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Contents

Federal Register

Vol. 63, No. 231

Wednesday, December 2, 1998

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 63, No. 231
Wednesday, December 2, 1998

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Part 2424

Negotiability Proceedings

AGENCY: Federal Labor Relations Authority.

ACTION: Final rule.

SUMMARY: The Chair and Members of the Authority component (the Authority) of the Federal Labor Relations Authority (the FLRA) revise the regulations concerning negotiability proceedings. The revisions are designed to expedite these proceedings and facilitate dispute resolution.

EFFECTIVE DATE: April 1, 1999.

ADDRESSES: Written comments received are available for public inspection during normal business hours at the Office of Case Control, Federal Labor Relations Authority, 607 14th Street, NW., Washington, D.C. 20424–0001.

FOR FURTHER INFORMATION CONTACT: Peter Constantine, Office of Case Control, at the address listed above or by telephone # (202) 482–6540.

SUPPLEMENTARY INFORMATION:

Background

In an effort to improve its decision-making processes, the Chair and Members of the Authority established an internal task force to study and evaluate the policies and procedures in effect concerning negotiability proceedings under 5 U.S.C. 7117. To this end, the Authority published a **Federal Register** notice (63 FR 19413) (April 20, 1998) inviting the public to submit written comments on several subjects relevant to negotiability proceedings, and to participate in a focus group held in May 1998 to discuss these matters.

Subsequently, the Authority proposed revisions to part 2424 of the Authority's regulations concerning negotiability proceedings. The proposed rule was published in the **Federal Register** and public comment was solicited on the proposed changes (63 FR 48130) (September 9, 1998). The Authority invited comment on the proposed rule in two ways: by convening meetings in October 1998 in Chicago, IL, Oakland, CA, and Washington, DC, and by offering the public an opportunity to submit written comments. Formal written comments were submitted by seven agencies, six exclusive representatives, and two individuals. In addition, over 80 individuals, representing many agencies and exclusive representatives, participated in meetings to discuss the proposed regulations. All comments, whether expressed orally in a meeting or submitted in writing, have been considered prior to publishing the final rule, and most comments are specifically addressed in the section-by-section analysis below. Revisions to the proposed rule have been made, for the most part, in response to suggestions and comments received.

Significant Changes

The final rule, like the proposed rule, involves important changes in the processing of negotiability appeals. The final rule incorporates significant changes from the proposed rule, based on consideration of comments received. The most significant change is that the Authority determined not to include in the final rule requirements that: (1) An exclusive representative file with the Authority a notice of intent to institute a negotiability appeal; and (2) parties participate in a conference with a representative of the FLRA prior to the filing of a petition for review by the exclusive representative concerning a proposal for bargaining. These proposed requirements would have applied only to bargaining proposals; they were not proposed to apply to disputes involving provisions that had been disapproved by agency heads under 5 U.S.C. 7114(c). The proposed notice of appeal and prefiling conference requirements were intended to provide an opportunity to explore resolution of the dispute, and narrow and clarify issues remaining to be resolved on appeal.

Many of the commenters to the proposed rule objected to the proposed notice of appeal and prefiling conference requirements. The reasons for these objections included comments that the notice of appeal and prefiling conference would lead to unnecessary delay in resolution of the negotiability appeal, and comments that the Authority did not have a sufficient interest in a prefiling dispute to warrant these regulatory requirements. Commenters generally agreed, however, that a conference that included representatives of the parties and the FLRA would be useful during the processing of a negotiability appeal.

In response to these comments, the final rule does not include the notice of appeal and prefiling conference requirements. Instead, the final rule provides for a ''post-petition conference'' to be held in cases involving a proposal or provision after the exclusive representative has filed its petition for review but before the agency files its statement of position. The purpose of the post-petition conference, which may be held in person or telephonically, is to ensure that the parties have a common understanding of the meaning and impact of the proposal or provision at issue; to determine whether there are factual disputes concerning the proposal or provision; and to discuss other relevant matters, including whether the parties wish to explore alternative dispute resolution.

The final rule also differs from the proposed rule by eliminating the provision that would have precluded parties from raising new arguments after the close of the filing conferences. The final rule requires that the agency raise and support in its statement of position all of its arguments that a proposal or provision is outside the duty to bargain or contrary to law, respectively. The exclusive representative, in its response, is required to raise and support any arguments opposing arguments made in the agency's statement of position. The agency is then provided with a right to file a submission not previously proposed: a reply to arguments raised for the first time in the exclusive representative's response. This submission is limited to replying to new arguments in the exclusive representative's response.

In other respects, the final rule retains significant aspects of the proposed rule. In particular, it establishes procedures designed to facilitate the resolution in one proceeding of all issues raised in

connection with a petition for review, including those issues previously processed exclusively under unfair labor practice or grievance procedures. Among other things, with one exception, the final rule retains the portion of the proposed rule that results in dismissal without prejudice of a petition for review where an unfair labor practice charge or grievance is pending over issues directly related to the petition.

The proposed rule has also been modified in many other respects, primarily in response to specific comments. All of the changes from the proposed rule are described in the following sectional analysis of the final rule.

Sectional Analyses

Sectional analyses of the amendments and revisions to part 2424, Negotiability Proceedings, are as follows:

Part 2424—Negotiability Proceedings

Subpart A—Applicability of This Part and Definitions

Section 2424.1

Commenters recommended that the Authority change the effective date of the rule to allow parties sufficient time to train employees and develop procedures to protect their respective interests under the revised rule. To address these concerns, the final rule establishes an April 1, 1999 effective date.

Section 2424.2

Numerous commenters responded favorably to the addition of a definition section to this part. Several changes have been made to particular definitions, in response to suggestions offered by commenters.

Changes have been made in subsection (a) and (c) to clarify and distinguish the two types of disagreements over the duty to bargain, which the proposed rule identified as ''bargaining disputes'' and ''negotiability disputes.'' Several commenters suggested that the term ''bargaining dispute'' was confusing in that it commonly is used to apply to a broader range of disputes than contemplated by the definition of the term in the proposed regulations, and other commenters suggested alternative terms. To address these concerns, the term ''bargaining dispute'' has been changed to ''bargaining obligation dispute'' in the final rule. The term ''negotiability dispute'' has been retained in the final rule. In order to avoid confusion over the disputes to which these terms apply, examples have been provided in both subsection (a) and subsection (c).

Several comments indicated that the concept of ''provision'' in subsection (f) appeared to be broader than its proposed definition and, in particular, should be defined to include a contract term imposed by the Federal Service Impasses Panel pursuant to 5 U.S.C. 7119 and disapproved by an agency head pursuant to 5 U.S.C. 7114(c). The final rule is modified to reflect that a provision encompasses any matter disapproved on agency head review.

With respect to the definition of ''service'' in subsection (g), the final rule remains unchanged from the proposed rule and requires that the exclusive representative serve its filings on both the agency's principal bargaining representative and the head of the agency. In this regard, the final rule does not incorporate the recommendation of one commenter that the requirement for the exclusive representative to serve copies of its filings be limited to service on the agency head, as required in 5 U.S.C. 7117(c)(2)(B). The Authority views service on both the agency's principal bargaining representative and the agency head as important to ensure that appropriate agency officials receive prompt notice of the exclusive representative's filing of the petition for review, as well as subsequent filings. Ensuring that appropriate agency officials receive prompt notice of the filing of a petition for review is particularly important in view of the requirement in § 2424.23 of the final regulations that appropriate agency officials be available and prepared to participate in a post-petition conference within a short time after the filing of the petition. Thus, although the final rule imposes a burden on exclusive representatives, this burden is outweighed, in the Authority's view, by the benefits resulting from the service requirement.

The final rule in subsection (h) modifies the definition of ''severance'' from that in the proposed rule to make clear that the purpose of severance is to determine whether a severed portion of a proposal or provision is within the duty to bargain, or contrary to law, in the event that some portions of the proposal or provision are found to be outside the duty to bargain or contrary to law. In effect, severing portions of a proposal or provision results in the creation of separate proposals or provisions. Thus, severed portions must have independent meaning, and any dispute over severed portions must be argued separately. Resolving bargaining obligation and negotiability disputes regarding portions of a proposal or provision lengthens the time necessary to issue decisions and orders, and requires expenditures of additional resources—separate arguments and responses—by both parties. Accordingly, exclusive representatives should request severance only in situations where they wish to bargain over portions of a proposal, or have only portions of a provision included in a collective bargaining agreement in the event that some portions are found to be outside the duty to bargain or contrary to law.

One commenter suggested that the definition of ''written allegation concerning the duty to bargain'' in subsection (i) be changed to ''written allegation'' or ''written allegation concerning the legality of a proposal or provision'' to eliminate any confusion associated with the term ''bargain,'' which is also used in the unfair labor practice context. Although the final rule does not adopt this suggestion, the definition of ''petition for review'' makes clear that appeals under part 2424 must involve a negotiability dispute: if only a bargaining obligation dispute is involved, then the appeal cannot be resolved under part 2424.

As discussed in further detail in the commentary to Subpart B, the definition of ''notice of intent to appeal'' in the proposed rule has been eliminated from the final rule.

Finally, one commenter recommended that the final rule define the term ''conditions of employment.'' The final rule does not adopt this recommendation because the definition of this term is set forth in 5 U.S.C. 7103 (a)(14), and its inclusion in the regulations would be duplicative.

Sections 2424.3–2424.9

These sections are reserved.

Subpart B—Alternative Dispute Resolution; Requesting and Providing Allegations Concerning the Duty To Bargain

As noted in the introductory discussion, the Authority received many comments objecting to the proposed prefiling requirement and, in particular, prefiling conferences. Commenters did not, however, object to the optional use of such procedures. Several commenters suggested that mandatory prefiling conferences would result in unnecessary delay and would involve the Authority too early in the negotiability process. Commenters also suggested that efforts directed at

alternative dispute resolution would be better handled through programs and/or agencies specifically designed for that purpose, such as the FLRA's Collaboration and Alternative Dispute Resolution Program (CADR) or the Federal Mediation and Conciliation Service. Other commenters questioned the legality of the proposed prefiling conditions as well as the proposal to preclude parties from later raising arguments that had not been raised during the prefiling conference. In response to these comments, the final rule eliminates all proposed prefiling conditions, including the notice of intent to appeal and the mandatory prefiling conferences. As discussed in the commentary to § 2424.10, however, parties are encouraged to explore opportunities for resolution of disputes that arise under part 2424.

Section 2424.10

Parties uniformly supported the retention of the CADR Program for voluntary dispute resolution. The final rule encourages parties to utilize the CADR process in an effort to reach a collaborative resolution of issues that arise under part 2424. In response to suggestions, the final rule includes point of contact information for the CADR office.

Section 2424.11

The final rule on requesting and providing written allegations concerning the duty to bargain has been modified to reflect the elimination of proposed prefiling conditions governing petitions for review. The rule retains the current procedure for requesting and providing allegations concerning the duty to bargain. In response to a commenter, the rule has been clarified to state that a union may file a petition for review where an agency does not respond to a written request for the agency's written allegation concerning the duty to bargain. The regulation has also been clarified to state that, if an agency provides the union an unrequested written allegation concerning the duty to bargain, then the union may choose either to file a petition for review or to wait and later request another written allegation from the agency. A union is required to file a petition for review, on penalty of losing its right to appeal the agency's allegation, only where the agency's written allegation is in response to a written request by the union.

Section 2424.12–2424.19

These sections are reserved.

Subpart C—Filing and Responding to a Petition for Review; Conferences

Section 2424.20

As noted in the earlier commentary concerning Subpart B, the prefiling conditions have been eliminated. The final rule has been modified to reflect this change.

One commenter suggested that agencies should be provided a right to file petitions. This suggestion was not adopted because 5 U.S.C. 7117(c), which mandates the negotiability procedure, provides for appeals by exclusive representatives only. In the event an agency believes that a union has refused to bargain over a mandatory subject of bargaining, it may file an unfair labor practice charge. *See American Federation of Government Employees* v. *Federal Labor Relations Authority*, 778 F.2d 850, 853 n.4 (D.C. Cir. 1985).

Section 2424.21

One commenter, noting that the proposed rule was silent on this matter, suggested that the final rule specify that an agency head disapproval of a provision under 5 U.S.C. 7114(c) triggers the time limit for filing a petition for review. The final rule incorporates this suggestion.

Section 2424.22

Several commenters asserted that the filing requirements were unnecessarily legalistic and burdensome. Commenters recommended that the final rule be revised to make clear the specific information the exclusive representative is required to provide in its petition for review. In response to these concerns, subsection (a), stating the purpose of the petition for review, has been added, and subsection (b) of the final rule, which specifies the information that must be included in a petition for review, has been amplified. Also in response to one comment, the final rule makes clear that an exclusive representative is required to provide the meaning of a proposal or provision in the petition for review. The final rule does not adopt the suggestion of one commenter to delete the requirement that a table of contents and table of authorities be included when a petition exceeds 25 double-spaced pages in length. These tables, which will be required only for lengthy submissions, will assist both the parties and the Authority in reviewing complex petitions.

One commenter questioned whether the proposed regulations intended to delete the procedure in § 2424.4(c) of the current regulations, which provides that filing an ''incomplete petition for review will result in the exclusive representative being asked to provide the missing or incomplete information.'' The commenter is correct in that a parallel section was not included in the proposed regulations, and is not included in the final regulations. The Authority does not intend by this to alter its current practice insofar as both parties are now, and will in the future continue to be, given an opportunity to correct minor or technical deficiencies in a filing. Such minor or technical deficiencies include failing to provide the correct number of copies of documents, or failing to include a statement of service. The consequences of failure to comply with an order requiring such correction are set forth in § 2424.32(d). However, the fact that the Authority will provide opportunities for parties to correct minor, technical deficiencies in filing does not mean that parties may reasonably rely on the Authority to provide them an opportunity to correct other deficiencies, such as failure to raise and support, or failure to respond to, an argument. Consistent with § 2424.32(c), these latter failures will, where appropriate, be deemed waivers or concessions.

In response to comments that certain matters, including exclusive representatives' requests for severance, and exclusive representatives' assertions that proposals or provisions constitute procedures and/or appropriate arrangements under 5 U.S.C. 7106(b) (2) and (3), respectively, would be better addressed at a later stage in the proceeding, the final rule has been changed. In particular, subsection (c) of the final rule does not require that an exclusive representative raise and address any request for severance in its petition for review. Moreover, the responsibility of the exclusive representative to raise any arguments concerning procedures and appropriate arrangements under 5 U.S.C. 7106 (b)(2) and (b)(3) has been moved to the exclusive representative's response to the agency's statement of position set forth in § 2424.25 of the final rule. However, an exclusive representative may choose to raise these matters in its petition for review. As discussed in the commentary to § 2424.24, if an exclusive representative raises such matters in its petition for review, then the agency is required to respond to the matters in its statement of position because failure to do so may be deemed a waiver or concession.

The final rule also modifies the requirement that the exclusive representative provide copies of authorities on which it relies. In

response to comments that this requirement would be burdensome, the rule limits the documents that must be provided to those not ''easily'' available to the Authority. This is intended to clarify that copies of such authorities as provisions in the United States Code, Government-wide regulations, and published precedent need not be provided. However, as agency regulations and such matters as sections in collective bargaining agreements are not easily available, copies of these must be provided. If a filing party is in doubt as to whether an authority it relies on is easily available to the Authority, the party is encouraged to seek guidance from the Case Control Office, whose address and telephone number appear in 5 CFR 2429.24.

Section 2424.23

As noted previously, the proposed rule required a prefiling conference in cases involving proposals for bargaining and a postfiling conference in cases involving provisions disapproved by an agency head under 5 U.S.C. 7114(c). Although commenters generally disfavored mandatory prefiling conferences, commenters generally favored postfiling conferences. The final rule provides in subsection (a) that a representative of the FLRA will, where appropriate, schedule and conduct a conference following the filing of a petition for review involving proposals and provisions. Although a post-petition conference is not required in all cases, it is expected that one will be held in most cases. In response to a suggestion that a time frame be provided for completion of the conference, the final rule provides that all reasonable efforts will be made to schedule and conduct the post-petition conference within 10 days of receipt of the petition for review.

One commenter objected that post-petition conferences should not include mandatory mediation or settlement discussions. Subsection (b) of the final rule has been modified to eliminate any suggestion that the post-petition conference is intended to mediate the dispute or require settlement. Nevertheless, it is envisioned that parties will be asked whether they would like to pursue alternative dispute resolution options, including CADR services. Subsection (b) reflects that the purpose of the conference is to assist the parties in discussing, clarifying and resolving the issues in the negotiability appeal. These issues include the meaning of a proposal or provision, whether there are factual disputes, and other matters. Where appropriate, modification of the wording of a proposal or provision to conform to the intended or agreed-upon meaning of the proposal or provision will be encouraged.

Several commenters objected to an automatic extension of the time limits under §§ 2424.24 and 2424.25. In response to these objections, subsection (b) is modified to reflect that the subject of extension of the time limits under §§ 2424.24 and 2424.25—specifically whether such extension is requested—will be discussed during the post-petition conference, and that the FLRA representative conducting the conference is authorized to grant a requested extension when it would effectuate the purposes of the Federal Service Labor-Management Relations Statute, 5 U.S.C. 7101 *et seq.* A request for an extension of time also may be filed pursuant to § 2429.23 of this subchapter.

Several commenters asserted that parties would be more likely to discuss, clarify and resolve their disputes if no record were made of the conference. Other commenters recommended that, if a record of the conference were prepared, then the Authority should make clear that parties are not limited to arguments and assertions made during the conference. The final rule retains the record of the conference, providing in subsection (c) that a written statement of the conference, including whether the parties agree on the meaning of the proposal or provision and other appropriate matters, will be prepared at, or following the conclusion of, the conference and will be provided to the parties by the FLRA representative. However, commenters' assertions that parties should not be prevented from raising and supporting new arguments after the conclusion of the conference are addressed by the modification to § 2424.32(c) of the final rule, which clarifies that an agency is not limited to the arguments it raises in a conference. As described in the commentary to § 2424.32(c), the final rule clarifies that an agency is precluded from raising a new argument only after the filing of its statement of position, and that an exclusive representative is so precluded only after the filing of its response to the statement of position. In this regard, the purpose of the requirement in § 2424.23 that the parties' representatives must be prepared and authorized to discuss, clarify, and resolve bargaining obligation and negotiability disputes is to facilitate discussion and understanding and, thereby to expedite resolution of a petition for review, not to ''lock'' the parties into particular arguments or prevent the parties from raising new arguments in their subsequent filings. The Authority intends, by this provision, to encourage the parties to engage in a frank and open discussion of issues raised by the petition for review.

Section 2424.24

The purpose of the statement of position has been added as subsection (a) of this section. Several commenters questioned whether the time limit for filing an agency's statement of position could be extended. As explained in the commentary to § 2424.23, an extension of time will be granted by the FLRA representative at the post-petition conference if it is requested and where the extension would effectuate the purposes of the Statute. An extension also may be requested under § 2429.23 of this subchapter. The final rule makes clear in subsection (b) that, unless an extension has been granted, the statement of position must be filed within 30 days after the date the head of the agency is served with a copy of the petition for review. Because the 30-day time limit for filing a statement of position is established by 5 U.S.C. 7117(c)(3), it cannot be shortened. Accordingly, the final rule does not adopt the suggestion of one commenter that the time limit for filing a statement of position be limited to 15 days. However, because it does not establish the Authority's jurisdiction over the petition for review, the 30-day time limit for filing a statement of position, as well as the time limit set forth in 5 U.S.C. 7117(c)(4) for filing the exclusive representative's response, may be extended upon request and when it would effectuate the purposes of the Statute.

Agencies uniformly objected, as previously noted, to the proposed rule precluding any arguments in the statement of position that were not raised in the conference prior to filing its statement of position. The final rule, in § 2424.32(c), is modified to reflect that an agency is not limited to arguments made in the post-petition conference; an agency is precluded from raising new arguments only after the filing of its statement of position.

Comments to the proposed rule viewed it as overly burdensome and unnecessary to require the agency to provide a copy of all the laws, rules, regulations, and other authorities cited. As set forth previously in connection with § 2424.22, the final rule is changed to require the agency to provide only those authorities that are not ''easily available.'' Also as set forth previously, examples of such materials include, but are not limited to, agency rules or

regulations and provisions of a collective bargaining agreement. As with § 2424.22, and for reasons stated in the commentary to that section, the final rule retains the requirement of a table of contents and a table of authorities when a statement of position exceeds 25 double-spaced pages in length.

One commenter noted that, with respect to severance, it would be unduly burdensome to anticipate how severance might affect proposals or provisions in general when the exclusive representative has not stated its position on severance. Responding to this concern, the final regulation clarifies in subsection (d) that an agency is required to respond to a severance request in its statement of position only when the exclusive representative has requested severance in its petition for review.

The Authority emphasizes that the agency is not limited in its statement of position to responding to matters raised in the exclusive representative's petition for review. However, under § 2424.32(c)(2), a failure to respond to an argument raised in the exclusive representative's petition for review may, where appropriate, be deemed a concession. Accordingly, the agency is required to respond to arguments made in the exclusive representative's petition for review, including arguments—such as severance and asserted exceptions to management's rights—that the exclusive representative is not required to include in a statement of position. Moreover, under § 2424.32(c)(1) of these regulations, the agency may not raise new arguments, in this or any other proceeding, after the filing of the statement of position. Therefore, the agency must raise and support in its statement of position all of its bargaining obligation and negotiability claims, whether or not those claims are responsive to requests and arguments made in the exclusive representative's petition for review.

Section 2424.25

As with §§ 2424.22 and 2424.24, a subsection—(a)—stating the purpose of the exclusive representative's response has been added. Several commenters suggested that the time limits for filing a response could not be extended. As noted earlier in connection with §§ 2424.23 and 2424.24, time limits may be extended when requested and when such extension will effectuate the purposes of the Statute. Thus, the final rule makes clear in subsection (b) that an exclusive representative's response must be filed within 15 days of service of the agency's statement of position, unless an extension of time has been granted.

Subsection (c) of the final rule has been modified, based on comments noted in the commentary to § 2424.22. The modification clarifies that, if the exclusive representative believes that a proposal or provision is within the obligation to bargain or is not contrary to law, respectively, because it comes within an exception to management rights under section 7106(a), then the exclusive representative is required to assert and support this claim either in its petition for review or in its response to the agency's statement of position. Exceptions to management rights, set forth in 5 U.S.C. 7106(b), include that a proposal or provision is bargainable at an agency's election, that the proposal or provision constitutes a procedure, and/or that it constitutes an appropriate arrangement. If the exclusive representative does not assert in its petition for review that an exception to management rights applies, then the exclusive representative must do so in its response to the agency's statement of position.

In general, the exclusive representative's response is limited to matters raised in the agency's statement of position. The only exception is a request for severance, which subsection (d) clarifies may be asserted for the first time in a response.

As with §§ 2424.22 and 2424.24 of the final rule, the requirement that the exclusive representative provide a copy of all laws, rules, regulations and authorities cited has been modified to include only those authorities not easily available to the Authority.

The Authority emphasizes that, under § 2424.32(c)(2), a failure to respond to an argument raised in the agency's statement of position may, where appropriate, be deemed a concession. Moreover, under § 2424.32(c)(1) of these regulations, the exclusive representative may not raise new arguments, in this or any other proceeding, after the filing of the response. Therefore, the exclusive representative must raise and support in its response all of its arguments in support of finding the proposal or provision within the duty to bargain or not contrary to law, respectively. With the exception of severance, the exclusive representative's response is limited to arguments raised in the agency's statement of position.

Section 2424.26

A new section permitting a reply by the agency has been added to the final rule. As outlined in the commentary to §§ 2424.22 and 2424.25, the exclusive representative is not required in the initial stage of the negotiability proceeding to anticipate agency arguments. In particular, an exclusive representative's arguments concerning exceptions to management rights and severance may be asserted for the first time in the exclusive representative's response to the agency's statement of position. In order that the agency has an opportunity to address arguments raised for the first time in the exclusive representative's response, this section of the final rule establishes that the agency may file a reply to such arguments. The agency reply constitutes a new filing that will, in some cases, extend the time necessary to resolve a petition for review. However, the Authority anticipates that permitting the filing of a reply will not delay decisions but, rather, will expedite them by providing a more complete record of the parties' arguments and authorities.

Subsection (a) of the final rule states the purpose of the agency's reply. Subsection (b) provides that an agency must file any reply within 15 days after it has been served with a copy of the exclusive representative's response. Subsection (c) of the final rule outlines the information to be included in the agency's reply and specifically limits the agency's reply to those matters raised in the exclusive representative's response to the agency's statement of position. Subsection (d) addresses the agency's responsibility to explain with particularity why the exclusive representative's request for severance, if any, is not appropriate. Service requirements are outlined in subsection (e) of the final rule.

The Authority emphasizes that an agency's reply is limited to arguments raised for the first time in the exclusive representative's response. Thus, as set forth earlier in the commentary to § 2424.24, the agency should respond fully in its statement of position to all arguments raised in the exclusive representative's petition for review, and should not defer such responses to its reply. A failure to respond to arguments raised in the exclusive representative's response may be deemed a concession under § 2424.32 of these regulations.

Section 2424.27

Noting that the Authority seldom accepts additional submissions, one commenter suggested that the regulations should reflect this practice. In particular, the commenter recommended that the Authority adopt an ''extraordinary circumstances'' standard concerning the filing of additional submissions. The final rule incorporates this suggestion and adopts the suggested standard. The final rule

also adopts the recommendation that any additional submission must be filed no later than 5 days after receipt of the Authority's order granting the request. The final rule does not adopt the suggestion that the time for filing an opposition to an additional submission be limited to 5 days after receipt of the additional submission and, instead, provides that an opposition be filed no later than 15 days after receipt of the additional submission. The additional time is provided in recognition of the fact that the responding party may have no advance notice that the submission will be filed and, as such, a 5-day response period is not sufficient.

Sections 2424.28–2424.29

These sections are reserved.

Subpart D—Processing a Petition for Review

Section 2424.30

Several commenters addressed the proposed rule establishing a new process for resolving petitions for review that concern both negotiability and bargaining obligation disputes. Those in favor of the proposed changes asserted that a unified process would be more efficient than the present system. Those opposed to the changes contended that the negotiability process does not lend itself to addressing bargaining obligation disputes and that the existing system does not need modification.

The Authority has determined that, with certain changes, the proposed rule should be made final. In this regard, the Authority's experience has been that the piecemeal resolution of bargaining obligation and negotiability claims is both inefficient and ineffective. The changes adopted in this rule will reduce duplicative administrative decision making and increase the likelihood that disputes will be resolved more timely.

With respect to the specific changes proposed, some commenters asserted that, where both a negotiability appeal and unfair labor practice charge have been filed, the exclusive representative should retain the right to select the procedure that would go forward. This suggestion was rejected, on the ground that unfair labor practice proceedings are, in these situations, better suited to resolving the entire dispute.

In this regard, with the sole exception of compelling need claims, which is discussed below, all bargaining obligation and negotiability claims may be adjudicated in an unfair labor practice proceeding. Further, unless excluded from the scope of the parties' grievance procedure by agreement, alleged unfair labor practices may be resolved under such negotiated procedures. Thus, with one exception, dismissing petitions for review where unfair labor practice charges have been filed does not jeopardize a party's ability to obtain adjudication of all claims. In addition, as clarified in § 2424.40(a), and with the exception of orders to bargain, remedies available in unfair labor practice proceedings under 5 U.S.C. 7118(a)(7) are not be available in Authority decisions and orders issued under this part. Accordingly, in situations where an exclusive representative has filed an unfair labor practice charge, requiring adjudication in a negotiability proceeding would deprive a prevailing exclusive representative of such remedies.

The one exception to the principle that all bargaining obligation and negotiability claims may be adjudicated in an unfair labor practice or grievance proceeding concerns petitions for review where the agency makes a negotiability claim that a proposal or provision conflicts with an agency regulation for which there is a compelling need under 5 U.S.C. 7117(b). Such compelling need claims must be resolved under the procedures of part 2424. *See Department of the Army, Aberdeen Proving Ground v. Federal Labor Relations Authority,* 485 U.S. 489 (1988) (compelling need determinations may not be adjudicated in an unfair labor practice proceeding). Moreover, an agency cannot be found to have committed an unfair labor practice by refusing to bargain over a proposal over which it has made a compelling need claim unless the Authority has made a prior compelling need determination in a proceeding under part 2424. *See Department of the Army, Soldier Support Center, Fort Benjamin Harrison, Office of the Director of Finance and Accounting, Indianapolis, Indiana, et al.,* 41 FLRA 926, 933 n.1 (1991). Thus, unless an agency's compelling need claim regarding a proposal or provision has previously been resolved by the Authority, there is no basis on which to dismiss the petition for review, or the portion of it relating to such proposal or provision, to permit resolution of all issues in an unfair labor practice or grievance proceeding.

