), including an acute condition or an acute exacerbation of a chronic condition.

(A) The patient must have been rehospitalized for exacerbations or complications of his/her custodial condition on a recurring basis in the prior year;

(B) The proposed case management treatment must be cost effective when compared to alternative treatment which would otherwise occur;

(C) The patient's condition at referral for case management is either acute or there are indicators of a rapidly approaching acute episode; and

(D) There is a primary caregiver.

(iii) *Domiciliary care.* The cost of services or supplies rendered to a beneficiary that would otherwise be excluded as domiciliary care (as defined in § 199.2) may be shared when determined by the Director, OCHAMPUS to be cost effective and clinically appropriate.

(iv) *In home services.* The cost of the following in-home services may be shared when determined by the Director, OCHAMPUS to be cost effective and clinically appropriate: nursing care, physical, occupational, speech therapy, medical social services, intermittent or part-time services of a home health aide, beneficiary transportation required for treatment plan implementation, and training for the beneficiary and primary caregiver sufficient to allow them to assume all feasible responsibility for the care of the beneficiary that will facilitate movement of the beneficiary to the least resource-intensive, clinically appropriate setting. (Qualifications for home health aides shall be based on the standards at 42 CFR 484.36.)

(v) *Waiver of custodial care limits.* The Director, OCHAMPUS may, in extraordinary cases, waive the custodial care day limits described in paragraph (e)(5)(ii) of this section and authorize this exception to benefits beyond the 30-day limit. The criteria for waiver of the 30-day limit shall be those set in paragraph (e)(5)(ii) of this section. Additionally, there must be a specific determination that discontinuation of this waiver of benefit limits will result in immediate onset or exacerbation of an acute care episode and require hospitalization or services or supplies which increase significantly the cost and intensity of care.

(6) *Case management acknowledgment.* The beneficiary, or representative, and the primary caregiver, shall sign a case management acknowledgment as a prerequisite to prior authorization of case management services. The acknowledgment shall include, in part, all of the following provisions:

(i) The right to participate fully in the development and ongoing assessment of the treatment;

(ii) That all health care services for which CHAMPUS cost sharing is sought shall be authorized by the case manager prior to their delivery;

(iii) That there are limitations in scope and duration of the planned case management treatment, including provisions to transition to other arrangements;

(iv) The conditions under which case management services are provided, including the requirement that the services must be cost effective and clinically appropriate; and

(v) That a beneficiary's participation in the case management program shall be discontinued for any of the following reasons:

(A) The loss of CHAMPUS eligibility;

(B) A determination that the services or supplies provided are not cost effective or clinically appropriate;

(C) The beneficiary, or representative, and/or primary caregiver, terminates participation in writing;

(D) The beneficiary and/or primary caregiver's failure to comply with requirements in this paragraph (i); or

(E) A determination that the beneficiary's condition no longer meets the requirements of participation as described in this paragraph (i).

(7) *Other administrative requirements.*

(i) Qualified providers of services or items not covered under the basic program, or who are not otherwise eligible for CHAMPUS-authorized status, may be authorized for a time-limited period when such authorization is essential to implement the planned treatment under case management. Such providers must not be excluded or suspended as a CHAMPUS provider, and must agree to participate on all claims related to the case management treatment.

(ii) Retrospective requests for authorization of waiver of benefit limits will not be considered. Authorization of waiver of benefit limits is allowed only after all other options for services or supplies have been considered and either appropriately utilized or determined to be clinically inappropriate and/or not cost-effective.

(iii) Experimental or investigational treatment or procedures shall not be cost-shared as an exception to standard benefits under this part.

(iv) CHAMPUS case management services may be provided by contractors designated by the Director, OCHAMPUS.

Dated: December 28, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–65 Filed 1–3–96; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 195

[Docket PS–140(b), Notice 4]

RIN 2137–AC34

Areas Unusually Sensitive to Environmental Damage

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

ACTION: Public workshop.

SUMMARY: RSPA invites industry, government representatives, and the public to a third workshop on unusually sensitive areas (USAs). The workshop's purpose is to openly discuss the guiding principles for determining areas unusually sensitive to environmental damage from a hazardous liquid pipeline release. This workshop is a continuation of the June 15–16, 1995 and October 17, 1995 workshops on USAs.

DATES: The workshop will be held on January 18, 1996 from 8:30 a.m. to 4 p.m. Persons who are unable to attend may submit written comments in duplicate by February 5, 1996. However, persons submitting guiding principles to be considered at the January 18 workshop must do so by January 12, 1996. Interested persons should submit as part of their written comments all material that is relevant to a statement of fact or argument. Late filed comments will be considered so far as practicable.

ADDRESSES: The workshop will be held at the U.S. Department of Transportation, Nassif Building, 400 Seventh Street, SW, Room 6200–04, Washington, DC. Non-federal employee visitors are admitted into the DOT headquarters building through the southwest entrance at Seventh and E Streets, SW. Persons who want to participate in the workshop should call (202) 366–2392 or e-mail their name, affiliation, and phone number to samesc@rspa.dot.gov before close of business January 12, 1996. The

workshop is open to all interested persons but RSPA may limit participation because of space considerations and the need to obtain a spectrum of views. Callers will be notified if participation is not open.

Send written comments in duplicate to the Dockets Unit, Room 8421, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590–0001. Identify the docket and notice numbers stated in the heading of this notice.

All comments and docketed materials will be available for inspection and copying in Room 8421 between 8:30 a.m. and 4:30 p.m. each business day. A summary of the workshop will be available from the Dockets Unit about three weeks after the workshop.

FOR FURTHER INFORMATION CONTACT: Christina Sames, (202) 366–4561, about this document, or the Dockets Unit, (202) 366–5046, for copies of this document or other material in the docket.

SUPPLEMENTARY INFORMATION: 49 U.S.C. 60109 requires the Secretary of Transportation to:

- Consult with the Environmental Protection Agency and describe areas that are unusually sensitive to environmental damage if there is a hazardous liquid pipeline accident, and
- Establish criteria for identifying each hazardous liquid pipeline facility and gathering line, whether otherwise subject to regulation, located in an area unusually sensitive to environmental damage in the event of a pipeline accident.

Consistent with the President's regulatory policy (E.O. 12866), RSPA wants to accomplish this congressional mandate at the least cost to society. Toward this end, RSPA is seeking early public participation in the rulemaking process by holding public workshops at which participants, including RSPA staff, may exchange views on relevant issues. RSPA hopes these workshops will enable government and industry to reach a better understanding of the problem and the potential solutions before proposed rules are issued.

On June 15 and 16, 1995, RSPA held a public workshop to openly discuss the criteria being considered to determine USAs (60 FR 27948; May 26, 1995). Participants included representatives from the hazardous liquid pipeline industry; the Departments of Interior, Agriculture, Transportation, and Commerce; the Environmental Protection Agency; non-government agencies; and the public. Participants at the workshop requested that additional workshops be held to further discuss this complex topic.

On October 17, 1995, RSPA held a second public workshop on USAs (60 FR 44824; August 29, 1995). The second workshop focused on developing a process that can be used to determine if an area is unusually sensitive to environmental damage. The American Petroleum Institute (API) provided information on their current research on USAs and recommended that the final definition consider the resource to be protected, the likelihood of a given pipeline to impact that resource, and what can be done to reduce the risk to the resource. Other participants recommended integrating factors concerning the likelihood of a rupture occurring and the severity of the consequence into the USA definition.

Participants at the workshop brainstormed guiding principles that could be used when determining if a given area is a USA and possible topics for additional USA workshops. API volunteered to conduct mini-workshops to discuss some of the technical issues and to bring their findings into larger forums.

The following is a summary of the guiding principles that were discussed at the October 17 workshop or submitted after the workshop by members of the pipeline industry or other Federal agencies. The guiding principles are separated into two categories: Substance and Process. Guiding principles on substance relate to the criteria that should be included in the USA definition. Guiding principles on process relate to how to evaluate the criteria to be included in the USA definition, the process to create the USA definition, and how to apply the USA definition. The lists are not prioritized or final. The lists sometimes include more than one recommendation which may conflict with one another. Conflicting views are labeled a. and b. under a common number for comparison. RSPA invites comments on these recommended guiding principles and invites submissions of additional guiding principles. This list and any additional guiding principles that are submitted to the docket before January 12 will be considered at the January 18 workshop:

Substance

1. Human health and safety are primary concerns.

2. Areas where there is serious threat of contamination to a drinking water ''zone of influence'' should be considered USAs.

3a. A resource must be subject to or threatened by irretrievable loss or injury before it can be considered a USA. or

3b. Areas where there is serious threat of contamination to a significant environmental or cultural resource should be considered a USA.

4a. USAs are biological or ecological in nature and should not include cultural, economic, or recreational resources. Cultural, economic, or recreational resources should be designated as separate categories and viewed as distinct entities. or

4b. Consider cultural resources and Indian tribal concerns when defining USAs.

5. Only areas in the trajectory of a potential spill, e.g. down gradient, should be considered when determining USAs.

6. It is expected that no pipeline operator is required to collect natural resources field data to determine USAs.

7. Highly volatile liquid (HVL) pipelines should not be included.

Process

1. The standards and criteria for resource sensitivity should be uniform on a national basis such that equivalent resources receive equivalent sensitivity assessments regardless of regionally based priorities.

2. The government agencies should describe and identify USAs so that the data will not be subject to various interpretations and will be applied consistently.

3. USAs should be subject to a systematic review process since USAs may change through time as species migrate, change location, or for other reasons. The USA definition should be explicit and practical in application.

4. The USA definition should be pilot tested, complete, and fully defined before OPS uses the definition in rulemaking. Each part of the USA definition should be pilot tested for validity, practicability, and workability.

5. Sources of USA data should be readily available to the public and uniform in criteria and standards.

6. Data quality objectives should include consistency, accuracy, and extent of coverage.

7. The extent of how much additional geographic area a criterion adds should be considered.

8. Risk elements mandated in 49 U.S.C. § 60109 to NOAA's Guidance for Facility and Vessel Response Plans (59 FR 14714; March 29, 1994) should be applied when determining USAs.

9. OPS should exempt operators that take proactive measures to minimize the potential for spills from additional requirements to protect USAs.

10. Consultation with land or resource managers may be necessary when operators consider a range of preventative measures in significant environmental resource areas.

11. The process should clarify how sensitive areas are protected under the Pipeline Safety Act of 1992 separate and apart from protection under the Oil Pollution Act of 1990.

Several recommendations were made that RSPA has determined are acceptable but are not guiding principles. These are:

1. Workshops for each phase of developing a USA definition should include appropriate technical experts, representatives, and field personnel with appropriate experience from agencies as well as industry.

2. Public workshops should be used to gather information on the criteria that will determine USAs. The USA definition should be complete before its use in a rulemaking. The implementation of resource assessment and protection under the USA definition could be phased.

3. All terms used in the USA definition should be defined.

4. National consistency in interpreting all definitions should be the goal.

The following are the additional workshops that were recommended during the October 17 workshop:

1. Guiding Principles Workshop.

2. Definitions of Terms Workshop.

3. Source Water Supply Workshop (Surface and Subsurface).

4. Biological Resources Workshop.

5. Cultural Resources and Indian Tribal Concerns Workshop.

6. Pilot Testing Process Workshop.

Persons interested in receiving a transcript of the first workshop or the summary of the second workshop, material presented at the first or second workshop, or comments submitted on the material presented in the first or second public workshop notice should contact the Dockets Unit at (202) 366–5046 and reference docket PS–140(b).

Issued in Washington, DC, on December 28, 1995.

Cesar DeLeon,

Deputy Associate Administrator for Pipeline Safety.

[FR Doc. 96–107 Filed 1–3–96; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register
Vol. 61, No. 3
Thursday, January 4, 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 Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of availability and intent.

SUMMARY: Notice is hereby given that three Federally owned cultivars of forage pearl millet, ''Tifleaf 3,'' ''Tift 8593,'' and ''Tift 93'', are available for licensing and that the United States Department of Agriculture, Agricultural Research Service, intends to grant an exclusive license to the University of Georgia Research Foundation. Applications for Plant Variety Protection Certificates for each of these cultivars have been filed with the Plant Variety Protection Office in the United States Department of Agriculture.

DATES: Comments must be received by no later than April 3, 1996.

ADDRESSES: Send comments to: USDA–ARS-Office of Technology Transfer, Beltsville Agricultural Research Center, Baltimore Boulevard, Building 005, Room 416, BARC–W, Beltsville, Maryland 20705–2350.

FOR FURTHER INFORMATION CONTACT: Andrew Watkins of the Office of Technology Transfer at the Beltsville address given above; telephone 301/504–6905.

SUPPLEMENTARY INFORMATION: The Federal Government's plant variety protection rights to this variety 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, for the University of Georgia Research Foundation 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, ARS 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. 96–77 Filed 1–3–96; 8:45 am]

BILLING CODE 3410–03–M

Rural Utilities Service

South Mississippi Electric Power Association; Finding of No Significant Impact

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Finding of No Significant Impact.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS) has made a finding of no significant impact (FONSI) with respect to its action related to an expansion and repowering project by South Mississippi Electric Power Association (SMEPA) at its existing Moselle Generating Station. The FONSI is the conclusion of an Environmental Assessment prepared by RUS. The Environmental Assessment is based on a environmental analysis submitted to RUS by SMEPA. RUS conducted an independent evaluation of the environmental analysis and concurs with its scope and content.

FOR FURTHER INFORMATION CONTACT: Lawrence R. Wolfe, Senior Environmental Protection Specialist, Engineering and Environmental Staff, RUS, South Agriculture Building, Ag Box 1569, Washington, DC 20250, telephone (202) 720–1784.

SUPPLEMENTARY INFORMATION: The proposed expansion and repowering project would be installed at SMEPA's existing Moselle Generating Station located in Jones County, Mississippi, approximately 2 miles west of Interstate 59 on Mississippi Highway 589. Currently in operation at this station are three 59 megawatt (MW) gas/oil fired steam turbines. The proposed facilities will utilize the existing plant infrastructure such as the natural gas and oil supply, electric transmission lines, and water system. SMEPA has optioned to purchase 20 acres contiguous with the north side of the Moselle site to accommodate the expansion needed for the additional generating facility.

The proposed facility will consist of a simple cycle combustion turbine and air-cooled generator. The turbine will have a generating output estimated to be between 80 and 120 megawatts (MW). The FONSI includes a combined cycle facility also under consideration by SMEPA which would be designed and constructed at a future date. The combined cycle facility would have a generating output estimated to be between 80 and 120 MW. This phase of the project would be conducted in conjunction with the repowering of the existing 59 MW number 3 steam turbine at the Moselle Generating Station. However, at this time RUS is only considering taking an action related to the simple cycle combustion phase of the proposed expansion and repowering which it considers to be justified by need.

The new simple cycle generation facility would be made up of the following components: combustion turbine generator, fuel oil forwarding system, flue gas scrubber, demineralized water monitoring system, generator step-up transformer, station auxiliary transformer, medium voltage switchgear auxiliary station supply, secondary unit switchgear, including low voltage, switchgear, motor control centers, and bus duct.

The facility will be designed to operate using natural gas as the primary fuel and number 2 fuel oil as the secondary fuel. Natural gas would be supplied via the existing gas pipeline at the site. Fuel oil will be shipped to the site by truck and stored on site in storage tanks.

The future addition of the combined cycle facility would involve the following components: combustion turbine generator, heat recovery steam generator, boiler feedwater system, flue gas scrubber, demineralized water transfer pumps, continuous emissions monitoring system, generator step-up transformer, station auxiliary transformer, medium voltage switchgear auxiliary station supply, secondary unit switchgear including low voltage switchgear, motor control centers, and bus duct.

The combined cycle facility would utilize many of the existing

infrastructure systems at the Moselle Generating Station.

A continuous emissions monitoring (CEM) system would be used to monitor flue gas emissions from both the simple cycle and the combined cycle facilities. The CEM would measure opacity, nitrogen oxides, carbon monoxide, oxygen, volatile organic compounds, and sulfur dioxide for the purpose of ensuring compliance with federal and State of Mississippi air quality standards.

The alternatives of no action, demand side management, power purchases, hydroelectric units, wind and solar power, geothermal power, and alternative site locations were considered.

Copies of the environmental assessment and FONSI are available for review at, or can be obtained from, RUS at the address provided herein or from Mr. Joey Ward, South Mississippi Electric Power Association, P.O. Box 15849, Hattiesburg, Mississippi, telephone (601) 268–2083. Interested parties wishing to comment on the adequacy of the Environmental Assessment should do so within 30 days of the publication of this notice. RUS will take no action that would approve clearing or construction activities related to this expansion and repowering project prior to the expiration of the 30-day comment period.

Dated: December 27, 1995.

Blaine D. Stockton, Jr.,

Acting Deputy Administrator Program Operations.

[FR Doc. 96–78 Filed 1–3–96; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122795B]

Endangered Species; Permits

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

ACTION: Issuance of an amendment of permit 747 (P45H).

SUMMARY: Notice is hereby given that NMFS has issued an amendment to a permit that authorizes a take of listed species for the purpose of scientific research and enhancement, subject to certain conditions set forth therein, to the U.S. Fish and Wildlife Service (FWS) located in Red Bluff, CA.

ADDRESSES: The action request and related documents are available for review in the following offices, by appointment:

Office of Protected Resources, F/PR8, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3226 (301–713–1401); and

Director, Southwest Region, NMFS, NOAA, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213 (310–980–4016).

SUPPLEMENTARY INFORMATION: The amendment of permit 747 was issued under the authority of section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–222).