In view of the foregoing comments and considerations, subsection (a) of the final rule is modified to clarify that there is an exception—a proposal or provision over which a compelling need negotiability claim is raised—to the requirement to dismiss a petition for review without prejudice in the event an unfair labor practice charge or grievance has been filed over issues directly related to the petition for review. Petitions for review, or portions of them, concerning proposals or provisions subject to compelling need claims will be processed under part 2424.

In addition, the rule is modified to provide that, within 30 days following *administrative* resolution of the unfair labor practice charge or grievance, an exclusive representative may refile the petition for review and the Authority will determine whether resolution of the petition is required. The reference in subsection (a) to administrative resolution is intended to exclude any time necessary for judicial review. That is, an exclusive representative may not await the outcome of judicial review in the unfair labor practice or grievance arbitration proceeding before refiling the petition for review. With regard to an arbitration award, for purposes of refiling a petition for review, the Authority will apply 5 U.S.C. 7122(b) and find an award final and binding in the event no timely exceptions to the award are filed with the Authority; if exceptions are timely filed, then the award is final and binding for purposes of refiling a petition for review when the Authority resolves the exceptions.

In determining whether resolution of the petition is required, the Authority will take into consideration such matters as whether, consistent with the resolution of the unfair labor practice charge or grievance, an Authority decision and order finding a proposal within the duty to bargain and directing bargaining could be enforced.

The final rule clarifies in subsection (b) how the Authority will process a petition for review where the exclusive representative has not pursued a bargaining obligation dispute in any other proceeding. As with the proposed rule, subsection (b) distinguishes between two categories of cases: (1) Cases where no bargaining obligation dispute exists; and (2) cases where both a negotiability dispute and a bargaining obligation dispute exist. With respect to the first category, the final rule remains unchanged from the proposed rule, providing that where there is no bargaining obligation dispute, the Authority will resolve the petition under the procedures of this part. With respect to the second category, subsection (b)(2) of the final rule provides that, where both a negotiability dispute and a bargaining obligation dispute exist, the Authority will inform the exclusive representative of any opportunity to file an unfair labor practice charge or grievance. If the exclusive representative pursues either

of these options, then the petition for review will be processed in accordance with subsection (a). If the exclusive representative does not pursue either of these options, then subsection (b)(2) of the final rule provides that the Authority will resolve all aspects necessary for disposition of the petition unless, in its discretion, the Authority determines that doing so is not appropriate.

Subsection (b)(2) provides two examples of situations to illustrate where it is not appropriate to resolve all aspects of the petition for review under part 2424. The first is where resolution of the bargaining obligation dispute would unduly delay resolution of the negotiability dispute. A specific example of this is a petition for review involving a negotiability dispute that is clearly controlled by existing precedent such that a decision resolving only the negotiability dispute could be issued expeditiously, but numerous bargaining obligation dispute issues also are present. In such a case, the Authority may conclude that prompt resolution of the negotiability dispute only is preferable to delaying issuance of a decision and order so as to resolve bargaining obligation dispute issues at the same time. The second, related situation set forth in subsection (b) is where the procedures in another, available forum are better suited to resolving the bargaining obligation dispute. An example of this is a petition for review involving a bargaining obligation dispute raising issues of first impression. In such a case, the Authority may conclude that unfair labor practice procedures, which permit participation of the General Counsel and, thereby, facilitate consideration of the General Counsel's views on the issues of first impression, are better suited to resolution of the bargaining obligation dispute than are the procedures in this part.

In circumstances where a proposal is within the duty to bargain, then any bargaining order under § 2424.40 would be expressly conditioned on resolution of the unresolved bargaining obligation dispute in a manner requiring bargaining. On the other hand, if the proposal is outside the duty to bargain or the provision is contrary to law, resolution of the bargaining obligation dispute would be unnecessary.

The Authority emphasizes that resolution of a petition for review involving bargaining obligation and negotiability disputes will not result in adjudication of whether an unfair labor practice has occurred. Such determination may be sought only pursuant to 5 U.S.C. 7116 and 7118. Accordingly, although an Authority decision and order under part 2424 may include determination of underlying legal issues that could also be determined in unfair labor practice proceedings—such as whether a proposed matter is covered by a collective bargaining agreement or whether the effect of a change in conditions of employment is de minimis—that determination will not be accompanied by a finding that an agency acted unlawfully by, for example, implementing a change in conditions of employment without bargaining. Such a finding can only be made in an unfair labor practice proceeding, or in a grievance proceeding determining whether an unfair labor practice occurred. In addition, as resolution of petitions for review under this part will not result in unfair labor practice adjudications, decisions and orders issued under this part will not, with the exception of orders to bargain, include remedies available under 5 U.S.C. 7118(a)(7) in unfair labor practice proceedings. Thus, if exclusive representatives desire such remedies, they should file an unfair labor practice charge or a grievance.

Section 2424.31

Clarification was sought as to when and how the Authority would undertake fact finding as set forth in § 2424.34 of the proposed rules. Comments also recommended that the Authority clarify the circumstances under which it would hold a hearing pursuant to § 2424.38 of the proposed rules. Based upon these comments, §§ 2424.34 and 2424.38 of the proposed rules have been consolidated and moved to this section.

Subsection (a) of the final rule clarifies the actions that the Authority may take when necessary to resolve disputed issues of material fact or when such actions would otherwise aid in decision making. These actions include those set forth in the proposed rule, including a hearing under 5 U.S.C. 7117(b) and (c). The reference in the proposed rule to ''fact finding'' has been deleted as unnecessary in view of the inclusion in subsection (d) of ''other appropriate action.''

One commenter suggested that fact finding be limited to unfair labor practice proceedings. This suggestion was rejected as inconsistent with the determination that bargaining obligation disputes could be resolved in the negotiability process.

Section 2424.32

This section of the final rule combines requirements set forth in §§ 2424.35 and 2424.37 of the proposed rule. The requirements have been combined to reduce repetition and clarify the parties' obligations.

Subsections (a) and (b) of the final rule retain the requirement in § 2424.37 (a) and (b) of the proposed rule specifying the parties' burdens. In particular, subsection (a) provides that the exclusive representative is responsible for raising and supporting arguments that, among other things, a proposal or provision is within the duty to bargain or not contrary to law, and subsection (b) provides that the agency has the burden of supporting arguments to the contrary.

Subsection (c) retains and modifies requirements set forth in §§ 2424.35 and 2424.37 of the proposed rules. In particular, subsection (c) specifies the consequences of a party's failure to raise, support, and/or respond to arguments and assertions. With respect to failure to raise and support arguments, subsection (c) states that such failure will, where appropriate, be deemed a waiver of such arguments. It also states that, absent good cause: (1) an agency may not raise in proceedings under part 2424 or any other proceeding arguments that could have been but were not raised in its statement of position or made responsively in its reply to the exclusive representative's response; and (2) an exclusive representative may not raise in proceedings under part 2424 or any other proceeding arguments that could have been but were not raised in the petition for review or responsively in the response to the agency's statement of position. With respect to failure to respond to arguments, subsection (c) states that such failure will, where appropriate, be deemed a concession to such arguments or assertions.

Numerous comments were received objecting to the proposed requirement that, in connection with petitions for review concerning proposals, parties raise all arguments and issues at the prefiling conference or be precluded from raising such arguments and issues at a later stage in the negotiability appeal process. As stated previously, that requirement has been eliminated. However, the final rule precludes agencies and exclusive representatives from raising new arguments after the filing of the statement of position and response, respectively.

Several commenters asserted that any regulation that deemed arguments not raised by an agency to be waived would be inconsistent with the decision of the United States Court of Appeals for the District of Columbia Circuit in *Department of Transportation* v. *FLRA*, 145 F.3d 1425 (D.C. Cir. 1998) (*FAA*).

The Authority has concluded that the final rule is not inconsistent with the decision in *FAA*. In this regard, *FAA* did not address an agency's failure to raise an argument. In fact, the court concluded that, in *FAA*, the agency had ''squarely presented an argument to the [Authority].'' *Id.* at 1428. In addition, the court in *FAA* applied the Authority's existing negotiability regulations, which do not directly address filing requirements, burdens, waivers, and concessions. However, even under the existing regulations, the court in *FAA* stated that an agency has a burden to ''direct the Authority's attention, with as much specificity as possible, to the statutes and regulations relevant to an agency's duty to bargain * * *'' *Id.* at 1428 (quoting *National Federation of Federal Employees, Local 1167* v. *FLRA*, 681 F.2d 886, 891 (D.C. Cir. 1982)).

One commenter suggested that a regulation that deems an agency's failure to raise an objection a ''waiver'' would violate Rule 55(e) of the Federal Rules of Civil Procedure, which provides that there cannot be a ''judgment by default entered against the United States * * * unless the claimant establishes a claim or right to relief by evidence satisfactory to the court.'' However, the principle underlying this rule does not apply to the rule at issue, as is explained in the authority relied on by the commenter. Specifically, in the decision cited by the commenter, the United States Court of Appeals for the 9th Circuit stated that ''rule 55(e) was directed at defaults in the narrow sense of the government's failure to answer or otherwise move against a complaint, and was not intended to preclude the imposition, at a later stage in the proceeding, of sanctions or other court action which prevent the government from presenting further evidence or otherwise augmenting the record.'' *Giampaoli* v. *Califano*, 628 F.2d 1190 (9th Cir. 1980).

One commenter suggested that a failure to rebut an assertion should result in the finding of an adverse inference rather than a waiver or concession. An adverse inference is an evidentiary presumption that takes place when a party fails ''to call a particular witness, or to take the stand as a witness in a civil case, or voluntarily to produce documents or other objects in his or her possession as evidence,'' when it ''would be natural under the circumstances'' for the party to do so. 2 John William Strong et al., *McCormick on Evidence* § 264, at 184 (4th ed. 1992); *see also Internal Revenue Service, Philadelphia Service Center,* 54 FLRA 674, 682 (1998). In negotiability disputes, the more comparable analogue for failing to rebut an assertion raised in a pleading is that set forth in Rule 12 of the Federal Rules of Civil Procedure. *See* 2 James Wm. Moore, *Moore's Federal Practice* § 12.20 (3d ed. 1998) (*Moore's*) (''Rule 12(b) requires a party to assert in the response to any pleading requiring a response, every legal or factual defense to the claims made.''). Thus, the final rule uses the more appropriate term of art for a failure to rebut arguments, which is ''waiver'' or ''concession.'' *See Moore's* § 12.22 (''Rule 12(h)(1) waives certain defenses omitted from a motion * * *.'').

The revised negotiability procedures are intended to resolve, in most cases, all issues with respect to an agency's obligation to bargain over specific proposals or provisions. Accordingly, the Authority does not anticipate additional administrative proceedings before the Authority arising from the circumstances that occasioned the negotiability appeal. In any subsequent proceedings which might occur, the parties will not be permitted to relitigate the obligation to bargain over the proposals or provisions that were the subject of the negotiability appeal. In this regard, applying the well established principle of *res judicata*, a party will be barred from litigating not only those issues actually addressed by the Authority, but also any issues that could have been raised by the party in the negotiability proceeding. *See Department of Health and Human Services, Social Security Administration*, 41 FLRA 755, 772 (1991) (discussing the principles of *res judicata*). Further, where judicial review or enforcement of the Authority's order is sought, section 7123(c) of the Statute bars the parties from raising issues not presented to the Authority.

Subsection (d) addresses a party's failure to participate in a post-petition conference under § 2424.23, procedures directed under § 2424.31, and a failure to respond to Authority orders. The subsection clarifies that, in addition to actions set forth in subsection (c), a failure to participate in a conference or to respond to an Authority order, such as an order directing correction of minor, technical deficiencies in a filing, may result in dismissal of a petition for review, with or without prejudice to the exclusive representative, or granting of the petition for review, with or without conditions. As noted previously in the commentary to § 2424.22, the Authority intends to continue its current practice of permitting a party to correct such minor, technical deficiencies as failing to provide the correct number of copies or failure to attach a certificate of service to a filing. However, a party should not rely on this practice to provide an opportunity for it to correct failures to raise, support, and respond to arguments. Where appropriate, these latter failures will be deemed waivers or concessions, and opportunities to correct the failures will not be provided.

Section 2424.33–2424.39

These sections are reserved.

Subpart E—Decision and Order

Section 2424.40

One commenter objected that the Authority should not issue any order concerning negotiability where there are unresolved bargaining obligation disputes. The Authority's current practice is to issue orders in negotiability cases where there are such unresolved issues, and the final rule will continue this practice in some cases. However, as distinct from current practice, if a bargaining order is issued and there is an unresolved bargaining obligation dispute, then the order will be conditioned on resolution of the bargaining obligation dispute in a manner requiring bargaining.

Another commenter requested that the Authority modify the regulations to require parties to implement portions of agreements that are not disputed. The Authority declines to do so on the ground that the partial implementation of contract terms in this situation is better addressed by the parties in ground rules or during the course of negotiations.

Consistent with the commentary to § 2424.30, subsection (a) is modified from the proposed rule to clarify that, with the exception of an order to bargain, the Authority's decision and order under part 2424 will not include remedies that could be obtained in an unfair labor practice proceeding under 5 U.S.C. 7118(a)(7). In other respects, the final rule is the same as the proposed rule.

Section 2424.41

One commenter noted that the use of the phrase ''specified period'' in the proposed rule may mislead parties into believing that the Authority would seek enforcement of an order before the 60-day period provided for in 5 U.S.C. 7123(a) had expired. In response to this concern, the final rule eliminates the phrase. However, the final rule is modified to make clear that the exclusive representative must bring to the attention of the appropriate Regional Director a failure to comply with an Authority order within a ''reasonable time'' following expiration of the 60-day

period. Failure to do so within a reasonable time may, if the matter is referred by the Regional Director to the Authority, result in the Authority determining not to seek enforcement of the order.

Sections 2424.42–2424.49

These sections are reserved.

Subpart F—Criteria for Determining Compelling Need for Agency Rules and Regulations

Section 2424.50

With one change to correct grammar, the final rule as promulgated is the same as the proposed rule.

Sections 2424.51–2424.59

These sections are reserved.

Other Regulatory Requirements

One commenter made several suggestions for modification of general regulatory requirements that were not responsive to particular sections in the proposed rules. In particular, the commenter requested that the Authority: (1) lengthen the time period for requesting reconsideration of a decision and order under part 2424; (2) modify the ''extraordinary circumstance'' requirement for obtaining reconsideration and grant reconsideration when the Authority's decision raises issues that could not have been anticipated by the parties before the decision, such as when the Authority decision creates a new legal standard; (3) promulgate a regulation requiring the Authority to seek the views of the parties whenever a case is remanded to the Authority on judicial review; and (4) modify existing regulations to permit the Office of Personnel Management (OPM) or any other Federal agency that administers laws having Federal Government-wide implications to intervene, obtain *amicus* status, or submit an advisory opinion in any case involving interpretation of such law.

With regard to the time period for requesting reconsideration, 5 C.F.R. 2429.17 provides that reconsideration of an Authority decision and order must be sought within 10 days after service of the decision and order. Although this time period is short, it encourages prompt consideration of any decision and order and permits, as necessary, correction of errors in the decision and order as quickly as possible. In addition, it applies to all Authority decisions and orders, not only those issued under part 2424. For these reasons, the Authority declines to extend the time period.

As for the ''extraordinary circumstances'' required for reconsideration under § 2429.17 of this subchapter, the existing standard, which requires case-by-case application, does not preclude a party from arguing that reconsideration should be granted because an Authority decision raises issues that could not have been anticipated. Moreover, extraordinary circumstances under § 2429.17 of this subchapter have been expressly interpreted to include situations where a change in the law affects dispositive issues. *See U.S. Department of the Air Force, 375th Combat Support Group, Scott Air Force Base, Illinois,* 50 FLRA 84 (1995). Thus, modification of the existing regulation is not necessary.

The Authority also finds it unnecessary to promulgate a regulation requiring it to seek the parties' views whenever a case is remanded to the Authority following judicial review. In some cases, for example, the remand is solely for the purpose of the Authority taking a particular action, such as dismissing a petition for review. *See National Treasury Employees Union and Nuclear Regulatory Commission,* 39 FLRA 182 (1991) (dismissing petition for review as moot on remand with instructions from the U.S. Court of Appeals for the Fourth Circuit). In such cases, requiring the Authority to obtain party views would unnecessarily lengthen the time necessary to resolve the dispute. Nevertheless, parties are not precluded from seeking permission from the Authority in any case to file an additional submission under § 2424.27.

Similarly, neither OPM nor any other Federal agency is precluded in any way from seeking to participate in any pending case as *amicus curiae* under § 2424.9 of this subchapter. In addition, the Authority requests advisory opinions as it deems appropriate under § 2429.15 of this subchapter. *See, e.g., American Federation of Government Employees, Local 2986 and U.S. Department of Defense, National Guard Bureau, The Adjutant General, State of Oregon,* 51 FLRA 1549 (1996) (Authority requested OPM views on interpretation of certain statutory and regulatory provisions and provided parties opportunity to respond to OPM's views); *National Association of Agriculture Employees and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine,* 51 FLRA 843 (1996) (same). As it is not apparent that, or how, these existing regulations are not sufficient to permit OPM and others to participate in Authority proceedings, the Authority declines to modify them or to create a separate regulatory requirement for intervention.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Authority has determined that these regulations, as amended, will not have a significant impact on a substantial number of small entities, because this rule applies to federal employees, federal agencies, and labor organizations representing federal employees.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act of 1995

The amended regulations contain no additional information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

List of Subjects in 5 CFR Part 2424

Administrative practice and procedure, Government employees, Labor management relations.

For the reasons set forth in the preamble, the Federal Labor Relations Authority revises 5 CFR Part 2424 to read as follows:

PART 2424—NEGOTIABILITY PROCEEDINGS

Subpart A—Applicability of This Part and Definitions

Sec.

Authority: 5 U.S.C. 7134.

Subpart A—Applicability of This Part and Definitions

§ 2424.1 Applicability of this part.

This part is applicable to all petitions for review filed after April 1, 1999.

§ 2424.2 Definitions.

In this part, the following definitions apply:

(a) *Bargaining obligation dispute* means a disagreement between an exclusive representative and an agency concerning whether, in the specific circumstances involved in a particular case, the parties are obligated to bargain over a proposal that otherwise may be negotiable. Examples of bargaining obligation disputes include disagreements between an exclusive representative and an agency concerning agency claims that:

(1) A proposal concerns a matter that is covered by a collective bargaining agreement; and

(2) Bargaining is not required over a change in bargaining unit employees' conditions of employment because the effect of the change is *de minimis.*

(b) *Collaboration and Alternative Dispute Resolution Program* refers to the Federal Labor Relations Authority's program that assists parties in reaching agreements to resolve disputes.

(c) *Negotiability dispute* means a disagreement between an exclusive representative and an agency concerning the legality of a proposal or provision. A negotiability dispute exists when an exclusive representative disagrees with an agency contention that (without regard to any bargaining obligation dispute) a proposal is outside the duty to bargain, including disagreement with an agency contention that a proposal is bargainable only at its election. A negotiability dispute also exists when an exclusive representative disagrees with an agency head's disapproval of a provision as contrary to law. A negotiability dispute may exist where there is no bargaining obligation dispute. Examples of negotiability disputes include disagreements between an exclusive representative and an agency concerning whether a proposal or provision:

(1) Affects a management right under 5 U.S.C. 7106(a);

(2) Constitutes a procedure or appropriate arrangement, within the meaning of 5 U.S.C. 7106(b)(2) and (3), respectively; and

(3) Is consistent with a Government-wide regulation.

(d) *Petition for review* means an appeal filed with the Authority by an exclusive representative requesting resolution of a negotiability dispute. An appeal that concerns only a bargaining obligation dispute may not be resolved under this part.

(e) *Proposal* means any matter offered for bargaining that has not been agreed to by the parties. If a petition for review concerns more than one proposal, then the term includes each proposal concerned.

(f) *Provision* means any matter that has been disapproved by the agency head on review pursuant to 5 U.S.C. 7114(c). If a petition for review concerns more than one provision, then the term includes each provision concerned.

(g) *Service* means the delivery of copies of documents filed with the Authority to the other party's principal bargaining representative and, in the case of an exclusive representative, also to the head of the agency. Compliance with part 2429 of this subchapter is required.

(h) *Severance* means the division of a proposal or provision into separate parts having independent meaning, for the purpose of determining whether any of the separate parts is within the duty to bargain or is contrary to law. In effect, severance results in the creation of separate proposals or provisions. Severance applies when some parts of the proposal or provision are determined to be outside the duty to bargain or contrary to law.

(i) *Written allegation concerning the duty to bargain means* an agency allegation that the duty to bargain in good faith does not extend to a proposal.

§ 2424.3 –2424.9 [Reserved]

Subpart B—Alternative Dispute Resolution; Requesting and Providing Allegations Concerning the Duty To Bargain

§ 2424.10 Collaboration and Alternative Dispute Resolution Program.

Where an exclusive representative and an agency are unable to resolve disputes that arise under this part, they may request assistance from the Collaboration and Alternative Dispute Resolution Program (CADR). Upon request, and as agreed upon by the parties, CADR representatives will attempt to assist the parties to resolve these disputes. Parties seeking information or assistance under this part may call or write the CADR Office at (202) 482–6503, 607 14th Street, NW., Washington, D.C. 20424–001. A brief summary of CADR activities is available on the Internet at www.flra.gov.

§ 2424.11 Requesting and providing written allegations concerning the duty to bargain.

(a) *General.* An exclusive representative may file a petition for review after receiving a written allegation concerning the duty to bargain from the agency. An exclusive representative also may file a petition for review if it requests that the agency provide it with a written allegation concerning the duty to bargain and the agency does not respond to the request within ten (10) days.

(b) *Agency allegation in response to request.* The agency's allegation in response to the exclusive representative's request must be in writing and must be served in accord with § 2424.2(g).

(c) *Unrequested agency allegation.* If an agency provides an exclusive

representative with an unrequested written allegation concerning the duty to bargain, then the exclusive representative may either file a petition for review under this part, or continue to bargain and subsequently request in writing a written allegation concerning the duty to bargain, if necessary.

§§ 2424.12–2424.19 [Reserved]

Subpart C—Filing and Responding to a Petition for Review; Conferences

§ 2424.20 Who may file a petition for review.

A petition for review may be filed by an exclusive representative that is a party to the negotiations.

§ 2424.21 Time limits for filing a petition for review.

(a) A petition for review must be filed within fifteen (15) days after the date of service of either:

(1) An agency's written allegation that the exclusive representative's proposal is not within the duty to bargain, or

(2) An agency head's disapproval of a provision.

(b) If the agency has not served a written allegation on the exclusive representative within ten (10) days after the agency's principal bargaining representative has received a written request for such allegation, as provided in § 2424.11(a), then the petition may be filed at any time.

§ 2424.22 Exclusive representative's petition for review; purpose; content; severance; service.

(a) *Purpose.* The purpose of a petition for review is to initiate a negotiability proceeding and provide the agency with notice that the exclusive representative requests a decision from the Authority that a proposal or provision is within the duty to bargain or not contrary to law, respectively. As more fully explained in paragraph (b) of this section, the exclusive representative is required in the petition for review to, among other things, inform the Authority of the exact wording and meaning of the proposal or provision as well as how it is intended to operate, explain technical or unusual terms, and provide copies of materials that support the exclusive representative's position.

(b) *Content.* A petition for review must be filed on a form provided by the Authority for that purpose, or in a substantially similar format. It must be dated and include the following:

(1) The exact wording and explanation of the meaning of the proposal or provision, including an explanation of special terms or phrases, technical language, or other words that are not in common usage, as well as how the proposal or provision is intended to work;

(2) Specific citation to any law, rule, regulation, section of a collective bargaining agreement, or other authority relied on by the exclusive representative in its argument or referenced in the proposal or provision, and a copy of any such material that is not easily available to the Authority;

(3) A statement as to whether the proposal or provision is also involved in an unfair labor practice charge under part 2423 of this subchapter, a grievance pursuant to the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter, and whether any other petition for review has been filed concerning a proposal or provision arising from the same bargaining or the same agency head review;

(4) Any request for a hearing before the Authority and the reasons supporting such request; and

(5) A table of contents and a table of legal authorities cited, if the petition exceeds 25 double-spaced pages in length.

(c) *Severance.* The exclusive representative may, but is not required to, include in the petition for review a statement as to whether it requests severance of a proposal or provision. If severance is requested in the petition for review, then the exclusive representative must support its request with an explanation of how each severed portion of the proposal or provision may stand alone, and how such severed portion would operate. The explanation and argument in support of the severed portion(s) must meet the same requirements for information set forth in paragraph (b) of this section.

(d) *Service.* The petition for review, including all attachments, must be served in accord with § 2424.2(g).

§ 2424.23 Post-petition conferences; conduct and record.

(a) *Timing of post-petition conference.* On receipt of a petition for review involving a proposal or a provision, a representative of the FLRA will, where appropriate, schedule a post-petition conference to be conducted by telephone or in person. All reasonable efforts will be made to schedule and conduct the conference within ten (10) days after receipt of the petition for review.

(b) *Conduct of conference.* The post-petition conference will be conducted with representatives of the exclusive representative and the agency, who must be prepared and authorized to discuss, clarify and resolve matters including the following:

(1) The meaning of the proposal or provision in dispute;

(2) Any disputed factual issue(s);

(3) Negotiability dispute objections and bargaining obligation claims regarding the proposal or provision;

(4) Whether the proposal or provision is also involved in an unfair labor practice charge under part 2423 of this subchapter, in a grievance under the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter; and

(5) Whether an extension of the time limits for filing the agency's statement of position and any subsequent filings is requested. The FLRA representative may, on determining that it will effectuate the purposes of the Federal Service Labor-Management Relations Statute, 5 U.S.C. 7101 *et seq.*, and this part, extend such time limits.

(c) *Record of the conference.* At the post-petition conference, or after it has been completed, the representative of the FLRA will prepare and serve on the parties a written statement that includes whether the parties agree on the meaning of the disputed proposal or provision, the resolution of any disputed factual issues, and any other appropriate matters.

§ 2424.24 Agency's statement of position; purpose; time limits; content; severance; service.

(a) *Purpose.* The purpose of an agency statement of position is to inform the Authority and the exclusive representative why a proposal or provision is not within the duty to bargain or contrary to law, respectively. As more fully explained in paragraph (c) of this section, the agency is required in the statement of position to, among other things, set forth its understanding of the proposal or provision, state any disagreement with the facts, arguments, or meaning of the proposal or provision set forth in the exclusive representative's petition for review, and supply all arguments and authorities in support of its position.

(b) *Time limit for filing.* Unless the time limit for filing has been extended pursuant to § 2424.23 or part 2429 of this subchapter, the agency must file its statement of position within thirty (30) days after the date the head of the agency receives a copy of the petition for review.

(c) *Content.* The agency's statement of position must be on a form provided by the Authority for that purpose, or in a substantially similar format. It must be dated and must:

(1) Withdraw either:

(i) The allegation that the duty to bargain in good faith does not extend to the exclusive representative's proposal, or

(ii) The disapproval of the provision under 5 U.S.C. 7114(c); or

(2) Set forth in full the agency's position on any matters relevant to the petition that it wishes the Authority to consider in reaching its decision, including a statement of the arguments and authorities supporting any bargaining obligation or negotiability claims, any disagreement with claims made by the exclusive representative in the petition for review, specific citation to any law, rule, regulation, section of a collective bargaining agreement, or other authority relied on by the agency, and a copy of any such material that is not easily available to the Authority. The statement of position must also include the following:

(i) If different from the exclusive representative's position, an explanation of the meaning the agency attributes to the proposal or provision and the reasons for disagreeing with the exclusive representative's explanation of meaning;

(ii) If different from the exclusive representative's position, an explanation of how the proposal or provision would work, and the reasons for disagreeing with the exclusive representative's explanation;

(3) A statement as to whether the proposal or provision is also involved in an unfair labor practice charge under part 2423 of this subchapter, a grievance pursuant to the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter, and whether any other petition for review has been filed concerning a proposal or provision arising from the same bargaining or the same agency head review;

(4) Any request for a hearing before the Authority and the reasons supporting such request; and

(5) A table of contents and a table of legal authorities cited, if the statement of position exceeds 25 double-spaced pages in length.

(d) *Severance.* If the exclusive representative has requested severance in the petition for review, and if the agency opposes the exclusive representative's request for severance, then the agency must explain with specificity why severance is not appropriate.

(e) *Service.* A copy of the agency's statement of position, including all attachments, must be served in accord with § 2424.2(g).

§ 2424.25 Response of the exclusive representative; purpose; time limits; content; severance; service.

(a) *Purpose.* The purpose of the exclusive representative's response is to inform the Authority and the agency why, despite the agency's arguments in its statement of position, the proposal or provision is within the duty to bargain or not contrary to law, respectively, and whether the union disagrees with any facts or arguments in the agency's statement of position. As more fully explained in paragraph (c) of this section, the exclusive representative is required in its response to, among other things, state why the proposal or provision does not conflict with any law, or why it falls within an exception to management rights, including permissive subjects under 5 U.S.C. 7106(b)(1), and procedures and appropriate arrangements under section 7106(b) (2) and (3). Another purpose of the response is to permit the exclusive representative to request the Authority to sever portions of the proposal or provision and to explain why and how it can be done.

(b) *Time limit for filing.* Unless the time limit for filing has been extended pursuant to § 2424.23 or part 2429 of this subchapter, within fifteen (15) days after the date the exclusive representative receives a copy of an agency's statement of position, the exclusive representative must file a response.

(c) *Content.* The response must be on a form provided by the Authority for that purpose, or in a substantially similar format. With the exception of a request for severance pursuant to paragraph (d) of this section, the exclusive representative's response is specifically limited to the matters raised in the agency's statement of position. The response must be dated and must include the following:

(1) Any disagreement with the agency's bargaining obligation or negotiability claims. The exclusive representative must state the arguments and authorities supporting its opposition to any agency argument, and must include specific citation to any law, rule, regulation, section of a collective bargaining agreement, or other authority relied on by the exclusive representative, and provide a copy of any such material that is not easily available to the Authority. The exclusive representative is not required to repeat arguments made in the petition for review. If not included in the petition for review, the exclusive representative must state the arguments and authorities supporting any assertion that the proposal or provision does not affect a management right under 5 U.S.C. 7106(a), and any assertion that an exception to management rights applies, including:

(i) Whether and why the proposal or provision concerns a matter negotiable at the election of the agency under 5 U.S.C. 7106(b)(1);

(ii) Whether and why the proposal or provision constitutes a negotiable procedure as set forth in 5 U.S.C. 7106(b)(2);

(iii) Whether and why the proposal or provision constitutes an appropriate arrangement as set forth in 5 U.S.C. 7106(b)(3); and

(iv) Whether and why the proposal or provision enforces an ''applicable law,'' within the meaning of 5 U.S.C. 7106(a)(2).

(2) Any allegation that agency rules or regulations relied on in the agency's statement of position violate applicable law, rule, regulation or appropriate authority outside the agency; that the rules or regulations were not issued by the agency or by any primary national subdivision of the agency, or otherwise are not applicable to bar negotiations under 5 U.S.C. 7117(a)(3); or that no compelling need exists for the rules or regulations to bar negotiations.

(3) A table of contents and a table of legal authorities cited if the response to an agency statement of position exceeds 25 double-spaced pages in length.

(d) *Severance.* If not requested in the petition for review, or if the exclusive representative wishes to modify the request in the petition for review, the exclusive representative may request severance in its response. The exclusive representative must support its request with an explanation of how the severed portion(s) of the proposal or provision may stand alone, and how such severed portion(s) would operate. The exclusive representative also must respond to any agency arguments regarding severance made in the agency's statement of position. The explanation and argument in support of the severed portion(s) must meet the same requirements for specific information set forth in paragraph (c) of this section.

(e) *Service.* A copy of the response of the exclusive representative, including all attachments, must be served in accord with § 2424.2(g).

§ 2424.26 Agency's reply; purpose; time limits; content; service.

(a) *Purpose.* The purpose of the agency's reply is to inform the Authority and the exclusive representative whether and why it disagrees with any facts or arguments made for the first time in the exclusive representative's response. As more fully explained in

paragraph (c) of this section, the Agency is required in the reply to, among other things, provide the reasons why the proposal or provision does not fit within any exceptions to management rights that were asserted by the exclusive representative in its response, and to explain why severance of the proposal or provision is not appropriate.

(b) *Time limit for filing.* Unless the time limit for filing has been extended pursuant to § 2424.23 or part 2429 of this subchapter, within fifteen (15) days after the date the agency receives a copy of the exclusive representative's response to the agency's statement of position, the agency may file a reply.

(c) *Content.* The reply must be on a form provided by the Authority for that purpose, or in a substantially similar format. The agency's reply is specifically limited to the matters raised for the first time in the exclusive representative's response. The agency's reply must state the arguments and authorities supporting its reply, cite with specificity any law, rule, regulation, section of a collective bargaining agreement, or other authority relied on, and provide a copy of any material that is not easily available to the Authority. The agency is not required to repeat arguments made in its statement of position. The agency's reply must be dated and must include the following:

(1) Any disagreement with the exclusive representative's assertion that an exception to management rights applies, including:

(i) Whether and why the proposal or provision concerns a matter included in section 7106(b)(1) of the Federal Service Labor-Management Relations Statute;

(ii) Whether and why the proposal or provision does not constitute a negotiable procedure as set forth in section 7106(b)(2) of the Federal Service Labor-Management Relations Statute;

(iii) Whether and why the proposal or provision does not constitute an appropriate arrangement as set forth in section 7106(b)(3) of the Federal Service Labor-Management Relations Statute;

(iv) Whether and why the proposal or provision does not enforce an ''applicable law,'' within the meaning of section 7106(a)(2) of the Federal Service Labor-Management Relations Statute;

(2) Any arguments in reply to an exclusive representative's allegation in its response that agency rules or regulations relied on in the agency's statement of position violate applicable law, rule, regulation or appropriate authority outside the agency; that the rules or regulations were not issued by the agency or by any primary national subdivision of the agency, or otherwise are not applicable to bar negotiations under 5 U.S.C. 7117(a)(3); or that no compelling need exists for the rules or regulations to bar negotiations; and

(3) A table of contents and a table of legal authorities cited, if the agency's reply to an exclusive representative's response exceeds 25 double-spaced pages in length.

(d) *Severance.* If the exclusive representative requests severance for the first time in its response, or if the request for severance in an exclusive representative's response differs from the request in its petition for review, and if the agency opposes the exclusive representative's request for severance, then the agency must explain with specificity why severance is not appropriate.

(e) *Service.* A copy of the agency's reply, including all attachments, must be served in accord with § 2424.2(g).

§ 2424.27 Additional submissions to the Authority.

The Authority will not consider any submission filed by any party other than those authorized under this part, provided however that the Authority may, in its discretion, grant permission to file an additional submission based on a written request showing extraordinary circumstances by any party. The additional submission must be filed either with the written request or no later than five (5) days after receipt of the Authority's order granting the request. Any opposition to the additional submission must be filed within fifteen (15) days after the date of the receipt of the additional submission. All documents filed under this section must be served in accord with § 2424.2(g).

§ 2424.28–2424.29 [Reserved]

Subpart D—Processing a Petition for Review

§ 2424.30 Procedure through which the petition for review will be resolved.

(a) *Exclusive representative has filed related unfair labor practice charge or grievance alleging an unfair labor practice.* Except for proposals or provisions that are the subject of an agency's compelling need claim under 5 U.S.C. 7117(a)(2), where an exclusive representative files an unfair labor practice charge pursuant to part 2423 of this subchapter or a grievance alleging an unfair labor practice under the parties' negotiated grievance procedure, and the charge or grievance concerns issues directly related to the petition for review filed pursuant to this part, the Authority will dismiss the petition for review. The dismissal will be without prejudice to the right of the exclusive representative to refile the petition for review after the unfair labor practice charge or grievance has been resolved administratively, including resolution pursuant to an arbitration award that has become final and binding. No later than thirty (30) days after the date on which the unfair labor practice charge or grievance is resolved administratively, the exclusive representative may refile the petition for review, and the Authority will determine whether resolution of the petition is still required.

(b) *Exclusive representative has not filed related unfair labor practice charge or grievance alleging an unfair labor practice.* Where an exclusive representative files only a petition for review under this part, the petition will be processed as follows:

(1) *No bargaining obligation dispute exists.* Where there is no bargaining obligation dispute, the Authority will resolve the petition for review under the procedures of this part.

(2) *A bargaining obligation dispute exists.* Where a bargaining obligation dispute exists in addition to the negotiability dispute, the Authority will inform the exclusive representative of any opportunity to file an unfair labor practice charge pursuant to part 2423 of this subchapter or a grievance under the parties' negotiated grievance procedure and, where the exclusive representative pursues either of these courses, proceed in accord with paragraph (a) of this section. If the exclusive representative does not file an unfair labor practice charge or grievance, the Authority will proceed to resolve all disputes necessary for disposition of the petition unless, in its discretion, the Authority determines that resolving all disputes is not appropriate because, for example, resolution of the bargaining obligation dispute under this part would unduly delay resolution of the negotiability dispute, or the procedures in another, available administrative forum are better suited to resolve the bargaining obligation dispute.

§ 2424.31 Resolution of disputed issues of material fact; hearings.

When necessary to resolve disputed issues of material fact in a negotiability or bargaining obligation dispute, or when it would otherwise aid in decision making, the Authority, or its designated representative, may, as appropriate:

(a) Direct the parties to provide specific documentary evidence;

(b) Direct the parties to provide answers to specific factual questions;

(c) Refer the matter to a hearing pursuant to 5 U.S.C. 7117(b)(3) and/or (c)(5); or

(d) Take any other appropriate action.

§ 2424.32 Parties' responsibilities; failure to raise, support, and/or respond to arguments; failure to participate in conferences and/or respond to Authority orders.

(a) *Responsibilities of the exclusive representative.* The exclusive representative has the burden of raising and supporting arguments that the proposal or provision is within the duty to bargain, within the duty to bargain at the agency's election, or not contrary to law, respectively, and, where applicable, why severance is appropriate.

(b) *Responsibilities of the agency.* The agency has the burden of raising and supporting arguments that the proposal or provision is outside the duty to bargain or contrary to law, respectively, and, where applicable, why severance is not appropriate.

(c) *Failure to raise, support, and respond to arguments.* (1) Failure to raise and support an argument will, where appropriate, be deemed a waiver of such argument. Absent good cause:

(i) Arguments that could have been but were not raised by an exclusive representative in the petition for review, or made in its response to the agency's statement of position, may not be made in this or any other proceeding; and

(ii) Arguments that could have been but were not raised by an agency in the statement of position, or made in its reply to the exclusive representative's response, may not be raised in this or any other proceeding.

(2) Failure to respond to an argument or assertion raised by the other party will, where appropriate, be deemed a concession to such argument or assertion.

(d) *Failure to participate in conferences; failure to respond to Authority orders.* Where a party fails to participate in a post-petition conference pursuant to § 2424.23, a direction or proceeding under § 2424.31, or otherwise fails to provide timely or responsive information pursuant to an Authority order, including an Authority procedural order directing the correction of technical deficiencies in filing, the Authority may, in addition to those actions set forth in paragraph (c) of this section, take any other action that, in the Authority's discretion, is deemed appropriate, including dismissal of the petition for review, with or without prejudice to the exclusive representative's refiling of the petition for review, and granting the petition for review and directing bargaining and/or rescission of an agency head disapproval under 5 U.S.C. 7114(c), with or without conditions.

§ 2424.33—2424.39 [Reserved]

Subpart E—Decision and Order

§ 2424.40 Authority decision and order.

(a) *Issuance.* Subject to the requirements of this part, the Authority will expedite proceedings under this part to the extent practicable and will issue to the exclusive representative and to the agency a written decision, explaining the specific reasons for the decision, at the earliest practicable date. The decision will include an order, as provided in paragraphs (b) and (c) of this section, but, with the exception of an order to bargain, such order will not include remedies that could be obtained in an unfair labor practice proceeding under 5 U.S.C. 7118(a)(7).

(b) *Cases involving proposals.* If the Authority finds that the duty to bargain extends to the proposal, or any severable part of the proposal, then the Authority will order the agency to bargain on request concerning the proposal. If the Authority finds that the duty to bargain does not extend to the proposal, then the Authority will dismiss the petition for review. If the Authority finds that the proposal is bargainable only at the election of the agency, then the Authority will so state. If the Authority resolves a negotiability dispute by finding that a proposal is within the duty to bargain, but there are unresolved bargaining obligation dispute claims, then the Authority will order the agency to bargain on request in the event its bargaining obligation claims are resolved in a manner that requires bargaining.

(c) *Cases involving provisions.* If the Authority finds that a provision, or any severable part thereof, is not contrary to law, rule or regulation, or is bargainable at the election of the agency, the Authority will direct the agency to rescind its disapproval of such provision in whole or in part as appropriate. If the Authority finds that a provision is contrary to law, rule, or regulation, the Authority will dismiss the petition for review as to that provision.

§ 2424.41 Compliance.

The exclusive representative may report to the appropriate Regional Director an agency's failure to comply with an order, issued in accordance with § 2424.40, that the agency must upon request (or as otherwise agreed to by the parties) bargain concerning the proposal or that the agency must rescind its disapproval of a provision. The exclusive representative must report such failure within a reasonable period of time following expiration of the 60-day period under 5 U.S.C. 7123(a), which begins on the date of issuance of the Authority order. If, on referral from the Regional Director, the Authority finds such a failure to comply with its order, the Authority will take whatever action it deems necessary to secure compliance with its order, including enforcement under 5 U.S.C. 7123(b).

§§ 2424.42—2424.49 [Reserved]

Subpart F—Criteria for Determining Compelling Need for Agency Rules and Regulations

§ 2424.50 Illustrative criteria.

A compelling need exists for an agency rule or regulation concerning any condition of employment when the agency demonstrates that the rule or regulation meets one or more of the following illustrative criteria:

(a) The rule or regulation is essential, as distinguished from helpful or desirable, to the accomplishment of the mission or the execution of functions of the agency or primary national subdivision in a manner that is consistent with the requirements of an effective and efficient government.

(b) The rule or regulation is necessary to ensure the maintenance of basic merit principles.

(c) The rule or regulation implements a mandate to the agency or primary national subdivision under law or other outside authority, which implementation is essentially nondiscretionary in nature.

§§ 2424.51—2424.59 [Reserved]

Dated: November 25, 1998.

Solly Thomas,

Executive Director, Federal Labor Relations Authority.

[FR Doc. 98–31970 Filed 12–1–98; 8:45 am]

BILLING CODE 6727–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–SW–41–AD; Amendment 39–10921; AD 98–24–35]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS–350B, B1, B2, BA, C, D, D1, and AS 355E, F, F1, F2, and N Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Eurocopter France Model AS–350B, B1, B2, BA, C, D, D1, and AS 355E, F, F1, F2, and N helicopters. This action requires measuring the tail rotor pitch change control rod (control rod) outboard spherical bearing for radial and axial play. If the play exceeds 0.008-inch, replacing the control rod with an airworthy control rod is required. This amendment is prompted by one accident and one incident. Investigations revealed a broken control rod on the helicopter involved in the accident and a severely worn control rod on the helicopter involved in the incident. This condition, if not corrected, could result in separation of the outboard spherical bearing ball from its outer race, rubbing of the body of the control rod against the tail rotor blade pitch horn clevis, failure of the control rod, and loss of control of the helicopter.

DATES: Effective December 17, 1998.

Comments for inclusion in the Rules Docket must be received on or before February 1, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 98–SW–41–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Mr. Shep Blackman, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5296, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: This amendment was prompted by an accident, which occurred in November 1996, and an incident, which occurred in August 1997, involving Model AS–350B2 helicopters offshore over the Gulf of Mexico. The DGAC, although notified by the FAA of both the accident and incident, has not issued an AD on this subject. There were two other unconfirmed incidents cited by the National Transportation Safety Board (based on manufacturer's reports) involving the same control rod, part number (P/N) 350A33–2145–01.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. The FAA has determined that AD action is necessary for products of this type design certified for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter France Model AS–350B, B1, B2, BA, C, D, D1, and AS 355E, F, F1, F2, and N helicopters of the same type design registered in the United States, this AD is being issued to prevent separation of the outboard spherical bearing ball from its outer race, rubbing of the body of the control rod against the tail rotor blade pitch horn clevis, failure of the control rod, and loss of control of the helicopter. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the controllability of the helicopter. Therefore, measuring the control rod outboard spherical bearing radial and axial play is required within 50 hours time-in-service, and this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Cost Impact

The FAA estimates that 507 helicopters will be affected by this AD, that it will take approximately 1 work hour, and that the average labor rate is $60 per work hour. Required parts will cost approximately $2,376 per helicopter. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $1,235,052 to perform the measurement and to replace both control rods on each helicopter in the fleet.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public 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 under the caption **ADDRESSES.** 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 evaluating the effectiveness of the AD action and 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 AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 98–SW–41–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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 that must be issued immediately to correct an unsafe condition in aircraft, and that it 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. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the

Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 98–24–35 Eurocopter France: Amendment 39–10921. Docket No. 98–SW–41–AD.

Applicability: Eurocopter France Model AS–350B, B1, B2, BA, C, D, D1, and AS 355E, F, F1, F2, and N helicopters, with tail rotor pitch change control rod (control rod), part number (P/N) 350A33–2145–01, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required within 50 hours time-in-service (TIS) after the effective date of this AD, unless accomplished previously, and thereafter at intervals not to exceed 50 hours TIS.

To prevent separation of the outboard spherical bearing ball from its outer race, rubbing of the body of the control rod against the tail rotor blade pitch horn clevis, failure of the control rod, and loss of control of the helicopter, accomplish the following:

(a) Using a dial indicator, measure the axial and radial play of the outboard spherical bearing on the control rod. If the play exceeds 0.008-inch, replace the control rod with an airworthy control rod.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on December 17, 1998.

Issued in Fort Worth, Texas, on November 19, 1998.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–31858 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–111–AD; Amendment 39–10923; AD 98–24–14]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Models 340A and 414A Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) 98–24–14, which was sent previously to all known U.S. owners and operators of certain Cessna Aircraft Company (Cessna) Models 340A and 414A airplanes that could be equipped with any WYE tube, part number (P/N) 9910299–25 or P/N 9910299–26, in the engine exhaust system. This AD requires removing from service any P/N 9910299–25 or P/N 9910299–26 engine exhaust system WYE tube. The AD resulted from reports of five instances where the engine exhaust components in the WYE tube were manufactured without welds on critical parts that are installed adjacent to the firewall. The actions specified by this AD are intended to detect and correct exhaust leaks caused by nonwelded exhaust system components, which could result in aluminum fuel lines bursting with consequent fuel spillage, an airplane fire, and/or an explosion.

DATES: Effective December 21, 1998, to all persons except those to whom it was made immediately effective by priority letter AD 98–24–14, issued November 13, 1998, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before January 26, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket 98–CE–111–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Information related to this AD may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Paul O. Pendleton, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas, 67209, telephone: (316) 946–4143; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Discussion

On November 13, 1998, the FAA issued priority letter AD 98–24–14, which applies to certain Cessna Models 340A and 414A airplanes that are equipped with any WYE tube, part number (P/N) 9910299–25 or P/N 9910299–26, in the engine exhaust system. This AD requires removing from service any P/N 9910299–25 or P/N 9910299–26 engine exhaust system WYE tube.

These P/N 9910299–25 or P/N 9910299–26 WYE tubes may be replaced with any of the following:

—P/N 9910299–8 (for the P/N 9910299–25) or P/N 9910299–9 (for the P/N 9910299–26) WYE tubes; or

—any other FAA-approved engine exhaust system WYE tube that is not P/N 9910299–25 or P/N 9910299–26.

The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may check the maintenance records to determine whether any WYE tube, P/N 9910299–25 or P/N 9910299–26, has been installed in the engine exhaust system between May 8, 1998, and December 21, 1998. If one of these WYE tubes is not installed, the AD does not apply and the owner/operator must make an entry into the aircraft records showing compliance with this AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

The FAA's Determination

Since an unsafe condition has been identified that is likely to exist or develop in certain Cessna Models 340A and 414A airplanes of the same type design that are equipped with any WYE

tube, P/N 9910299–25 or P/N 9910299–26, in the engine exhaust system, the FAA issued AD 98–24–14 by priority letter in order to detect and correct exhaust leaks caused by nonwelded exhaust system components. This condition could result in aluminum fuel lines bursting with consequent fuel spillage, an airplane fire, and/or an explosion.

Determination of the Effective Date of the AD

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on November 13, 1998, to all known U.S. operators of certain Cessna Models 340A and 414A airplanes that could be equipped with any WYE tube, P/N 9910299–25 or P/N 9910299–26, in the engine exhaust system. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective as to all persons.

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 evaluating the effectiveness of the AD action and 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 AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 98–CE–111–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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 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. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

98–24–14 Cessna Aircraft Company: Amendment 39–10923; Docket No. 98–CE–111–AD.

Applicability: The following airplane models and serial numbers, certificated in any category, that are equipped with any WYE tube, part number (P/N) 9910299–25 or P/N 9910299–26, in the engine exhaust system:

Model	Serial numbers
340A	215 through 1817.
414A	1 through 1212.

Note 1: This AD allows the aircraft owner or pilot to check the maintenance records to determine whether any WYE tube, P/N 9910299–25 or P/N 9910299–26, has been installed in the engine exhaust system between May 8, 1998, and December 21, 1998 (the effective date of this AD). See paragraph (c) of this AD for authorization.

Note 2: Cessna is considering issuing service information pertaining to this subject. This AD takes precedence over any existing or future service information on this subject.

Note 3: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To detect and correct exhaust leaks caused by nonwelded exhaust system components, which could result in aluminum fuel lines bursting with consequent fuel spillage, an airplane fire, and/or an explosion, accomplish the following:

(a) Prior to further flight after the effective date of this AD, remove from service any P/N 9910299–25 or P/N 9910299–26 engine exhaust system WYE tube.

These P/N 9910299–25 or P/N 9910299–26 WYE tubes may be replaced with any of the following in accordance with the instructions in the applicable maintenance manual or other applicable FAA-approved document:

(1) P/N 9910299–8 (for the P/N 9910299–25) or P/N 9910299–9 (for the P/N 9910299–26) WYE tubes; or (2) Any other FAA-approved engine exhaust system WYE tube that is not P/N 9910299–25 or P/N 9910299–26.

(b) As of the effective date of this AD, no person shall install, on any affected airplane,

any P/N 9910299–25 or P/N 9910299–26 engine exhaust system WYE tube.

(c) The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may check the maintenance records to determine whether any WYE tube, P/N 9910299–25 or P/N 9910299–26, has been installed in the engine exhaust system between May 8, 1998, and December 21, 1998 (the effective date of this AD). If one of these WYE tubes is not installed, the AD does not apply and the owner/operator must make an entry into the aircraft records showing compliance with this AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(d) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Rm. 100, Mid-Continent Airport, Wichita, Kansas, 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from Wichita ACO.

(e) Information related to this AD may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(f) This amendment becomes effective on December 21, 1998, except those persons to whom it was made immediately effective by priority letter AD 98–24–14, issued November 13, 1998, which contained the requirements of this amendment.

Issued in Kansas City, Missouri, on November 24, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–32045 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–334–AD; Amendment 39–10929; AD 98–24–51]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 Series Airplanes Equipped with Certain Collins LRA–900 Radio Altimeters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting airworthiness directive (AD) T98–24–51 that was sent previously to all known U.S. owners and operators of certain McDonnell Douglas Model MD–11 series airplanes by individual telegrams. This AD requires a revision to the Airplane Flight Manual to prohibit autopilot coupled autoland operations in certain conditions; or, for certain airplanes, replacement of certain Collins LRA–900 radio altimeters with Collins LRA–700 radio altimeters. This action is prompted by a report that a fault in certain Collins LRA-900 radio altimeters could result in an incorrect and unbounded output of radio altitude to other airplane systems. The actions specified by this AD are intended to prevent an undetected anomalous radio altitude signal that is passed along to the flare control law of the flight control computer, which could cause the airplane to flare too high or too low during landing, and consequently result in a hard landing.

DATES: Effective December 7, 1998, to all persons except those persons to whom it was made immediately effective by telegraphic AD T98–24–51, issued November 19, 1998, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before February 1, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–334–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Information pertaining to this amendment may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Aerospace Engineer, ANM–130L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5347; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: On November 19, 1998, the FAA issued telegraphic AD T98–24–51, which is applicable to certain McDonnell Douglas Model MD–11 series airplanes equipped with certain Collins LRA–900 radio altimeters. That action was prompted by a report from Rockwell Collins that a fault in certain Collins LRA–900 radio altimeters has been identified, which could result in an incorrect and unbounded output of radio altitude to other airplane systems.

The fail-operational autoland installation on McDonnell Douglas Model MD–11 series airplanes utilizes a dual-dual architecture that relies on the self-monitoring capability of the Collins LRA–900 radio altimeters. Any undetected anomalous radio altitude signal that is passed along to the flare control law of the flight control computer (FCC) could cause the initiation of the flare mode at an altitude that is either too high or too low for safe landing during autoland operations.

This fault does not affect airplanes equipped with either an autoland system architecture that utilizes triplex radio altimeter sensors or a dual fail-passive autoland architecture. The triplex radio altimeter sensors are able to ''vote out'' the undetected radio altimeter anomaly. The dual fail-passive autoland architecture compares both radio altimeters and passively disconnects when the signals do not match (i.e., radio altimeter miscompare).

In light of these findings, the FAA has determined that the reported anomaly is limited to airplanes with fail-operational autoland systems with a dual-dual fail-operational radio altimeter architecture.

An undetected anomalous radio altitude signal that is passed along to the flare control law of the FCC, if not corrected, could cause the airplane to flare too high or too low during landing, and consequently result in a hard landing.

Explanation of Requirements of the Rule

Since the unsafe condition described is likely to exist or develop on other airplanes of the same type design, the FAA issued telegraphic AD T98–24–51 to require a revision to the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to prohibit autopilot coupled autoland operations in certain conditions; or, for certain airplanes, replacement of certain Collins LRA–900 radio altimeters with Collins LRA–700 radio altimeters.

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual telegrams issued on November 19, 1998, to all known U.S. owners and operators

of certain McDonnell Douglas Model MD–11 series airplanes equipped with certain Collins LRA–900 radio altimeters. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public 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 shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. 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 evaluating the effectiveness of the AD action and 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 AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–334–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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 that must be issued immediately to correct an unsafe condition in aircraft, and that it 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. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–24–51 McDonnell Douglas: Amendment 39–10929. Docket 98–NM–334–AD.

Applicability: Model MD–11 series airplanes, equipped with certain Collins LRA–900 radio altimeters, having part number 822–0334–002, 822–0334–020, or 822–0334–220; certificated in any category.

Compliance: Required as indicated, unless accomplished previously. To detect and correct an undetected anomalous radio altitude signal that is passed along to the flare control law of the flight control computer, which could cause the airplane to flare too high or too low during landing, and consequently result in a hard landing, accomplish the following:

(a) Within 24 hours after the effective date of this AD, accomplish either paragraph (a)(1) or (a)(2) of this AD:

(1) Revise the Limitations Section of the FAA-approved Airplane Flight Manual to include the following statement:

''Autopilot coupled autoland operations below 100 feet above ground level (AGL) are prohibited.''

(2) For airplanes on which the LRA–700 radio altimeter installation has been approved in accordance with Type Certificate or Supplemental Type Certificate procedures: Replace both Collins LRA–900 radio altimeters having part number 822–0334–002, 822–0334–020, or 822–0334–220, with Collins LRA–700 radio altimeters having part number 622–4542–221.

(b) As of the effective date of this AD, no person shall install on any airplane a Collins LRA–900 radio altimeter, having part number 822–0334–002, 822–0334–020, or 822–0334–220.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on December 7, 1998, to all persons except those persons to whom it was made immediately effective by telegraphic AD T98–24–51, issued on November 19, 1998, which contained the requirements of this amendment.

Issued in Renton, Washington, on November 25, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–32100 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–AWP–12]

Revocation of Class D and Class E Airspace, Crows Landing, CA; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date and correction.