The amendment of permit 747 was issued on December 20, 1995. Permit 747 authorizes FWS to take endangered Sacramento River winter-run chinook salmon (Oncorhynchus tshawytscha) associated with scientific research and enhancement activities. The amendment provides an extension of the permit for 90 days; a moratorium on the collection of adult listed fish for broodstock for the duration of the permit; and authorization to release juvenile, listed, artificially-propagated, winter-run chinook salmon in December, 1995, rather than January, 1996 as previously authorized.

Permit 747 was to expire on December 31, 1995. An extension of the permit is necessary to allow FWS to continue research and enhancement activities until new permits replace permit 747 and to have an opportunity to address technical concerns with FWS' listed fish artificial propagation program, as proposed in their new section 10 enhancement permit application, P45V (60 FR 58334, November 27, 1995). Genetics research has found that FWS' artificial propagation of winter-run chinook salmon has likely resulted in some hybridization with spring-run chinook salmon. In addition, hatchery-produced winter-run chinook salmon have not been returning to the mainstem Sacramento River as intended, but rather have been returning to Battle Creek where Coleman National Fish Hatchery is located, apparently as a result of imprinting on Battle Creek water.

The purpose of the moratorium on the collection of adult listed fish for broodstock is to avoid compromising the genetic integrity of the winter-run chinook salmon population due to the present circumstances and to avoid a significant drain on the 1996 spawning population if juveniles continue to imprint exclusively on Battle Creek. The earlier juvenile fish release is an attempt to improve the likelihood that the fish will imprint on mainstem Sacramento River water. Any suspected progeny of hybrid crosses between winter-run chinook salmon and spring-run chinook salmon will not be released. The amendment is in effect for the duration of the permit. The new expiration date of permit 747 is March 31, 1996.

Issuance of the amendment, as required by the ESA, was based on a finding that such action: (1) Was requested in good faith, (2) will not operate to the disadvantage of the listed species that is the subject of the permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA and the NMFS regulations governing listed species permits.

Dated: December 27, 1995.

Ann D. Terbush,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–99 Filed 1–3–96; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Chicago Mercantile Exchange Proposed Futures and Futures Options Contracts on Four Currency Cross-Rates

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures and options contracts.

SUMMARY: The Chicago Mercantile Exchange (CME or Exchange) has applied for designation as a contract market in futures and options contracts in four currency cross-rates: the Deutsche Mark/French Franc, the Deutsche Mark/Italian Lira, the Deutsche Mark/Spanish Peseta, and the Deutsche Mark/Swedish Krona. The Director of the Division of Economic Analysis (Division) of the Commission, acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposals for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATES: Comments must be received on or before February 5, 1996.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity

Futures Trading Commission, 1155 21st Street NW, Washington, DC 20581. Reference should be made to the CME futures and options on four currency cross-rates.

FOR FURTHER INFORMATION CONTACT: Please contact Steve Sherrod of the Division of Economic Analysis, Commodity Futures Trading Commission, 1155 21st Street NW, Washington, DC 20581, telephone 202–418–5277.

SUPPLEMENTARY INFORMATION: Copies of the terms and conditions will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 1155 21st Street, N.W., Washington, D.C. 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address or by phone at (202) 418–5097.

Other materials submitted by the CME in support of the applications for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR part 145 (1987)), except to the extent they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed terms and conditions, or with respect to other materials submitted by the CME, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581 by the specified date.

Issued in Washington, DC, on December 29, 1995.

Blake Imel,

Acting Director.

[FR Doc. 96–138 Filed 1–3–96; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Ballistic Missile Defense Advisory Committee; Notice of Advisory Committee Meeting

Summary: The Ballistic Missile Defense (BMD) Advisory Committee will meet in closed session in Colorado Springs, Colorado, on January 29–30, 1996.

The mission of the BMD Advisory Committee is to advise the Secretary of Defense and Deputy Secretary of Defense, through the Under Secretary of Defense for Acquisition and Technology, on all matters relating to acquisition, system development and technology for defense against the ballistic missile threat.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended by 5 U.S.C., Appendix II, it is hereby determined that this BDM Advisory Committee meeting concerns matters listed in 5 U.S.C. 552b(c)(1), and accordingly the meeting will be closed to the public.

Dated: December 28, 1995.

Linda M. Bynum,

OSD Federal Liaison Officer, Department of Defense.

[FR Doc. 96–66 Filed 1–3–96; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Army Science Board; Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 10 January 1996.

Time of Meeting: 1300–1700.

Place: Pentagon–Washington, DC.

Agenda: The Army Science Board's Research and Development (R&D) Sub-panel for the study on ''Reengineering the Acquisition and Modernization Processes of the Institutional Army'' will meet for briefings and discussions on the R&D processes and ways to improve efficiency. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of this meeting. For further information, please contact Michelle Diaz at (703) 695–0781.

Michelle P. Diaz,

Acting Administrative Officer, Army Science Board.

[FR Doc. 96–92 Filed 1–3–96; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board; Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 24 January 1996.

Time of Meeting: 1300–1700.

Place: Pentagon—Washington, DC.

Agenda: The Army Science Board's Research and Development (R&D) Sub-panel for the study on ''Reengineering the Acquisition and Modernization Processes of the Institutional Army'' will meet for briefings and discussions on the R&D processes and ways to improve efficiency. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of this meeting. For further information, please contact Michelle Diaz at (703) 695–0781.

Michelle P. Diaz,

Acting Administrative Officer, Army Science Board.

[FR Doc. 96–98 Filed 1–3–96; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–90–000]

Columbia Gas Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

December 28, 1995.

Take notice that on December 21, 1995, Columbia Gas Transmission Corporation (Columbia) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, to become effective February 1, 1996.

Third Rev Eleventh Revised Sheet No. 28
First Rev Fourth Revised Sheet No. 262
Third Revised Sheet No. 395
First Revised Sheet No. 466

The instant filing is being submitted pursuant to Article X, Resolution of Gas Supply Realignment and Order Nos. 500/528 Costs, of the ''Customer Settlement'' in Docket No. GP94–02, et al., approved by the Commission on June 15, 1995 (71 FERC 61,337 (1995)). The Customer Settlement became effective on November 28, 1995, when the Bankruptcy Court's November 15, 1995 order approving Columbia's Plan of Reorganization became final. Under the terms of Article X, Columbia is entitled to recover the sum of $1 million from ITS customers through a $0.01/Dth surcharge as full and complete satisfaction of any right it may have to

recover Gas Supply Realignment Costs, Order No. 500/528 Costs, overriding royalties, and all Producer Contract Rejection Costs in the Bankruptcy Proceedings. The tariff sheets being filed herein set forth the indicated $0.01/Dth surcharge applicable to Rate Schedule ITS to be applied against ITS quantities until a total amount of $1 million has been collected, plus FERC Interest on the uncollected amounts which shall accrue commencing February 1, 1996. Columbia will true up recoveries from its interruptible customers for these amounts upon collection of the total amount recoverable by Columbia.

Therefore, Columbia is submitting for filing herein, Section 42 Recovery of Article X Costs to its FERC Gas Tariff, Second Revised Volume No. 1, to provide for the recovery and true up of the above described costs.

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, Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. Pursuant to Section 154.210 of the Commission's Regulations, all such motions or protests must be filed not later than 12 days after the date of the filing noted above. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–82 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER94–1188–008]

LG&E Power Marketing Inc.; Notice of Filing

December 28, 1995.

Take notice that on December 18, 1995, LG&E Power Marketing Inc. filed a Notice of a Change in Status.

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 January 12, 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–127 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–89–000]

Mississippi River Transmission Corporation; Notice of Proposed Changes in FERC Tariff

December 28, 1995.

Take notice that on December 21, 1995, Mississippi River Transmission Corporation (MRT) tendered for filing the following tariff sheets to Third Revised Volume No. 1 of its FERC Gas Tariff (Tariff):

Fifteenth Revised Sheet No. 5
Fifteenth Revised Sheet No. 6

MRT states that the purpose of this filing is to adjust its rates to reflect additional Gas Supply Realignment Costs (GSRC) of $352,789, plus applicable interest, pursuant to Section 16.3 of the General Terms and Conditions of MRT's Tariff. MRT states that its filing includes the ''Price Differential'' cost of continuing to perform under certain gas supply contracts during the months of July through September 1995 and GSRC Buyout/Buydown costs incurred during the period June 23, 1995 through November 20, 1995. MRT states that it filing also reflects the removal of GSRC surcharges attributable to its Initial GSRC Recovery Period which ends on December 31, 1995.

MRT requests an effective date of January 1, 1996 for these tariff sheets. MRT states that copies of its filing are available for inspection at its business offices, located in St. Louis, Missouri, and have been mailed to all of its affected customers and the State Commissions of Arkansas, Missouri and Illinois.

Any person desiring to be heard or protest said filing should file a motion to intervene or protests with the Federal Energy Regulatory Commission, 888 First Street, Washington, DC 20426, in accordance with Sections 385.211 and 385.214 of the Commisson's Rules and Regulations. Pursuant to Section 154.210 of the Commission's regulations, all such motions and protests must be filed not later than 12 days after the date of the filing noted above. 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 available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–83 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP95–326–006 and RP95–242–007]

Natural Gas Pipeline Company of America; Notice of Compliance Filing

December 28, 1995.

Take notice that on December 20, 1995, Natural Gas Pipeline Company of America (Natural) tendered for filing proposed changes in its FERC Gas Tariff, Sixth Revised Volume No. 1, to become effective December 1, 1995.

Natural states that the purpose of this filing is to comply with the Commission's ''Order Accepting Tariff Sheets, Subject to Conditions, and Granting Abandonment'' issued November 30, 1995 in Docket No. RP95–326–001, *et al.*

Natural requests whatever waivers may be necessary to permit the tariff sheets as submitted to become effective December 1, 1995.

Natural states that copies of the filing are being mailed to all parties on the restricted service list in the referenced dockets.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. Pursuant to Section 154.210 of the Commission's Regulations, all such protests must be filed not later than 12 days after the date of the filing noted above. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cash,

Secretary.

[FR Doc. 96–86 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–3–001]

Northern Natural Gas Company; Notice of Compliance Filing

December 28, 1995.

Take notice that on December 20, 1995, Northern Natural Gas Company (Northern), tendered for filing changes in its FERC Gas Tariff, Fifth Revised Volume No. 1. Northern asserts that the purpose of this filing is to comply with the Commission's order issued October 26, 1995, in Docket No. RP96–3–000.

This filing is to establish the revised 1995–1996 SBA Cost Recovery surcharge rate. Therefore, Northern has filed 8th Revised Seventeenth Revised Sheet Nos. 50 and 51 and Twenty-Sixth Revised Sheet No. 53 to revise these surcharges effective January 1, 1996.

Northern states that copies of this filing were served upon the Company's customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street N.E., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. Pursuant to Section 154.210 of the Commission's regulations, all such protests must be filed not later than 12 days after the date of the fling noted above. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestant a party to the proceedings. Copies of this filing are on file with the Commission and are available for inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–85 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–113–000]

Shell Gas Pipeline Company; Notice of Petition for Declaratory Order

December 28, 1995.

Take notice that on December 20, 1995, Shell Gas Pipeline Company (SGPC), P.O. Box 576, Houston, Texas 77001, filed a petition for declaratory order in Docket No. CP96–113–000, requesting that the Commission declare that certain facilities SGPC proposes to construct and operate in the Outer Continental Shelf (OCS) would have the primary function of gathering natural gas and would thereby be exempt from the Commission's jurisdiction pursuant to Section 1(b) of the Natural Gas Act. These natural gas pipeline and appurtenant facilities, known as the Garden Banks Gathering System, will be located entirely in OCS waters and will consist of a 50-mile, 30-inch diameter pipeline with multiple lateral lines that will deliver gas into the 30-inch pipeline from various committed production blocks. The facts are fully set forth in the petition on which is on file with the Commission and open to public inspection.

SGPC requests that the Commission evaluate the proposed Garden Banks Gathering System under the ''current modified primary function test'' used by the Commission to apply its jurisdiction over OCS facilities, and not to delay acting on its petition pending the outcome of Commission review of current policies regarding jurisdiction over OSC facilities in the Notice of Inquiry issued in Docket No. RM96–5–000.

Any person desiring to be heard or to make a protest with reference to said petition should, on or before January 18, 1996, file with the Federal Energy Regulatory Commission (888 First Street, NE, Washington, DC 20426) a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Lois D. Cashell,

Secretary.

[FR Doc. 96–88 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–114–000]

Southern Natural Gas Company; Notice of Application

December 28, 1995.

Take notice that on December 21, 1995, Southern Natural Gas Company (Southern), P.O. 2563, Birmingham, Alabama 35202–2563, filed an application in Docket No. CP96–114–000 pursuant to Sections 7(b) and Section 7(c) of the Natural Gas Act requesting permission and approval to abandon certain pipeline and appurtenant facilities and for a certificate of public convenience and necessity authorizing it to construct, install and operate modifications to certain facilities, all as more fully set forth in the application on file with the Commission and open to public inspection.

Southern requests authorization to (1) abandon by sale to the City of LaGrange, Georgia (LaGrange) approximately 34 miles of Southern's Grantville Lateral, commencing in Troup County, Georgia and extending to and including Southern's existing Grantville meter station in Coweta County, Georgia, and two laterals extending from this pipeline, as well as appurtenant facilities including five meter stations and one regulator station and (2) to modify and operate the LaGrange No. 2 meter station at Milepost 33.74 on Southern's Auburn-Grantville Line in Troup County, Georgia. Southern estimates the total cost of these facilities to be $202,000, which will be reimbursed to Southern by LaGrange.

Southern states that the abandonment will result in reduced operating expenses. The Auburn-Grantville Line, a long small-diameter pipeline with multiple meter stations, extends off of Southern's mainline facilities. Southern states that since the line is over 40 years old, maintenance expenses are relatively high. By the sale to LaGrange, Southern asserts that it will realize future savings on repairs. Southern states that as part of the purchase, LaGrange has agreed to extend the term of and increase contract demand under its firm transportation agreement with Southern, which will benefit Southern's system. Southern states that the proposal will not result in any abandonment of transportation service or change in the quality of such service to Southern's shippers and has been consented to by all of the operators of the delivery points to be affected. Southern states that all existing customers which are served at delivery points on the portion of the line to be sold have agreed to be served at the modified LaGrange No. 2 meter station.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 18, 1996, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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 application 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 and permission and approval for the proposed abandonment 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 Southern to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96–87 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–112–000]

Southern Natural Gas Company; Notice of Application for Authorization to Abandon Facilities

December 28, 1995.

Take notice that, on December 19, 1995, Southern Natural Gas Company (Southern), AmSouth-Sonat Tower, Birmingham, Alabama 35203, filed an application in Docket No. CP96–112–000, pursuant to Section 7(b) of the Natural Gas Act and Part 157 of the Commission's Regulations, for authorization to abandon its Alabaster Lime Lateral, along with a meter station and related facilities, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

Southern's Alabaster Lime lateral is a 2-inch diameter pipeline that is approximately 1.215 miles in length. It extends from milepost 25.969 on the Bessemer-Calera line, located in Section 3, T21S, R3W, in Shelby County, Alabama, to Chemical Lime Company's (ChemLime) plant in Section 35, T20S, R3W, in Alabaster, Alabama. Southern requests authorization to abandon the Alabaster Lime Lateral in-place. Southern also requests authorization to abandon, by removal, its meter station at the ChemLime plant (including the regulator) and the orderizer located at the tap on the Bessemer-Calera Line. Southern states that the Alabaster Lime Lateral and meter station which it proposes to abandon are used to provide interruptible transportation solely to the ChemLime plant, that the ChemLime plant is the only delivery point on the Alabaster Lime Lateral, and that ChemLime is the only customer that will be affected by the proposed abandonment. Southern further states that it seeks to abandon these facilities because the cost of keeping the Alabaster Lime Lateral and meter station in service has increased to the point that it is no longer economically feasible to do so.

Any person desiring to be heard, or to make any protest with reference to said application should, on or before January 18, 1996, file with the Federal Energy Regulatory Commission, Washington DC 20426, a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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 the 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 the jurisdiction conferred upon the Federal Energy Regulatory Commission's 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 application, if no motion to intervene is filed within the time required herein, or 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 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 provide for, unless otherwise advised, it will be unnecessary for Southern to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96–89 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM96–7–29–000]

Transcontinental Gas Pipe Line Corporation; Notice of Proposed Changes in FERC Gas Tariff

December 28, 1995.

Take notice that on December 21, 1995, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing certain revised tariff sheets to its FERC Gas Tariff, Third Revised Volume No. 1 enumerated in Appendix A attached to the filing.

Transco states that the purpose of the instant filing is to track rate changes attributable to storage service purchased from CNG Transmission Corporation (CNG) under its Rate Schedule GSS the costs of which are included in the rates and charges payable under Transco's Rate Schedules LSS and GSS. This tracking filing is being made pursuant to Section 4 of Transco's Rate Schedule LSS and Section 3 of Transco's Rate Schedule GSS.

Appendices B and C attached to the filing contain explanations of the rate changes and details regarding the computation of the revised LSS and GSS rates, respectively.

Transco states that copies of the filing are being mailed to each of its LSS and GSS customers and interested State Commissions.

In accordance with the provisions of Section 154.16 of the Commission's Regulations, copies of this filing are available for public inspection, during regular business hours, in a convenient form and place at Transco's main office at 2800 Post Oak Boulevard in Houston, Texas.

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, Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. Pursuant to Section 154.210 of the Commission's regulations, all such motions or protests must be filed not later than 12 days after the date of the filing noted above. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–81 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP96–88–000]

Trunkline Gas Company; Notice of Proposed Changes in FERC Gas Tariff

December 28, 1995.