SUMMARY: This document confirms the effective date of a direct final rule which revokes the Class D and Class E airspace areas below 1200 feet above ground level (AGL) associated with Crows Landing, CA and changes the name from Crows Landing NALF to NASA Crows

Landing in the legal description of the remaining controlled airspace as published in the direct final rule. The correction amends the latitude of the Class E airspace area (E5) from 1200 feet and above, which was published incorrectly in the direct final rule; request for comments. The correct latitude is 37°38′00″.

DATES: The direct final rule published in 63 FR 45394 is effective at 0901 UTC, December 3, 1998. This correction is effective on December 3, 1998.

FOR FURTHER INFORMATION CONTACT: Debra Trindle, Air Traffic Division, Airspace Specialist, AWP–520.10, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261; telephone: (310) 725–6613.

SUPPLEMENTARY INFORMATION: On August 26, 1998, the FAA published in the **Federal Register** a direct final rule; request for comments which revoked the Class D and Class E airspace areas below 1200 feet AGL associated with Crows Landing Airport, CA. (FR Document 98–22749, 63 FR 45394, Airspace Docket No. 98–AWP–12). An error was subsequently discovered in the publication of the docket. The latitude of the Class E5 airspace area was incorrectly stated in the direct final rule; request for comments. This error was typographical only and the FAA did not intend to revise the dimensions of the existing Class E5 airspace area. After review of all available information related to the subject present above, the FAA has determined that air safety and the public interest require adoption of the rule. The FAA has determined that this correction will not change the meaning of the action nor add any additional burden on the public beyond that already published. This action corrects the error and confirms the effective date of the direct final rule.

The FAA uses the direct final rulemaking procedure for a noncontroversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on December 3, 1998. No adverse comments were received, therefore this document confirms that this direct final rule will become effective on that date.

Correction

In rule FR Doc. 98–22749 published in the **Federal Register** on August 26, 1998, 63 FR 45394, make the following correction to the airspace description;

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 NASA Crows Landing, CA [Revised]

NASA Crows Landing CA
(Lat. 37°24′29″N, long. 121°06′34″W)

That airspace extending upward from 1,200 feet above the surface bounded on the north by lat. 37°38′00″N, on the east by the west edge of V–109, on the southwest by the northeast edge of V–107 and on the west by long. 121°31′04″W.

Issued in Los Angeles, California on November 19, 1998.

Leonard A. Mobley,

Acting Manger, Air Traffic Division, Western Pacific Region.

[FR Doc. 98–32132 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–42]

Amendment to Class E Airspace; Wellington, KS

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Wellington, KS.

DATES: The direct final rule published at 63 FR 51808 is effective on 0901 UTC, January 28, 1999.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on September 29, 1998 (63 FR 51808). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 28, 1999. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on November 17, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–32137 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–38]

Amendment to Class E Airspace; Trenton, MO

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Trenton, MO.

DATES: The direct final rule published at 63 FR 51807 is effective on 0901 UTC, January 28, 1999.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on September 29, 1998 (63 FR 51807). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 28, 1999. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on November 17, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–32136 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–36]

Amendment to Class E Airspace; Wichita Mid-Continent Airport, KS

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Wichita, KS.

DATES: The direct final rule published at 63 FR 51814 is effective on 0901 UTC, January 28, 1999.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on September 29, 1998 (63 FR 51814). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 28, 1999. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on November 6, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–32135 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29403; Amdt. No. 1903]

RIN 2120–AA65

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows.

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which affected airport is located; or
3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25083 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between the SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on November 27, 1998.

Richard O. Gordon,

Acting Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLSRNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV/SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	SIAP
11/10/98	AL	DOTHAN	DOTHAN	8/7974	ILS RWY 32, AMDT 7D...
11/12/98	TN	SHELBYVILLE	BOMAR FIELD-SHELBYVILLE MUNI	8/8022	VOR/DME RNAV RWY 18, AMDT 3...
11/12/98	TN	SHELBYVILLE	BOMAR FIELD-SHELBYVILLE MUNI	8/8023	VOR/DME RWY 18, AMDT 4...
11/12/98	TN	SHELBYVILLE	BOMAR FIELD-SHELBYVILLE MUNI	8/8024	VOR RWY 18, AMDT 5...
11/12/98	TN	SHELBYVILLE	BOMAR FIELD-SHELBYVILLE MUNI	8/8025	VOR RWY 36, AMDT 15...
11/13/98	MN	ST. PAUL	LAKE ELMO	8/8036	NDB OR GPS RWY 3, AMDT 3A...
11/16/98	PA	PITTSBURGH	PITTSBURGH INTL	8/8065	VOR/DME OR GPS RWY 14, AMDT 1...
11/16/98	SC	PELION	PELION CORPORATE	8/8064	VOR OR GPS–A, AMDT 2...
11/17/98	NC	ASHEVILLE	ASHEVILLE REGIONAL	8/8101	NDB OR GPS RWY 16, AMDT 15...
11/17/98	NC	ASHEVILLE	ASHEVILLE REGIONAL	8/8103	NDB OR GPS RWY 34, AMDT 18...
11/17/98	NC	ASHEVILLE	ASHEVILLE REGIONAL	8/8104	ILS RWY 34, AMDT 23A...
11/17/98	NC	ASHEVILLE	ASHEVILLE REGIONAL	8/8105	ILS RWY 16, AMDT 3...
11/18/98	MI	TRAVERSE CITY	CHERRY CAPITAL	8/8120	ILS RWY 28, AMDT 12A...
11/18/98	NC	ASHEVILLE	ASHEVILLE REGIONAL	8/8121	RADAR–1, AMDT 5...
11/19/98	UT	SALT LAKE CITY	SALT LAKE CITY INTL	8/8140	ILS RWY 35, AMDT 1...
11/20/98	FL	CRESTVIEW	BOB SIKES	8/8161	VOR OR GPS–A, AMDT 11...
11/20/98	SC	ORANGEBURG	ORANGEBURG MUNI	8/8159	VOR RWY 5, AMDT 4A...
11/20/98	SC	ORANGEBURG	ORANGEBURG MUNI	8/8160	NDB OR GPS RWY 5, ORIG–A...
11/20/98	SC	ROCK HILL	ROCK HILL/YORK COUNTY/BRYANT FIELD.	8/8172	GPS RWY 2, ORIG–A...
11/20/98	SC	ROCK HILL	ROCK HILL/YORK COUNTY/BRYANT FIELD.	8/8173	VOR OR GPS–A, AMDT 9A...
11/20/98	SC	ROCK HILL	ROCK HILL/YORK COUNTY/BRYANT FIELD.	8/8174	GPS RWY 20, ORIG–A...
11/20/98	SC	ROCK HILL	ROCK HILL/YORK COUNTY/BRYANT FIELD.	8/8176	NDB RWY 2, ORIG–B
11/20/98	WI	RHINELANDER	RHINELANDER–ONIEDA COUNTY	8/8178	ILS RWY 9, AMDT 6A...
11/23/98	MN	WINONA	WINONA MUNI–MAX CONRAD FIELD	8/8209	GPS RWY 29, AMDT 1...
11/23/98	TX	HOUSTON	GEORGE BUSH INTERCONTINENTAL AIRPORT/HOUSTON.	8/8201	ILS RWY 14L, AMDT 11...

FDC date	State	City	Airport	FDC No.	SIAP
11/23/98	TX	HOUSTON	BEORGE BUSH INTERCONTINENTAL AIRPORT/HOUSTON.	8/8204	VOR/DME RWY 14L, AMDT 15B...
11/23/98	TX	HOUSTON	GEORGE BUSH INTERCONTINENTAL AIRPORT/HOUSTON.	8/8207	GPS RWY 14L, ORIG–A...
11/23/98	TX	HOUSTON	GEORGE BUSH INTERCONTINENTAL AIRPORT/HOUSTON.	8/8211	VOR/DME OR GPS RWY 32R, AMDT 13B...
11/23/98	TX	HOUSTON	GEORGE BUSH INTERCONTINENTAL AIRPORT/HOUSTON.	8/8212	ILS RWY 32R, AMDT 10...

[FR Doc. 98–32131 Filed 12–1–98; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29402; Amdt. No. 1902]

RIN 2120–AA65

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace system, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT

Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on November 27, 1998.

Richard O. Gordon,

Acting Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

AUTHORITY: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPS; § 97.33 RNAV SIAPS; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective 31 December, 1998*

Carlsbad CA, McClellan-Palomar, ILS RWY 24, Amdt 8
Fairfield, IA, Fairfield Muni, VOR/DME RNAV RWY 36, Amdt 1C, CANCELLED
Kansas City, MO, Kansas City Intl, LOC BC RWY 27, Amdt 12, CANCELLED
New York, NY, LaGuardia, VOR/DME OR GPS–H, Amdt 2
Rock Hill, SC, Rock Hill/York County/BryantField, LOC RWY 2, Orig-B, CANCELLED
Rock Hill, SC, Rock Hill/York County/BryantField, ILS RWY 2, Orig

* * * *Effective 28 January, 1999*

Brewton, AL, Brewton Muni, GPS RWY 6, Orig
Chino, CA, Chino, ILS RWY 26R, Amdt 5
Fortuna, CA, Rohnerville, VOR RWY 11, Amdt 3
Fortuna, CA, Rohnerville, GPS RWY 11, Orig
Fortuna, CA, Rohnerville, GPS RWY 29, Orig
Tracy, CA, Tracy Muni, VOR OR GPS–A, Amdt 5
Tracy, CA, Tracy Muni, NDB RWY 25, Orig
Tracy, CA, Tracy Muni, NDB RWY 12, Orig
Tracy, CA, Tracy Muni, GPS RWY 25, Orig
Tracy, CA, Tracy Muni, GPS RWY 30, Orig
Craig, CO, Craig-Moffat, GPS RWY 7, Orig
Craig, CO, Craig-Moffat, GPS RWY 25, Orig
Titusville, FL, Space Coast Regional, GPS RWY 9, Orig
Valparaiso, IN, Porter County Muni, NDB RWY 27, Amdt 6
Valparaiso, IN, Porter County Muni, VOR/DME RNAV RWY 9, Amdt 3
Valparaiso, IN, Porter County Muni, GPS RWY 9, Orig
Valparaiso, IN, Porter County Muni, GPS RWY 27, Orig
Baltimore, MD, Martin State, NDB OR GPS RWY 15, Amdt 8
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, VOR/DME OR GPS RWY 16, Orig, CANCELLED
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, VOR OR GPS RWY 34, Amdt 10
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, NDB RWY 34, Amdt 7
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, ILS RWY 34, Amdt 1
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, GPS RWY 16, Orig
Granite Falls, MN, Granite Falls Muni, VOR/DME RWY 34, Orig
Granite Falls, MN, Granite Falls Muni, GPS RWY 34, Orig
Longville, MN, Longville Muni, NDB RWY 31, OriG
Moorhead, MN, Moorhead Muni, VOR–A, Orig
Orr, MN, Orr Regional, NDB RWY 13, Amdt 8
Orr, MN, Orr Regional, GPS RWY 13, Orig
Owatonna, MN, Owatonna Muni, VOR OR GPS RWY 12, Amdt 10
Owatonna, MN, Owatonna Muni, VOR/DME RWY 30, Amdt 4
Two Harbors, MN, Richard B. Helgeson, NDB RWY 24, Amdt 1
Two Harbors, MN, Richard B. Helgeson, GPS RWY 24, Orig
Ft. Leonard Wood, MO, VOR OR GPS RWY 14, Orig, CANCELLED
Ft. Leonard Wood, MO, VOR OR GPS RWY 32, Orig, CANCELLED
Ft. Leonard Wood, MO, LOC, RWY 14, Amdt 1, CANCELLED
Ft. Leonard Wood, MO, NDB RWY 32, Orig, CANCELLED
Teterboro, NJ, Teterboro, FMS/ILS RWY 6, Orig
Teterboro, NJ, Teterboro, ILS, RWY 6, Amdt 29
Teterboro, NJ, Teterboro, COPTER ILS RWY 6, Amdt 1
Dunkirk, NY, Chautauqua County/Dunkirk, VOR RWY 6, Amdt 2
Dunkirk, NY, Chautauqua County/Dunkirk, VOR RWY 24, Amdt 7
Dunkirk, NY, Chautauqua County/Dunkirk, GPS RWY 6, Orig
Dunkirk, NY, Chautauqua County/Dunkirk, GPS RWY 24, Orig
Dunkirk, NY, Chautauqua County/Dunkirk, GPS RWY 33, Orig
Manteo, NC, Dare County Regional, NDB RWY 5, Amdt 5
Manteo, NC, Dare County Regional, NDB RWY 17, Amdt 5
Manteo, NC, Dare County Regional, GPS RWY 5, Orig
Manteo, NC, Dare County Regional, GPS RWY 17, Orig
Manteo, NC, Dare County Regional, GPS RWY 23, Orig
Rutherfordton, NC, Rutherford Co-Marchman Field, LOC RWY 1, Amdt 1
Rutherfordton, NC, Rutherford Co-Marchman Field, NDB RWY 1, Amdt 5
Rutherfordton, NC, Rutherford Co-Marchman Field, GPS RWY 1, Amdt 1
Aberdeen, SD, Aberdeen Regional, VOR/DME OR GPS RWY 13, Amdt 12
Aberdeen, SD, Aberdeen Regional, VOR OR GPS RWY 31, Amdt 20
Aberdeen, SD, Aberdeen Regional, LOC/DME BC RWY 13, Amdt 10
Aberdeen, SD, Aberdeen Regional, NDB RWY 31, Amdt 10
Aberdeen, SD, Aberdeen Regional, ILS RWY 31, Amdt 13
Aberdeen, SD, Aberdeen Regional, GPS RWY 35, Orig
Nashville, TN, Nashville International, VOR/DME OR GPS RWY 13, Amdt 13
Baytown, TX, Baytown, NDB RWY 14, Orig-A, CANCELLED
Baytown, TX, Baytown, NDB RWY 32, Orig-A, CANCELLED

[FR Doc. 98–32130 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 305

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act (''Appliance Labeling Rule'')

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''Commission'') amends its Appliance Labeling Rule by publishing new ranges of comparability to be used on required labels for refrigerators, refrigerator-freezers, and freezers. The Commission also announces that the ranges of comparability for central air conditioners and heat pumps, which were published on September 16, 1996 (61 FR 48620), will remain in effect until further notice. Finally, the Commission is amending the portions of Appendices H (Cooling Performance and Cost for Central Air Conditioners) and I (Heating Performance and Cost for

Central Air Conditioners) to Part 305 that contain cost calculation formulas. These amendments change the figures in the formulas to reflect the current Representative Average Unit Cost of Electricity that was published on December 8, 1997 (62 FR 64574), by the Department of Energy (''DOE'').

EFFECTIVE DATE: March 2, 1999.

FOR FURTHER INFORMATION CONTACT: James Mills, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580 (202–326–3035).

SUPPLEMENTARY INFORMATION: The Appliance Labeling Rule (''Rule'') was issued by the Commission in 1979 (44 FR 66466 (Nov. 19, 1979)) in response to a directive in the Energy Policy and Conservation Act of 1975.[1] The Rule covers eight categories of major household appliances: refrigerators and refrigerator-freezers, freezers, dishwashers, clothes washers, water heaters (this category includes storage-type water heaters, instantaneous water heaters, and heat pump water heaters), room air conditioners, furnaces (this category includes boilers), and central air conditioners (this category includes heat pumps). The Rule also covers pool heaters (59 FR 49556 (Sept. 28, 1994)), and contains requirements that pertain to fluorescent lamp ballasts (54 FR 28031 (July 5, 1989)), certain plumbing products (58 FR 54955 (Oct. 25, 1993)), and certain lighting products (59 FR 25176 (May 13, 1994)).

The Rule requires manufacturers of all covered appliances and pool heaters to disclose specific energy consumption or efficiency information (derived from the DOE test procedures) at the point of sale in the form of an ''EnergyGuide'' label and in catalogs. It also requires manufacturers of furnaces, central air conditioners, and heat pumps either to provide fact sheets showing additional cost information, or to be listed in an industry directory showing the cost information for their products. The Rule requires that manufacturers include, on labels and fact sheets, an energy consumption or efficiency figure and a ''range of comparability.'' This range shows the highest and lowest energy consumption or efficiencies for all comparable appliance models so consumers can compare the energy consumption or efficiency of other models (perhaps competing brands) similar to the labeled model. The Rule requires that manufacturers also include, on labels for some products, a secondary energy usage disclosure in the form of an estimated annual operating cost on a specified DOE national average cost for the fuel the appliance uses.

Section 305.8(b) of the Rule requires manufacturers, after filing an initial report, to report annually (by specified dates for each product type [2]) the estimated annual energy consumption or energy efficiency ratings for the appliances derived from tests performed pursuant to the DOE test procedures. Because manufacturers regularly add new models to their lines, improve existing models, and drop others, the data base from which the ranges of comparability are calculated is constantly changing. Under Section 305.10 of the Rule, to keep the required information on labels consistent with these changes, the Commission publishes new ranges (but not more often than annually) if an analysis of the new information indicates that the upper or lower limits of the ranges have changed by more than 15%. Otherwise, the Commission publishes a statement that the prior ranges remain in effect for the next year.

New Ranges of Comparability for Refrigerators, Refrigerator-Freezers, and Freezers

The Commission has analyzed annual submissions of data for refrigerators, refrigerator-freezers, and freezers. The submissions have resulted in new ranges of comparability figures for these products. In compiling these ranges of comparability, the Commission did not include the estimated annual energy consumption of models with energy consumption in excess of DOE's current energy conservation standards for this category, which became effective on January 1, 1993 (16 CFR 430.32(a) (1995)). After that date, became illegal to distribute in commerce products that exceed those standards. Because the standards have been in place for almost six years, the number of legally produced, but nonconforming, products still in the marketplace is likely to be small. Therefore, it is not appropriate to include those products in the ranges. The new ranges will supersede the current ranges for refrigerators, refrigerator-freezers, and freezers, which were published on November 13, 1995 (60 FR 56945).

Changes Applicable to Disclosures for Central Air Conditioners and Heat Pumps

The 1995 data submission for central air conditioners and heat pumps has been completed, and the Commission has determined that the upper and lower limits of the ranges of comparability for these products, which were published on September 16, 1996 (61 FR 48620), have not changed by more than 15%. Therefore, the Commission is announcing that those ranges will remain in effect until further notice.

The Commission is amending in this Notice, however, the cost calculation formulas appearing in the Appendices (H and I) to Part 305 that contain, for central air conditioners and heat pumps, heating and cooling performance costs and the ranges of comparability. These formulas must be provided on fact sheets and in directories so consumers can calculate their own costs of operation for the central air conditioners and heat pumps that they are considering purchasing. This amendment changes the figures in the formulas to reflect the current Representative Average Unit Cost of Electricity—8.42 cents per kilo watt-hour—that was published on December 8, 1997, by DOE (62 FR 64574) and by the Commissioner on December 29, 1997 (62 FR 67560).

Amendments

In consideration of the foregoing, the Commission amends Appendices A1 through A8, B1 through B3, H, and I of its Appliance Labeling Rule by publishing the following ranges of comparability for use in the labeling and catalog sales of refrigerators, refrigerator-freezers, and freezers and the following amendments to the cost calculation formulas that manufacturers of central air conditioners and heat pumps must include on fact sheets and in directories, beginning March 2, 1999.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR Part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

2. Appendix A1 to Part 305 is revised to read as follows:

[1] 42 U.S.C. 6294. The statute also requires DOE to develop test procedures that measure how much energy the appliances use, and to determine the representative average cost a consumer pays for the different types of energy available.

[2] Reports for refrigerators, refrigerator-freezers, and freezers are due August 1. Reports for central air conditioners and heat pumps are due July 1.

APPENDIX A1 TO PART 305—REFRIGERATORS WITH AUTOMATIC DEFROST

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 2.5	327	327
2.5 to 4.4	301	398
4.5 to 6.4	370	434
6.5 to 8.4	419	419
8.5 to 10.4	419	467
10.5 to 12.4	391	454
12.5 to 14.4	(*)	(*)
14.5 to 16.4	588	588
16.5 and over	438	668

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

3. Appendix A2 to Part 305 is revised to read as follows:

APPENDIX A2 TO PART 305—REFRIGERATORS AND REFRIGERATOR-FREEZERS WITH MANUAL DEFROST

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 2.5	256	307
2.5 to 4.4	301	358
4.5 to 6.4	268	377
6.5 to 8.4	378	405
8.5 to 10.4	343	430
10.5 to 12.4	435	435
12.5 to 14.4	(*)	(*)
14.5 to 16.4	(*)	(*)
16.5 to 18.4	438	438
18.5 to 20.4	(*)	(*)
20.5 to 22.4	(*)	(*)
22.5 to 24.4	(*)	(*)
24.5 to 26.4	(*)	(*)
26.5 to 28.4	(*)	(*)
28.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

4. Appendix A3 to Part 305 is revised to read as follows:

APPENDIX A3 TO PART 305—REFRIGERATOR-FREEZERS WITH PARTIAL AUTOMATIC DEFROST

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption 9kWh/yr.)	
	Low	High
Less than 10.5	376	510
10.5 to 12.4	454	538
12.5 to 14.4	(*)	(*)
14.5 to 16.4	(*)	(*)
16.5 to 18.4	(*)	(*)
18.5 to 20.4	(*)	(*)
20.5 to 22.4	(*)	(*)
22.5 to 24.4	(*)	(*)
24.5 to 26.4	(*)	(*)
26.5 to 28.4	(*)	(*)
28.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

5. Appendix A4 to Part 305 is revised to read as follows:

APPENDIX A4 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH TOP-MOUNTED FREEZER WITHOUT THROUGH-THE-DOOR ICE SERVICE

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5	427	525
10.5 to 12.4	449	568
12.5 to 14.4	496	624
14.5 to 16.4	437	666
16.5 to 18.4	518	697
18.5 to 20.4	526	741
20.5 to 22.4	559	767
22.5 to 24.4	598	800
24.5 to 26.4	609	825
26.5 to 28.4	(*)	(*)
28.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

6. Appendix A5 to Part 305 is revised to read as follows:

APPENDIX A5 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH SIDE-MOUNTED FREEZER WITHOUT THROUGH-THE-DOOR ICE SERVICE

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5	452	525
10.5 to 12.4	480	480
12.5 to 14.4	(*)	(*)
14.5 to 16.4	(*)	(*)
16.5 to 18.4	(*)	(*)
18.5 to 20.4	710	783
20.5 to 22.4	685	825
22.5 to 24.4	720	848
24.5 to 26.4	776	875
26.5 to 28.4	(*)	(*)
28.5 and over	911	950

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

7. Appendix A6 to Part 305 is revised to read as follows:

APPENDIX A6 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH BOTTOM-MOUNTED FREEZER WITHOUT THROUGH-THE-DOOR ICE SERVICE

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5	463	463
10.5 to 12.4	(*)	(*)
12.5 to 14.4	(*)	(*)
14.5 to 16.4	666	666
16.5 to 18.4	706	709
18.5 to 20.4	593	757
20.5 to 22.4	524	789
22.5 to 24.4	(*)	(*)
24.5 to 26.4	(*)	(*)
26.5 to 28.4	(*)	(*)
28.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

8. Appendix A7 to Part 305 is revised to read as follows:

APPENDIX A7 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH TOP-MOUNTED FREEZER WITH THROUGH-THE-DOOR ICE SERVICE

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5	(*)	(*)
10.5 to 12.4	(*)	(*)
12.5 to 14.4	(*)	(*)
14.5 to 16.4	(*)	(*)
16.5 to 18.4	(*)	(*)
18.5 to 20.4	(*)	(*)
20.5 to 22.4	840	840
22.5 to 24.4	(*)	(*)
24.5 to 26.4	905	905
26.5 to 28.4	(*)	(*)
28.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

9. Appendix A8 to Part 305 is revised to read as follows:

APPENDIX A8 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH SIDE-MOUNTED FREEZER WITH THROUGH-THE-DOOR ICE SERVICE

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5	(*)	(*)
10.5 to 12.4	(*)	(*)
12.5 to 14.4	(*)	(*)
14.5 to 16.4	(*)	(*)
16.5 to 18.4	(*)	(*)
18.5 to 20.4	734	934
20.5 to 22.4	714	967
22.5 to 24.4	685	1000
24.5 to 26.4	760	1042
26.5 to 28.4	735	1080
28.5 and over	765	1144

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

10. Appendix B1 to Part 305 is revised to read as follows:

APPENDIX B1 TO PART 305—UPRIGHT FREEZERS WITH MANUAL DEFROST

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 5.5	250	349
5.5 to 7.4	(*)	(*)
7.5 to 9.4	373	416
9.5 to 11.4	448	456
11.5 to 13.4	468	474
13.5 to 15.4	509	534
15.5 to 17.4	562	565
17.5 to 19.4	(*)	(*)
19.5 to 21.4	615	627
21.5 to 23.4	(*)	(*)
23.5 to 25.4	(*)	(*)
25.5 to 27.4	(*)	(*)
27.5 to 29.4	(*)	(*)
29.5 and over	685	685

(*) No date submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

11. Appendix B2 To Part 305 is revised to read as follows:

APPENDIX B2 TO PART 305—UPRIGHT FREEZERS WITH AUTOMATIC DEFROST

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/hr.)	
	Low	High
Less than 5.5	504	516
5.5 to 7.4	(*)	(*)
7.5 to 9.4	(*)	(*)
9.5 to 11.4	(*)	(*)
11.5 to 13.4	(*)	(*)
13.5 to 15.4	728	774
15.5 to 17.4	784	821
17.5 to 19.4	876	878
19.5 to 21.4	800	896
21.5 to 23.4	(*)	(*)
23.5 to 25.4	(*)	(*)
25.5 to 27.4	(*)	(*)
27.5 to 29.4	(*)	(*)
29.5 and over	687	687

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

12. Appendix B3 to Part 305 is revised to read as follows:

APPENDIX B3 TO PART 305—CHEST FREEZERS AND ALL OTHER FREEZERS

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh.yr.)	
	Low	High
Less than 5.5	212	260
5.5 to 7.4	291	293
7.5 to 9.4	322	322
9.5 to 11.4	347	349
11.5 to 13.4	391	399
13.5 to 15.4	434	441
15.5 to 17.4	(*)	(*)
17.5 to 19.4	493	493
19.5 to 21.4	529	529
21.5 to 23.4	552	588
23.5 to 15.4	620	629
25.5 to 27.4	(*)	(*)
27.5 to 29.4	(*)	(*)
29.5 and over	(*)	(*)

*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

Appendix H—[Amended]

13. In section 2 of Appendix H or Part 305, the text and formulas are amended by removing the figure ''8.31¢'' wherever it appears and by adding, in its place, the figure ''8.42¢''. In addition, the text and formulas are amended by removing the figure ''12.47¢'' wherever it appears and by adding, in its place, the figure ''112.64¢''.

Appendix I—[Amended]

14. In section 2 of Appendix I of Part 305, the text and formulas are amended by removing the figure ''8.31¢'' wherever it appears and by adding, in its place, the figure ''8.42¢''. In addition, the text and formulas are amended by removing the figure ''12.47¢'' wherever it appears and by adding, in its place, the figure ''12.64¢''.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–32079 Filed 12–1–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol Tartrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Intervet, Inc. The ANADA provides for use of butorphanol tartrate injection for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed ANADA 200–239 that provides for veterinary prescription use of Dolorex® (butorphanol tartrate) injection intravenously for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

ANADA 200–239 is approved as a generic copy of Fort Dodge Animal Health's NADA 135–780 for Torbugesic® for horses. The ANADA is approved as of September 28, 1998, and the regulations are amended in 21 CFR 522.246(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of the application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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: 21 U.S.C. 360b.

2. Section 522.246 is amended by revising paragraph (b) to read as follows:

§ 522.246 Butorphanol tartrate injection.

* * * * *

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

* * * * *

Dated: November 5, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–32022 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Chlortetracycline and Salinomycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved chlortetracycline and salinomycin Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and as an aid in the reduction of mortality due to *E. coli* infections.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301–827–0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200–261 and 200–262 that provide for combining approved ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline) and Sacox® or Bio–Cox® (30 or 60 g/lb salinomycin sodium) Type A medicated articles to make Type C medicated broiler feeds containing chlortetracycline 500 grams per ton (g/t) and salinomycin 40 to 60 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200–261 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140–859. Alpharma Inc.'s ANADA 200–262 is approved as a generic copy of Hoechst Roussel's ANADA 200–095. Alpharma Inc.'s ANADA's 200–261 and 200–262 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.550 is amended by revising paragraph (a)(3) to read as follows:

§ 558.550 Salinomycin.