Take notice that on December 21, 1995, Trunkline Gas Company (Trunkline) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets, to become effective January 21, 1996:

First Revised Sheet No. 1
Second Revised Sheet No. 3
First Revised Sheet No. 80
Second Revised Sheet No. 214
First Revised Sheet No. 381

Trunkline states the revised tariff sheets reflect the cancellation of Rate Schedule USS, which was established to sell gas to converting customers for the fourteen months following the effective date of Trunkline's restructured tariff. All service agreements under Trunkline's Rate Schedule USS terminated on or before October 31, 1994.

Trunkline states that a copy of this filing is available for public inspection during regular business hours at Trunkline's office at 5400 Westheimer Court, Houston, Texas 77056–5310. In addition a copy of this filing was mailed to affected shippers and interested state regulatory agencies.

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 Sections 385.214 and 385.211 of the Commission's Rules and Regulations. Pursuant to Section 154.210 of the Commission's regulations, all such motions or protests must be filed not later than 12 days after the date of the filing noted above. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 96–84 Filed 1–3–96; 8:45 am]

BILLING CODE 6717–01–M

FEDERAL RESERVE SYSTEM

Evans Bancshares, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than January 30, 1996.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Evans Bancshares, Inc., Evansdale, Iowa; to acquire 100 percent of the voting shares of Olmsted National Bank, Rochester, Minnesota, a *de novo* bank.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Wilson Bancshares, Inc., Wilson, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of The Wilson State Bank, Wilson, Kansas.

Board of Governors of the Federal Reserve System, December 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–95 Filed 1–3–96; 8:45 am]

BILLING CODE 6210–01–F

Mellon Bank Corporation, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless 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 January 22, 1996.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Mellon Bank Corporation, Pittsburgh, Pennsylvania; to engage *de novo* through its subsidiary, Mellon Bank, F.S.B., Paramus, New Jersey, in trust activities by acquiring certain assets from various banks and trust company subsidiaries of KeyCorp, Cleveland, Ohio, and thereby engage in trust activities, pursuant to § 225.25(b)(3) of the Board's Regulation Y.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230

South LaSalle Street, Chicago, Illinois 60690:

1. Firstbank of Illinois Co., Springfield, Illinois; to engage *de novo* through its subsidiary, MidCountry Financial, Inc., Highland, Illinois, in consumer finance business, pursuant to § 225.25(b)(1)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–96 Filed 1–3–96; 8:45 am]

BILLING CODE 6210–01–F

National Bank of Greece, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than January 22, 1996.

A. Federal Reserve Bank of New York (William L. Rutledge, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. National Bank of Greece, Athens, Greece; to retain shares of Worthington Limited Partnership, New York, New York, and thereby indirectly engage in acquiring and servicing loans and leases pursuant to §§ 225.25(b)(1) and (b)(5) of the Board's Regulation Y.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. The Sumitomo Bank, Limited, Osaka, Japan; to acquire through The Sumitomo Bank New York Trust Company, New York, New York, the trust business of Daiwa Bank Trust Company, New York, New York, and the custody business of the New York branch of The Daiwa Bank, Limited, Osaka, Japan, and thereby engage in trust company functions, pusuant to § 225.25(b)(3) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–97 Filed 1–3–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93P–0310]

White Chocolate Deviating From Identity Standard; Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is amending an extended temporary permit issued to Hershey Foods Corp. (Hershey) to market test products identified, in part, as ''white chocolate'' that deviate from the U.S. standards of identity for chocolate products, e.g., chocolate liquor, sweet chocolate, milk chocolate, buttermilk chocolate, skim milk chocolate, or mixed dairy product chocolates. The purpose of the amendment to the extended temporary permit is to allow Hershey to collect data on consumer acceptance of a different product, containing white chocolate, that also contains chocolate cookies, and to identify mass production problems.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17) concerning temporary permits, FDA gave notice in the Federal Register of November 5, 1993 (58 FR 59050), that a temporary permit had been issued to Hershey Foods Corp., P.O. Box 810, Hershey, PA 17033. The temporary permit was issued to market test products containing a component designated as ''white chocolate'' and to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The white chocolate component of these products deviates from the standards of identity for certain chocolate products, e.g., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 163.123), milk chocolate (21 CFR 163.130), buttermilk chocolate (21 CFR 163.135), skim milk chocolate (21 CFR 163.140), or mixed dairy product chocolates (21 CFR 163.145) in that: (1) It is prepared without the nonfat components of the ground cacao nibs, but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) safe and suitable antioxidants are added. The test component meets all the other requirements of the standards for chocolate products in 21 CFR part 163.

Subsequently, Hershey requested that their temporary permit (Docket No. 93P–0310) be extended to allow for additional time for the firm to continue to collect data on consumer acceptance of the products while the agency takes action on two petitions (Docket Nos. 86P–0297/CP 2 and 86P–0297/CP 3 (see 59 FR 67302, December 29, 1994, for discussion)) to establish a standard of identity for white chocolate that were submitted by Hershey and by the Chocolate Manufacturers Association. FDA granted the request for the extension and provided for continued testing on an annual basis of up to 21,800,000 kilograms (kg) (48,000,000 pounds (lb)) of the test product. The test products bear the fanciful names ''Hershey's Hugs, Mini Hershey's Kisses Hugged by White Chocolate'' and ''Hershey's Hugs, Mini Hershey's Kisses Hugged by White Chocolate, with Almonds.'' In the Federal Register of December 29, 1994 (59 FR 67302), FDA extended the expiration date of the

permit so that the permit expires either on the effective date of a final rule to establish a standard of identity for white chocolate, which may result from the petitions, or 30 days after termination of such rulemaking.

Hershey is now requesting that the extended temporary permit be amended to provide for up to 13,600,000 kg (30,000,000 lb) of a different product, containing white chocolate, that also contains chocolate cookies. Hershey is also requesting that the permit be amended to allow an additional plant where this product can be manufactured.

The agency finds that it is in the interest of the consumer to amend the extended temporary permit to allow for market testing of another product containing white chocolate. Therefore, under the provisions of § 130.17(f), FDA is modifying the extended temporary permit granted to Hershey to provide for the market testing of up to 13,600,000 kg (30,000,000 lb) of the new test product on an annual basis in addition to the 21,800,000 kg (48,000,000 lb) of test product authorized in the original permit. The new test product, in bar and bite size forms, will bear the fanciful name ''Hershey's Cookies 'n' Creme Chocolate Cookie Bits in White Chocolate.'' The white chocolate meets the compositional requirements of the current temporary permit. FDA is also modifying the extended temporary permit to provide for an additional plant at Hershey Chocolate, U.S.A., 19 East Chocolate Ave., Hershey, PA 17033, where the product may be manufactured. The product will be distributed nationwide.

Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101. This amended extended permit expires either on the effective date of a final rule to establish a standard of identity for white chocolate, which may result from the petitions, or 30 days after termination of such rulemaking. All other conditions and terms of the extended permit remain the same.

Dated: December 15, 1995.

F. Edward Scarbrough,

Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–124 Filed 1–3–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95S–0199]

Report of the Fluoroquinolone Working Group; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report of the Center for Veterinary Medicine's (CVM's) Fluoroquinolone Working Group (FQWG). The report addresses issues and contains recommendations regarding policies and procedures related to approval of fluoroquinolone (FQ) antimicrobial drugs in food animals. The report of the FQWG is in response to concerns that approval of FQ drugs for use in food animals may result in increased development of FQ resistance in zoonotic organisms harbored by food animals that are transmitted to humans and cause disease.

DATES: Written comments on the report may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the report to the Communication and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the report to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville MD, 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the report and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Linda A. Grassie, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the report of CVM's FQWG. The report addresses issues and recommendations concerning approval of FQ drugs for use in food animals. In response to concerns that approval of FQ drugs for use in food animals may result in increased development of FQ resistance in zoonotic organisms harbored by food animals that are transmitted to humans and cause disease. FDA convened a joint meeting of the CVM and Center for Drug Evaluation and Research advisory committees on May 11 and 12, 1994. Members of the joint advisory committee stated that FQ drugs could be approved for use in food animals, if CVM restricts their use so that FQ's are safe and effective under approved conditions of use and recommended that CVM monitor the emergence of FQ resistance. In response to the public health concerns that were raised, CVM formed the FQWG to provide recommendations of policies and procedures relevant to the approval of FQ drugs in food animals. FDA is announcing that the report of the FQWG has been accepted by the Director, CVM, and is available for public inspection and comment.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the report of CVM's FQWG. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the heading of this document. The report, appendices, and comments may be seen at the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

The report and recommendations represent the agency's current position on the issues discussed therein, however, they do not create or confer any rights, privileges, or benefits for or on any person, nor do they operate to bind FDA in any way. CVM will consider any comments received in determining the continued appropriateness of the recommendations in the report regarding the approval of FQ's for animal use.

Dated: December 27, 1995.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–125 Filed 1–3–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. FR–4007–D–01]

Delegation of Concurrent Authority to the Deputy Secretary

AGENCY: Office of The Secretary, HUD.

ACTION: Notice of delegation of concurrent authority.

SUMMARY: The Secretary of Housing and Urban Development is delegating to the Deputy Secretary of Housing and Urban Development, Dwight P. Robinson, concurrently with the Secretary, the power and authority vested in or delegated or assigned to the Secretary of Housing and Urban Development, with the exception of the power to sue and be sued.

EFFECTIVE DATE: December 28, 1995.

FOR FURTHER INFORMATION CONTACT: Sam E. Hutchinson, Associate General Counsel for Human Resources Law, Office of General Counsel, Department of Housing and Urban Development, Room 10242, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–0888. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d), the Secretary of Housing and Urban Development may delegate any of the Secretary's functions, powers and duties to such officers and employees of the Department as the Secretary may designate, and may authorize successive redelegations of such functions, powers and duties as determined to be necessary or appropriate. In the delegation of authority issued today, the Secretary is delegating to the Deputy Secretary of Housing and Urban Development, Dwight P. Robinson, all the power and authority vested in or delegated or assigned to the Secretary of Housing and Urban Development, to be exercised concurrently with the Secretary, with the exception of the power to sue and be sued.

Accordingly, the Secretary delegates as follows:

Section A. Authority Delegated

The Deputy Secretary of Housing and Urban Development, Dwight P. Robinson, is hereby authorized, concurrently with the Secretary, to exercise all the power and authority vested in or delegated or assigned to the Secretary of Housing and Urban Development.

Section B. Authority Excepted

There is excepted from the authority delegated under Section the authority to sue and be sued.

Section C. Delegation of Concurrent Authority Superseded

The Delegation of Concurrent Authority to the President, Government National Mortgage Association, published in the Federal Register on February 13, 1995, at 60 FR 8250, is hereby superseded.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: December 28, 1995.

Henry G. Cisneros,

Secretary of Housing and Urban Development.

[FR Doc. 96–101 Filed 1–3–96; 8:45 am]

BILLING CODE 4210–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Lower Snake River District; Notice of Meeting

SUMMARY: The Lower Snake River District Resource Advisory Council will hold two meetings to discuss and develop draft statewide standards for rangeland health and guidelines for managing livestock grazing on public lands. Public comment periods will be held at 1 p.m. on January 25 and at 8 p.m. on February 15.

DATES: January 25, 1996 beginning at 8:15 a.m.; and February 15, 1996, beginning at 6:30 p.m.

ADDRESSES: The meetings will be held at the Idaho State Office of the Bureau of Land Management, 3380 Americana Terrace, Boise, Idaho, 83706.

FOR FURTHER INFORMATION CONTACT: Barry Rose, Lower Snake River District Office (208–384–3393).

Barry Rose,

Public Affairs Specialist.

[FR Doc. 96–91 Filed 1–3–96; 8:45 am]

BILLING CODE 1020–GG–P

INTERSTATE COMMERCE COMMISSION

[Docket No. AB–43 (Sub-No. 169X)]

Illinois Central Railroad Company—Abandonment Exemption—in West Feliciana Parish, LA

Illinois Central Railroad Company (IC) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon approximately 0.8 miles of its line of railroad between milepost LB–9.7 to milepost LB–10.5 near Riddle (Zee), in West Feliciana Parish, LA.

IC has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) all overhead traffic previously routed over this line has been rerouted to alternate lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to use of this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 3, 1996, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29[3] must be filed by January 16, 1996. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 24, 1996, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, 1201 Constitution Ave., N.W., Washington, DC 20423.[4]

A copy of any pleading filed with the Commission should be sent to applicant's representative: Myles L. Tobin, Illinois Central Railroad Company, 455 North Cityfront Plaza Dr., 20th Floor, Chicago, IL 60611.

If the notice of exemption contains false or misleading information, the exemption is void *ab initio.*

IC has filed an environmental report which addresses the abandonment's

[1] A stay will be issued routinely by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Environmental Analysis in its independent investigation) cannot be made before the effective date of the notice of exemption. *See Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental concerns is encouraged to file its request as soon as possible in order to permit the Commission to review and act on the request before the effective date of this exemption.

[2] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

[4] Legislation to sunset the Commission on December 31, 1995, and transfer remaining functions is currently under consideration. Until further notice, parties submitting pleadings should continue to use the current name and address.

effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by January 9, 1996. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA is available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 28, 1995.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–136 Filed 1–3–96; 8:45 am]

BILLING CODE 7035–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. Part 110]

General and Specific Licenses Authorizing Exports of Nuclear Reactor Components, Substances, and Items Under Section 109b of the Atomic Energy Act to EURATOM; Order Suspending Licenses (Effective January 1, 1996)

I

The licensees that are subject to this order are authorized by the Nuclear Regulatory Commission (''NRC'' or ''Commission'') through general and specific licenses granted under Section 109b of the Atomic Energy Act of 1954, as amended (AEA), and 10 C.F.R. Part 110 to export nuclear reactor components, substances, and items for nuclear end uses to EURATOM on the basis of assurances provided by EURATOM to the U.S. pursuant to Section 109b (''EURATOM assurances''). The expiration date of the EURATOM assurances underlying the NRC's general and specific license authorizations for exports of nuclear reactor components, substances, and items under Section 109b is tied to the expiration date of the current Agreement for Cooperation between the U.S. and EURATOM under Section 123 of the AEA.

II

The EURATOM assurances will expire on December 31, 1995, the expiration date of the current Agreement for Cooperation between the U.S. and EURATOM. Although a new Section 123 Agreement for Cooperation has been approved by authorities on both sides,[1] the U.S. has not received new Section 109b assurances from EURATOM. The NRC is prohibited from authorizing any exports of nuclear reactor components, substances, and items to a foreign nation under Section 109b in the absence of such assurances from the foreign nation.

III

Accordingly, pursuant to Sections 109b, 161b, 161i, 183, and 186 of the AEA, and 10 C.F.R. §§ 110.50(a) (1) and (2) and 110.52, from January 1, 1996 until such time that the U.S. receives the assurances required for exports of nuclear reactor components, substances, and items under Section 109b of the AEA from EURATOM or its individual member countries,[2] NRC general and specific license authorizations under Section 109b and 10 C.F.R. §§ 110.26 and 110.42(b) for exports of nuclear reactor components to EURATOM countries are suspended.[3] This suspension order will expire by operation of law when the assurances required under Section 109b are received from EURATOM or its individual member countries. The NRC will publish notice of the receipt of these assurances in the Federal Register.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland this 28th day of December, 1995.

Carlton R. Stoiber,

Director, Office of International Programs.

[FR Doc. 96–111 Filed 1–3–96; 8:45 am]

BILLING CODE 7590–01–M

[1] The new Agreement must sit before Congress for review for up to 90 days of continuous legislative session.

[2] The EURATOM Member States are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and the United Kingdom. Licensees authorized under general or specific licenses to make Section 109b exports to Austria, Finland, Spain, or Sweden may continue direct exports to these countries because they have provided separate bilateral assurances to the U.S. that remain in effect.

[3] In accordance with 10 C.F.R. § 110.52(c), the Commission finds that Licensees need not be afforded an opportunity to reply and be heard because this action is required by operation of law and the common defense and security.

[Docket No. 50–285]

Omaha Public Power District, Fort Calhoun Station, Unit 1; Exemption

I

The Omaha Public Power District (OPPD or the licensee) holds Facility Operating License No. DPR–40, which authorizes operation of the Fort Calhoun Station, Unit 1. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (the Commission) now or hereafter in effect. The facility consists of one pressurized water reactor located at the licensee's site in Washington County, Nebraska.

II

Section 50.54(q) of 10 CFR part 50 requires a licensee authorized to operate a nuclear power reactor to follow and maintain in effect emergency plans which meet the standards of 10 CFR 50.47(b) and the requirements of Appendix E to 10 CFR part 50. Section IV.F.2.c of Appendix E requires that each licensee at each site conduct an exercise with offsite authorities such that the State and local government emergency plans for each operating reactor site are exercised biennially. Section IV.F.2 also requires full or partial participation by State and local governments within the plume exposure pathway emergency planning zone (EPZ).

The NRC may grant exemptions from the requirements of the regulations which, pursuant to 10 CFR 50.12(a), are (1) authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) present special circumstances. Section 50.12(a)(2)(v) of 10 CFR 50 describes the special circumstances where an exemption would provide only temporary relief from the applicable regulations and the licensee or applicant has made good faith efforts to comply with the regulations.

III

By letter dated December 8, 1995, and supplemental letter dated December 15, 1995, OPPD requested a schedular exemption from the requirements of 10 CFR 50, Appendix E, Section IV.F.2.c that requires a biennial exercise with State and local government authorities within the plume exposure pathway emergency planning zone (EPZ). The licensee has requested to postpone, until the first quarter of 1996, the offsite portion of the biennial full-scale

emergency preparedness exercise which had been scheduled for November 1995.

This schedular exemption is requested by the licensee since the Federal Emergency Management Agency (FEMA) and the States had to cancel their evaluation and participation in the offsite portion of the exercise conducted on November 14, 1995. This request resulted from the impasse relative to passage of the Federal budget that caused a shutdown of FEMA and lack of funding for some State appropriations.

The licensee provided the following basis for supporting the requested schedular exemption:

OPPD, along with the States of Nebraska and Iowa, as well as local officials and volunteer agencies, were fully prepared to conduct a biennial full-scale emergency exercise for the Fort Calhoun Station (FCS) on November 14, 1995. The onsite and offsite objectives and scenario were approved respectively by NRC and FEMA. This exercise was designed to satisfy the requirements of 10 CFR 50, Appendix E, Section IV.F.2.c. The last biennial exercise was conducted on June 29–30, 1993.

In the weeks prior to the exercise, FEMA was unsure whether it could support the exercise as the result of the Federal budget impasse. Some State of Nebraska personnel were also affected by the budget crisis in that some State positions are federally funded. The licensee satisfactorily conducted the onsite portion of the exercise in the absence of full participation by the States and evaluation by FEMA. There were no identified exercise weaknesses associated with the onsite portion of the exercise.

Based upon a review of the licensee's request for a schedular exemption from the requirements of 10 CFR 50, Appendix E, Section IV.F.2.c, the staff finds that the exemption would provide only temporary relief from the applicable regulations.

IV

Accordingly, the Commission has determined pursuant to 10 CFR 50.12, this exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. The Commission further determines that special circumstances described by 10 CFR 50.12(a)(2)(v) exist in that granting the exemption would provide only temporary relief from the applicable regulations and the licensee has made good faith efforts to comply with the regulations.

Therefore, the Commission hereby grants Omaha Public Power District an exemption from the requirements of 10 CFR 50, Appendix E, Section IV.F.2.c.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will have no significant impact on the quality of the human environment (60 FR 66995).

Dated at Rockville, Maryland, this 28th day of December 1995.

This exemption is effective upon issuance.

For the Nuclear Regulatory Commission.

Gail H. Marcus,

Acting Director, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–112 Filed 1–3–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–352 and 50–353]

Philadelphia Electric Company; Correction

The December 6, 1995, Federal Register contained a ''Notice of Issuance of Amendment to Facility Operating Licenses,'' for the Limerick Generating Station, Units 1 and 2. This notice corrects the notice published in the Federal Register on December 6, 1995, (60 FR 62500). The ''Amendment Nos.'' Section should read ''105 and 69.''

Dated at Rockville, Maryland, this 27th day of December 1995.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–2, Division of Reactor Projects–I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 96–109 Filed 1–3–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 72–14 (50–346)]

Toledo Edison Co., Davis-Besse Nuclear Power Station, Independent Spent Fuel, Storage Installation; Exemption

I

Toledo Edison Company (the licensee), under the general license in Part 72, Subpart K, is authorized to receive and store spent fuel from its Davis-Besse Nuclear Power Station at an independent spent fuel storage installation (ISFSI) located on the Davis-Besse Nuclear Power Station site. This facility is located at the licensee's site in Oak Harbor, Ohio.

II

Pursuant to 10 CFR 72.7, the Nuclear Regulatory Commission (NRC) may grant exemptions from the requirements of the regulations in 10 CFR Part 72 as it determines are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest.

Section 72.82(e) of 10 CFR Part 72 requires each licensee to provide a report of preoperational test acceptance criteria and test results to the appropriate NRC Regional Office with a copy to the Director, Office of Nuclear Material Safety and Safeguards, at least 30 days prior to receipt of spent fuel or high-level radioactive waste for storage in an ISFSI. The purpose of the 30-day waiting period is to allow the NRC an opportunity to review test results prior to initial operation of the ISFSI. If an exemption from the requirement of 10 CFR 72.82(e) for a 30-day waiting period was granted, the licensee still would be required to submit the necessary report; however, the licensee could thereafter start loading the first cask before the end of the 30-day period.

III

By letter dated September 22, 1995, the licensee requested a schedular exemption pursuant to 10 CFR 72.7 from the requirement of 10 CFR 72.82(e). The licensee committed to submit its report no less than 3 days prior to receipt of spent fuel at its ISFSI. The licensee's exemption request to reduce the 30-day waiting period to 3 days was based on the licensee's need to assure the availability of adequate storage space in Davis-Besse's spent fuel pool to support a refueling outage scheduled to begin in April 1996. To meet that schedule, spent fuel must be removed from the pool and loaded into the dry storage casks at the Davis-Besse plant for transport to the ISFSI prior to receipt of new fuel in February 1996. Because moving and loading the canisters into the horizontal storage modules occurs outside the auxiliary building, and because conducting such activities during inclement weather would complicate these activities, the licensee had planned to begin loading activities in October 1995. Delays, however, have forced the licensee to postpone its schedule. Nonetheless, the need for and underlying basis of the licensee's exemption requests remains. Granting the requested exemption from the 30-day waiting period in 10 CFR 72.82(e) would assist the licensee in assuring it has sufficient time to complete loading operations for dry cask storage before the end of January 1996 while, to the extent possible, minimizing the need to conduct fuel handling activities during inclement weather. Moreover, as noted below, the NRC has completed review of the

licensee's preoperational test report and therefore does not need the full 30 days contemplated by 10 CFR 72.82(e).

In a letter dated December 18, 1995, the licensee reiterated the need for the requested exemption and provided additional information on current circumstances supporting NRC approval. The December 18 letter (and additional information in it) are not necessary to a favorable consideration of the exemption request by NRC. However, the letter confirms the propriety of an exemption.

The NRC conducted an inspection related to the manufacture of the storage canisters at the vendor's fabrication site, and on July 7, 1995, issued a Confirmatory Action Letter to the vendor. The vendor responded to the Confirmatory Action Letter on September 5, 20, 22, and October 2 and 3, 1995. In a letter dated October 12, 1995, NRC found the vendor's responses acceptable. NRC was able to resolve the inspection issues based on the additional information provided by the vendor which included documentation of design changes and associated safety evaluations, engineering analysis regarding the minimum required canister wall thickness, the results of measurements of the actual wall thickness of the canisters, and detailed information on leak testing performed. NRC verified the adequacy of the additional information provided by the vendor and the safety of the canisters and the transfer cask by performing detailed reviews, engineering evaluations, and inspections.

Since receipt of the first canisters on site, NRC has observed selected portions of the preoperational testing activities and has reviewed associated test procedures and results. The licensee submitted the report of preoperational test acceptance criteria and test results required by 10 CFR 72.82(e) to NRC Region III on December 14, 1995. The preoperational tests conducted by the licensee included, among other things, the actual exercise of the licensee's written procedures for loading and unloading the storage canisters. The licensee reviewed the results of these tests, made changes and subsequently approved the canister loading and unloading procedures. The NRC observed licensee's validation of the acceptability of these procedures and is satisfied with the results.

IV

Based on the aforementioned oversight and inspection of the preoperational testing activities at the Davis-Besse ISFSI, as well as the NRC's review of the licensee's report of preoperational test criteria and results, the NRC finds that Toledo Edison has satisfactorily addressed all of the safety issues associated with cask loading, handling, and storage. The results of these NRC activities confirm there is adequate assurance that the cask can perform its intended safety functions and that Toledo Edison has the necessary equipment and procedures in place, as well as appropriately trained personnel, to safely conduct spent fuel cask handling activities.

Accordingly, the NRC has determined in accordance with 10 CFR 72.7 that this exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC hereby grants the licensee an exemption from the 30-day waiting period required by 10 CFR 72.82(e). The effective date of this exemption shall be December 26, 1995. This exemption will allow the licensee, effective December 26, to commence loading spent fuel into the dry storage canister, for subsequent transfer to and storage in the Davis-Besse ISFSI. The exemption also permits the licensee, prior to December 26, to start any necessary work that is a prerequisite to loading fuel on December 26. While not providing Toledo Edison Company the full schedular relief it requested, the exemption will result in the Company being able to begin dry storage activities approximately two weeks earlier than without the exemption.

The documents related to this proposed action are available for public inspection and for copying (for a fee) at the NRC Public Document Room at the Gelman Building, 2120 L Street, NW, Washington, DC 20555, and at the Local Public Document Room located in the William Carlson Library, University of Toledo, 2801 West Bancroft Avenue, Toledo, Ohio 43605.

Pursuant to 10 CFR 51.32, the NRC has determined that granting this exemption will have no significant impact on the quality of the human environment (60 FR 52709).

Dated at Rockville, Maryland this 20th day of December 1995.

For the Nuclear Regulatory Commission.

William D. Travers,

Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–110 Filed 1–3–96; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF GOVERNMENT ETHICS

Advance Notice of Proposed Modified Form for Requesting Access to Executive Branch Public Financial Disclosure Reports and Other Covered Records to Be Submitted to OMB for Approval Under the Paperwork Reduction Act

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice.

SUMMARY: The Office of Government Ethics plans to submit a slightly modified OGE form used by persons for requesting access to executive branch public financial disclosure reports and other covered records for approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. This modified form will replace the existing one.

DATES: Comments on this proposal should be received by March 19, 1996.

ADDRESSES: Comments should be sent to William E. Gressman, Office of Government Ethics, Suite 500, 1201 New York Avenue, NW., Washington, DC 20005–3917.

FOR FURTHER INFORMATION CONTACT: Mr. Gressman at the Office of Government Ethics; telephone: 202–523–5757, ext. 1110; FAX: 202–523–6325. A copy of OGE's draft form may be obtained, without charge, by contacting Mr. Gressman.

SUPPLEMENTARY INFORMATION: The Office of Government Ethics is planning to submit, after this notice and comment period (with any modifications that may appear warranted), a proposed modified OGE Form 201 ''Request to Inspect or Receive Copies of SF 278 Executive Branch Personnel Public Financial Disclosure Report or Other Covered Record'' for three-year approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Once finally approved by OMB and adopted by OGE, the modified version of this OGE form will replace the existing version (whose paperwork clearance is scheduled to expire at the end of next July).

The Office of Government Ethics, as the supervising ethics office for the executive branch of the Federal Government under the Ethics in Government Act (the ''Ethics Act''), is planning to modify and update the existing access form. That form, the OGE Form 201, collects information from, and provides certain information to, persons who seek access to SF 278 reports and other covered records. The form reflects the requirements of the

Ethics Act and OGE's implementing regulations that must be met by a person before access can be granted. These requirements relate to information about the identity of the requester, as well as any other person on whose behalf a record is sought, and a notification of prohibited uses of SF 278 reports. See section 105 (b) and (c) of the Ethics Act, 5 U.S.C. app., sec. 105 (b) and (c), and 5 CFR 2634.603 (c) and (f). For many years, OGE has disseminated to executive branch departments and agencies a locally reproducible uniform form to serve as the statutorily required written application to inspect or receive copies of SF 278 reports and other covered records. Departments and agencies are encouraged to utilize the OGE Form 201, but they can, if they so choose, continue to use or develop their own forms (see the discussion below).

This proposed modified version of the OGE Form 201 will add express mention (in part III of the form) to another category of materials subject to public access under the Ethics Act—Ethics Act-qualified blind trust and qualified diversified trust instruments and the list of assets transferred to such trusts (& of assets sold in the case of a qualified blind trust). See 5 CFR 2634.603(g)(2). The other change to the form would add to the part C public burden information block a statement required under the 1995 amendments to the paperwork law to the effect that ''an agency may not conduct or sponsor, and no person is required to respond to, a collection of information unless it displays a currently valid OMB control number,'' together with a parenthetical mention that such number is displayed in the upper right-hand corner of the front page of the OGE Form 201.

In light of OGE's experience over the past three years (1993–1995), the estimate of the total number of access forms expected to be filed annually at OGE by members of the public (primarily by news media, public interest groups and private citizens) is proposed to be adjusted up somewhat from 250 to 275 (access requests by other Federal agencies or Federal employees are not included). The estimated average amount of time to complete the form, including review of the instructions, remains at ten minutes. Thus, the overall estimated annual public burden for the OGE Form 201 for forms filed at the Office of Government Ethics will increase from 42 hours in the current OMB paperwork inventory listing (250 forms X 10 minutes per form—number rounded off) to 46 hours (275 forms X 10 minutes per form—number rounded off). Moreover, OGE estimates, based on the agency ethics program questionnaire responses for the past couple of years, that some 1,500 access request forms will be filed each year at the other executive branch departments and agencies.

The Office of Government Ethics expects that the new form should be ready, after OMB clearance, for dissemination to executive branch departments and agencies next summer. The Office of Government Ethics will provide appropriate guidance and phase-in time to departments and agencies once the new form is available. The new form will be made available free-of-charge to departments and agencies on paper, on electronic disk and on OGE's electronic bulletin board entitled ''The Ethics Bulletin Board System'' (TEBBS). In addition, if there is sufficient interest, OGE will consider making available a future electronic version of the form, to allow persons the option of preparing it on a computer. The Office of Government Ethics also will permit departments and agencies to photocopy or have copies printed of the form as well as to develop or utilize, on their own, electronic versions of the form provided that they precisely duplicate the paper original to the extent possible. As noted above, agencies can also develop their own access forms, provided all the information required by the Ethics Act and OGE regulations is placed on the form, along with appropriate Privacy Act and paperwork notices with the attendant clearances being obtained therefor.

Public comment is invited on each aspect of the proposed modified OGE Form 201 as set forth in this notice, including specifically views on the need for and practical utility of this proposed modified collection of information, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology).

Comments received in response to this notice will be summarized for, and may be included with, the OGE request for OMB paperwork approval for this modified information collection. The comments will also become a matter of public record.

Approved: December 28, 1995.

Donald E. Campbell,

Deputy Director, Office of Government Ethics.

[FR Doc. 96–94 Filed 1–3–96; 8:45 am]

BILLING CODE 6345–01–U

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–36650; File No. S7–24–89]

Joint Industry Plan; Solicitation of Comments and Order Approving Amendment No. 7 to Reporting Plan for Nasdaq/National Market Securities Traded on an Exchange on an Unlisted or Listed Basis, Submitted by the National Association of Securities Dealers, Inc., and the Boston, Chicago and Philadelphia Stock Exchanges

December 28, 1995.

On December 28, 1995, the National Association of Securities Dealers, Inc., and the Boston, Chicago, and Philadelphia Stock Exchanges (collectively, ''Participants'') [1] submitted to the Commission proposed Amendment No. 7 to a joint transaction reporting plan (''Plan'') for Nasdaq/National Market securities traded on an exchange on an unlisted or listed basis.[2] Amendment No. 7 would extend the effectiveness of the plan through March 5, 1996.[3] This order approves Amendment No. 7 to the Plan, thereby approving its operation through March 5, 1996.

[1] The signatories to the Plan, i.e., the National Association of Securities Dealers, Inc. (''NASD''), and the Chicago Stock Exchange, Inc. (''Chx'') (previously, the Midwest Stock Exchange, Inc.), the Philadelphia Stock Exchange, Inc. (''Phlx''), and the Boston Stock Exchange, Inc. (''BSE''), are the ''Participants.'' The BSE, however, joined the Plan as a ''Limited Participant,'' and reports quotation information and transaction reports only in Nasdaq/National Market (previously referred to as ''Nasdaq/NMS'') securities listed on the BSE. Originally, the American Stock Exchange, Inc., was a Participant to the Plan, but did not trade securities pursuant to the Plan, and withdrew from participation in the Plan in August 1994.

[2] Section 12 of the Act generally requires an exchange to trade only those securities that the exchange lists, except that Section 12(f) of the Act permits unlisted trading privileges (''UTP'') under certain circumstances. For example, Section 12(f), among other things, permits exchanges to trade certain securities that are traded over-the-counter (''OTC/UTP''), but only pursuant to a Commission order or rule. The present order fulfills this Section 12(f) requirement. For a more complete discussion of this Section 12(f) requirement, *see* November 1995 Extension Order, *infa* note 3, at n. 2.

[3] On November 13, 1995, the Commission extended the effectiveness of the Plan through December 12, 1995, by partially approving Amendment No. 6. Amendment No. 6 requested an extension of the effectiveness of the Plan through December 29, 1995. *See* Securities Exchange Act Release No. 36481 (November 13,1 995), 60 FR 58119 (''November 1995 Extension Order''). Thereafter, the Commission approved the remainder of Amendment No. 6 by approving operation of the Plan through December 29, 1995. *See* Securities Exchange Act Release No. 36589 (December 13, 1995), 60 FR 65696 (''December 1995 Extension Order'').

I. Background

The Commission originally approved the Plan on June 26, 1990.[4] The Plan governs the collection, consolidation and dissemination of quotation and transaction information for Nasdaq/National Market securities listed on an exchange or traded on an exchange pursuant to UTP. The Commission has extended the effectiveness of the Plan six times since then to allow the Participants to trade pursuant to the Plan while they finalize their negotiations for revenue sharing under the plan.[5]

As originally approved by the Commission, the Plan required the Participants to complete their negotiations regarding revenue sharing during the one-year pilot period. The January 1995 Extension Order approved the effectiveness of the Plan through August 12, 1995. Since January 1995, the Commission has expected the Participants to conclude their financial negotiations promptly and to submit a filing to the Commission that reflected the results of the negotiations. Moreover, the Commission's August 1995 Extension Order required the Participants to submit a filing concerning revenue sharing on or before August 31, 1995. The Commission's December 1995 Extension Order noted that request, and further requested that the Participants submit to the Commission, on or before December 20, 1995, a proposed revenue sharing amendment, along with a proposed amendment to extend the effectiveness of the Plan through the pending period for the financial proposal.

The Commission currently believes it is appropriate to extend the effectiveness of the Plan through March 5, 1996, so that operation of the Plan may continue while the Commission awaits these amendments and prepares them for publication in the Federal Register.