(a) * * *

(3) To 046573 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

* * * * *

Dated: November 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–32141 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8790]

RIN 1545–AU38

Definition of Reasonable Basis

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the accuracy-related penalty. These amendments are necessary to define reasonable basis and to make conforming changes to existing regulations. These regulations affect any taxpayer that files a tax return.

DATES: Effective date. These regulations are effective December 2, 1998.

Applicability date. For dates of applicability, see §§ 1.6662–2(d) and 1.6664–1(b)(2).

FOR FURTHER INFORMATION CONTACT: Beverly A. Baughman, 202–622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 1, 1995, the IRS issued final regulations [TD 8617 (60 FR 45661)], relating to the accuracy-related penalty under chapter 1 of the Internal Revenue Code. Those regulations provided guidance concerning the reasonable basis standard for purposes of (1) the negligence penalty under section 6662(b)(1), and (2) the disclosure exception to the penalties for disregarding rules or regulations under section 6662(b)(1) and the substantial understatement of income tax under section 6662(b)(2). In the preamble to the final regulations, the IRS and Treasury Department requested comments and suggestions on providing further guidance on the reasonable basis standard. On November 12, 1996, proposed regulations [IA–42–95 (1996–49 I.R.B. 21) (see § 601.601(d)(2)(ii)(*b*) of this chapter)] defining reasonable basis and making conforming changes to the final regulations relating to the accuracy-related penalty were published in the **Federal Register** (61 FR 58020).

Written comments responding to the notice of proposed rulemaking were received. A public hearing was held on February 25, 1997. After consideration of all the comments, the proposed regulations under section 6662 relating to the definition of reasonable basis for purposes of the accuracy-related penalty are adopted as revised by this Treasury decision.

In addition, on August 5, 1997, the Taxpayer Relief Act (TRA) of 1997, Pub. L. 105–34 (111 Stat. 788), was enacted. The Act added a restriction regarding whether or not a corporation has a reasonable basis for its tax treatment of an item for purposes of reducing the amount of the substantial understatement penalty. This restriction has been incorporated into the final regulations.

Explanation of Provisions and Summary of Comments

These final regulations provide that a return position will have a reasonable basis for purposes of the accuracy-related penalties if it is reasonably based on one or more certain authorities. Also, if the return position does not satisfy the reasonable basis standard, a reasonable cause and good faith exception may still apply.

One commentator suggested that the substantial authority standard in § 1.6662–4(d)(3)(ii) of existing regulations and the reasonable basis standard in § 1.6662–3(b)(3) of the proposed regulations be expanded to include as authority a well-reasoned construction of the applicable regulatory provisions in addition to the statutory provisions. The substantial authority standard in § 1.6662–4(d)(3)(ii) has not been expanded to reflect this comment. However, the definition of reasonable basis in § 1.6662–3(b)(3) has been clarified to include an explicit cross-reference to the nature of the analysis discussion in § 1.6662–4(d)(3)(ii) of the substantial authority regulations.

Several commentators suggested that the final regulations explain where the reasonable basis standard ranks in the hierarchy of return position standards. This suggestion was not adopted. The final regulations do not rank the standards formally because such a comparison would change the focus of the reasonable basis regulations from the taxpayer's obligation to determine his or her tax liability in accordance with the internal revenue laws to the probability of the return position prevailing in litigation.

Several commentators supported the exclusion of a numerical qualification of the reasonable basis standard in the proposed regulations because they believed that such a qualification would encourage arbitrary and mechanical application of the standards and create bad precedent outside the scope of the reasonable basis standard. The final regulations do not include a numerical qualification.

One commentator requested that the final regulations refer specifically to Rev. Rul. 59–60 (1959–1 C.B. 237) (see § 601.601(d)(2)(ii)(*b*) of this chapter), which provides guidance regarding the valuation of stock of closely held corporations for estate and gift tax purposes. The final regulations do not adopt this suggestion. It is not necessary to include a reference to a specific revenue ruling because § 1.6662–4(d)(3)(iii) of the existing regulations already lists revenue rulings as an acceptable type of authority.

One commentator requested that the final regulations clarify the effect of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66 (107 Stat. 312), and the reasonable cause and good faith exception under section 6664 on a taxpayer's access to prepayment litigation in Tax Court. The final regulations do not adopt this suggestion. It is not necessary to clarify that a taxpayer has access to prepayment litigation in Tax Court because under section 6665 the Tax Court has jurisdiction to redetermine additions to tax in the same manner as the underlying tax.

Pursuant to the Taxpayer Relief Act of 1997, Pub. L. 105–34 (111 Stat. 788), § 1.6662–4(e)(3) has been added to the final regulations. That section provides that for purposes of reducing the amount of the substantial understatement penalty by making an adequate disclosure, a corporation will not be treated as having a reasonable basis for its tax treatment of an item attributable to a multi-party financing transaction entered into after August 5, 1997, if the treatment does not clearly reflect the income of the corporation.

The Chief Counsel for Advocacy of the Small Business Administration requested that the preamble to the regulations explain why the IRS has concluded that this regulation is not subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6). The Chief Counsel for Advocacy submits that the regulations tighten the definition of reasonable basis and, thus, impose a de facto recordkeeping requirement because they may require small businesses to keep and maintain records (such as the documents referred to in § 1.6662–4(d)(3)(iii)) to support tax reporting decisions.

After carefully considering these comments, the IRS and Treasury have

concluded that this regulation is not subject to the Regulatory Flexibility Act, 5 U.S.C. § 603 (1994). That section requires a regulatory flexibility analysis for an interpretative rule involving the internal revenue laws only to the extent the interpretative rule imposes a collection of information requirement on small entities. A collection of information requirement is defined in 5 U.S.C. § 601(7) (1994) to mean the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either (i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States, or (ii) answers to questions posed to agencies, instrumentalities, or employees of the United States that are to be used for general statistical purposes.

Furthermore, the phrase, recordkeeping requirement, is defined in 5 U.S.C. 601(8) (1994) as a requirement imposed by an agency on persons to maintain specified records. Ever since this term was first used in the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the IRS and Treasury have consistently interpreted the phrase as applying only when Treasury regulations directly require persons to maintain specified records. We believe this interpretation is consistent with the explicit statutory language as well as Congressional intent to apply the law only to situations in which government agencies require persons to maintain particular records.

Thus, we believe the final regulations do not impose a recordkeeping requirement or other collection of information requirement, as defined in 5 U.S.C. 601(7), (8) (1994). The regulations do not impose on taxpayers additional requirements to either report information to the IRS or to keep specified records. Because the regulations do not contain a reporting requirement or other collection of information requirement, the provisions of the Regulatory Flexibility Act do not apply.

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) does not apply to these regulations. 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 the impact of the proposed regulations on small business. The Chief Counsel for Advocacy submitted comments on these regulations, which are discussed above.

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

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is 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 1.6662–0 is amended by:

1. Adding the entry for § 1.6662–2(d)(4).
2. Removing the entries for § 1.6662–3(b)(3)(i) and (ii).
3. Adding the entry for § 1.6662–4(e)(3).
4. Revising the entry for § 1.6662–7(d).
5. Removing the entries for § 1.6662–7(d)(1) and (2).

The revision and additions read as follows:

§ 1.6662–0 Table of contents.

* * * * *

§ 1.6662–2 Accuracy-related penalty.

* * * * *

(d) * * *

(4) Special rule for reasonable basis.

* * * * *

§ 1.6662–4 Substantial understatement of income tax.

* * * * *

(e) * * *

(3) Restriction for corporations.

* * * * *

§ 1.6662–7 Omnibus Budget Reconciliation Act of 1993 changes to the accuracy-related penalty.

* * * * *

(d) Reasonable basis.

Par 3. Section 1.6662–2 is amended by:

1. Revising the second sentence in paragraph (d)(1).
2. Revising the first sentence in paragraph (d)(2).
3. Adding paragraph (d)(4).

The addition and revisions read as follows:

§ 1.6662–2 Accuracy-related penalty.

* * * * *

(d) * * * (1) * * * Except as provided in the preceding sentence and in paragraphs (d)(2), (3), and (4) of this section, §§ 1.6662–1 through 1.6662–5 apply to returns the due date of which (determined without regard to extensions of time for filing) is after December 31, 1989, but before January 1, 1994. * * *

(2) *Returns due after December 31, 1993.* Except as provided in paragraphs (d)(3) and (4) of this section and the last sentence of this paragraph (d)(2), the provisions of §§ 1.6662–1 through 1.6662–4 and § 1.6662–7 (as revised to reflect the changes made to the accuracy-related penalty by the Omnibus Budget Reconciliation Act of 1993) and of § 1.6662–5 apply to returns the due date of which (determined without regard to extensions of time for filing) is after December 31, 1993. * * *

* * * * *

(4) *Special rules for reasonable basis.* Section 1.6662–3(b)(3) applies to returns filed on or after December 2, 1998.

Par. 4. Section § 1.6662–3 is amended by:

1. Revising the third sentence in paragraph (b)(1) introductory text.
2. Revising paragraph (b)(3).

The revisions read as follows:

§ 1.6662–3 Negligence or disregard of rules or regulations.

* * * * *

(b)* * * (1) * * * A return position that has a reasonable basis as defined in paragraph (b)(3) of this section is not attributable to negligence. * * *

* * * * *

(3) *Reasonable basis.* Reasonable basis is a relatively high standard of tax reporting, that is, significantly higher than not frivolous or not patently improper. The reasonable basis standard is not satisfied by a return position that is merely arguable or that is merely a colorable claim. If a return position is reasonably based on one or more of the authorities set forth in § 1.6662–4(d)(3)(iii) (taking into account the relevance and persuasiveness of the authorities, and subsequent developments), the return position will generally satisfy the reasonable basis standard even though it may not satisfy the substantial authority standard as defined in § 1.6662–4(d)(2). (See § 1.6662–4(d)(3)(ii) for rules with

respect to relevance, persuasiveness, subsequent developments, and use of a well-reasoned construction of an applicable statutory provision for purposes of the substantial understatement penalty.) In addition, the reasonable cause and good faith exception in § 1.6664–4 may provide relief from the penalty for negligence or disregard of rules or regulations, even if a return position does not satisfy the reasonable basis standard.

* * * * *

Par. 5. Section 1.6662–4 is amended by:

1. Revising the second sentence in paragraph (d)(2).

2. Adding paragraph (e)(3).

The addition and revision reads as follows:

§ 1.6662–4 Substantial understatement of income tax.

* * * * *

(d) * * *

(2) * * * The substantial authority standard is less stringent than the more likely than not standard (the standard that is met when there is a greater than 50-percent likelihood of the position being upheld), but more stringent than the reasonable basis standard as defined in § 1.6662–3(b)(3). * * *

* * * * *

(e) * * *

(3) *Restriction for corporations.* For purposes of paragraph (e)(2)(i) of this section, a corporation will not be treated as having a reasonable basis for its tax treatment of an item attributable to a multi-party financing transaction entered into after August 5, 1997, if the treatment does not clearly reflect the income of the corporation.

* * * * *

Par. 6. In § 1.6662–7, paragraph (d) is revised to read as follows:

§ 1.6662–7 Omnibus Budget Reconciliation Act of 1993 changes to the accuracy-related penalty.

* * * * *

(d) *Reasonable basis.* For purposes of §§ 1.6662–3(c) and 1.6662–4(e) and (f) (relating to methods of making adequate disclosure), the provisions of § 1.6662–3(b)(3) apply in determining whether a return position has a reasonable basis.

Par. 7. Section 1.6664–0 is amended by:

1. Revising the entry for § 1.6664–4(c)(2).

2. Removing the entries for §§ 1.6664–4(c)(1)(iii), (c)(2)(i), and (c)(2)(ii).

3. Adding the entry for § 1.6664–4(g)(3).

The revision and addition reads as follows:

§ 1.6664–0 Table of contents.

* * * * *

§ 1.6664–4 Reasonable cause and good faith exception to section 6662 penalties.

* * * * *

(c) * * *

(2) Advice defined.

* * * * *

(g) * * *

(3) Special rules.

* * * * *

Par. 8. In § 1.6664–4, paragraph (g) is revised to read as follows:

§ 1.6664–4 Reasonable cause and good faith exception to section 6662 penalties.

* * * * *

(g) *Valuation misstatements of charitable deduction property*—(1) *In general.* There may be reasonable cause and good faith with respect to a portion of an underpayment that is attributable to a substantial (or gross) valuation misstatement of charitable deduction property (as defined in paragraph (g)(2) of this section) only if—

(i) The claimed value of the property was based on a qualified appraisal (as defined in paragraph (g)(2) of this section) by a qualified appraiser (as defined in paragraph (g)(2) of this section); and

(ii) In addition to obtaining a qualified appraisal, the taxpayer made a good faith investigation of the value of the contributed property.

(2) *Definitions.* For purposes of this paragraph (g):

Charitable deduction property means any property (other than money or publicly traded securities, as defined in § 1.170A–13(c)(7)(xi)) contributed by the taxpayer in a contribution for which a deduction was claimed under section 170.

Qualified appraisal means a qualified appraisal as defined in § 1.170A–13(c)(3).

Qualified appraiser means a qualified appraiser as defined in § 1.170A–13(c)(5).

(3) *Special rules.* The rules of this paragraph (g) apply regardless of whether § 1.170A–13 permits a taxpayer to claim a charitable contribution deduction for the property without obtaining a qualified appraisal. The rules of this paragraph (g) apply in addition to the generally applicable rules concerning reasonable cause and good faith.

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

Approved: November 17, 1998.

Donald C. Lubick,

Acting Assistant Secretary of the Treasury.

[FR Doc. 98–31985 Filed 12–1–98; 8:45 am]

BILLING CODE 4830–01–u

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300746; FRL–6038–4]

RIN 2070–AB78

Metolachlor; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the herbicide metolachlor and its metabolites in or on spinach at 0.3 parts per million (ppm) for an additional 18-month period, to May 15, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on spinach. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective December 2, 1998. Objections and requests for hearings must be received by EPA, on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300746], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300746], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk

may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)–308–9367; e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of November 29, 1996 (61 FR 60617–60622) (FRL–5574–7), which announced that on its own initiative under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of metolachlor and its metabolites in or on spinach at 0.3 ppm, with an expiration date of November 15, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of metolachlor on spinach for this year growing season due to the loss of the product Antor 4E (diethatyl ethyl), an herbicide used on spinach. Antor is no longer manufactured, and the remaining stocks of Antor have been exhausted since 1993.

Spinach growers produce spinach on highly drained organic muck soils. Presently there is no pre-emergence herbicide registered to control annual grasses and certain broadleaf weeds in spinach. Without a pre-emergence herbicide, it is doubtful that germinating spinach seed will be able to compete with weeds for space, light, nutrients, and water, thus making it economically unfeasible to produce and process spinach. Alternative control practices consisting of field selection and hand hoeing will not solve weed control problems that exist in spinach due to the loss of Antor. Applicants claim that without the use of metolachlor growers will suffer significant economic losses. After having reviewed the submission, EPA concurs that emergency conditions exist for this state. EPA has authorized under FIFRA section 18 the use of metolachlor on spinach for control of broadleaf weeds.

EPA assessed the potential risks presented by residues of metolachlor in or on spinach. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of November 29, 1996. Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 18-month period. Although this tolerance will expire and is revoked on May 15, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on spinach after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file

format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP– 300746]. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule extends a time-limited tolerance that was previously established by EPA under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

Since this extension of an existing time-limited tolerance does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 15, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

§ 180.368 [Amended]

2. Section 180.368, by amending paragraph (b), by revising the date for the commodity ''spinach'' from ''11/15/98'' to read ''5/15/00.''

[FR Doc. 98–32002 Filed 12–01–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300758; FRL–6045–3]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in or on field corn forage at 0.1 parts per million (ppm), field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on field corn. This regulation establishes maximum permissible levels for residues of imidacloprid in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on May 1, 2000.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300758], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300758], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300758]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the insecticide imidacloprid, in or on field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. These tolerances will expire and are revoked on May 1, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Imidacloprid on Field Corn and FFDCA Tolerances

The states of Illinois and Iowa requested the use of imidacloprid on field corn to control the flea beetle because the flea beetle has been shown to be a vector of a bacteria that causes Stewart's Wilt in corn. Stewart's wilt can cause serious yield loss when infection occurs early in the growing

season. Also, many countries require seed fields to be inspected for Stewart's wilt infected plants, and will not allow seed from these fields to be sent to their country. The United States is a major producter of seed corn for the world. EPA has authorized under FIFRA section 18 the use of imidacloprid on field corn for control of corn flea beetles (a vector of Stewart's wilt) in Illinois and Iowa. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of imidacloprid in or on field corn. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on May 1, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on field corn after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether imidacloprid meets EPA's registration requirements for use on field corn or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than Illinois and Iowa to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for imidacloprid, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997)(FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action EPA has sufficient data to assess the hazards of imidacloprid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent on field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imidacloprid are discussed below.

1. *Acute toxicity*. Acute Reference dose (RfD): 0.42 milligrams per kilogram of bodyweight per day (mg/kg bwt/day). The endpoint selected for assessment of acute dietary risk is 42 mg/kg bwt/day (Lowest Observed Effect Level (LOEL)) from an acute neurotoxicity study in rats. A NOAEL was not established in this study. The uncertainty factors (UF) are 10X for inter-, 10X for intra-species variations, and 3X for FQPA.

2. *Short- and intermediate-term toxicity*. Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. A short-term aggregate risk assessment (oral exposure) is required for hand-to-mouth residential exposure. The Agency utilized the acute toxicological endpoint for this risk assessment. The acute dietary endpoint is based upon dose-related decreases in motor activity in female rats from an acute neurotoxicity study.

3. *Chronic toxicity*. EPA has established the RfD for imidacloprid at 0.057 milligrams/kilogram/day (mg/kg/day). This RfD is based on decreased body weight gains in female rats and increased number of thyroid lesions in male rats from a combined chronic toxicity/carcinogenicity study at 16.9 mg/kg bwt/day LOEL. The No Observed Adverse Effect Level (NOAEL) in this study was established at 5.7 mg/kg bwt/day. An uncertainty factor of 100 is required for all population subgroups (10X for inter-species variation and 10X for intra-species variation). For chronic dietary risk assessment, the Agency determined that the FQPA safety factor could be reduced to 3X and should be applied to all population subgroups.

4. *Carcinogenicity*. Imidacloprid has been classified by the Agency as a Group E chemical, no evidence of carcinogenicity for humans, thus, a cancer risk assessment is not required.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances, some time-limited, are currently established (40 CFR 180.472) for the combined residues of the insecticide imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on a variety of raw agricultural and animal commodities at levels ranging from 0.02 ppm in eggs to 15 ppm in raisins, waste. Risk assessments were conducted by EPA to assess dietary exposures and risks from imidacloprid as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. Application of the 3X safety factor to the Acute RfD results in an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Acute RfD for all population subgroups

This acute dietary (food) risk assessment used the Theoretical Maximum Residue Contribution (TMRC) which assumes tolerance level residues and 100% crop-treated. The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this acute dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing

Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99th percentile) and percentage of the Acute RfD utilized are shown in the following Table 1.

TABLE 1.—ACUTE DIETARY (FOOD ONLY) EXPOSURE ANALYSIS BY DEEM FOR IMIDACLOPRID

Population Subgroup	Exposure @ 99th Percentile (mg/kg bwt/day)	Percent Acute RfD[1]
U.S. Population (48 states)	0.051	12
All infants (< 1 yr)	0.067	16
Nursing infants (< 1 yr)	0.096	23
Non-nursing infants (< 1 yr)	0.059	14
Children (1–6 yrs)	0.086	20
Children (7–12 yr)	0.058	14

[1] Percentage reference dose (% Acute RfD) = Exposure/Acute RfD X 100%

The subgroups listed above are: (1) the U.S. population (48 states) and (2) those for infants and children. There are no other subgroups for which the percentage of the Acute RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the reference dose (chronic RfD) of 0.057 mg/kg bwt/day. This RfD (RfD = NOAEL/UF) is based on the NOAEL of 5.7 mg/kg bwt/day in male rats from the chronic toxicity/carcinogenicity study in rats, and an uncertainty factor (UF) of 100. The FQPA Safety Factor for enhanced sensitivity of infants and children was reduced to 3X. For this risk assessment, the FQPA factor applies to all population subgroups. Application of the 3X safety factor to the chronic RfD results in an acceptable chronic dietary exposure (food plus water) of 33.3% or less of the chronic RfD for all population subgroups.

In conducting this chronic dietary (food only) risk assessment, EPA used: (1) tolerance level residues for field corn and all other commodities with published, pending, permanent or time-limited, imidacloprid tolerances; and, (2) percent crop-treated (%CT) information for some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure. The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing imidacloprid tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a TMRC that is equivalent to the percentages of the Chronic RfD in the following Table 2:

TABLE 2.—CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEM FOR IMIDACLOPRID

Population Subgroup	Exposure (mg/kg/day)	Percent Reference Dose[1] (%Chronic RfD)
U.S. Population (48 States)	0.0032	5.6
All Infants (<1 year old)	0.0039	6.9
Nursing Infants (<1 year old)	0.0014	2.4
Non-Nursing Infants (<1 year old)	0.0050	8.7
Children (1–6 years old)	0.0074	13
Children (7–12 years old)	0.0046	8.2
U.S. Population (Autumn Season)	0.0032	5.7
Northeast Region	0.0032	5.7
Western Region	0.0033	5.7
Non-hispanic (Other Than Black or White)	0.0036	6.2

[1] Percentage reference dose (% Chronic RfD) = Exposure/Chronic RfD X 100%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and (3) the other subgroups for which the percentage of the Chronic RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).

2. *From drinking water.* There is no established Maximum Contaminant Level for residues of imidacloprid in drinking water. No health advisory levels for imidacloprid in drinking water have been established.

Imidacloprid is persistent, water soluble, and fairly mobile. Thus, residues of imidacloprid may be transported to both surface and ground waters. As a condition of registration, the Agency is requiring the submission of the results of two prospective ground water monitoring studies. Results from these studies are not yet available. EPA used estimates for the concentration of imidacloprid in surface and ground waters.

The Agency used PRZM1 (Pesticide Root Zone Model - simulates the transport of a pesticide off the agricultural field) and EXAMS (EXposure Analysis Modeling System - simulates fate and transport of a pesticide in surface water) models to estimate concentrations of imidacloprid residues in surface water.

The Agency used the SCI-GROW (Screening Concentration In GROund Water) model to estimate the concentration of imidacloprid residues in ground water. SCI-GROW is a prototype model for estimating ''worst case'' ground water concentrations of pesticides. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded.

i. *Acute exposure and risk.* Estimated concentrations of imidacloprid in surface and ground water for acute exposure analysis are 4.1 and 1.1 grams per liter (parts per million) (µg/L parts per billion (ppb)), respectively. These estimated concentrations of imidacloprid in surface and ground water are based upon an application rate of 0.5 lbs active ingredient per acre per year (ai/A/year).

For purposes of risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 4.1 µg/L) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the acute endpoint. These DWLOCs for various population categories are summarized in the following Table 3.

TABLE 3.—DRINKING WATER LEVELS OF CONCERN FOR ACUTE EXPOSURE TO IMIDACLOPRID[1]

Population Category[2]	Acute RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4, 5, 6] (µg/L)
U.S. Population (48 states) (male)	0.42	0.051	0.089	3100
U.S. Population (48 states) Females	0.42	0.051	0.089	2700
Nursing Infants (<1 year old)	0.42	0.096	0.044	440

[1] Values are expressed to two significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = Chronic or Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Food Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] EPA Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] EPA Default daily drinking rates are 2 L/day for adults and 1 L/day for children.

ii. *Short-term risk*. For purposes of risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 4.1 µg/L, see above) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the short-term endpoint.

EPA has calculated a DWLOC for short-term exposure to imidacloprid in drinking water for the population subgroup Children, 1 to 6 years old. This DWLOC is for short-term exposure to imidacloprid from home garden and turf uses. A DWLOC for short-term exposure from imidacloprid pet uses was not determined as the exposure level from the home garden and turf uses is higher than that of the pet uses. Thus, the DWLOC for the imidacloprid pet uses will be higher than that of the home garden and turf uses. The DWLOC for short-term exposure to imidacloprid is summarized in the following Table 4.

TABLE 4.—DRINKING WATER LEVELS OF CONCERN FOR SHORT-TERM EXPOSURE TO IMIDACLOPRID[1]

Population Subgroup	Total Exposure[2] (mg/kg bwt/day)	Max. Exposure from Water[3] (mg/kg bwt/day)	Body-weight (kg)	Daily Water Consumption (Liters)	DWLOC[4, 5, 6] (µg/L)
Children (1–6 years)	0.080	0.060	10	1	600

[1] Values are expressed to two significant figures.
[2] Total Exposure = sum of exposures from chronic food plus home turf and garden uses.
[3] Maximum Water Exposure (Short-term) (mg/kg/day) = Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Total Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] EPA Default body weight is: All Infants/Children, 10 kg.
[6] EPA Default daily drinking rate is 1 L/day for children.

The DWLOC for short-term exposure to imidacloprid was calculated relative to the Acute RfD which was utilized for estimating risk for short-term oral exposure to imidacloprid. To calculate the DWLOC for short-term exposure relative to an acute toxicity endpoint, the sum of chronic dietary food exposure (from DEEM) plus the oral exposure from imidacloprid home garden and turf uses was subtracted from one-third the Acute RfD to obtain the acceptable short-term exposure to imidacloprid in drinking water. The value of one-third the Acute RfD was utilized to account for the FQPA Safety Factor of 3X. DWLOCs were then calculated using default body weights and drinking water consumption figures.

iii. *Chronic exposure and risk*. Estimated concentrations of imidacloprid in surface and ground water for chronic exposure analysis are 0.1 and 1.1 µg/L (ppb), respectively. These estimated concentrations of imidacloprid in surface and ground water are based upon an application rate of 0.5 lbs ai/A/year.

For purposes of chronic risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 1.1 µg/L) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in the following Table 5.

TABLE 5.—DRINKING WATER LEVELS OF CONCERN FOR CHRONIC EXPOSURE TO IMIDACLOPRID[1]

Population Category[2]	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4, 5, 6] (µg/L)
U.S. Population (48 states) (male)	0.057	0.0032	0.0158	550
Females U.S. Population (48 states)	0.057	0.0032	0.0158	470
Children (1–6)	0.057	0.0074	0.0116	120
Non-hispanic other than black or white	0.057	0.0036	0.0154	540

[1] Values are expressed to two significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic or Acute) (mg/kg/day) = Chronic or Acute RfD (mg/kg/day)/3 (to account for FQPA factor of 3X) - Food Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] EPA Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] EPA Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7] Total Exposure for Short-term Exposure = sum of exposures from chronic food plus home turf and garden uses.

iv. *Conclusions concerning residues in drinking water (all time periods).* The estimated concentrations of imidacloprid in surface and ground water are less than the Agency's levels of concern for imidacloprid in drinking water as a contribution to acute, short-term and chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this section 18, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of acute, short-term and chronic exposure for which EPA has reliable data) would not result in an unacceptable estimate of acute, short-term and chronic aggregate human health risk at this time.

EPA bases this determination on a comparison of estimated concentrations of imidacloprid in surface water to back-calculated ''levels of concern'' for imidacloprid in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in these actions. The estimate of imidacloprid in surface water is derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of imidacloprid in drinking water as a part of the acute, short-term and chronic aggregate risk assessment process.

3. *From non-dietary exposure.* Imidacloprid is currently registered for use on the following residential non-food sites: ornamentals (e.g., flowering and foliage plants, ground covers, turf, lawns, et al.), tobacco, golf courses, walkways, recreational areas, household or domestic dwellings (indoor/outdoor), and cats/dogs.

i. *Acute exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required because of the demonstrated absence of dermal and inhalation toxicity.

ii. *Chronic exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required because of the demonstrated absence of dermal and inhalation toxicity.

iii. *Short- and intermediate-term exposure and risk.* Oral exposure due to the registered residential uses of imidacloprid may result. Thus, a residential short-term risk assessment via the oral route is required. See Unit III(D)(4) of this preamble for a full discussion of this exposure and risk.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether imidacloprid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, imidacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food will utilize 12% of the Acute RfD for the most highly exposed population subgroup (U.S. population - all seasons). All other population subgroups which include adults have acute risk estimates (food only) below that of the population subgroup U.S. Population - all seasons. For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Acute RfD is needed to protect the safety of all population subgroups. The estimated exposures at the 99th percentile for all population subgroups that include adults utilize less than 33.3% of the Acute RfD.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Acute RfD for adults. Under current Agency

guidelines, the registered non-dietary uses of imidacloprid do not constitute an acute exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to adults from acute aggregate exposure to imidacloprid residues.

2. *Chronic risk.* Using the partially refined exposure assumptions described in Unit III(B)(1)(ii) of this preamble, and taking into account the completeness and reliability of the toxicity data, the Agency has estimated the chronic exposure to imidacloprid from food will utilize 6.2% of the chronic RfD for the most highly exposed adult population subgroup, non-hispanic (other than black or white). All other population subgroups which include adults have chronic (non-cancer) risk estimates (food only) below that of the population subgroup non-hispanic (other than black or white). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the chronic RfD is needed to protect the safety of all population subgroups. The estimated exposures for all adult population subgroups utilize less than 33.3% of the chronic RfD.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Chronic RfD. Under current Agency guidelines, the registered non-dietary uses of imidacloprid do not constitute a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to adults from chronic aggregate exposure to imidacloprid residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Dermal and inhalation short- and intermediate term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. Short- and intermediate-term oral exposure are not expected for adult population subgroups. A discussion of short and intermediate term oral exposure and risk for children 1–6 years old can be found in Unit III.D.4 of this preamble.

4. *Aggregate cancer risk for U.S. population.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, thus, a cancer risk assessment is not required.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a developmental toxicity study with Sprague-Dawley rats, groups of pregnant animals (25/group) received oral administration of imidacloprid (94.2%) at 0, 10, 30, or 100 mg/kg bwt/day during gestation days 6 through 16. Maternal toxicity was manifested as decreased body weight gain at all dose levels and reduced food consumption at 100 mg/kg bwt/day. No treatment-related effects were seen in any of the reproductive parameters (i.e., Cesarean section evaluation). At 100 mg/kg bwt/day, developmental toxicity manifested as wavy ribs (fetus =7/149 in treated vs. 2/158 in controls and litters, 4/25 vs. 1/25). For maternal toxicity, the LOEL was 10 mg/kg bwt/day (LDT) based on decreased body weight gain; a NOAEL was not established. For developmental toxicity, the NOAEL was 30 mg/kg bwt/day and the LOEL was 100 mg/kg bwt/day based on increased wavy ribs.

In a developmental toxicity study with Chinchilla rabbits, groups of 16 pregnant does were given oral doses of imidacloprid (94.2%) at 0, 8, 24 or 72 mg/kg bwt/day during gestation days 6 through 18. For maternal toxicity, the NOAEL was 24 mg/kg bwt/day and the LOEL was 72 mg/kg bwt/day based on mortality, decreased body weight gain, increased resorptions, and increased abortions. For developmental toxicity, the NOAEL was 24 mg/kg bwt/day and the LOEL was 72 mg/kg bwt/day based on decreased fetal body weight, increased resorptions, and increased skeletal abnormalities.

iii. *Reproductive toxicity study.* In a two-generation reproductive toxicity study, imidacloprid (95.3%) was administered to Wistar/Han rats at dietary levels of 0, 100, 250, or 700 ppm (0, 7.3, 18.3, or 52.0 mg/kg bwt/day for males and 0, 8.0, 20.5, or 57.4 mg/kg bwt/day for females). For parental/systemic/reproductive toxicity, the NOAEL was 250 ppm (18.3 mg/kg bwt/day) and the LOEL was 750 ppm (52 mg/kg bwt/day), based on decreases in body weight in both sexes in both generations. Based on these factors, the Agency determined that the review be revised to indicate the parental/systemic/reproductive NOAEL and LOEL to be 250 and 700 ppm, respectively, based upon the body weight decrements observed in both sexes in both generations.

iv. *Pre- and post-natal sensitivity.* The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study data did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs.

v. *Conclusion.* There is a need for a developmental neurotoxicity study for assessment of potential alterations of functional development. However, the Agency has determined that this data gap does not preclude the establishment/continuance of tolerances. The 10X safety factor to account for enhanced sensitivity of infants and children (as required by FQPA) was reduced to 3X and the factor applies to all population subgroups.

2. *Acute risk.* Using the conservative TMRC exposure assumptions described

in Unit III.B.1.i of this preamble, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food will utilize 23% of the Acute RfD for the most highly exposed population subgroup that includes children (Nursing infants, <1 year). All other population subgroups which include children have acute risk estimates (food only) below that of the population subgroup Nursing Infants (<1 year). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Acute RfD is needed to protect the safety of all population subgroups. The estimated exposures for all population subgroups at the 99th percentile utilize less than 33.3% of the Acute RfD.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Acute RfD. Under current EPA guidelines, the registered non-dietary uses of imidacloprid do not constitute an acute exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to children from acute aggregate exposure to imidacloprid residues.

3. *Chronic risk.* Using the partially refined exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the chronic exposure to imidacloprid from food will utilize 13% of the Chronic RfD for the most highly exposed population subgroup that includes children (Children, 1–6 years old). All other population subgroups which include children have chronic risk estimates (food only) below that of the population subgroup Children, 1–6 years old). For imidacloprid, it was determined that an acceptable acute dietary exposure (food plus water) of 33.3% or less of the Chronic RfD for all population subgroups is needed to protect the safety of all population subgroups. The estimated exposures for all population subgroups which include children utilize less than 33.3% of the Acute RfD. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the Chronic RfD. Under current EPA guidelines, the registered non-dietary uses of imidacloprid do not constitute a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to children from chronic aggregate exposure to imidacloprid residues.

4. *Short- or intermediate-term risk.* Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. However, a short term residential oral risk assessment is required. In addition to its food uses, imidacloprid is registered for use on turf, home gardens and pets. EPA has identified potential short-term oral exposures to children for these uses. These exposures include the following scenarios:

- Incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer.
- Ingestion of pesticide-treated turfgrass.
- Incidental ingestion of soil from treated gardens.
- Incidental ingestion of pesticide residues on pets from hand-to-mouth transfer.

According to current EPA policy, these exposures are considered to be short-term oral exposures. Incidental ingestion of pesticide residues on pets from hand-to mouth transfer may occur during the same period as the exposures from the turf and home garden uses. However, children's exposures from pet and turf uses are not expected to both occur at the high-end level. Therefore, these exposures were considered in separate estimates of risk.

A short-term oral endpoint was not identified for imidacloprid. According to current EPA policy, if an oral endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (Acute RfD = 0.42 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk. Short-term aggregate exposure is defined by EPA to be average food and water exposure (chronic exposure) plus residential exposure. The short-term risk estimates for the population subgroup Children, 1 to 6 years old, is summarized below in Tables 6 and 7. This population subgroup was chosen because it has the highest chronic food exposure and because toddlers have the highest exposure from the residential uses.

TABLE 6.—SHORT-TERM AGGREGATE EXPOSURE AND RISK (INCLUDES TURF AND GARDEN USES OF IMIDACLOPRID)

Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	Percent Acute RfD[3]
Children (1 to 6 years old)	0.0074	0.072	0.079	19%

[1] Residential Exposure = total of imidacloprid exposure from incidental ingestion of residues on lawns from hand-to-mouth transfer plus ingestion of pesticide-treated grass plus ingestion of soil from treated gardens.
[2] Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3] Percent Acute RfD = Total Exposure (mg/kg bwt/day) x 100% Acute RfD (0.42 mg/kg bwt/day)

TABLE 7.—SHORT-TERM AGGREGATE EXPOSURE AND RISK (INCLUDES THE PET USE OF IMIDACLOPRID)

Population Subgroup	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure[1] (mg/kg bwt/day)	Total Exposure[2] (mg/kg bwt/day)	Percent Acute RfD[3]
Children (1 to 6 years old)	0.0074	0.058	0.065	16%

[1] Residential Exposure = total of imidacloprid exposure from incidental ingestion of residues on pets from hand-to-mouth transfer.
[2] Total Exposure = Chronic Food Exposure plus Residential Exposure.
[3] Percent Acute RfD = Total Exposure (mg/kg bwt/day) x 100% Acute RfD (0.42 mg/kg bwt/day)

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant, cottonseed, field corn, ruminants and poultry have previously been submitted. The nature of imidacloprid residues in plants and animals is adequately understood. The residue of concern is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, as specified in 40 CFR 180.472.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

A study on field corn RAC's has been submitted. This study has not been reviewed in detail. Residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, are not expected to exceed 0.1 ppm in field corn forage, 0.2 ppm in field corn stover (fodder) and 0.05 ppm in field corn grain. Since this section 18 proposed use is a seed treatment, a tolerance for aspirated grain fractions is not required.

A study on field corn processing has been submitted. In this study, field corn grown from imidacloprid-treated (3.5-7 oz ai/A, 7X) seed were harvested at maturity and processed by wet and dry milling. All processed fractions contained residues of imidacloprid and its metabolites at levels less than the limit of quantification (<0.05ppm). Residues of imidacloprid and its metabolites did not concentrate into the field corn processed products. The Agency concludes tolerances for imidacloprid and its metabolites are not required for field corn processed commodities.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum Residue Limits (MRL) for imidacloprid on field corn. Thus, harmonization is not an issue for this section 18.

E. Rotational Crop Restrictions

Data concerning the metabolism of imidacloprid in rotational crops were previously submitted. In conjunction with this study, EPA has concluded that a rotation interval of 12 months is appropriate for all crops except those with imidacloprid tolerances which may be rotated at anytime. In conjunction with PP 6F4765, tolerances for inadvertent residues in/on the crop groups Cereal Grains, Forage, Fodder and Straw of Cereal Grains, Legume Vegetables and the Foliage of Legume Vegetables; and the crops sweet corn, soybeans and safflower have been proposed in conjunction with a 30-day plantback interval for these crops.

EPA has recently recommended in favor of the granting of these tolerances and the 30–day plant back interval. EPA concludes the following rotation restriction is adequate for this section 18: Any crops, except those having imidacloprid tolerances, sweet corn, soybeans and safflower and the crops of the crop groups Cereal Grains and Legume Vegetables, may be planted back one year following imidacloprid applications. The crops sweet corn, soybeans, and safflower, and the crops of the crop groups Cereal Grains and Legume Vegetables may be rotated 30–days after the last imidacloprid treatment. Other crops having imidacloprid tolerances/uses may be rotated at anytime.

V. Conclusion

Therefore, the tolerance is established for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in field corn forage at 0.1 ppm, field corn stover (fodder) at 0.2 ppm, and field corn grain at 0.05 ppm ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's

contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300758] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 16, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.472, the table to paragraph (b) by adding alphabetically entries for field corn forage, field corn stover (fodder), and field corn grain, to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.*
* * *

Commodity	Parts per million	Expiration/ Revocation Date
* * *	*	*
Field corn forage	0.1	5/1/00
Field corn stover (fodder)	0.2	5/1/00
Field corn grain	0.05	5/1/00
* * *	*	*

* * * * *

[FR Doc. 98–31686 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300700A; FRL–6040–4]

RIN 2070–AB78

Triasulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: EPA is issuing a technical amendment to a tolerance regulation for triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] that published in the **Federal Register** on August 18, 1998.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300700A], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300700A], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP300700A]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5697; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the August 18, 1998 issue of the **Federal Register** EPA issued a regulation establishing tolerances for residues of triasulfuron [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] in or on cattle, kidney; goat, kidney; grass, forage; grass, hay; horse, kidney; and sheep, kidney. Novartis Crop Protection, Inc., requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). At the time of the petition, (63FR 29401, May 29, 1998) Novartis Crop Protection, Inc., also requested that tolerances be established for residues of this herbicide in or on hog kidney. Inadvertently, hog kidney was left out of the August 18, 1998 final rule that amended 40 CFR 180.459. This document corrects the August 18, 1998 regulation by adding tolerances for residues in or on hog kidney.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with

the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300700A] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ADDRESSES at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order

13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 15, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, part 180 is amended as follows:

PART 180 — [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.459 is amended by adding alphabetically an entry for ''Hog, kidney'' to the table in paragraph (a) to read as follows:

§ 180.459 Triasulfuron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hog, kidney	0.5
* * * * *	

[FR Doc. 98–31685 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300745; FRL–6036–3]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebuconazole in or on hops. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on hops. This regulation establishes a maximum permissible level for residues of tebuconazole in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2,000.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300745], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300745], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300745]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara A. Madden, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, e-mail: madden.barbara@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide tebuconazole in or on hops at 4.0 part per million (ppm). This tolerance will expire and is revoked on December 31, 2,000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new

safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associatedwith the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for tebuconazole on hops and FFDCA Tolerances

The States of Idaho, Oregon, and Washington availed themselves of the authority to declare a crisis exemption to use tebuconazole for control of Powdery mildew (*Sphaerotheca macularis*) on hops. Powdery mildew is a serious hop disease in many hop growing areas in the world. The elimination of commercial hop production in New York during the early part of this century is largely blamed on this disease. Since this disease has not been observed in the Pacific Northwest until very recently, no effective fungicides are registered for use on hops to control it. Sulfur is the only pesticide available, but does not provide effective control. The pathogen is airborne and spreads quickly, primarily during the months of July and August, which are critical to hop production. EPA has authorized under FIFRA section 18 the use of tebuconazole on hops for control of Powdery mildew (*Sphaerotheca macularis*) in Idaho, Oregon, and Washington. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebuconazole in or on hops. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2,000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on hops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether tebuconazole meets EPA's registration requirements for use on hops or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebuconazole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho, Oregon, and Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebuconazole, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997)(FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action EPA has sufficient data to assess the hazards of tebuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebuconazole on hops at 4.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebuconazole are discussed below.

1. *Acute toxicity*. The acute reference dose (acute RfD) of 0.1 milligrams/kilogram/day (mg/kg/day) for tebuconazole was established based on a developmental toxicity study in mice with a No-Observed-Adverse-Effect-Level (NOAEL) of 10 mg/kg/day for developmental toxicity. At the Lowest-Observed-Adverse-Effect-Level (LOAEL) of 30 mg/kg/day, an increased incidence of runts (fetuses weighing less than 1.3 gram) were observed. An uncertainty

factor of 100 (10X for inter-species extrapolation and 10X for intra-species variability) was applied to the NOAEL of 10 mg/kg/day to calculate the acute RfD of 0.1 mg/kg/day. EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children (as required by FQPA) should be retained. This determination is based on the results of the developmental toxicity study in mice used to establish the acute RfD, other developmental toxicity studies in mice, rats and rabbits and the structural relationship of tebuconazole to several other triazole pesticides which also have been shown to induce developmental toxicity in rats and/or rabbits. For acute dietary exposure, EPA determined that the 10X safety factor is applicable to the subpopulations females (13+ years old), as well as infants and children because the effects seen were developmental and are presumed to occur following ''acute'' exposures. For subpopulations other than females (13+ years old), infants and children, a toxicological endpoint was not identified. Application of the 10X safety factor for enhanced susceptibility of infants and children to the acute RfD of 0.1 mg/kg/day results in an acceptable acute dietary exposure (food plus water) of 10% or less of the acute RfD.

2. *Short- and intermediate-term toxicity.* Toxicological endpoints for short- or intermediate-term dermal toxicity were not identified. Adverse systemic effects were not observed in dermal developmental toxicity studies in mice or rats at the limit dose of 1,000 mg/kg/day or in a 21–day dermal toxicity study in rabbits at the limit dose of 1,000 mg/kg/day. Therefore, risk assessments for short- or intermediate-term dermal exposure were not conducted.

A NOAEL of 0.0106 mg/liter/day (equivalent to 2.9 mg/kg/day) was identified as the toxicological endpoint for short- and intermediate-term (and chronic) inhalation toxicity based on a 21–day inhalation toxicity study in rats. At the LOAEL of 0.1558 mg/liter/day, piloerection and increased liver *O*-demethylase and *N*-demethylase activity were observed in both males and females. EPA determined that the 10X safety factor to account for enhanced susceptibility of infants and children (as required by FQPA) is not applicable for inhalation toxicity for the currently registered residential exposures to tebuconazole. A Margin of Exposure (MOE) of 100 or more for short- or intermediate-term non-dietary risk is acceptable for all subpopulations.

3. *Chronic toxicity.* EPA has established a chronic RfD for tebuconazole at 0.03 mg/kg/day. This RfD is based on a 1–year chronic feeding study in dogs in which the NOAEL was 100 ppm (2.96 mg/kg/day in males and 2.94 mg/kg/day in females) and the LOAEL was 150 ppm (4.39 mg/kg/day in males and 4.45 mg/kg/day in females), based on histopathological changes in the adrenal gland (hypertrophy of the zona fasciculata and fatty changes in the zona glomerulosa in both sexes and lipid hyperplasia in the cortex in males). An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. EPA determined that the 10X factor for enhanced susceptibility of infants and children (as required by FQPA) is not applicable for chronic dietary exposure. A chronic dietary exposure (food plus water) of 100% or less of the Chronic RfD is acceptable for all subpopulations.

4. *Carcinogenicity.* Tebuconazole is classified as a Group C (possible human) carcinogen. This decision was primarily based on results in a 91–week carcinogenicity study in mice in which the following effects were observed:

i. A statistically significant increase in the incidence of hepatocellular adenomas, carcinomas and combined adenomas/carcinomas in male mice at the highest dose tested (279 mg/kg/day).

ii. A statistically significant increase in the incidence of hepatocellular carcinomas and combined adenomas/carcinomas in female mice at the highest dose tested (366 mg/kg/day). In addition, tebuconazole is structurally related to several other triazole pesticides that produce similar liver tumors in mice. For the purpose of carcinogenic risk assessment, the RfD methodology is used to estimate human risk.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.474) for the residues of tebuconazole, in or on a variety of raw agricultural commodities. Tolerances have been established for milk and meat byproducts in connection with use of tebuconazole under a previous section 18. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebuconazole as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. An acute dietary endpoint of concern was identified for subpopulations females (13+ years old), as well as infants and children. For acute dietary exposure, EPA determined that the 10X safety factor for enhanced susceptibility of infants and children (as required by FQPA) is applicable to all of these subpopulations. Application of the 10X safety factor for enhanced susceptibility of infants and children to the acute RfD of 0.1 mg/kg/day results in an acceptable acute dietary exposure (food plus water) of 10% or less of the acute RfD.

An acute dietary (food only) probablistic risk analysis submitted in conjunction with another action was used to estimate acute dietary risk. The following assumptions were utilized in the Monte Carlo analysis: (a) Percent crop treated data were used for all commodities; (b) maximum residue levels from crop field trials for single serving commodities such as bananas and peaches were utilized; (c) average residue levels from crop field trials were used for blended commodities such as fruit juices, grains and oils; (d) anticipated residue levels for ruminant commodities were calculated using a livestock diet constructed using anticipated residue levels for livestock feed items. This analysis should be considered highly refined. This analysis was run with 2,000 iterations. The results of the Monte Carlo analysis indicate that the percent of acute RfD for all children and infants subgroups as well as females 13+ years old are all below 10% of the RfD: nursing infants (< 1 year old), 7%; non-nursing infants (< 1 year old), 7%; children (1 to 6 years old) 9%, children (7 to 12 years old) 3%; all infants (< 1 year old), 7%; females (13 years plus old), 3%.

ii. *Chronic exposure and risk.* The Agency conducted a chronic dietary exposure analysis and risk assessment. The analysis evaluated individual food consumption as reported by respondents in the USDA 1977–78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. In conducting the chronic dietary risk assessment, the Agency made very conservative assumptions (100% of hops, pistachios and wheat and all other commodities having tebuconazole tolerances will contain residues and those residues will be at tolerance level) which results in an overestimation of human dietary exposure. Thus, in making a safety determination for these tolerances, the Agency is taking into account this conservative exposure assessment.

The existing tebuconazole tolerances (published, pending, and including the necessary section 18 tolerance(s)) result

in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to percentages of the RfD below 100% for all subgroups (i.e., U.S. population, 11% and non-nursing infants (< 1 year old), the most highly exposed subgroup, 37%).

2. *From drinking water.* Based on present data in the Agency files, tebuconazole is persistent and relatively immobile. There are no established Maximum Contaminant Level or health advisory levels for residues of tebuconazole in drinking water. Monitoring data for residues of tebuconazole in surface and ground water are not available. Tebuconazole is not included in the Pesticides in Ground Water Database (USEPA, 1992), and it was not an analyte in the National Pesticide Survey (USEPA, 1990).

EPA estimated exposure for tebuconazole for both surface and ground water based on available modeling. Environmental concentrations for surface water were estimated using modeling from GENEEC (Generic Estimated Environmental Concentration). For surface water, the maximum concentrations were used for acute risk calculations, the annual means (1–10 years old) for chronic risk calculations. Current Agency policy allows that a factor of 3 be applied to GENEEC model values when determining whether or not a level of concern has been exceeded. If the GENEEC model value is ≧ 3 times the drinking water level of concern (DWLOC), the pesticide is considered to have passed the screen. Acute and chronic ground water concentrations were estimated using the SCI-GROW (Screening Concentration in Ground Water) model. For the purposes of the screening level assessment, the maximum and average annual concentrations in ground water are not believed to vary significantly. DWLOCs will be compared directly to values.

i. *Acute exposure and risk.* DWLOCs were calculated for acute exposures to tebuconazole in surface and ground water for females 13+ years old and children (1–6 years old). Relative to an acute toxicity endpoint, the acute dietary food exposure (from the probablistic analysis) was subtracted from the ratio of the acute NOAEL to the appropriate percentage acute RfD to obtain the acceptable acute exposure to tebuconazole in drinking water. DWLOCs were then calculated from this acceptable exposure using default body weights (60 kg for females and 10 kg for children) and drinking water consumption figures (2 liters for females and 1 liter for children). Based on these calculations EPA's DWLOC for acute dietary risk is 14 parts per billion (ppb) for children (1–6 years old) and 200 ppb for females 13+ years old.

Maximum concentrations of tebuconazole in surface and ground water are estimated to be 14 ppb and 0.3 ppb, respectively. The maximum estimated concentrations of tebuconazole in surface and ground water are less than EPA's levels of concern for acute exposure in drinking water for the females 13+ and children.

ii. *Chronic exposure and risk.* EPA has calculated DWLOCs for chronic exposures to tebuconazole in surface and ground water. To calculate the DWLOC for chronic exposures relative to a chronic toxicity endpoint, the chronic dietary food exposure was subtracted from the chronic RfD (0.03 mg/kg/day) to obtain the acceptable chronic exposure to tebuconazole in drinking water. DWLOCs were then calculated from this exposure using default body weights (70 kg for U.S. population, 60 kg for females and 10 kg for children) and drinking water consumption figures (2 liters U.S. population and females and 1 liter children). Based on these calculations EPA's DWLOCs for chronic risk are 950 ppb for the U.S. population, 780 ppb for females and 190 ppb for non-nursing infants (< 1 year old).

Estimated annual average concentrations of tebuconazole in surface water and ground water are 10 ppb and 0.3 ppb, respectively. The estimated annual average concentrations of tebuconazole in surface and ground water are less than EPA's levels of concern for chronic exposure in drinking water.

3. *From non-dietary exposure.* No short- or intermediate-term dermal toxicological endpoints were identified. Tebuconazole's registered residential uses are for the formulation of wood-based composite products, wood products for in-ground contact, plastics, exterior paints, glues and adhesives. Currently, the only residential end-use products on the market are for exterior treated wood use. Exposure via incidental ingestion (by children) and inhalation are not a concern for these products which are used outdoors. No paints or other end-use products containing tebuconazole are available for interior use. Accordingly, residential exposure is not expected at this time.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether tebuconazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebuconazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebuconazole has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* A toxicological endpoint was identified for acute dietary risk assessments for subpopulations females (13+ years old), infants and children. The 10X safety factor for enhanced susceptibility of infants and children as required by FQPA is applicable for all of these subgroups. Therefore, 10% or less of the acute RfD of 0.1 mg/kg/day results in an acceptable acute dietary exposure (food plus water).

An acute dietary (food only) probablistic risk analysis resulted in 3% of the acute RfD utilized for females (13+ years old). The maximum estimated concentrations of tebuconazole in surface and ground water are less than EPA's levels of concern for acute exposure in drinking water for the females 13+. Currently the only residential end-use products on the market are for exterior treated wood use. Exposure via incidental ingestion (by children) and inhalation are not a concern for these products which are used outdoors. No paints or other end-use products containing tebuconazole are available for interior use. Accordingly residential exposure is not expected with these uses. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate acute risk at the present time.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize 11% of the RfD for the U.S. population. The major identifiable

subgroup with the highest aggregate exposure from food is Non-Nursing Infants (< 1 year old), discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. As stated above, residential exposure to tebuconazole is not expected for the currently registered uses. Despite the potential for exposure to tebuconazole in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate chronic risk at the present time.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. No short- or intermediate-term dermal toxicological endpoints were identified. Also, no residential exposure is expected from the current residential uses. Thus, no risk assessments were conducted for residential exposure. Therefore, EPA concludes with reasonable certainty that tebuconazole does not contribute significantly to the aggregate short- and intermediate-term risk at the present time.

4. *Aggregate cancer risk for U.S. population*. Tebuconazole is classified as a Group C (possible human) carcinogen. Since, for the purpose of carcinogenic risk assessment the RfD methodology was used, the discussion for Chronic risk (11% of RfD utilized) in Unit III.D.2 above applies to cancer risk as well. Therefore, EPA concludes with reasonable certainty that tebuconazole does not contribute significantly to the aggregate cancer risk at the present time.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—* i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of tebuconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In two associated oral developmental toxicity studies in mice, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 20 mg/kg/day, based on decreased hematocrit and effects in the liver. The developmental toxicity NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day, based on increased numbers of runts (fetuses weighing less than 1.3 grams). In addition, at 100 mg/kg/day, frank malformations in the skull, brain and spinal column and a reduced rate of ossification in the cranium were observed. In a dermal developmental toxicity study in mice, no toxicologically significant maternal toxicity or developmental toxicity was observed at the limit dose of 1,000 mg/kg/day.

In an oral developmental toxicity study in rats, the maternal NOAEL was 30 mg/kg/day and the LOAEL was 60 mg/kg/day, based on increased liver weight. The developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 60 mg/kg/day, based on delayed ossification of several bones and increased numbers of fetuses with supernumerary ribs. In addition, at 120 mg/kg/day, increased resorptions, decreased fetal body weights and frank malformations in two fetuses (missing tail, agnatha, microtomia and anophthalmia) were observed. In a dermal developmental toxicity study in rats, no toxicologically significant maternal toxicity or developmental toxicity was observed at the limit dose of 1,000 mg/kg/day.

In an oral developmental toxicity study in rabbits, the maternal NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on decreased body weight gain and decreased food consumption during the dosing period. The de velopmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on increased postimplantation loss, increased frank malformations, hydrocephalus and delayed ossification of bones. In another oral developmental toxicity study in rabbits, the maternal NOAEL was < 10 mg/kg/day and the LOAEL was 10 mg/kg/day, based on increased incidences of single cell necrosis (minimal severity) in liver cells. The maternal NOAEL from this study was not used to determine the acute RfD because single cell necrosis was not considered to result from a single exposure. The developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on increased postimplantation loss, decreased fetal body weights, increased percentage of fetuses with abnormalities (including runts, hemidiaphragm, limb abnormalities and neural tube defects characterized as meningocoele and spina bifida) and delayed ossification of bones.

iii. *Reproductive toxicity study.* In a 2–generation reproduction study in rats, the parental (systemic) toxicity NOAEL was 15 mg/kg/day and the LOAEL was 50 mg/kg/day, based on loss of hair, decreased body weights, decreased food consumption, increased severity of spleen hemosiderosis and decreased liver and kidney weights. For offspring toxicity, the NOAEL was 15 mg/kg/day and the LOAEL was 50 mg/kg/day, based on decreased pup body weights from birth through weeks 3–4 in all litter groups.

iv. *Pre- and post-natal sensitivity.* The above studies meet the standard toxicology data requirements, as required for a food-use chemical, in 40 CFR part 158. However, after evaluation of the findings in these studies, particularly with respect to effects on the fetal nervous system, together with a consideration of neurotoxic effects observed in several other developmental toxicity studies on structurally related triazole pesticides, the Agency requested a postnatal developmental neurotoxicity study in rats (Guideline 83–6) be conducted. The EPA notes effects on the nervous system of fetuses in studies on tebuconazole occurred only at doses of 100 mg/kg/day or

higher--i.e. at doses at least tenfold higher than the developmental toxicity NOAEL (10 mg/kg/day) to be used for the assessment of acute dietary risk.