II. Extension of Certain Exemptive Relief

In conjunction with the Plan, on a temporary basis scheduled to expire on December 29, 1995, the Commission granted an exemption from Rule 11Ac1–2 under the Act regarding the calculated best bid and offer (''BBO''), and granted the BSE an exemption from the provision of Rule 11Aa3–1 under the Act that requires transaction reporting plans to include market identifiers for transaction reports and last sale data. This order extends these exemptions through march 5, 1996. Further, this extension will remain in effect only if the Plan continues in effect through that date pursuant to a Commission order.[6] The Commission continues to believe that this exemptive relief is appropriate through March 5, 1996.

III. Comments on the Operation of the Plan

In the January 1995 Extension Order, the August 1995 Extension Order, the September 1995 Extension Order, the October 1995 Extension Order, and the November 1995 Extension Order, the Commission solicited, among other things, comment on: (1) Whether the BBO calculation for the relevant securities should be based on price and time only (as currently is the case) or if the calculation should include size of the quoted bid or offer; and (2) whether there is a need for an intermarket linkage for order routing and execution and an accompanying trade-through rule. The Commission continues to solicit comment on these matters.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Room. All submissions should refer to File No. S7–24–89 and should be submitted by January 25, 1996.

V. Conclusion

The Commission finds that proposed Amendment No. 7 to the Plan to extend the operation of the Plan and the financial negotiation period through March 5, 1996, is appropriate and in furtherance of Section 11A of the Act. The Commission finds further that extension of the exemptive relief through March 5, 1996, as described above, also is consistent with the Act and the Rules thereunder. Specifically, the Commission believes that these extensions should serve to provide the Participants with more time to conclude their financial negotiations and to submit the necessary filings to the Commission. This, in turn, should further the objects of the Act in general, and specifically those set forth in Sections 12(f) and 11A of the Act and in Rules 11Aa3–1 and 11Aa3–2 thereunder.

It is therefore ordered, pursuant to Sections 12(f) and 11A of the Act and (c)(2) of Rule 11Aa3–2 thereunder, that Amendment No. 7 to the Joint Transaction Reporting Plan for Nasdaq/National Market securities traded on an exchange on an unlisted or listed basis is hereby approved and trading pursuant to the Plan is hereby approved on a temporary basis through March 5, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(29).

Jonathan G. Katz,

Secretary.

[FR Doc. 96–128 Filed 1–3–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36631; File No. SR–CSE–95–08]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Cincinnati Stock Exchange, Inc. Relating to Exchange Rule 11.10, National Securities Trading System Fees

December 21, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on November 16, 1995 the Cincinnati Stock

[4] *See* Securities Exchange Act Release No. 28146 (June 26, 1990), 55 FR 27917 (''1990 Approval Order''). For a detailed discussion of the history of UTP in OTC securities, and the events that led to the present plan and pilot program, *see* 1994 Extension Order, *infra* note 5.

[5] *See* Securities Exchange Act Release No. 34371 (July 13, 1994), 59 FR 37103 (''1994 Extension Order''). *See also* Securities Exchange Act Release No. 35221, (January 11, 1995), 60 FR 3886 Release No. 36102 (August 14, 1995), 60 FR 43626 (''August 1995 Extension order''), Securities Exchange Act Release No. 36226 (September 13, 1995), 60 FR 49029 (''September 1995 Extension Order''), Securities Exchange Act Release No. 36368 (October 13, 1995), 60 FR 54091 (''October 1995 Extension Order''), and the November and December 1995 Extension Orders, *supra* note 3.

[6] In the December 1995 Extension Order, the Commission extended these exemptions through December 29, 1995. Pursuant to a request made by the NASD, this order further extends the effectiveness of the relevant exemptions through March 5, 1996. *See* letter from Richard Ketchum, Chief Operating Officer and Executive Vice President, NASD, to Jonathan G. Katz, Secretary, Commission, dated December 22, 1995.

[1] 15 U.S.C. 78s(b)(1).

Exchange, Inc. (''CSE'' or ''Exchange'') 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. On December 1, 1995, the Exchange submitted Amendment No. 1 text to the proposed rule change.[2] On December 20, 1995, the Exchange submitted Amendment No. 2 to the proposed rule change.[3] 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 Exchange hereby amends Rule 11.10 regarding fees imposed by the Exchange. The text of the proposed rule change is as follows [new text is italicized; deleted text is bracketed]:

Rule 11.10 National Securities Trading System Fees

A. Agency Transactions.

Except for Preferenced transactions, members acting as an agent will be charged $0.0025 per share ($0.25/100 shares) for public agency transactions. [except that there will be no transaction fee charge for public agency limit orders executed from the CSE limit order book.]

B. through F. No. Change.

G. Proprietary (principal) Transactions.

1. *All* Designated Dealers, *except those acting as Preferencing Dealers or Contributing Dealers,* will be charged *$0.005 per share ($0.50/100 shares)* [$.0075 per share ($0.75/100 shares)] for principal transactions *excluding ITS transactions.* [unless acting as Dealer of the Day, a Preferencing Dealer or a Contributing Dealer except, ITS Transactions] *Designated Dealers* will be billed $0.0050 per share on outbound *ITS* trades and $0.0000 per share on inbound *ITS* trades. *All Designated Dealers' charges are* subject to *the minimum charges set forth in* paragraph 5 below. (Billable shares shall not exceed 650,000 shares times the number of trading days in any given month.)

2. through 5. No Change.

H. through M. No Change.

[2] *See* Letter from Robert Ackermann, Vice President Regulatory Services, CSE, to Glen Barrentine, Team Leader, Division of Market Regulation, SEC, dated December 1, 1995. In Amendment No. 1, the Exchange clarified that Designated Dealer (''DD'') transactions resulting from trades assigned to the DD acting as ''Dealer of the Day'' are charged at the rate of $0.005 per share.

[3] *See* Letter from Robert Ackermann, Vice President Regulatory Services, CSE, to Glen Barrentine, Team Leader, Division of Market Regulation, SEC, dated December 20, 1995. In Amendment No. 2, the Exchange submitted revised text to proposed CSE Rule 11.10 G(1).

II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change

1. Purpose

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

The Exchange has determined to amend the fee charged limit orders executed through the facilities of the Exchange's limit order book such that the fee charged for market orders and limit orders executed through that facility will be the same.[4] Additionally, the fee charged Designated Dealers[5] has been lowered.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[6] in general and furthers the objectives of Section 6(b)(4)[7] in particular in that it provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes or changes a due, fee, or other charge imposed by the Exchange and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and subparagraph (e) of Rule 19b–4 thereunder.[9]

At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Cincinnati Stock Exchange. All submissions should refer to File No. SR–CSE–95–08 and should be submitted by January 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

[4] In order to encourage all members to place public agency limit orders on the CSE book, the Exchange in August 1994 amended Rule 11.10 to eliminate the transaction charge on public agency limit orders. *See* Securities Exchange Act Release No. 34493, (August 5, 1994), 59 FR 41531 (August 12, 1994) (approving File No. SR–CSE–94–6).

[5] A Designated Dealer (''DD'') is a proprietary member who maintains a minimum net capital of at least the greater of $100,000 or the amount required under Rule 15c3–1 of the Act, and who has been approved by the Exchange's Securities Committee to perform market functions by entering bids and offers for securities designated by the Securities Committee to be traded in the CSE's National Securities Trading System (''designated issues'') into that System. *See* CSE Rule 11.9(a)(3). The DD status obligates the dealer to guarantee execution of all public agency market orders and agency limit orders up to 2,099 shares. *See* Release No. 34493, *supra* note 4.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4.

[10] 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–79 Filed 1–3–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36630; File No. SR–NYSE–95–40]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to Fees for Terminal Equipment

December 21, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on November 30, 1995 the Stock Exchange, Inc. (''NYSE'' or ''Exchange'') 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

Beginning January 2, 1996, the Exchange plans to charge a fee of $3,600 per annum for a package of terminal equipment that its members and member organizations use to operate the Exchange's Broker Booth Support System (''BBSS'') from their ''upstairs'' offices.[2] Previously, the Exchange has not charged for this terminal equipment, because it was installed and operated on a trial basis.

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

The Exchange's BBSS is designed for use by its members and member organizations either in their booth spaces on the Trading Floor or in their ''upstairs'' offices or both.[3] The BBSS is an order management system providing order processing capabilities as well as access to other services such as market data, the Exchange's On-Line Comparison System,[4] and information services. Booth routing, a feature offered through BBSS, enables Exchange members and member organizations to algorithmically route market and limited price orders to their booths or to a specialist based on share size and price parameters, as may be determined by each participant.

The Exchange has charged a fee[5] for BBSS terminal equipment located in members' and member organizations' floor booth spaces since July 1, 1994, but does not currently charge for terminals located in members' and member organizations' ''upstairs'' offices because they were installed and operated on a trial basis.[6]

Now, however, the Exchange has concluded its trial, and the number of ''upstairs'' installations are proliferating.[7] Commencing on January 2, 1996, the Exchange intends to charge a fee of $3,600.00 per annum for a package of hardware, consisting of a terminal, keyboard, and printer, that is necessary to operate the BBSS. This charge is in line with the charge for the use of similar equipment located on its Trading Floor,[8] and will enable the Exchange to recoup part of its development and hardware costs.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[9] in general and furthers the objectives of Section 6(b)(4)[10] in particular in that it provides for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the proposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes or changes a due, fee, or other charge imposed by the Exchange and, therefore, has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and subparagraph (e) of Rule 19b–4 thereunder.[12]

At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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

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[1] 15 U.S.C. 78s(b)(1).

[2] The terminal equipment is necessary to access the BBSS.

[3] Telephone conversation on December 8, 1995 between George A. Villasana, Attorney, Market Regulation, SEC and Dennis Covelli, Vice President, Post Trade Services, NYSE.

[4] The NYSE's On-Line Comparison System allows NYSE clearing members to submit trade data on certain securities on trade date to NYSE for initial comparison. Compared trades are submitted by the NYSE to a ''qualified clearing agency'' to complete the clearance and settlement process. *See* Securities Exchange Act Release No. 34153 (June 3, 1994), 59 FR 30071 (June 10, 1994) (order approving File No. SR–NYSE–94–08).

[5] The NYSE provides its members and member organizations with one BBSS terminal per booth without charge. The exchange charges its members and member organizations $3,600 per annum for each additional BBSS terminal installed in each booth with access to the BBSS. Telephone conversation on December 13, 1995 between George A. Villasana, Attorney, Market Regulation, SEC and Dennis Covelli, Vice President, Post Trade Services, NYSE.

[6] *See* Securities Exchange Act Release No. 34395 (July 18, 1994), 59 FR 38007 (July 26, 1994) (order approving File No. SR–NYSE–94–25).

[7] While the number of terminals on the NYSE floor is approximately 400, the number of terminals in the ''upstairs'' offices is approximately 20. *See supra* note 5.

[8] *See supra* note 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4.

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 the inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the New York Stock Exchange, Inc. All submissions should refer to File No. SR–NYSE–95–40 and should be submitted by January 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–80 Filed 1–3–96; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21626; File No. 812–9580–01]

Great-West Life & Annuity Insurance Company et al.

December 27, 1995.

AGENCY: Securities and Exchange Commission (the ''SEC'' or the ''Commission'').

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the ''1940 Act'').

APPLICANTS: Great-West Life & Annuity Insurance Company (''GWL&A''), Maxim Series Account (the ''Separate Account''), and The Great-West Life Assurance Company (''Great-West'').

RELEVANT 1940 ACT SECTIONS: Order requested under Section 6(c) of the 1940 Act for exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act.

SUMMARY OF THE APPLICATION: Applicants seek an order permitting the deduction of mortality and expense risk charges from: (i) the assets of the Separate Account in connection with the offer and sale of certain flexible premium variable annuity contracts (the ''Contracts'') issued with a guaranteed death benefit, and of variable annuity contracts established in the future (the ''Future Contracts'') which are substantially similar in all material respects to the Contracts (''Future Contracts''); and (ii) the assets of separate accounts (''Future Accounts'') established in the future by GWL&A—which are substantially similar to the Separate Account—in connection with the offer and sale of Contracts and Future Contracts.

FILING DATE: The application was filed on April 25, 1995. An amended and restated application was filed on October 16, 1995.

HEARING OF NOTIFICATION OF THE HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on this application by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the Commission by 5:30 p.m. on January 22, 1996 and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, by certificate of service. Hearing requests should state the nature of the interest, the reason for the request, and the issues contested. Persons may request notification of the date of the hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W. Washington, D.C. 20549. Applicants: Beverly A. Byrne, Esq., The Great-West Life Assurance Company, 8515 East Orchard Road, Englewood, CO 80111.

FOR FURTHER INFORMATION CONTACT: Patrice M. Pitts, Special Counsel, 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 is available for a fee from the Public Reference Branch of the Commission.

Applicants' Representations

1. GWL&A, a stock life insurance company, originally was organized under Kansas law as the National Interment Association. In 1963, the company's name was changed to Ranger Life Insurance Company, and later was changed to Insuramerica Corporation; in February 1982, the company assumed its current name. In September 1990, GWL&A redomesticated and now is organized under the laws of Colorado. GWL&A is wholly-owned by Great West, which is a subsidiary of Great-West Lifeco Inc., an insurance holding company which, in turn, is a subsidiary of Power Financial Corporation, a financial services company.

2. The Separate Account was established by GWL&A under the laws of Kansas on June 24, 1981, and now exists under the laws of Colorado as a result of the redomestication of GWL&A in 1990. The Separate Account is a unit investment trust registered under the 1940 Act. The Separate Account acts as a funding vehicle for flexible premium variable annuity contracts—including the Contracts—which have a guaranteed death benefit, as well as for other flexible premium annuity contracts without a guaranteed death benefit (''Standard Death Benefit Contracts'').

3. The Separate Account currently has fourteen investment divisions, twelve of which invest solely in corresponding investment portfolios of Maxim Series Fund, Inc. (''Maxim''), and two of which invest solely in corresponding investment portfolios of TCI Portfolios, Inc. (''TCI''). (Maxim and TCI shall be referred to herein collectively as the ''Funds.'') Each investment division is subdivided into six subaccounts, two of which are used for allocation under the Standard Death Benefit Contracts and the Contracts in connection with retirement plans (''qualified plans'') that qualify for favorable federal income tax treatment under Sections 401 and 408 of the Internal Revenue Code as well as retirement plans not receiving such favorable tax treatment (''non-qualified plans''). The remaining four subaccounts are used for allocations under other contracts previously offered by GWL&A—through the Separate Account—in connection with qualified and non-qualified plans. In the future, GWL&A may establish additional divisions within the Separate Account to invest in other portfolios of the Funds or in other investments, and may issue other contracts—including Future Contracts—which may be funded by the Separate Account or by Future Separate Accounts.

4. Each of the Funds is a registered open-end, diversified investment company under the 1940 Act; each consists of one or more investment series or portfolios which pursue different investment objectives and policies and have distinct investment advisers. GWL&A purchases and redeems portfolio shares for the corresponding investment divisions of the Separate account at net asset value. Shares of the Funds also are offered to other affiliated or unaffiliated separate accounts of insurance companies offering variable annuity contracts or variable life insurance policies.

5. The principal underwriter of the Contracts, Great-West, is registered with the Commission under the Securities and Exchange Act of 1934 as a broker-dealer, and is a member of the National Association of Securities Dealers, Inc.

6. The minimum initial purchase payment for a Contract used in connection with a non-qualified plan is $5,000; the minimum initial purchase payment for a Contract used in connection with a qualified plan is $2,000. Additional purchase payments

[13] 17 CFR 200.30–3(a)(12).

for both non-qualified plan and qualified plan Contracts must be at least $500, except for payments made through an automatic contribution plan, which are subject to a $50 minimum. The Contracts also permit periodic payments and partial surrenders.

7. Prior to issuance of a Contract, the Contract owner selects a ''Retirement Date'' on which annuity payments are to begin. All or part of the Contract value may be placed under one or more of the annuity payout options available under the Contract, or the Contract owner may elect to receive the Contract value in a lump sum of the Retirement Date.

8. The Contracts provide for the payment of a death benefit. If the Annuitant dies before the Retirement Date, a death benefit will be paid to the designated beneficiary in an amount which is the greater of either: (a) the Contract value as of the date of death, less premium taxes, if any; or (b) the guaranteed death benefit, less premium taxes, if any. The guaranteed death benefit equals the initial purchase payment on the date the Contract is issued, and thereafter is adjusted upon each purchase payment, partial surrender, or periodic payment. The guaranteed death benefit is recalculated at the end of each calendar year by adding interest at an annual effective rate of 5%. At any date (other than the end of a calendar year) the guaranteed death benefit equals the lesser of: (a) The guaranteed death benefit as of the end of the last calendar year, plus any subsequent purchase payments, and less any partial surrenders and periodic payments; or (b) the result of the following calculation—Contract value after the last partial surrender or periodic payment made during the calendar year, multiplied by the guaranteed death benefit prior to such partial surrender or periodic payment, divided by the Contract value prior to such partial surrender or periodic payment.

9. Various fees and expenses are deducted under the Contracts. Prior to the Retirement Date, an annual maintenance charge of $27 will be deducted from the Contract value to compensate GWL&A for administrative services. The charge will not exceed the cost of services to be provided over the life of the Contract, in accordance with the provisions of Rule 26a–1 under the 1940 Act. GWL&A does not anticipate any profit from this charge.

10. Any premium or other taxes levied by any government entity with respect to the Contracts or the Separate Account will be paid by GWL&A. If the Contract value is used to purchase an annuity under the annuity payout options, the dollar amount of any premium tax previously paid or payable upon annuitization by GWL&A will be charged against Contract value. The applicable premium tax rates currently range from 0% to 2.50%.