On the basis of comparative NOAELs and LOAELs, it was determined there was no indication of increased susceptibility of the offspring of mice, rats or rabbits resulting from prenatal and/or postnatal exposure to tebuconazole. However, the maternal effects observed in the developmental toxicity studies at the LOAEL were of minimal concern and did not increase substantially in severity at higher doses, whereas the developmental effects at the LOAEL were pronounced and at higher doses were quite severe (including frank malformations) in mice (at 100 mg/kg/day), rats (at 120 mg/kg/day) and rabbits (at 100 mg/kg/day). Based on a consideration of all the above findings, the Agency retained the 10X factor for enhanced susceptibility to infants and children. The 10X factor is applicable to acute dietary exposures for the subpopulations females (13+ years old), infants and children. The 10x factor for enhanced sensitivity of infants and children is not applicable to chronic exposure analysis.

v. *Conclusion*. There is a complete toxicity data base for tebuconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. An acute dietary (food only) probablistic risk analysis resulted in the following percentages for the acute RfD: nursing infants (< 1 year old), 7%; non-nursing infants (< 1 year old), 7%; children (1 to 6 years old) 9%, children (7 to 12 years old) 3%; and all infants (< 1 year old), 7%. The maximum estimated concentrations of tebuconazole in surface and ground water are less than EPA's levels of concern for acute exposure in drinking water for children. Currently the only residential end-use products on the market are for exterior treated wood use. Exposure via incidental ingestion (by children) and inhalation are not a concern for these products which are used outdoors. No paints or other end-use products containing tebuconazole are available for interior use. Accordingly residential exposure is not expected with these uses. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate acute risk at the present.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize up to 37% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. As stated above, residential exposure to tebuconazole is not expected for the currently registered uses. Despite the potential for exposure to tebuconazole in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate chronic risk at the present time.

4. *Short- or intermediate-term risk*. As stated above, residential exposure to tebuconazole is not expected for the currently registered uses.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebuconazole residues.

IV. Other Considerations

A. Metabolism In Plants

The metabolism of tebuconazole in or on grapes, wheat, and peanuts have been reviewed. The nature of the residue in wheat is adequately understood. For the purposes of this section 18, the nature of the residue in hops is considered to be adequately understood (by translation from grapes, wheat and peanuts). The residue of concern in plants is tebuconazole *per se*.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method entitled ''Gas Chromatographic Method [GLC/TSD] for Determination of Residues of Tebuconazole in Crops, Processed Products, Soil and Water'' (PP #9F3724) is adequate to enforce time-limited tolerances for residues of tebuconazole in or on hops. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

Residues of tebuconazole *per se* are not expected to exceed 4.0 ppm in or on dried hops cones as a result of this section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for residues of tebuconazole in or on dried hops cones. International harmonization is thus not an issue for this time-limited tolerance.

E. Rotational Crop Restrictions

A plantback interval of 120 days after last application for crops not listed on the label is required. However, rotation restrictions are not applicable to hops as these crops are not normally rotated.

V. Conclusion

Therefore, the tolerance is established for residues of tebuconazole in hops at 4.0 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the

contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300745] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a

report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 6, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.474, in the table to paragraph (b)(1) by adding an entry for ''Hops'' to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Hops	4.0	12/31/00

* * * * *

[FR Doc. 98–31684 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300755; FRL–6041–3]
RIN 2070–AB78

Primisulfuron-Methyl; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the herbicide primisulfuron-methyl and its metabolites in or on bluegrass hay at 0.1 part per million (ppm) for an additional 18–month period, to April 30, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on bluegrass grown for seed. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA, on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300755], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300755], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300755]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 267, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–9356; e-mail: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of December 17, 1997 (62 FR 66014) (FRL–5753–6), which announced that on its own initiative and under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of primisulfuron-methyl and its metabolites in or on bluegrass hay at 0.1 ppm, with an expiration date of October 31, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food or feed that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or a period for public comment.

EPA received a request to extend the use of primisulfuron-methyl on bluegrass grown for seed for this year's growing season due to the situation remaining an emergency. Several factors, including increased no-till practices for soil conservation, reduced open burning, and climatic conditions, have contributed to the proliferation of grassy weeds to unacceptable levels in Kentucky bluegrass fields in Idaho and Washington. Presence of these grassy weed seeds in the end product makes the grass seed unmarketable in many areas, and without control of these weeds, growers were expected to suffer significant economic losses. After having reviewed the submission, EPA concurs that emergency conditions exist for these states. EPA has authorized under FIFRA section 18 the use of primisulfuron-methyl on bluegrass grown for seed for control of grassy weeds in bluegrass grown for seed.

EPA assessed the potential risks presented by residues of primisulfuron-methyl in or on bluegrass hay. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be

consistent with the new safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of December 17, 1997. Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section FFDCA 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 18–month period. Although this tolerance will expire and is revoked on April 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on bluegrass hay after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP Docket for this rule. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300755] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule extends a time-limited tolerance that was previously established by EPA under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since this extension of an existing time-limited tolerance that was established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels, or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not

issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 30, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

§ 180.452 [Amended]

2. In § 180.452, paragraph (b), in the table, amend the entry ''Bluegrass hay'' by removing the expiration date ''10/31/98'' and adding in its place ''4/30/00''.

[FR Doc. 98–31681 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300743A; FRL–6043–6]
RIN 2070-AB78

Imidacloprid; Extension of Tolerance for Emergency Exemptions; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule correction.

SUMMARY: EPA published in the **Federal Register** of October 7, 1998, extension of time-limited tolerances for the residues of imidacloprid and its metabolites in or on certain commodities. The amendatory language was incorrect, and this document corrects that language.

DATES: This regulation became effective October 7, 1998.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–9367; e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA published in the **Federal Register** of October 7, 1998, on page 53826 (FRL–6037–2), in FR Doc. 98–26903, extension of time-limited tolerances for the residues of imidacloprid and its metabolites in or on the citrus fruits crop group at 1.0 part per million (ppm), dried citrus pulp at 5.0 ppm, beet roots at 0.3 ppm, turnip roots at 0.3 ppm, and turnip tops 3.5 ppm, with an expiration date of November 29, 1998 for beets and turnips, and December 31, 1998 for citrus, extended to June 30, 2000. The amendatory language was incorrect, and this document corrects that language.

I. Regulatory Assessment Requirements

This final rule does not impose any new requirements. It only implements a technical correction to a previously issued **Federal Register** notice. Any assessments necessary for the original final rule being corrected through this action are discussed in that final rule and are not affected by today's action. In fact, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). For the same reason, it does not require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments*, (63 FR 27655, May 19, 1998), or Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority*

Populations and Low-Income Populations (59 FR 7629, February 16, 1994). In addition, since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

II. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This is a technical correction to the **Federal Register** and is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 4, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[CORRECTED]

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

Authority: 21 U.S.C. 346a and 371.

§ 180.472 [Amended]

In § 180.472, in the issue of October 7, 1998, on page 53829, in FR Doc. 98–26903, the amendatory language item number 2, for § 180.472, is corrected to read as follows:

2. In § 180.472, in the table to paragraph (a), in the third column, for the commodities ''beet roots,'' ''beet tops,'' ''turnip roots,'' and ''turnip tops'' the date ''11/29/98'' is revised to read ''6/30/00'', and in the table to paragraph (b), in the third column, for the commodities ''citrus fruits crop group'' and ''dried citrus pulp'' the date ''12/31/98'' is revised to read ''6/30/00''.

[FR Doc. 98–31965 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300747; FRL–6038–5]

RIN 2070–AB78

Cymoxanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of cymoxanil (2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide) in or on dried hops. This action is in connection with a crisis exemption declared under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on dried hops. This regulation establishes a maximum permissible level for residues of cymoxanil in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on April 15, 2000.

DATES: This regulation is effective December 2, 1998. Objections and requests for hearings must be received by EPA on or before February 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300747], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300747], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300747]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9364, e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide cymoxanil (2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide), in or on dried hops at 1 part per million (ppm). This tolerance will expire and is revoked on April 15, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (November 13, 1996, 61 FR 58135)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a

tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Cymoxanil on Hops and FFDCA Tolerances

On July 16, 1998, the Idaho Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of cymoxanil on hops for control of downy mildew.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cymoxanil in or on dried hops. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on April 15, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dried hops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether cymoxanil meets EPA's registration requirements for use on hops or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of cymoxanil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cymoxanil, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (November 26, 1997, 62 FR 62961)(FRL–5754–7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action EPA has sufficient data to assess the hazards of cymoxanil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide on dried hops at 1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cymoxanil are discussed below.

1. *Acute toxicity*. For females 13+, the developmental no observed adverse effect level (NOAEL) = 4 mg/kg/day based on an increase in skeletal malformations of the cervical and thoracic vertebrae and ribs at 8 milligrams/kilogram/day (mg/kg/day). EPA has determined that the 10x factor to account for enhanced sensitivity of infants and children should be reduced to 3x. For acute dietary risk assessment, a margin of exposure (MOE) of 300 is required for protection of females 13+ from acute dietary exposure to cymoxanil. A dose and endpoint were not selected for the general U.S. population and infants and children because there were no effects observed in oral toxicological studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that could be attributable to a single exposure (dose).

2. *Chronic toxicity*. EPA has established the Reference dose (RfD) for cymoxanil at 0.013 mg/kg/day. This RfD is based on a NOAEL of 4.08 mg/kg/day and an uncertainty factor of 300. NOAEL established from a combined chronic toxicity/carcinogenicity study in rats, based on decreases in body weight and body weight gain, reduced food efficiency and histopathological lesions in the eyes and testes of males at 30.3 mg/kg/day lowest observed effect level (LOEL). EPA has determined that the 10x factor to account for enhanced sensitivity of infants and children should be reduced to 3x.

3. *Carcinogenicity*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to asses the carcinogenic potential, cymoxanil was classified as a ''not likely'' human carcinogen.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.503) for the residues of 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide, in or on potatoes. In addition, a time-limited tolerance in or tomatoes has also been established. Risk assessments were conducted by EPA to assess dietary exposures and risks from cymoxanil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute exposure analysis for female (13+) subgroup was performed using tolerance level residues and 100 percent crop treated and resulted in an acceptable MOE of 300.

ii. *Chronic exposure and risk.* EPA has concluded that the percent of the RfD that will be utilized by chronic dietary exposure to residues of cymoxanil is less than 5% for all population subgroups. EPA does not consider the chronic dietary risk to exceed the level of concern.

2. *From drinking water.* EPA has calculated drinking water levels of concern for acute exposure to cymoxanil in drinking water for females (13+ years old) to be 280 parts per billion (ppb). For chronic (non-cancer), the drinking water levels of concern are 440 and 120 ppb for U.S. population, children (1-6 years old), respectively. EPA has determined that cymoxanil and its degradates should not pose a threat to ground water. The estimated maximum concentration of cymoxanil in surface water is 4.13 ppb.

i. *Acute exposure and risk.* The maximum estimated concentrations of cymoxanil in surface water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to acute aggregate exposure. Taking into account the present uses and this proposed use, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water would not result in unacceptable levels of aggregate human health risk at this time.

ii. *Chronic exposure and risk.* The maximum estimated concentrations of cymoxanil in surface water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to chronic aggregate exposure. Taking into account the present uses and this proposed use, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure.* Cymoxanil is not currently registered for use on residential non-food sites.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether cymoxanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cymoxanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cymoxanil has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (November 26, 1997, 62 FR 62961).

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* From the acute dietary (food only) risk assessment, a high-end exposure estimate was calculated for the subgroup, females 13+ years. The maximum estimated concentrations of cymoxanil in surface and ground water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of cymoxanil in drinking water do not contribute significantly to the aggregate acute human health risk at the present time.

2. *Chronic risk.* Using the Dietary Exposure Evaluation Model, EPA has concluded that aggregate exposure to cymoxanil from food will utilize 2% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years old) ''discussed below.'' EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The estimated average concentrations of cymoxanil in surface and ground water are less than EPA's levels of concern for cymoxanil in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

3. *Aggregate cancer risk for U.S. population.* A cancer risk assessment is not needed since cymoxanil was classified as a ''not likely'' human carcinogen.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cymoxanil residues.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of cymoxanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. This is the case. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual

toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

EPA determined that for cymoxanil, the 10x factor for the enhanced sensitivity of infants and children will be reduced to 3x for the following reasons:

a. There was no sensitivity to perinatal animals following pre- and/or postnatal exposure with cymoxanil. In one prenatal developmental toxicity study in rabbits, where sensitivity was suggested by observations of developmental toxicity at a dose which was not maternally toxic, the lower developmental NOEL was attributed to inadequacies in study design and conduct.

b. There were no data gaps for the assessment of potential effects on offspring following in utero and/or postnatal exposure to cymoxanil via the standard screening studies required by 40 CFR Part 158. However, following a weight-of-the-evidence review of the database, which suggested that neuropathological lesions could result from long-term exposure to cymoxanil, a developmental neurotoxicity study in rats was recommended.

ii. *Developmental toxicity studies.* The NOAEL was 4 mg/kg/day and the LOEL was 8 mg/kg/day based on an increase in skeletal malformations of the cervical and thoracic vertebrae and ribs; at 32 mg/kg/day, cleft palate was also observed.

iii. *Reproductive toxicity study.* For parental systemic toxicity, the NOAEL was 100 ppm (6.5 mg/kg/day for males, 7.9 mg/kg/day for females) and LOEL was 500 ppm based on reduced premating body weight, body weight gain, and food consumption for P males; and decreased gestation and lactation body weight for F1 females. For offspring systemic toxicity, the NOAEL was 100 ppm (6.5 mg/kg/day for males, 7.9 mg/kg/day for females) and the LOEL was 500 ppm (32.1 mg/kg/day for males, 40.6 mg/kg/day for females) based on decreased F1 pup viability on postnatal days 0-4 and on a significant reduction in F2b pup weight.

iv. *Pre- and post-natal sensitivity.* The developmental toxicity and multigeneration reproduction study data demonstrated no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to cymoxanil. Overall, in the developmental toxicity studies in rats and rabbits, and in the 2-generation reproductive toxicity study with cymoxanil in rats, offspring toxicity was observed only at treatment levels which were toxic to parental adults.

v. *Conclusion.* There were no data gaps for the assessment of potential effects on offspring following in utero and/or postnatal exposure to cymoxanil via the standard screening studies required by 40 CFR Part 158. However, following a weight-of-the-evidence review of the database, which suggested that neuropathological lesions could result from long-term exposure to cymoxanil, a developmental neurotoxicity study in rats is required. There is a complete toxicity database for cymoxanil and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* The large acute dietary MOEs calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

3. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cymoxanil from food will range from 1% for nursing infants less than one year old, up to 5% for children (1-6 years old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to cymoxanil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cymoxanil residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in tomatoes and potatoes is adequately understood. For purposes of this action, EPA was willing to translate these data to hops. The residues of concern in hops are cymoxanil per se, as specified in 40 CFR 180.503.

B. Analytical Enforcement Methodology

An adequate enforcement method (DuPont Method AMR 2358-92, unpublished) is available to enforce the proposed tolerance on hops. Quantitation is by GLC using a nitrogen/phosphorus detector.

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

Residues of cymoxanil are not expected to exceed 1.0 ppm in/on hops, dried. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

D. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for cymoxanil on hops. Therefore, no compatibility problems exist for the proposed tolerance on hops.

E. Rotational Crop Restrictions

Residues in rotational crops are not expected as hops fields are not rotated.

V. Conclusion

Therefore, the tolerance is established for residues of 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide in dried hops at 1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 1, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be

accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket controlnumber [OPP–300747] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use ofspecial characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in **ADDRESSES** at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on

matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 15, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.503 is amended, by alphabetically adding to the table in paragraph (b), the commodity to read as follows:

§ 180.503 Cymoxanil; tolerance for residues.

(a) * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Hops, dried	1	4/15/00

[FR Doc. 98–32003 Filed 12–1–98; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 970129015–8287–08; I.D. 042597B]

RIN 0648–AI84

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Harbor Porpoise Take Reduction Plan Regulations

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

ACTION: Final rule; notice of availability of take reduction plan.

SUMMARY: Pursuant to the Marine Mammal Protection Act (MMPA), NMFS issues a final rule to implement a harbor porpoise take reduction plan (HPTRP) in the Gulf of Maine and Mid-Atlantic waters. The HPTRP is contained in the HPTRP/ Environmental Assessment/ Final Regulatory Flexibility Analysis (HPTRP/EA/FRFA), available upon request (see addresses below). In the Gulf of Maine, these final regulations put into place a series of time and area closures where pingers are required: in the Mid-Coast Closure Area (September 15 through May 31), the Massachusetts Bay and Cape Cod South Closure Areas (December 1 through February 28/29 and April 1 through May 31) and establish a new closure area, the Offshore Closure Area, where pingers are required November 1 through May 31. A complete closure has been added in the Cashes Ledge Closure Area, February 1–28/29. These regulations require any fishermen using pingers in the closed areas where pingers are allowed, to receive training and be certified in pinger use. A certificate must be carried onboard the vessel. In the Mid-Atlantic, this plan closes New Jersey waters from January 1 through April 30 to large and small mesh gear unless gear meets the specified gear modifications. This plan closes southern Mid-Atlantic waters from February 1 through April 30 to large and small mesh gear unless gear meets the specified gear modifications. This plan closes New Jersey waters from April 1–April 20 and southern Mid-Atlantic waters from February 15–March 15 for large mesh gear. The region known as the New Jersey Mudhole is closed to small and large mesh gear from February 15–March 15. All small and large mesh gear in the Mid-Atlantic must be tagged by January 1, 2000.

DATES: Effective January 1, 1999, except for § 229.33 (a)(2) which becomes effective December 2, 1998, § 229.33(a)(5) which becomes effective December 8, 1998, and § 229.33(a)(3) and (a)(4) which become effective December 16, 1998.

ADDRESSES: Copies of the draft plan prepared by the Gulf of Maine Take Reduction Team (GOMTRT), the final report from the Mid-Atlantic Take Reduction Team (MATRT) and the HPTRP/EA/FRFA may be obtained from Donna Wieting, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226.

FOR FURTHER INFORMATION CONTACT: Donna Wieting, NMFS, 301–713–2322, or Laurie Allen, NMFS, Northeast Region, 978–281–9291.

SUPPLEMENTARY INFORMATION: This final rule implements a take reduction plan (TRP) for the Gulf of Maine (GOM) stock of harbor porpoise, a strategic marine mammal stock that interacts with the Northeast (NE) multispecies gillnet fishery and with the Mid-Atlantic coastal gillnet fishery. A strategic stock is a stock: (1) for which the level of direct human-caused mortality exceeds the potential biological removal (PBR) level (the maximum number of animals, not including natural mortalities, that may be annually removed from a marine mammal stock without compromising the ability of that stock to reach or maintain its optimum population level); (2) that is declining and is likely to be listed under the Endangered Species Act (ESA) in the foreseeable future; or (3) that is listed as a threatened or endangered species under the ESA. NMFS proposed listing the GOM harbor porpoise as threatened under the ESA (58 FR 3108, January 7, 1993), but no final action has been taken on that proposal.

The NE multispecies sink gillnet fishery is a Category I fishery, and the Mid-Atlantic coastal gillnet fishery is a Category II fishery, as classified under Section 118 of the MMPA. A Category I fishery is a fishery that has frequent incidental mortality and serious injury

of marine mammals. A Category II fishery is a fishery that has occasional serious injuries and mortalities of marine mammals.

Section 118 of the MMPA requires NMFS to develop and implement a TRP to assist in the recovery or to prevent the depletion of each strategic stock that interacts with a Category I or II fishery. The immediate goal of a TRP is to reduce, within 6 months of its implementation, the level of mortality and serious injury of strategic stocks incidentally taken in the course of commercial fishing operations to less than the PBR levels established for such stocks. The long-term goal of a TRP is to reduce the level of mortality and serious injury of strategic stocks incidentally taken in the course of commercial fishing operations to a level approaching a zero mortality rate (ZMRG).

Stock Assessment and Incidental Takes by Fishery

The PBR level for GOM harbor porpoise throughout their range is 483 animals (62 FR 3005, January 21, 1997). The estimated total annual average mortality from the NE and Mid-Atlantic gillnet fisheries is 2,040. This estimate is based on a 5-year (1990–1995) average mortality estimate of 1,833 (Waring *et al.*, 1997) for the GOM and based on preliminary analysis of 1995 and 1996 data from the Mid-Atlantic of 207 animals (Palka, unpublished data).

Take Reduction Teams (TRTs)

NMFS convened the GOMTRT in February 1996. The goal of the GOMTRT was to develop a consensus draft TRP to reduce the incidental take of harbor porpoise in sink gillnets in the GOM to the PBR level for that stock within 6 months of the TRP's implementation. The GOMTRT focused only on bycatch off New England's coast (Maine to Rhode Island). The GOMTRT was convened with the understanding that a separate take reduction team (TRT) would address harbor porpoise bycatch in the Mid-Atlantic.

While the individual Teams did not specifically address whether measures are necessary to reach the ZMRG at this time, the TRT process will address the ZMRG after the initial measures have been monitored. NMFS and the TRT can then determine whether further reductions, if any, may be necessary to reach the long-term goal.

The GOMTRT included representatives of the NE multispecies sink gillnet fishery, NMFS, state marine resource managers, the New England Fishery Management Council (NEFMC), environmental organizations, and academic and scientific organizations. The GOMTRT met five times between February and July 1996 and submitted a consensus draft TRP (draft GOMTRP) to NMFS in August 1996.

Soon after NMFS received the draft GOMTRP, the NEFMC enacted Framework Adjustment 19 (61 FR 55774, October 29, 1996) to the NE Multispecies Fishery Management Plan (FMP). Based on this action, NMFS modified the draft GOMTRP to be consistent with Framework Adjustment 19. NMFS published an initial proposed rule to implement a TRP for harbor porpoise in the GOM (62 FR 43302, August 13, 1997). The proposed rule to implement the GOMTRP was available for a 60-day public comment period.

NMFS reconvened the GOMTRT in December 1997 to evaluate new bycatch data that suggested that the GOMTRP would not achieve PBR for harbor porpoise in the GOM. NMFS reopened the public comment period on the GOMTRP proposed rule for one month during the deliberations of the GOMTRT.

At the December 1997 meeting, the GOMTRT agreed on a number of additional measures for bycatch reduction that were presented to NMFS in the form of a report on January 14, 1998 (RESOLVE, 1998). In their recommendations, the GOMTRT took into account the significant changes in groundfish conservation measures proposed under Framework 25 of the NE Multispecies FMP which partially overlapped existing marine mammal closures (Framework 25 was under consideration by the NEFMC during the GOMTRT meeting in December 1997 and was not implemented until May, 1998). Framework 25 allowed continued use of pingers in the Mid-coast area from March 25 through April 25 and closed the Jeffreys Ledge portion of the Mid-Coast area year-round.

The GOMTRT recommended the following measures to achieve PBR: (1) maintain the existing Northeast Closure from August 15 through September 13; (2) close Cape Cod South from March 1 through March 31; (3) close Massachusetts Bay from March 1 through March 31; (4) close the Mid-Coast area from March 24 through April 26; (5) require pingers from September 15 through March 24 and April 26 through May 31 in the Mid-Coast area; (6) require pingers from September through May in the Cape Cod South area; (7) require pingers the months of February and April in the Massachusetts Bay area; and (8) require pingers September 1 through May 31 in the Offshore area.

In February 1997, NMFS convened the MATRT to address the incidental bycatch of harbor porpoise in Mid-Atlantic gillnet fisheries (from New York through North Carolina). The MATRT included representatives of the Mid-Atlantic coastal gillnet fisheries, NMFS, state marine resource managers, the Mid-Atlantic Fishery Management Council (MAFMC), the NEFMC, the Atlantic States Marine Fisheries Commission (ASMFC), environmental organizations, and academic and scientific organizations. The MATRT submitted a report to NMFS on August 25, 1997, which included both consensus and non-consensus recommendations.

The MATRT recommended management measures specific to the two predominant coastal gillnet fisheries, i.e., the monkfish and dogfish fisheries. It recommended that the timeframe for effectiveness be from January through April off New Jersey and from February through April off the southern Mid-Atlantic (Delaware, Maryland, Virginia and North Carolina). The management measures that the team suggested focused on those gear characteristics that demonstrated the most potential for bycatch reduction. For the monkfish fishery, these measures included reduced floatline length, larger twine size, tie downs, and a limit of 80 nets. For the dogfish fishery, the measures included reduced floatline length, larger twine size, and a 45-net limit. Additionally, the MATRT recommended time/area closures for the monkfish fishery in New Jersey waters (February 15–March 15) and in the southern Mid-Atlantic (20 day block between February and April, chosen by the fishermen) but no time/area closures for the dogfish fishery.

Both the GOMTRT and the MATRT recommended certain non-regulatory measures. The non-regulatory aspects of the HPTRP are discussed in the HPTRP/EA/FRFA. The following summarizes NMFS efforts to address the concerns raised by the GOMTRT and MATRT:

(1) As part of the HPTRP, NMFS is developing a research plan to assess long-term ecosystem impacts from widespread use of pingers.

(2) As part of a monitoring strategy for the HPTRP, NMFS is working with the ASMFC on the Atlantic Coastal Cooperative Statistics Program to provide managers with more timely bycatch and fisheries information on the Atlantic Coast.

(3) NMFS is investigating options for providing support to fishermen for pinger technology.

(4) NMFS began pinger training and certification for all fishermen who wish

to use pingers in the closed areas in September 1998.

(5) NMFS has expanded its capabilities to do analytical research by hiring additional staff for its Northeast Fisheries Science Center (NEFSC). Additional resources will be considered during normal funding and staffing allocation discussions in light of other agency responsibilities.

(6) NMFS has expanded its capabilities to observe the Mid-Atlantic fisheries by exploring alternative platforms to obtain a better characterization of coastal fisheries that were not accessible to the traditional Sea Sampling Observer Program.

(7) The HPTRP provides for voluntary skipper education workshops in the Mid-Atlantic.

(8) Although NMFS has expanded its capabilities with respect to observing the Mid-Atlantic fisheries, NMFS will continue to increase observer coverage at levels consistent with a valid sampling scheme because of limited resources. Additionally, NMFS is expanding observation from alternative platforms and is increasing responsiveness to observed strandings.

To provide the necessary coordination between the Teams and consistency across the regions, NMFS, at the recommendation of the GOMTRT, included several members of the GOMTRT on the MATRT. NMFS will strive to ensure that data on bycatch and effort in both areas will be shared with both teams. A specific discussion of these recommendations and NMFS'' response are contained in the HPTRP/EA/FRFA.

Proposed Rule/HPTRP

NMFS combined the GOMTRP and MATRT report into one proposed HPTRP and proposed rule which was published on September 11, 1998 (63 FR 48670). The proposed HPTRP was based in large part on recommendations by the GOMTRT and the MATRT and was divided into a GOM component and a Mid-Atlantic component. NMFS is considering whether or not the two Teams should continue to meet separately or whether some or all of the meetings should be combined.

Final Rule/HPTRP

Gulf of Maine Component

Table 1 sets forth the HPTRP management measures for the Gulf of Maine in the final rule (see Figure 1).

TABLE 1.—GULF OF MAINE TIME/AREA CLOSURES TO GILLNET FISHING AND PERIODS DURING WHICH PINGER USE ARE REQUIRED UNDER THE FINAL RULE/HPTRP

Northeast Area:	
August 15–September 13	Closed.
Mid-Coast Area:	
September 15–May 31	Closed, gillnet with pingers allowed.
Massachusetts Bay Area:	
December 1–February 28/29	Closed, gillnet with pingers allowed.
March 1–31	Closed.
April 1–May 31	Closed, gillnet with pingers allowed.
Cape Cod South Area:	
December 1—February 28/29	Closed, gillnet with pingers allowed.
March 1–31	Closed.
April 1–May 31	Closed, gillnet with pingers allowed.
Offshore Area:	
November 1–May 31	Closed, gillnet with pingers allowed.
Cashes Ledge Area:	
February 1–28/29	Closed.