11. The Separate Account and its investment divisions will bear their own operating expenses and charges for federal income tax, should such taxes be incurred by GWL&A in connection with the operation of the Separate Account. No charge is made by GWL&A for transfers of Contract value among Separate Account investment divisions.

12. No front-end sales load will be deducted from premium payments under the Contracts. Rather, upon any total or partial surrender of Contract Value prior to the Retirement Date, a contingent deferred sales charge will be deducted from purchase payments which have been credited to a Contract for fewer than seven years. Once per year, however, up to 10% of the Contract value as of December 31 of the calendar year prior to the year in which the amount is being surrendered may be withdrawn without incurring a contingent deferred sales charge. Total surrender charges will not exceed 7% of the purchase payment under the Contract.

13. A daily charge equal to an effective annual rate of 1.45% of the net asset value of the Separate Account attributable to the Contracts will be imposed to compensate GWL&A for bearing certain mortality and expense risks in connection with the Contracts. Of this amount, 0.85% is allocable to the mortality risk apart from that associated with the guaranteed death benefit, 0.20% is allocable to the mortality risk associated with the guaranteed death benefit, and 0.40% is allocable to the expense risk. The mortality and expense risk charge is guaranteed by GWL&A and cannot be increased.

14. The annual mortality and expense risk charge assessed under Future Contracts will be the same as that mentioned above. In addition, there will be no front-end sales charge for Future Contracts, and the maximum contingent deferred sales charge will not exceed 7% of the amount distributed.

15. The mortality risk under the Contract is that, upon selection of an annuity payout option with a life contingency, annuitants will live longer than GWL&A's actuarial projections indicate, thereby resulting in higher than expected annuity payments. GWL&A also assumes a mortality risk under the Contract if the death of an annuitant results in a death benefit being payable under the Contract. GWL&A is at risk to the extent that the amount of the guaranteed death benefit exceeds the Contract value as of the date of death.

16. The expense risk borne by GWL&A under the Contracts is that the charges for administrative expenses, which charges are guaranteed for the life of the Contracts, may be insufficient to cover the actual costs of issuing and administering the Contracts.

Applicants' Legal Analysis

1. Applicants request an order of the Commission under Section 6(c) for exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to the extent necessary to permit the deduction of a maximum charge of 1.45% for the assumption of mortality and expense risks from the assets of: (a) The Separate Account in connection with the issuance of the Contracts or Future Contracts; and (b) any Future Separate Accounts in connection with the issuance of Contracts or Future Contracts. Applicants submit that the requested exemption is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

2. Section 6(c) of the 1940 Act authorizes the Commission to exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from the provisions of the 1940 Act, and the rules promulgated thereunder, if and to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

3. Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act, as herein pertinent, prohibit a registered unit investment trust and any depositor or underwriter thereof from selling periodic payment plan certificates unless the proceeds of all payments are deposited with a qualified trustee or custodian and are held under arrangements which prohibit any payment to the depositor or principal underwriter. Exception is made for fees, not exceeding any such reasonable amounts as the Commission may prescribe, for performing bookkeeping and other administrative services.

4. Applicants submit that their request would promote competitiveness in the variable annuity contract market by eliminating the need for GWL&A to file redundant exemptive applications, thereby reducing GWL&A's administrative expenses and maximizing the efficient use of

GWL&A's resources. Applicants further submit that the delay and expenses involved in having to seek exemptive relief repeatedly would impair GWL&A's ability effectively to take advantage of business opportunities as they arise. Further, if GWL&A were required to seek exemptive relief repeatedly with respect to the issues addressed in this application, investors would not receive any benefit or additional protection thereby. Thus, Applicants believe that the requested exemption is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

5. Applicants represent that the mortality and expense risk charge of 1.25% (which includes all risk charges imposed under the Contracts except the 0.20% mortality risk charge for the guaranteed death benefit) is within the range of industry practice for variable annuity contracts which, while not offering a guaranteed death benefit feature, are otherwise comparable to the Contracts. This representation is based upon Applicants' analysis of publicly available information regarding the aggregate level of the mortality and expense risk charges under such comparable variable annuity contracts currently being offered in the insurance industry, taking into consideration such factors as current charge levels, the manner in which charges are imposed, the presence of charge-level or annuity-rate guarantees, and the markets in which the contracts will be offered. Applicants represent that GWL&A will maintain at the administrative offices at its headquarters, and make available to the Commission, a memorandum detailing the variable annuity products analyzed in the course of, and the methodology and results of, its comparative survey.

6. Applicants represent that before relying on exemptive relief resulting from this application in connection with any Future Contracts funded through the Separate Account or Future Separate Accounts, they will determine that the mortality and expense risk charge of 1.25% imposed under such Future Contracts (which includes all risk charges imposed under the Future Contracts except the 0.20% mortality risk charge for the guaranteed death benefit) will be within the range of industry practice for variable annuity contracts which, while not offering a guaranteed death benefit feature, are otherwise comparable to the Future Contracts. GWL&A will maintain at the administrative offices at its headquarters, and make available to the Commission, a memorandum detailing the variable annuity products analyzed in the course of, and the methodology and results of, its comparative survey.

7. Applicants also hereby represent that the mortality risk charge of 0.20% for the guaranteed death benefit is reasonable in relation to the additional mortality risks assumed by GWL&A in offering a guaranteed death benefit under the Contracts. This representation is based upon GWL&A's examination of a large number of trials at different issue ages to determine the expected additional cost of offering a guaranteed death benefit. GWL&A fist projected hypothetical asset returns using generally accepted actuarial simulation methods. GWL&A then calculated hypothetical accumulated values by applying the projected asset returns to the initial value in a hypothetical account for each asset return pattern generated. GWL&A compared each accumulated value so calculated to the amount of the guaranteed death benefit payable in the event of the hypothetical annuitant's death during the year in question. GWL&A also studies recent published actuarial statistics regarding the costs associated with similar enhanced or guaranteed death benefits, and sought reinsurance bids in relation to the guaranteed death benefit. GWL&A will maintain at the administrative offices at its headquarters, and make available to the Commission, a memorandum detailing the methodology used in determining that an additional level cost of 0.20% for the guaranteed death benefit is reasonable in relation to the additional risks assumed by GWL&A in offering such a death benefit under the Contracts.

8. Before relying on exemptive relief resulting from this application in connection with any Future Contracts funded through the Separate Account or any Future Separate Accounts, GWL&A will prepare and maintain at the administrative office at its headquarters, and make available to the Commission, a memorandum detailing the methodology used in determining that an additional level cost of 0.20% for a guaranteed death benefit is reasonable in relation to the additional risks assumed by GWL&A in offering such a death benefit under the Future Contracts.

9. GWL&A does not believe that the contingent deferred sales charges imposed under the Contracts will necessarily cover the expected costs of distributing the Contracts. Any ''shortfall'' will be made up from the assets of the general account of GWL&A, which will include amounts derived from the mortality and expense risk charges. GWL&A has concluded that there is a reasonable likelihood that the distribution financing arrangement being used in connection with the Contracts will benefit the Separate Account and the Contract owners. The basis for this conclusion is set forth in a memorandum which will be maintained by GWL&A at the administrative offices at its headquarters, and will be made available to the Commission.

10. Applicants recognize that the contingent deferred sales charges that may be imposed under Future Contracts may not necessarily be sufficient to cover the expected costs of distributing such contracts. Any ''shortfall'' will be made up from the assets of the general account, which will include amounts derived from the mortality and expense risk charges imposed under Future Contracts. Applicants represent that before relying on exemptive relief resulting from this application in connection with the Future Contracts funded through the Separate Account or any Future Separate Accounts, GWL&A will determine that there is a reasonable likelihood that the distribution financing arrangements being used in connection with the Future Contracts will benefit the Separate Account or any Future Separate Accounts and their respective Future Contract owners. GWL&A will maintain at the administrative offices at its headquarters, and make available to the Commission, a memorandum setting forth the basis for this conclusion.

11. Applicants also represent that the Separate Account and any Future Separate Accounts will invest only in underlying funds which have undertaken, in the event they should adopt a plan for financing distribution expenses pursuant to Rule 12b–1 of the 1940 Act, to have such a plan formulated and approved by their board of directors/trustees, a majority of whom are not interested persons of any such funds.

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. 96–132 Filed 1–3–96; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 21629; 812–9850]

Mutual Fund Group, et al.; Notice of Application

December 28, 1995.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the ''Act'').

APPLICANTS: Mutual Fund Group (''MFG''), Mutual Fund Trust, Mutual Fund Variable Annuity Trust, Growth & Income Portfolio, Capital Growth Portfolio, International Equity Portfolio, Global Fixed Income Portfolio (collectively, the ''Chase Funds''); Atlanta Capital Management Company (''Atlanta Capital''); and The Chase Manhattan Bank, National Association (the ''Adviser'').

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from section 15(a).

SUMMARY OF APPLICATION: The Chase Manhattan Corporation (''Chase''), the Adviser's holding company, will be merged with Chemical Banking Corporation (''CBC''). The merger will result in the assignment, and thus the termination, of the Chase Funds' existing investment advisory and sub-advisory contracts with the Adviser and Atlanta Capital, a sub-adviser. Applicants request an order to permit the implementation, without shareholder approval, of interim advisory and sub-advisory contracts, during a period of up to 120 days following January 31, 1996. The order also will permit the Adviser and Atlanta Capital to receive fees earned under the interim advisory and sub-advisory contracts following approval by the Chase Funds' shareholders.

FILING DATES: The application was filed on November 6, 1995 and amended on December 28, 1995.

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 SEC's Secretary 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 January 22, 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 such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants: The Chase Manhattan Bank, National Association, One Chase Manhattan Plaza, New York, New York 10081; Atlanta Capital Management Company, Two Midtown Plaza, 1360 Peachtree Street, Suite 1600, Atlanta, Georgia 30309; all other applicants, 125 West 55th Street, New York, New York 10019.

FOR FURTHER INFORMATION CONTACT: Marianne H. Khawly, Staff Attorney, at (202) 942–0562, or Robert A. Robertson, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. The Chase Funds are registered open-end management investment companies. The Adviser is a national banking association and is a wholly-owned subsidiary of Chase, a bank holding company. Each Chase Fund has entered into a investment advisory agreement with the Adviser. The Adviser and Atlanta Capital have entered into an investment sub-advisory agreement pursuant to which Atlanta Capital acts as sub-adviser to a portfolio of MFG, IEEE Balanced Fund (the sub-advisory agreement together with the investment advisory agreements, the ''Existing Agreements'').

2. On August 27, 1995, CBC and Chase entered into an Agreement and Plan of Merger, pursuant to which Chase will be merged with and into CBC (the ''Holding Company Merger''). CBC will be the surviving corporation and will continue its corporate existence under the name ''The Chase Manhattan Corporation.'' The Holding Company Merger will be effected as a stock transaction, with the outstanding shares of Chase common stock being exchanged for newly issued shares of CBC common stock at a predetermined exchange rate. Applicants anticipate that the Holding Company Merger will occur on or before January 31, 1996. Subsequent to the Holding Company Merger, the Adviser will be merged with Chemical Bank, a wholly-owned direct subsidiary of CBC (the ''Bank Merger'' and together with the Holding Company Merger, the ''Mergers''). The surviving bank will continue operations under the name ''The Chase Manhattan Bank.''

3. On December 11, 1995, the respective shareholders of Chase and CBC voted to approve the Holding Company Merger. At a special meeting held on December 14, 1995, the respective Boards of Trustees of the Chase Funds (the ''Boards'') met to discuss the Mergers. During this meeting, the Boards, met to discuss the Mergers. During this meeting, the Boards, including a majority of the Board members who are not ''interested persons,'' as that term is defined in the Act (the ''Independent Trustees''), of the respective Chase Funds, with the advice and assistance of counsel to the Independent Trustees, made a full evaluation of interim investment advisory and sub-advisory agreements (the ''Interim Agreements''). In accordance with section 15(c) of the Act, the Boards voted to approve the Interim Agreements. The Boards of each Chase Fund also voted to recommend that shareholders of each Chase Fund approve the Interim Agreements.

4. In approving the Interim Agreements, the Boards concluded that payment of the advisory and sub-advisory fees during the interim period would be appropriate and fair because there will be no diminution in the scope and quality of services provided to the Chase Funds, the fees to be paid are unchanged from the fees paid under the Existing Agreements, the fees would be maintained in an interest-bearing escrow account until payment is approved or disapproved by shareholders, and the nonpayment of fees would be inequitable to the Adviser (including its successor in the event that the Bank Merger occurs during the interim period, the ''Successor'') and Atlanta Capital in view of the substantial services to be provided.

5. Chase and CBC expect a combination of Chase Funds and registered investment companies that are advised by CBC subsidiaries (collectively, the ''CBC Funds'') into a family of mutual funds with consistent structural characteristics where appropriate, consolidated management, consistent share class structures, rationalized investment objectives and policies, and consolidated marketing efforts (the ''Fund Family Combination''). Applicants expect that a number of Chase Funds will consummate a transaction with (a) an

existing CBC Fund providing for the transfer of substantially all of the assets of one such fund to the other in exchange for the other's shares, or (b) a CBC Fund to be newly created providing for the transfer of substantially all of the assets of such Chase Fund to the newly created CBC Fund in exchange for shares of the newly created CBC Fund (each such transaction, a ''Fund Merger'').

6. Applicants believe that it will not be possible to complete the Fund Family Combination or any of the expected Fund Mergers prior to the Holding Company Merger. Accordingly, applicants request an exemption from section 15(a) of the Act to permit the implementation, without shareholder approval, of the Interim Agreements. The exemption would cover the period commencing on the date of the Holding Company Merger and continuing through the date the Interim Agreements are approved or disapproved by shareholders of the respective Chase Funds, which period shall be no longer than 120 days after January 31, 1996 (the ''Interim Period''). Applicants also request that such relief extend to the Bank Merger during the Interim Period.

Applicants' Legal Analysis

1. Section 15(a) prohibits an investment adviser from providing investment advisory services to an investment company except under a written contract that has been approved by a majority of the investment company's voting securities. The section further requires that the written contract provide for its automatic termination in the event of an assignment. Section 2(a)(4) of the Act defines ''assignment'' to include any direct or indirect transfer of a contract by the assignor or of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor.

2. Section 2(a)(9) defines ''control'' as the power to exercise a controlling influence over the management or policies of a company. Beneficial ownership of more than 25% of a company's voting securities is presumed to constitute control.

3. Upon consummation of the Holding Company Merger, approximately 43% of the voting securities of the surviving corporation will be owned by the current Chase shareholders and 57% will be owned by the current CBC shareholders. Thus, the Holding Company Merger may be deemed to result in an ''assignment'' of the Existing Agreements. Therefore, these agreements will terminate by their terms. Similarly, the Bank Merger may be deemed to result in an ''assignment'' of the Interim Agreements, thus terminating these agreements.

4. Rule 15a–4 provides, among other things, that if an advisory contract is terminated by assignment, the investment adviser may continue to act as such for 120 days at the previous compensation rate if a new contract is approved by the board of directors of the investment company, and if the investment adviser or a controlling person of the investment adviser does not directly or indirectly receive money or other benefit in connection with the assignment. Because Chase and the Adviser will receive a benefit in connection with the assignment of the contracts, applicants may not rely on the rule.

5. Absent the requested relief, applicants believe that it may be necessary, in the case of most Chase Funds, to undertake multiple proxy solicitations within a relatively short time frame. Applicants believe that engaging in the solicitation of multiple proxies from the shareholders of a single investment company for approvals arising out of the same series of events would be confusing to shareholders, burdensome, inefficient, costly, and not in the best interests of the Chase Funds or their shareholders.

6. Applicants believe that the requested relief will allow for the orderly completion of the Fund Mergers and the Fund Family Combination, as well as reasonable adjournments of shareholder meetings if necessary to obtain sufficient shareholder responses to proxy solicitations to obtain the various approvals as may be necessary in connection with the Fund Mergers.

7. Section 6(c) of the Act provides that the SEC may exempt any person, security, or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief from section 15(a) meets this standard.

Applicants' Conditions

Applicants agree as conditions to the requested exemptive relief that:

1. Each Interim Agreement will have the same terms and conditions as the respective Existing Agreement, except for the effective and termination dates.

2. Fees earned by the Adviser (or the Successor, if applicable) and Atlanta Capital and paid by a Chase Fund during the Interim Period in accordance with the Interim Agreement will be maintained in an interest-bearing escrow account, and amounts in such account (including interest earned on such paid fees) will be paid to the Adviser (or the Successor, if applicable) and in the case of IEEE Balanced Fund, paid to Atlanta Capital only upon approval of the related Chase Fund shareholders or, in the absence of such approval, to the related Chase Fund.

3. Each Chase Fund will hold meetings of shareholders to vote on approval of the related Interim Agreement, on or before the 120th day following January 31, 1996.

4. Chase, CBC and/or one or more subsidiaries of the foregoing will pay the costs of preparing and filing this application. Chase, CBC and/or one or more subsidiaries of the foregoing will pay the costs relating to the solicitation of the approvals of the Chase Fund shareholders, to the extent such costs relate to the shareholder approval of Interim Agreements necessitated by the Mergers.

5. The Adviser (or the Successor, if applicable) and Atlanta Capital, as the case may be, will take all appropriate actions to ensure that the scope and quality of advisory and other services provided to the Chase Funds under the Interim Agreements will be at least equivalent, in the judgment of the respective Boards, including a majority of the Independent Trustees, to the scope and quality of services previously provided. In the event of any material change in personnel providing services under the Interim Agreements, the Adviser (or the Successor, if applicable) or Atlanta Capital, as the case may be, will apprise and consult the Boards of the affected Chase Funds to assure that such Boards, including a majority of the Independent Trustees, are satisfied that the services provided by the Adviser (or the Successor, if applicable) or Atlanta Capital, as the case may be, will not be diminished in scope or quality.

For the SEC, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–129 Filed 1–3–96; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 95–99; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1994 Alfa Romeo 164 Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1994 Alfa Romeo 164 passenger cars are eligible for importation.

SUMMARY: This notice announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that a 1994 Alfa Romeo 164 that was not originally manufactured to comply with all applicable Federal motor vehicle safety standards is eligible for importation into the United States because (1) it is substantially similar to a vehicle that was originally manufactured for importation into and sale in the United States and that was certified by its manufacturer as complying with the safety standards, and (2) it is capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is February 5, 1996.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9:30 am to 4 pm].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A) (formerly section 108(c)(3)(A)(i)(I) of the National Traffic and Motor Vehicle Safety Act (the Act)), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115 (formerly section 114 of the Act), and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the Federal Register.

Liphardt & Associates of Ronkonkoma, New York (''Liphardt'') (Registered Importer 90–004) has petitioned NHTSA to decide whether 1994 Alfa Romeo 164 passenger cars are eligible for importation into the United States. The vehicle which Liphardt believes is substantially similar is the 1994 Alfa Romeo 164 that was manufactured for importation into, and sale in, the United States and certified by its manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared the non-U.S. certified 1994 Alfa Romeo 164 to its U.S. certified counterpart, and found the two vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Liphardt submitted information with its petition intended to demonstrate that the non-U.S. certified 1994 Alfa Romeo 164, as originally manufactured, conforms to many Federal motor vehicle safety standards in the same manner as its U.S. certified counterpart, or is capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that the non-U.S. certified 1994 Alfa Romeo 164 is identical to its U.S. certified counterpart with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence* * * *, 103 *Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 105 *Hydraulic Brake Systems,* 106 *Brake Hoses,* 107 *Reflecting Surfaces,* 109 *New Pneumatic Tires,* 111 *Rearview Mirrors;* 113 *Hood Latch Systems,* 116 *Brake Fluid,* 118 *Power Window Systems;* 124 *Accelerator Control Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 203 *Impact Protection for the Driver From the Steering Control System,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 211 *Wheel Nuts, Wheel Discs and Hubcaps,* 212 *Windshield Retention,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 301 *Fuel System Integrity,* and 302 *Flammability of Interior Materials.*

Additionally, the petitioner states that the non-U.S. certified 1994 Alfa Romeo 164 complies with the Bumper Standard found in 49 CFR Part 581.

Petitioner also contends that the vehicle is capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* (a) substitution of appropriate symbols on the brake failure, parking brake, and seat belt warning lamps; (b) installation of a U.S.-model speedometer.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* (a) installation of U.S.-model headlamp assemblies which incorporate sealed beam headlamps and front sidemarkers; (b) installation of U.S.-model taillamps; (c) installation of a high mounted stop lamp.

Standard No. 110 *Tire Selection and Rims:* installation of a tire information placard.

Standard No. 114 *Theft Protection:* installation of a warning buzzer in the steering lock electrical circuit.

Standard No. 115 *Vehicle Identification Number: installation of a VIN plate that can be read from outside the left windshield pillar, and VIN reference label on the edge of the door or latch post nearest the driver.*

Standard No. 208 *Occupant Crash Protection:* installation of a seat belt warning buzzer. The petitioner states that the vehicle is equipped with an air bag and knee bolster that have identical part numbers to those found on its U.S.-certified counterpart.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, S.W., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered.

Notice of final action on the petition will be published in the Federal Register pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141 (a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: December 29, 1995.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 96–106 Filed 1–3–96; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning new Form W–7, Application for IRS Individual Taxpayer Identification Number.

DATES: Written comments should be received on or before March 4, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, T:FP, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Martha R. Brinson, (202) 622–3869, Internal Revenue Service, T:FP, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Application for IRS Individual Taxpayer Identification Number

OMB Number: To be assigned later.

Form Number: W–7.

Abstract: Proposed regulations under section 6109 of the Internal Revenue Code introduce a new type of taxpayer identifying number called the ''IRS individual taxpayer identification number'' (ITIN). When available, individuals who currently do not have, and are not eligible to obtain, social security numbers can apply for this number. Taxpayers may use this number when required to furnish a taxpayer identifying number under regulations. An ITIN would be applied for on Form W–7 and is intended for tax use only.

Current Actions: This is a new collection of information.

Type of Review: New OMB approval.

Affected Public: Individuals.

Estimated Number of Respondents: 500,000.

Estimated Time Per Respondent: 56 minutes.

Estimated Total Annual Burden Hours: 470,000.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection request.

Garrick R. Shear,

IRS Reports Clearance Officer

[FR Doc. 96–63 Filed 1–3–96; 8:45 am]

BILLING CODE 4830–01–U

Sunshine Act Meetings

Federal Register
Vol. 61, No. 3
Thursday, January 4, 1996

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, January 9, 1996 at 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or processings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Wednesday, January 10, 1996 at 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C. (Ninth Floor)

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Title 26 Certification Matters.

Draft Advisory Opinion 1995–37: Ralph W. Holmen, National Association of Realtors (NAR).

Draft Advisory Opinion 1995–40: Barbara E. Wixon, (Continental Airlines).

Draft Advisory Opinion 1995–42: Rep. Jim McCrery, on behalf of McCrery for Congress.

Draft Advisory Opinion 1995–43: Stephen M. Sacks on behalf of Arnold & Porter.

Draft Advisory Opinion 1995–44: Paul E. Sullivan, Esq. on behalf of Forbes for President Committee, Inc.

Draft Advisory Opinion 1995–45: Michael Spivak, Treasurer, Dr. John Hagelin for President 1996.

Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 219–4155.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 96–176 Filed 1–2–96; 3:19 pm]

BILLING CODE 6715–01–M

federal register

Thursday
January 4, 1996

Part II

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonisation, Guidelines Availability: Impurities in New Drug Substances; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0325]

International Conference on Harmonisation; Guideline on Impurities in New Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Impurities in New Drug Substances.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State.

DATES: Effective January 4, 1996. Submit written comments at any time.

ADDRESSES: Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Copies of the guideline are available from the Consumer Affairs Branch (previously the CDER Executive Secretariat Staff) (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Robert W. Trimmer, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0370.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the Federal Register of September 22, 1994 (59 FR 48740), FDA published a draft tripartite guideline entitled ''Impurities in New Drug Substances.'' The notice gave interested persons an opportunity to submit comments by December 6, 1994.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held in March 1995.

The guideline is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State. The guideline is not intended to apply to new drug substances used during the clinical research stage of development or clinical trials. The guideline also does not apply to biological/biotechnological substances, peptides, oligonucleotides, radiopharmaceuticals, fermentation and semisynthetic products derived from that process, herbal products, and crude products of animal or plant origin. Impurities in new drug substances are addressed in the guideline from two perspectives: (1) Chemistry aspects—classification and identification of impurities, report generation, setting specifications, and a brief discussion of analytical procedures; and (2) safety aspects—guidance for qualifying impurities that were not present in batches of the new drug substance used in safety and clinical studies and/or impurity levels substantially higher than in those batches.

In the past, guidelines have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to state procedures or standards of general applicability that are not legal requirements but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, the guideline is not being issued under the authority of § 10.90(b). Although this guideline does not create or confer any rights on or for any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member state.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed, and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the Federal Register.

Interested persons may, at any time, submit to the Docket Management Branch (address above) written comments on the guideline. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The text of the guideline follows:

Impurities in New Drug Substances

1. Preamble

This document is intended to provide guidance for registration applications on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a region or member state. It is not intended to apply to the regulation of new drug substances used during the clinical research

stage of development. Biological/biotechnological, peptide, oligonucleotide, radiopharmaceutical, fermentation and semisynthetic products derived therefrom, herbal products, and crude products of animal or plant origin are not covered. Impurities in new drug substances are addressed from two perspectives:

Chemistry aspects include classification and identification of impurities, report generation, setting specifications, and a brief discussion of analytical procedures; and

Safety aspects include specific guidance for qualifying impurities which were not present in batches of new drug substance used in safety and clinical studies and/or impurity levels substantially higher than in those batches. Threshold limits are defined, below which, qualification is not needed.

2. Classification of Impurities

Impurities may be classified into the following categories:

- Organic Impurities (Process and Drug Related)
- Inorganic Impurities
- Residual Solvents

Organic impurities may arise during the manufacturing process and/or storage of the new drug substance. They may be identified or unidentified, volatile or nonvolatile, and include:

- Starting Materials
- By-Products
- Intermediates
- Degradation Products
- Reagents, Ligands, and Catalysts

Inorganic impurities may derive from the manufacturing process. They are normally known and identified, and include:

- Reagents, Ligands, and Catalysts
- Heavy Metals
- Inorganic Salts
- Other Materials (e.g., Filter Aids, Charcoal, etc.)

Solvents are organic or inorganic liquids used during the manufacturing process. Since these are generally of known toxicity, the selection of appropriate controls is easily accomplished.

Excluded from this document are: Extraneous contaminants which should not occur in new drug substances and are more appropriately addressed as good manufacturing practice issues; polymorphic form, a solid state property of the new drug substance; and enantiomeric impurities.

3. Rationale for the Reporting and Control of Impurities

3.1 Organic Impurities

The applicant should summarize those actual and potential impurities most likely to arise during the synthesis, purification, and storage of the new drug substance. This summary should be based on sound scientific appraisal of the chemical reactions involved in the synthesis, impurities associated with raw materials which could contribute to the impurity profile of the new drug substance, and possible degradation products. This discussion may only include those impurities that may reasonably be expected based on knowledge of the chemical reactions and conditions involved.

In addition, the applicant should summarize the laboratory studies conducted to detect impurities in the new drug substance. This summary should include test results of batches manufactured during the development process and batches from the proposed commercial process, as well as results of intentional degradation studies used to identify potential impurities that arise during storage. Assessment of the proposed commercial process may be deferred until the first batch is produced for marketing. The impurity profile of the drug substance lots intended for marketing should be compared with those used in development and any differences discussed.

The studies conducted to characterize the structure of actual impurities present in the new drug substance at or above an apparent level of 0.1 percent (e.g., calculated using the response factor of the drug substance) should be described. Note that all recurring impurities at or above the 0.1 percent level in batches manufactured by the proposed commercial process should be identified. Degradation products observed in stability studies at recommended storage conditions should be similarly identified. When identification of an impurity is not feasible, a summary of the laboratory studies demonstrating the unsuccessful effort should be included in the application. Where attempts have been made to identify impurities below the 0.1 percent level, it is useful to also report the results of these studies.

Identification of impurities below apparent levels of 0.1 percent is generally not considered necessary. However, identification should be attempted for those potential impurities that are expected to be unusually potent, producing toxic or pharmacologic effects at a level lower than 0.1 percent. In all cases, impurities should be qualified as described later in this guide. Although it is common practice to round analytical results of between 0.05 and 0.09 percent to the nearest number (i.e., 0.1 percent), for the purpose of these guidelines, such values would not be rounded to 0.1 percent and these impurities would not require identification.

3.2 Inorganic Impurities

Inorganic impurities normally are detected and quantitated using pharmacopeial or other appropriate procedures. Carry over of catalysts to the new drug substance should be evaluated during development. The need for inclusion or exclusion of inorganic impurities in the new drug substance specifications should be discussed. Limits should be based on pharmacopeial standards or known safety data.

3.3 Solvents

The control of residues of the solvents used in the manufacturing process for the new drug substance should be discussed. Any solvents which may appear in the drug substance should be quantified using analytical procedures with an appropriate level of sensitivity. Pharmacopeial or other appropriate procedures should be utilized. Limits should be based on pharmacopeial standards or known safety data taking into consideration dose, duration of treatment, and route of administration. Particular attention should be given to quantitation of toxic solvents used in the manufacturing process.

4. Analytical Procedures

The registration application should include documented evidence that the analytical procedures are validated and suitable for the detection and quantitation of impurities. Differences in the analytical procedures used during development and proposed for the commercial product should be discussed in the registration application.

Organic impurity levels can be measured by a variety of techniques, including those which compare an analytical response for an impurity to that of an appropriate reference standard or to the response of the new drug substance itself. Reference standards used in the analytical procedures for control of impurities should be evaluated and characterized according to their intended uses. The drug substance may be used to estimate the levels of impurities. In cases where the response factors are not close, this practice may still be acceptable, provided a correction factor is applied or the impurities are, in fact, being overestimated. Specifications and analytical procedures used to estimate identified or unidentified impurities often are based on analytical assumptions (e.g., equivalent detector response, etc.). The assumptions should be discussed in the registration application.

5. Reporting Impurity Content of Batches

Analytical results should be provided for all batches of the new drug substance used for clinical, safety, and stability testing, as well as batches representative of the proposed commercial process. The content of individual identified and unidentified and total impurities observed in these batches of the new drug substance should be reported with the analytical procedures indicated. A tabulation (e.g., spreadsheet) of the data is recommended. Impurities should be designated by code number or by an appropriate descriptor, e.g., retention time. Levels of impurities which are present but are below the validated limit of quantitation need not be reported. When analytical procedures change during development, reported results should be linked with the procedure used, with appropriate validation information provided. Representative chromatograms should be provided. Chromatograms of such representative batches, from methods validation studies showing separation and detectability of impurities (e.g., on spiked samples), along with any other impurity tests routinely performed, can serve as the representative impurity profiles. The applicant should ensure that complete impurity profiles (i.e., chromatograms) of individual batches are available if requested. A tabulation should be provided which links the specific new drug substance batch to each safety study and each clinical study in which it has been used.

For each batch of the new drug substance, the report should include:

- Batch Identity and Size
- Date of Manufacture
- Site of Manufacture
- Manufacturing Process
- Impurity Content, Individual and Total

- Use of Batches
- Reference to Analytical Procedure Used

6. Specification Limits for Impurities

The specifications for a new drug substance should include limits for impurities. Stability studies, chemical development studies, and routine batch analyses can be used to predict those impurities likely to occur in the commercial product. The selection of impurities to include in the new drug substance specifications should be based on the impurities found in batches manufactured by the proposed commercial process. Those impurities selected for inclusion in the specifications for the new drug substance are referred to as ''specified impurities'' in this guideline. Specified impurities may be identified or unidentified and should be individually listed in the new drug substance specifications.

A rationale for the inclusion or exclusion of impurities in the specifications should be presented. This rationale should include a discussion of the impurity profiles observed in the safety and clinical development batches, together with a consideration of the impurity profile of material manufactured by the proposed commercial process. Specific identified impurities should be included along with recurring unidentified impurities estimated to be at or above 0.1 percent. For impurities known to be unusually potent or to produce toxic or unexpected pharmacological effects, the quantitation/detection limit of the analytical methods should be commensurate with the level at which the impurities must be controlled. For unidentified impurities, the procedure used and assumptions made in establishing the level of the impurity should be clearly stated. Unidentified impurities included in the specifications should be referred to by some appropriate qualitative analytical descriptive label (e.g., ''unidentified A,'' ''unidentified with relative retention of 0.9''). Finally, a general specification limit of not more than 0.1 percent for any unspecified impurity should be included.

Limits should be set no higher than the level that can be justified by safety data, and, unless safety data indicate otherwise, no lower than the level achievable by the manufacturing process and the analytical capability. In other words, where there is no safety concern, impurity specifications should be based on data generated on actual batches of the new drug substance allowing sufficient latitude to deal with normal manufacturing and analytical variation, and the stability characteristics of the new drug substance. Although normal manufacturing variations are expected, significant variation in batch-to-batch impurity levels may indicate that the manufacturing process of the new drug substance is not adequately controlled and validated.

In summary, the new drug substance specifications should include, where applicable, limits for:

Organic Impurities:

- Each Specified Identified Impurity
- Each Specified Unidentified Impurity at or above 0.1 percent
- Any Unspecified Impurity, with a limit of not more than 0.1 percent
- Total Impurities

Residual Solvents

Inorganic Impurities

A summation of assay value and impurity levels generally may be used to obtain mass balance for the test sample. The mass balance need not add to exactly 100 percent because of the analytical error associated with each analytical procedure. The summation of impurity levels plus the assay value may be misleading, for example, when the assay procedure is nonspecific (e.g., potentiometric titrimetry) and the impurity level is relatively high.

7. Qualification of Impurities

Qualification is the process of acquiring and evaluating data which establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified. The applicant should provide a rationale for selecting impurity limits based on safety considerations. The level of any impurity present in a new drug substance that has been adequately tested in safety and/or clinical studies is considered qualified. Impurities that are also significant metabolites present in animal and/or human studies do not need further qualification. A level of a qualified impurity higher than that present in a new drug substance can also be justified based on an analysis of the actual amount of impurity administered in previous safety studies.

If data are not available to qualify the proposed specification level of an impurity, studies to obtain such data may be needed when the usual qualification threshold limits given below are exceeded:

Maximum daily dose	Qualification threshold
≤ 2 grams (g)/day	0.1 percent or 1 milligram per day intake (whichever is lower)
> 2 g/day	0.05 percent

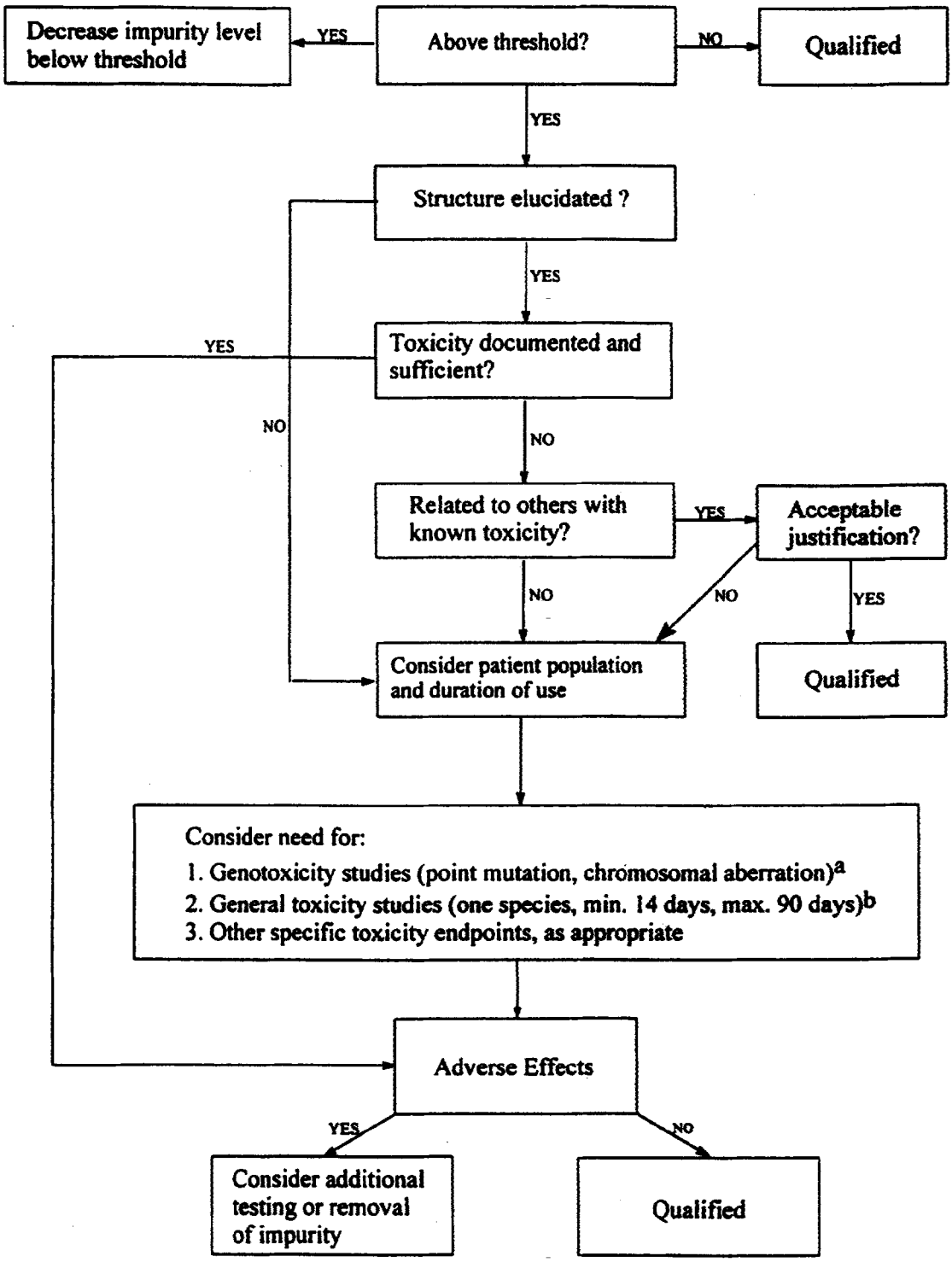
Higher or lower threshold limits for qualification of impurities may be appropriate for some individual drugs based on scientific rationale and level of concern, including drug class effects and clinical experience. For example, qualification may be especially important when there is evidence that such impurities in certain drugs or therapeutic classes have previously been associated with adverse reactions in patients. In these instances, a lower qualification threshold limit may be appropriate. Conversely, a higher qualification threshold limit may be appropriate for individual drugs when the level of concern for safety is less than usual based on similar considerations (e.g., patient population, drug class effects, clinical considerations). Technical factors (manufacturing capability and control methodology) may be considered as part of the justification for selection of alternative threshold limits. Proposals for alternative threshold limits are considered on a case-by-case basis.

The ''Decision Tree for Safety Studies'' (Attachment I) describes considerations for the qualification of impurities when thresholds are exceeded. In some cases, decreasing the level of impurity below the threshold may be simpler than providing safety data. Alternatively, adequate data may be available in the scientific literature to qualify an impurity. If neither is the case, additional safety testing should be considered. The studies desired to qualify an impurity will depend on a number of factors, including the patient population, daily dose, route, and duration of drug administration. Such studies are normally conducted on the new drug substance containing the impurities to be controlled, although studies using isolated impurities are seen as acceptable.

BILLING CODE 4160–01–F

Attachment I

DECISION TREE FOR SAFETY STUDIES



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[a] If considered desirable, a minimum screen for genotoxic potential should be conducted. A study to detect point mutations and one to detect chromosomal aberrations, both in vitro, are seen as an acceptable minimum screen.

[b] If general toxicity studies are desirable, study(ies) should be designed to allow comparison of unqualified to qualified material. The study duration should be based on available relevant information and performed in the species most likely to maximize the potential to detect the toxicity of an impurity. In general, a minimum duration of 14 days and a maximum duration of 90 days are seen as acceptable.

8. New Impurities

During the course of a drug development program, the qualitative impurity profile of the new drug substance may change, or a new impurity may appear as a result of, for example, synthetic route changes, process optimization, or scale-up. New impurities may be identified or unidentified. Such changes call for consideration of the need for qualification of the level of the impurity, unless it is below the threshold values as noted above. When a new impurity exceeds the threshold, the ''Decision Tree for Safety Studies'' should be consulted. Safety studies should compare the new drug substance containing a representative level of the new impurity with previously qualified material, although studies using the isolated impurity are also seen as acceptable (these studies may not always have clinical relevance).

9. Glossary

Chemical Development Studies: Studies conducted to scale-up, optimize, and validate the manufacturing process for a new drug substance.

Enantiomers: Compounds with the same molecular formula as the drug substance, which differ in the spatial arrangement of atoms within the molecule and are nonsuperimposable mirror images.

Extraneous Substance: An impurity arising from any source extraneous to the manufacturing process.

Herbal Products: Medicinal products containing, exclusively, plant material and/or vegetable drug preparations as active ingredients. In some traditions, materials of inorganic or animal origin may also be present.

Identified Impurity: An impurity for which a structural characterization has been achieved.

Impurity: Any component of the new drug substance which is not the chemical entity defined as the new drug substance.

Impurity Profile: A description of the identified and unidentified impurities present in a new drug substance.

Intermediate: A material produced during steps of the synthesis of a new drug substance which must undergo further molecular change before it becomes a new drug substance.

Ligand: An agent with a strong affinity to a metal ion.

New Drug Substance: The designated therapeutic moiety which has not been previously registered in a region or member state (also referred to as a new molecular entity or new chemical entity). It may be a complex, simple ester, or salt of a previously approved drug substance.

Polymorphism: The occurrence of different crystalline forms of the same drug substance.

Potential Impurity: An impurity which, from theoretical considerations, may arise from or during manufacture. It may or may not actually appear in the new drug substance.

Qualification: The process of acquiring and evaluating data which establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified.

Reagent: A substance, other than a starting material or solvent, which is used in the manufacture of a new drug substance.

Safety Information: The body of information that establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified.

Solvent: An inorganic or an organic liquid used as a vehicle for the preparation of solutions or suspensions in the synthesis of a new drug substance.

Specified Impurity: Identified or unidentified impurity that is selected for inclusion in the new drug substance specifications and is individually listed and limited in order to assure the safety and quality of the new drug substance.

Starting Material: A material used in the synthesis of a new drug substance which is incorporated as an element into the structure of an intermediate and/or of the new drug substance. Starting materials normally are commercially available and of defined chemical and physical properties and structure.

Toxic Impurity: Impurities having significant undesirable biological activity.

Unidentified Impurity: An impurity which is defined solely by qualitative analytical properties (e.g., chromatographic retention time).

Validated Limit of Quantitation: For impurities at a level of 0.1 percent, the validated limit of quantitation should be less than or equal to 0.05 percent. Impurities limited at higher levels may have higher limits of quantitation.

Dated: December 21, 1995.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–64 Filed 1–3–96; 8:45 am]

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federal register

Thursday
January 4, 1996

Part III

Department of Justice

Bureau of Prisons

28 CFR Part 545

Inmate Work and Performance Pay Program; Final Rule

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 545

[BOP–1027–F]

RIN 1120–AA29

Inmate Work and Performance Pay Program

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons is amending its regulations on inmate work and performance pay in conformance with revised provisions governing drug abuse treatment programs and pretrial inmates. In addition to making these conforming amendments, the Bureau is also revising various terms defined in the regulations, updating examples cited, and adding exception procedures pertinent to pay reduction and work evaluation. This amendment is intended to provide for the more efficient operation of Bureau institution work programs.

EFFECTIVE DATE: January 4, 1996.

ADDRESSES: Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 514–6655.

SUPPLEMENTARY INFORMATION: The Bureau of Prisons is amending its regulations on Inmate Work and Performance Pay. A final rule on this subject was published in the Federal Register on October 1, 1984 (49 FR 38915) and was amended on May 21, 1991 (56 FR 23478) and July 10, 1991 (56 FR 31530). A proposed rule on the conforming provisions of the drug abuse treatment programs was published January 7, 1994 (59 FR 1240), and a final rule for those provisions was published October 21, 1994 (59 FR 53342). A final rule for the conforming amendments to the provisions on pretrial inmates was published November 22, 1994 (59 FR 60284).

The January 7, 1994 proposed rule on drug abuse treatment programs (28 CFR 550, subpart F) included conforming amendments to inmate work/program assignment (§ 545.23(a)) and to eligibility for performance pay (§ 545.25(d)). No comment was received on these provisions. These conforming amendments are being adopted as final with the following adjustments. Paragraph (a) of § 545.20 is revised in order to conform to recommended Federal Register codification practice, to include reference to drug treatment programming, and to make consistent reference to education (rather than educational) program. In § 545.21, paragraph (f) is revised to include reference to drug treatment programming and education programs. As proposed, § 545.23(a) was to be amended by revising the last sentence to include reference to the drug treatment program. This reference is more accurately stated in the second sentence, and the Literacy Program is given as an example of program involvement mandated by either Bureau policy or statute. For ease of reference, the entire paragraph is revised. In § 545.24(d), the reference to ''educational'' has been revised as ''education''. The provision on eligibility for performance pay in proposed § 545.25(d) has been revised for the sake of simplification. Paragraph (a)(2) of § 545.25 has been revised to include the acronym for General Education Development in the reference to the Bureau's literacy program. There is no change in the intent of these two paragraphs. In § 545.26, paragraph (e)(1) is revised to include reference to education programs. Section 545.28 is being revised as an administrative measure to allow for the payment of the limited financial incentives authorized by the provisions of the drug abuse treatment programs (§ 550.57(a)(1)).

The November 22, 1994 final rule on pretrial inmates removed references to waiver of separation because the decision to maintain separation in instances where the design, structure, and operation of the institution may make separation not practicable is made by staff. Section 545.23(b) accordingly has been revised to remove similar reference.

Changes to the definitions in § 545.21 include the following. The definition of inmate in paragraph (a) has been removed, because this definition is covered more generally in 28 CFR 500.1. A new paragraph (a) has been added to define the phrase ''physically and mentally able.'' Paragraph (c) has been revised to include Federal Prison Industries' acronym rather than its trade name. Paragraphs (d) through (g) have been redesignated as paragraphs (e) through (h) in order to add a new definition for ''commissary assignment.'' This assignment, also referenced in newly revised § 545.23(a), operates under the Bureau's Trust Fund Division.

In § 545.26, the Bureau is adding a provision in paragraph (d) to make exception for a reduction in inmate pay based upon absence from a scheduled assignment. This exception provides the Bureau the flexibility to continue payment in instances where the Assistant Director, Correctional Programs Division deems this advisable. In paragraph (e), the Bureau is adding a similar provision with respect to work evaluations. This exception may be invoked at independent camps in instances where, in order to conserve staff resources, staff may monitor an inmate's performance on a periodic basis rather than a monthly basis when the inmate has received exceptional evaluations over an extended period.

Because the additions to the proposed regulations either relieve a restriction on the inmate or are administrative in nature, the Bureau finds good cause for exempting the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and a delay in the effective date. Members of the public may submit comments concerning this rule by writing to the previously cited address. These comments will be considered but will receive no response in the Federal Register.

The Bureau of Prisons has determined that this rule is not a significant regulatory action for the purpose of E.O. 12866, and accordingly this rule was not reviewed by the Office of Management and Budget. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (Pub. L. 96–354), does not have a significant impact on a substantial number of small entities.

List of Subjects in 28 CFR Part 545

Prisoners.

Kathleen M. Hawk,

Director, Bureau of Prisons.

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(p), part 545 in subchapter C of 28 CFR, chapter V is amended as set forth below.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT

PART 545—WORK AND COMPENSATION

1. The authority citation for 28 CFR 545 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3013, 3571, 3572, 3621, 3622, 3624, 3663, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4126, 5006–5024 (Repealed October 12, 1984 as to offenses committed after that

date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

2. In § 545.20, paragraph (a) is revised to read as follows:

§ 545.20 Purpose and scope.

(a) The Bureau of Prisons operates an inmate work program within its institutions. To the extent practicable, the work program:

(1) Reduces inmate idleness, while allowing the inmate to improve and/or develop useful job skills, work habits, and experiences that will assist in post-release employment; and

(2) Ensures that activities necessary to maintain the day-to-day operation of the institution are completed.

Sentenced inmates who are physically and mentally able to work are required to participate in the work program. When approved by the Warden or designee, drug treatment programming, education, or vocational training may be substituted for all or part of the work program.

* * * * *

3. In § 545.21, paragraphs (a) and (c) are revised, paragraphs (d) through (g) are redesignated as paragraphs (e) through (h), and a new paragraph (d) is added and newly designated paragraph (f) is revised to read as follows:

§ 545.21 Definitions.

(a) *Physically and mentally able.* For purposes of this rule, this shall include inmates with disabilities who, with or without reasonable accommodation, can perform the essential function of the work assignment.

* * * * *

(c) *Industry assignment.* A Federal Prison Industries (FPI) work assignment.

(d) *Commissary assignment.* A Trust Fund work assignment.

* * * * *

(f) *Part-time work assignment.* A work assignment to which an inmate is assigned for only a portion of the scheduled work day. Part-time work assignments are ordinarily made in conjunction with drug treatment programming, education, and/or vocational training programs.

* * * * *

4. In § 545.23, paragraphs (a) and (b) are revised to read as follows:

§ 545.23 Inmate Work/Program Assignment.

(a) Each sentenced inmate who is physically and mentally able is to be assigned to an institutional, industrial, or commissary work program. Exception shall be made to allow for inmate participation in an education, vocational, or drug abuse treatment program, on either a full or part-time basis, where this involvement is mandated by Bureau policy or statute (for example, the Literacy Program). Where such participation is not required by either policy or statute, exception may be made to allow an inmate to participate in an education, vocational, or drug abuse treatment program rather than work full-time upon the request of the inmate and approval of the Warden or designee.

(b) A pretrial inmate may not be required to work in any assignment or area other than housekeeping tasks in the inmate's own cell and in the community living area, unless the pretrial inmate has signed a waiver of his or her right not to work (see 28 CFR part 551, subpart J).

* * * * *

§ 545.24 [Amended]

5. In § 545.24, paragraph (d) is amended by revising in the first sentence the word ''educational'' to read ''education''.

6. In § 545.25, paragraph (a)(2) is revised and a new paragraph (d) is added to read as follows:

§ 545.25 Eligibility for performance pay.

(a) * * *

(2) Literacy program (GED) participation;

* * * * *

(d) An inmate who refuses participation, withdraws, is expelled, or otherwise fails attendance or examination requirements of the drug abuse education course shall be held at the lowest pay grade (Grade 4).

7. In § 545.26, paragraphs (d), (e) introductory text, and (e)(1) are revised to read as follows:

§ 545.26 Performance pay provisions.

* * * * *

(d) An inmate is eligible to receive performance pay only for those hours during which the inmate is actually performing satisfactory work or actively participating in an education or vocational training program. Absences from an inmate's scheduled assignment for such reasons as call-outs, visits, sick call, interviews, or making telephone calls shall be deducted from the monthly number of hours worked and will accordingly reduce the amount of pay received by the inmate. Any exception to such reduction in pay must be approved by the Assistant Director, Correctional Programs Division, Central Office.

(e) *Work Evaluation.* At the end of each month the work detail/program supervisor shall compute on an evaluation form the hours worked by the inmate and the pay to be awarded. The supervisor shall also rate the inmate's performance over the past month in each of several categories. For example, an inmate may be rated in such categories as quality of work, quantity of work, initiative, ability to learn, dependability, response to supervision and instruction, safety and care of equipment, ability to work with others, and overall job proficiency. Any exception to the work performance evaluation procedures cited above requires approval of the Assistant Director, Correctional Programs Division, Central Office.

(1) An inmate shall receive performance pay only for those hours during which the inmate is satisfactorily performing work or is actively participating in an education/vocational program.

* * * * *

8. Section 545.28 is revised to read as follows:

§ 545.28 Achievement awards.

(a) With prior approval of the Education Department, each inmate who completes the Literacy program, Vocational Training, or related trades classroom work that is part of a certified apprenticeship program may be granted an achievement award from performance pay funds.

(b) With prior approval of the Psychology Services Department, each inmate who is making satisfactory progress or completes a residential drug treatment program may also be granted an achievement award from performance pay funds.

[FR Doc. 96–126 Filed 1–3–96; 8:45 am]

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