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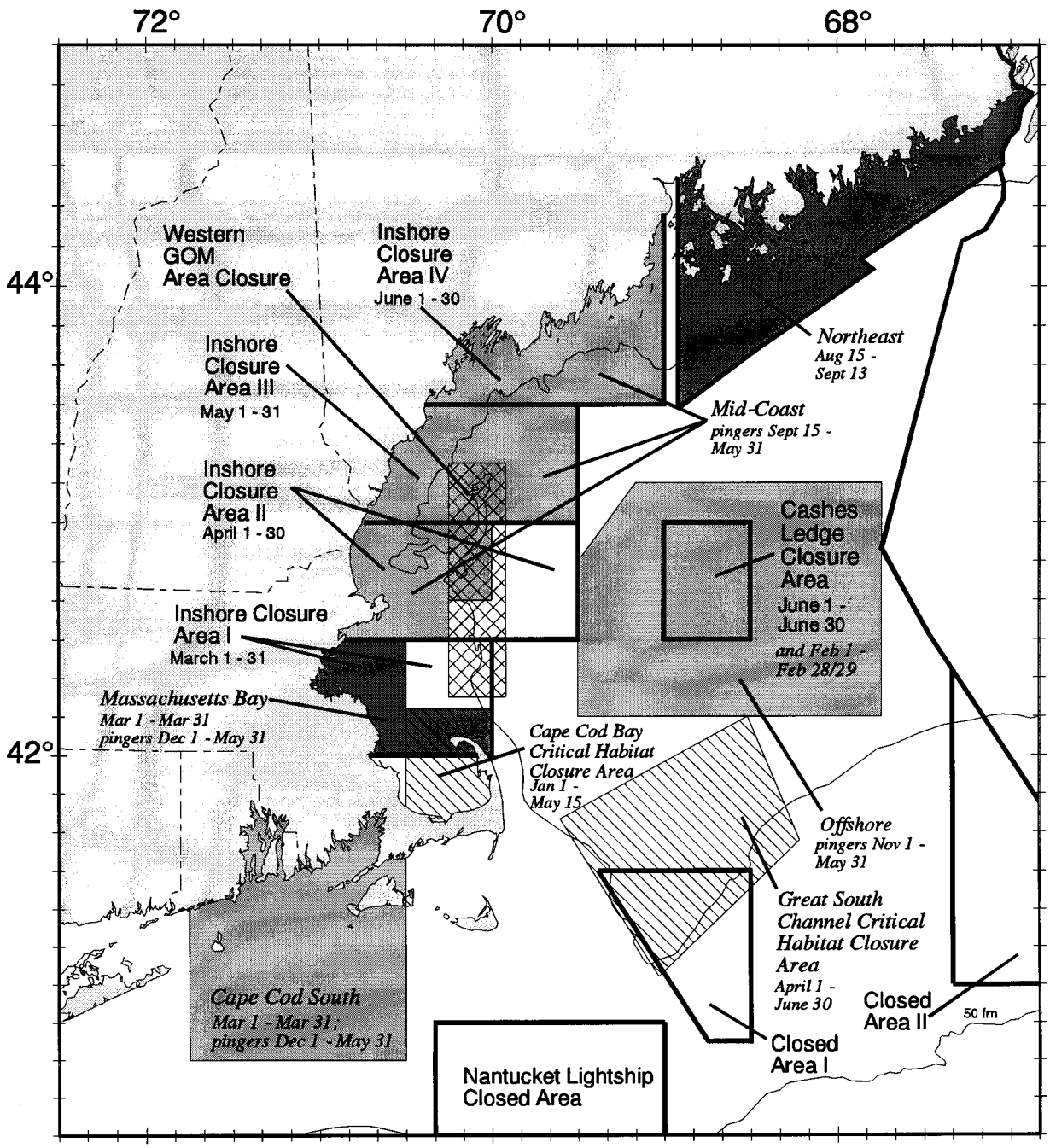

Figure 1. Chart of closures under the Gulf of Maine component of the Harbor Porpoise Take Reduction Plan and closures under the Northeast Multispecies Fishery Management Plan (FMP). Areas on the chart delineated by bold, linear outline with labels in regular type correspond to NE Multispecies FMP; labels in italic type identify shaded areas of harbor porpoise measures.

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The HPTRP regulations maintain the comprehensive approach of the proposed rule.

The proposed HPTRP would have closed the Northeast Area to sink gillnet fishing from August 15 through September 13 of each year. The final rule makes no changes to this measure.

The proposed HPTRP did not include a complete closure in the Mid-Coast Area but required pingers from September 15 through May 31. The final rule represents no changes from the proposed rule.

The proposed HPTRP provided that Massachusetts Bay remain closed in March, the time of year during which most known takes in the region were recorded, and proposed that pingers be required during February, April, and May to reduce the take of harbor porpoise in other spring months. Based on public comments and to address data which showed observed takes in the winter months in Massachusetts Bay, pinger requirements are extended to include the months of December and January in this final rule.

In the South Cape area, the proposed HPTRP would have required pingers from September 15 through February, and then again in April to account for uncertainty in estimated bycatch in this area throughout the year. Based on public comments and on the lack of observed takes in the fall months, this final rule changes the beginning of the time period for pinger requirements from September 15 to December 1. To account for observed takes that have occurred later in the spring, the HPTRP has extended the pinger requirement to include May 1 through 31. These changes are expected to ease the burden (both in economic terms and in terms of the additional effort expended to use pingers) on the South Cape fishermen by allowing for more fishing time without pingers. This change is not expected to affect projected bycatch reduction from the South Cape area because, based on current observer data, the plan will achieve the same or greater bycatch reduction in May, when takes have been observed, than in the fall months.

The proposed HPTRP provided for closing the Cashes Ledge section of the Offshore area in February and would have required pingers from September 15 through May in the broader Offshore area. The final HPTRP does not change the Cashes Ledge closure in February but modifies the time of pinger use to begin November 1, rather than September 15, based on lack of observed takes between September 15 through October 31. These changes ease the burden (both in economic terms and in terms of the additional effort expended to use pingers) on New Hampshire and Maine fishermen during the times of no observed bycatch. This change should not affect overall plan effectiveness because, based on current observer data, little bycatch reduction is expected in September and October in the Offshore area.

Mid-Atlantic Component

Tables 2 and 3 set forth the HPTRP management measures for the large mesh (includes gillnet with mesh size of greater than 7 inches (17.78cm) to 18 inches (45.72cm)) and small mesh (includes gillnet with mesh size of greater than 5 inches (12.7 cm) to less than 7 inches (17.78cm)) gillnet fisheries in the Mid-Atlantic (see Figure 2).

TABLE 2.—MANAGEMENT MEASURES FOR THE LARGE MESH GILLNET FISHERY (INCLUDES GILLNET WITH MESH SIZE GREATER THAN 7 INCHES (17.78CM) TO 18 INCHES (45.72CM)) IN THE MID-ATLANTIC UNDER THE FINAL RULE/HPTRP

Floatline Length:	
New Jersey Mudhole	Less than or equal to 3,900 ft (1188.7 m).
New Jersey Waters (excluding the Mudhole)	Less than or equal to 4,800 ft (1463.0 m).
Southern Mid-Atlantic waters	Less than or equal to 3,900 feet (1188.7 m).
Twine Size	
All Mid-Atlantic Waters	Greater than or equal to .90 mm (.035 inches).
Tie Downs	
All Mid-Atlantic Waters	Required.
Net Cap	
All Mid-Atlantic Waters	80 nets.
Net Size	A net must be no longer than 300 feet (91.4m) long.
Net Tagging	Requires all nets to be tagged by January 01, 2000.
Time/Area Closures:	
New Jersey waters to 72°30′ W. longitude (including the Mudhole)	Closed from April 1–April 20.
New Jersey Mudhole	Closed from February 15—March 15.
Southern Mid-Atlantic waters (MD, DE, VA, NC) to 72°30′ W. longitude	Closed from February 15–March 15.

TABLE 3.—MANAGEMENT MEASURES FOR THE SMALL MESH GILLNET FISHERY (INCLUDES GILLNET WITH MESH SIZE OF GREATER THAN 5 INCHES (12.7 CM) TO LESS THAN 7 INCHES (17.78CM)) IN THE MID-ATLANTIC UNDER THE FINAL RULE/HPTRP

Floatline Length:	
New Jersey waters	Less than or equal to 3,000 feet (914.4 m).
Southern Mid-Atlantic waters	Less than or equal to 2,118 feet (645.6 m).
Twine Size:	
All Mid-Atlantic waters	Greater than or equal to .81 mm (.031 inches).
Net Cap:	
All Mid-Atlantic waters	45 nets.
Net Size	A net must be no longer than 300 feet (91.4m) long.
Net Tagging	Requires all nets to be tagged by January 1, 2000.
Time/Area Closures:	
New Jersey Mudhole	Closed from February 15–March 15.

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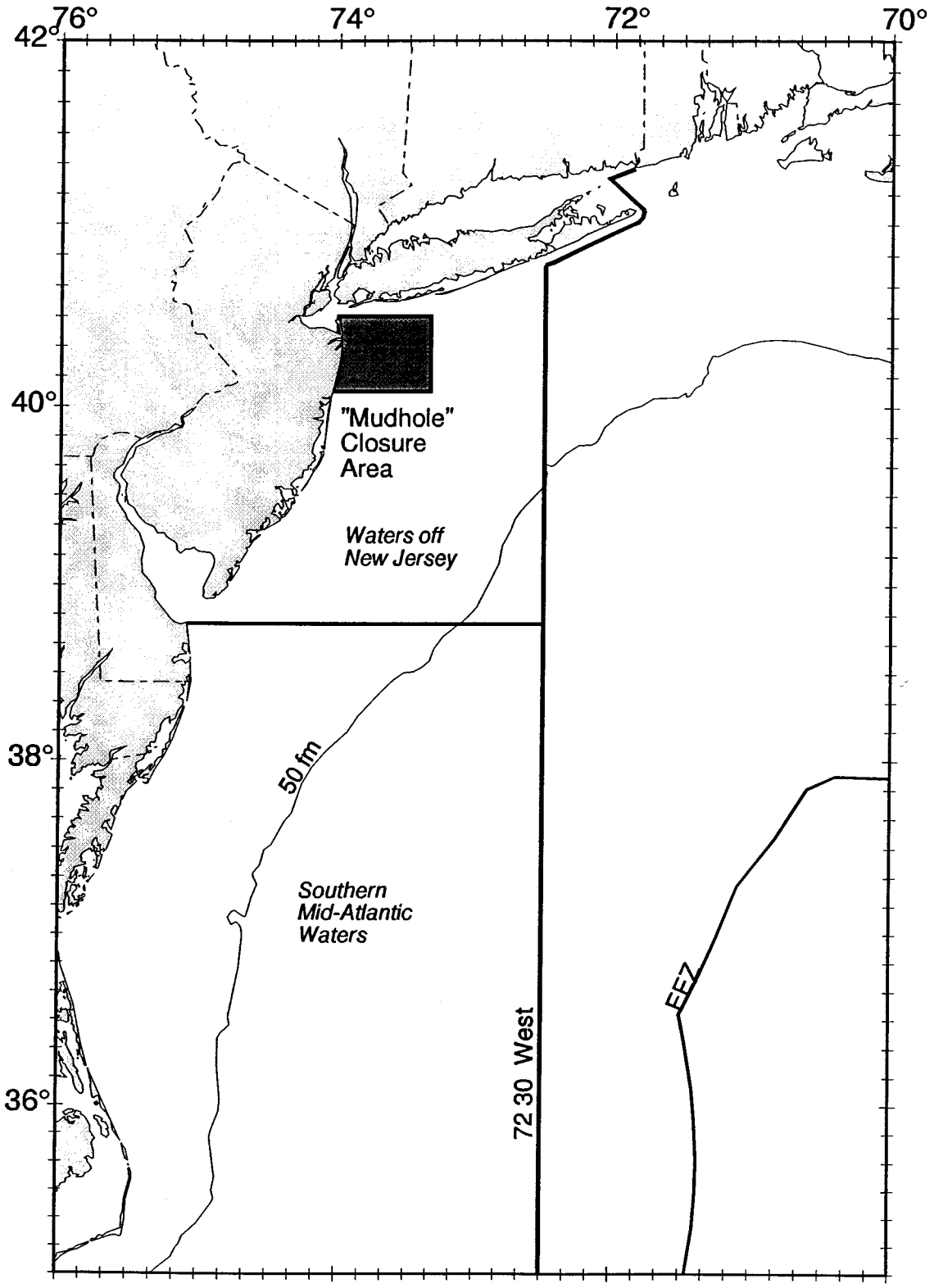

Figure 2. Mid-Atlantic component

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The Mid-Atlantic component of the HPTRP is generally consistent with the proposed HPTRP, except as discussed below. The gear modifications in the final HPTRP remain the same as in the proposed HPTRP. The effective period remains the same as described in the proposed HPTRP: January 1 through April 30 for New Jersey waters, and February 1 through April 30 for southern Mid-Atlantic waters. Additionally, stratification by fishery based on mesh size remains the same as in the proposed HPTRP.

The most significant change from the proposed HPTRP is the application of the management measures within the small mesh fishery. In the proposed plan, the small mesh fishery was defined as all those fisheries employing mesh size of less than 7 inches (17.78 cm). Stranding data and related bycatch information suggest that certain small mesh fisheries could be a source of harbor porpoise bycatch. This information, along with the assumptions inherent in the bycatch analyses, led NMFS to propose that these fisheries be subject to some of the regulatory measures in the proposed HPTRP.

Based upon further review and as the result of public comment, NMFS has decided to exclude fisheries with mesh size 5 inches (12.7 cm) and less from the HPTRP regulations at this time. The reasons for this are that the number of observed takes in these mesh sizes currently available in the data is limited. However, given the concerns associated with the possible bycatch from these fisheries discussed above, NMFS will reevaluate the observer and stranding data, particularly from alternative platforms, for these fisheries in the spring, 1999 and address the issue of mesh sizes 5 inches (12.7 cm) or less at that time.

Given the models and assumptions used in the subfishery bycatch analysis and the predicted effect of using the recommended gear characteristics based on small and large mesh gillnet categories, excluding the mesh sizes of 5 inches (12.7 cm) and less at this time does not change the expected 79 percent or greater reduction in harbor porpoise bycatch in the Mid-Atlantic.

In addition to the 30-day public comment period and publication of the proposed rule in the **Federal Register**, NMFS issued a press release announcing the availability of the proposed rule and summarizing the major issues in the proposed rule. The final rule will govern fishing by the NE Multispecies and Mid-Atlantic gillnet fisheries in the GOM and Mid-Atlantic. NMFS expects that implementation of this rule will reduce within 6 months of its implementation the bycatch of harbor porpoise to below their PBR level.

Response to Comments

Comments on the Take Reduction Team Process and General Comments

Comment 1: One commenter stated that each country and each region should be treated equally and be separately responsible for specified shares of PBR and bycatch reduction. This commenter noted that combining the two plans raises the issue of how NMFS will allocate PBR between the two jurisdictions in the future. Since the Mid-Atlantic accounts for only 10 percent of the mortality, this is unfair to them. Three commenters recommended keeping PBR only on a jurisdictional basis. One commenter recommended reconvening both the GOMTRT and MATRT to address the allocation issue.

Response: NMFS disagrees that there is an allocation problem. Each region is treated separately for respective shares of PBR. This issue was discussed in detail during the Mid-Atlantic TRT meetings. Combining the two plans into one final rule does not change the basis for the reductions accepted by the separate TRTs. Specifically, each region agreed to reduce its respective bycatch by 79 percent of the estimated level of bycatch for that region. For example, if the Mid-Atlantic region takes only an estimated 200 animals, they need to achieve a 79 percent reduction which translates to a reduction of 158 animals. If the GOM has an estimated take level of 1800 animals, they also need to achieve a 79 percent reduction, but this translates to a reduction of 1422 animals. These are equal reductions based on the respective levels of bycatch; i.e., one region is not compensating for the other. This strategy is both equitable and fair and was accepted by the GOMTRT and MATRT.

Comment 2: One commenter noted that the **Federal Register** publication notice for the proposed rule (63 FR 48671) indicated that Canadian sink gillnet takes are approximately 100 animals, and the HPTRP will achieve the necessary PBR reduction including the Canadian takes. The commenter asked how NMFS will incorporate fluctuations in Canadian interaction levels in the HPTRP. The commenter also asked how a higher level of lethal Canadian interactions would affect the annual HPTRP review and why an approximate count is acceptable for Canadian take whereas the total PBR estimate is a firm point estimate. Another commenter recommended that NMFS strongly encourage efforts to request the Department of Fisheries and Oceans (DFO), Canada, to consider the HPTRP.

Response: Under the MMPA, takes throughout the range of the species are considered in developing management measures in the TRPs. Since the HPTRT is expected to meet semi-annually the first year, and annually thereafter, changes in information on Canadian takes, as available, can be evaluated by the TRT at the same time U.S. bycatch information is discussed and recommendations made on all these issues at the same time. NMFS has detailed data on both bycatch in U.S. fisheries and Canadian fisheries. This allows for a more accurate estimate of total bycatch in U.S. and Canada fisheries. For Canadian takes, the U.S. receives information from the Canadian Government on bycatch in its fisheries. NMFS has already met with representatives of the Canadian government to discuss the HPTRP in U.S. waters and encourage the Canadians to participate in reducing the overall fishing mortality on this stock. As a result, Canada developed its Harbor Porpoise Conservation Plan and has implemented an observer program which has documented a continuous reduction in bycatch in their Bay of Fundy gillnet fisheries.

Comment 3: Five commenters asked how NMFS will incorporate the anticipated harbor porpoise conservation benefits when the FMPs for monkfish and spiny dogfish are published and the American shad intercept gillnet fishery is phased out. Another commenter noted that upcoming management plans on both dog sharks and monkfish have not been considered by NMFS in constructing the HPTRP. This commenter stated that the most obvious problem with the HPTRP is the lack of information on the restrictions proposed by the FMPs for monkfish and spiny dogfish and their anticipated conservation benefits to harbor porpoise. Another commenter criticized NMFS for not considering the protection that will be afforded under a number of FMPs, including Atlantic Sturgeon, Monkfish, Dogfish, Bluefish Amendment 1, Amendment 1 to Shad and River Herring.

Response: NMFS generally discussed the impacts of the proposed FMPs for monkfish and dogfish in the proposed HPTRP. NMFS did not analyze the proposed FMP management measures in detail because, during the development of the proposed HPTRP, these plans were not yet final. Given that FMPs may change significantly prior to a final vote by the responsible Fishery Management

Council (FMC), NMFS felt it unwise and impractical to guess at the final FMC recommendations. However, concurrent with the development of the HPTRP proposed rule, the Monkfish FMP was voted on and a final FMP package with a preferred alternative was submitted to NMFS on October 27, 1998, by the NEFMC and the MAFMC. The preferred alternative, now under consideration by the NEFMC and the MAFMC, will provide no benefits to harbor porpoise conservation in the near future because the regulations do not become effective until May 1, 1999. Since the HPTRP must show a reduction in bycatch within 6 months of implementation and the majority of harbor porpoise bycatch occurs during the months of January through April, the HPTRP must go into effect in early January 1999 to reduce impacts to harbor porpoise in the spring 1999 fishery.

If the Monkfish FMP goes into effect, the expected harbor porpoise conservation benefits appear to be the result of overall effort reduction through Days-At-Sea and Total Allowable Catch restrictions. However, any conservation benefits may be negated as a result of the relatively high gill net limits set by the FMP. According to the MATRT, the average number of nets employed by Mid-Atlantic fishermen is 80 nets. The Monkfish FMP, if approved, would allow fishermen to use up to 160 nets.

The biggest differences between the Monkfish FMP and the HPTRP are in the mandatory time outs. The 20-day block during April, May, and June required under the Monkfish FMP would have little additional reduction in harbor porpoise bycatch. If the fishermen take their 20-day block (under the Monkfish FMP) in early April in New Jersey, there could be a conservation benefit—but it would mirror only what is currently required in the HPTRP and would not result in any additional benefits. If the 20 days are taken in May or June in New Jersey or April through June in the southern Mid-Atlantic, there will be little if no benefit to harbor porpoise because harbor porpoise are not usually taken in those areas at those times.

Regarding the other upcoming FMP, the Dogfish FMP is still under development; therefore it is unclear what the Councils' preferred alternative is regarding that plan. NMFS believes it is premature to analyze the possible impacts of the Dogfish FMP without a preferred alternative. The other plans are still either in the development phase or will not go into effect until after the spring 1999 fishery, thereby not providing any clear benefits to harbor porpoise in the required 6-month time frame.

As stated in the proposed rule, the HPTRP measures are expected to be reevaluated on a yearly basis. NMFS will consider any new regulations that may affect harbor porpoise or the implementation of this plan and evaluate whether management measures need to be changed at that time.

Comment 4: One commenter recommended that the HPTRT be convened semiannually to see if the HPTRP is meeting objectives.

Response: NMFS intends to reconvene the teams semiannually the first year of plan implementation in order to track the plan's progress toward the 6-month MMPA goal. Whether or not reconvening the TRTs semi-annually after that first year is necessary would depend on the circumstances.

Comment 5: One commenter recommended that NMFS coordinate HPTRP development with annual FMP adjustments that will occur for the Multispecies, Monkfish, and possibly Dogfish FMPs. FMP evaluation will begin in November, and recommendations will be provided to the Council every December. Any changes to plans will be submitted by the Council to NMFS by February 1 each year, with implementation on May 1.

Response: NMFS agrees that close coordination with the Fishery Management Councils on annual changes that will affect fisheries is a good idea. During the first year of plan implementation, the TRT will meet in the summer of 1999 to discuss the plan's progress and recommend any changes to the plan based on the spring fishery's results. In finalizing recommendations, NMFS would have the opportunity to coordinate with the Councils in the fall at the same time the Councils are considering adjustments for fishery management purposes.

Comment 6: One commenter recommended that NMFS should review Framework 25 to see whether there are ancillary benefits to harbor porpoise that have not been included in the proposed rule. If Framework 25 results in more positive benefits than projected, NMFS should consider reducing the 8½-month pinger requirement in the Mid-Coast area.

Response: Framework 25 was evaluated using the available data to determine ancillary benefits to harbor porpoise reduction. The benefits of Framework 25 were included in the analysis to determine how much additional reduction was needed from the HPTRP measures (see the EA for detailed information). When bycatch information is reviewed for spring of 1999, further information will be available to evaluate the impacts of implementation of Framework 25 during 1997 and 1998.

The HPTRP has an overall strategy for the entire GOM that is expected to reach MMPA goals for this fishery. Individual areas cannot be viewed in a vacuum. The Mid-Coast area has made progress in reducing bycatch by using pingers. Therefore, contrary to supporting a reduction in pinger use, this fact supports the continued use of pingers so that bycatch continues to remain under control. This plan will not work if bycatch reduction achieved in one area is replaced with bycatch increases in another area because mitigation measures have been removed.

Comment 7: One comment supported the need for the proposed regulations and noted that the proposed regulations can work well with the FMPs developed by NEFMC and MAFMC.

Response: NMFS agrees.

Comment 8: One commenter stated that the process was inappropriately delayed and, consequently, requested an additional public comment period.

Response: NMFS agrees that the process experienced delays for many reasons. Significant public comment was received throughout the TRT process, including an additional meeting in December 1997 for the GOM. Addressing the harbor porpoise bycatch issue has been an ongoing process since the early 1990s, and most of the measures in the TRT draft plan from 1996 had already been put into place through framework actions implemented under the NE Multispecies FMP. While the proposed rule published in September 1998 goes beyond these measures, NMFS determined that 30 days was sufficient for additional comments, given the long history of public involvement.

Comment 9: Several commenters felt that because small mesh fishermen in the Mid-Atlantic were not adequately involved in the TRT process, any regulations affecting this segment of the fishery should be open to public hearings.

Response: NMFS disagrees that the small mesh fishermen did not have the opportunity to be represented in the MATRT. The MATRT included a number of industry representatives and state fishery management agencies. In addition, the MATRT meetings were open to the public. However, many fishermen typically using this type of gear in nearshore fisheries in the Mid-Atlantic, while present at the start of the MATRT process, did not participate

once the MATRT agreed to address only the monkfish and dogfish subfisheries.

Comment 10: One commenter complemented the Press Guide which explained the proposed regulations but noted that the northern and eastern boundaries of the Mudhole were in error.

Response: The actual chart provided in the Press Guide was correct. However, NMFS agrees that the accompanying text contained errors in the northern and eastern boundaries. NMFS will review the Press Guide and revise it based on final regulations.

Comment 11: One commenter requested that the analysis from the GOM pinger experiment be given to the MAFMC. The commenter stated that a consensus recommendation could be developed with the new results from the GOM experiment.

Response: NMFS will provide the MAFMC with the results of the 1997 pinger experiment, which can also be discussed at the next meeting of the MATRT.

Comment 12: One commenter stated that combining the Mid-Atlantic and GOM TRTs is not a good idea. The fisheries are not the same, and this approach would only weaken the position fishermen hold on the TRTs.

Response: NMFS agrees that the fisheries are different; that is why distinct strategies were maintained for each region even though both geographic areas were included in one set of regulations. The regulations would not have been different had they gone through two separate rulemaking processes. NMFS is considering whether or not the two teams should continue to meet separately or whether some or all of the meetings should be combined.

Comment 13: One commenter notes that the statement ''the HPTRP is based in large part on recommendations in the draft GOMTRP and the MATRT report'' is not accurate. NMFS has expanded the terms of the regulation so significantly that NMFS has jeopardized any future TRT discussions because participants cannot be assured that their time, deliberations, and consensus will be honored and accepted by NMFS.

Response: NMFS disagrees that the terms of the regulation have been expanded significantly from the two TRT recommendations. The GOM plan retained the strategy of discrete closures surrounded by larger areas of pinger use as recommended by the TRT at its December 1997 meeting. The strategy of gear modifications based on gear types that reflected locally prevailing practices in the Mid-Atlantic were retained. In both cases, some changes were made in the final regulations based on new information and comments received during the public comment period. The TRT deliberations are integral to the process and provided valuable insight into how these issues between stakeholders might be resolved. Individual team member contributions are invaluable, and the teams are to be fully commended for persevering through a difficult process. Changes made to those recommendations reflect actions considered necessary to meet agency obligations under the law, to reflect concerns of all constituents, and to be certain that regulations are enforceable. This process is relatively new and both TRT participants and NMFS have learned ways the process can be improved. NMFS agrees that continued efforts at communication between NMFS and the teams throughout the process is necessary for the process to maintain its integrity.

Comment 14: One commenter questioned whether the proposed rule discusses the new information that has warranted the changes that NMFS has made from the 1997 proposed rule. The commenter stated that no conclusive information was presented at the December 16—17 meeting resulting in any consensus or recommendation from that meeting to warrant those changes.

Response: Recommendations did come out of the December 16—17, 1997, meeting, and they are reflected in the GOMTRT's report of January 14, 1998. NMFS agreed with many of the GOMTRT's recommendations, and the proposed rule (September 11, 1998) incorporated most of the Team's recommendations. NMFS agrees that this was not a consensus report. The August 1997 proposed GOMTRP provided for a variety of measures, including requirements for fishery closures and closures with pingers aimed at harbor porpoise protection that were ultimately implemented under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The 1996 bycatch data revealed that these measures were ineffective at reducing overall bycatch, and, based on this new information, NMFS concluded that the changes to the original proposed GOMTRP were warranted. These data and historical management measures are discussed in detail in the EA.

Comment 15: One commenter stated that there is confusion because some areas are closed for both groundfish conservation and harbor porpoise protection. In some areas that are closed for harbor porpoise protection only, fishing with gillnets is permitted with approved pingers. This distinction between areas closed for harbor porpoise conservation and areas closed for groundfish conservation should be clearly articulated as a matter of general policy in the final rule. This would obviate the need to initiate a framework adjustment each time a groundfish conservation closure was shifted or lifted if it occurred in an area also closed for harbor porpoise protection.

Response: Since the harbor porpoise regulations are promulgated under the MMPA, the regulations will remain in effect regardless of shifts in groundfish closures under the Magnuson-Stevens Act. However, the effects of changes in groundfish closures on the effectiveness of the HPTRP would need to be reviewed and changes made to the plan, if appropriate, to retain its effectiveness.

Comment 16: One commenter recommended including a definition of baitnets in the rule.

Response: A description of baitnets is provided in the regulations for the NE Multispecies FMP (50 CFR § 648.81 (f)(2)(ii)) as ''a single pelagic gillnet, not longer than 300 feet (91.44 m) and not greater than 6 ft (1.83 m) deep, with a maximum mesh size of 3 inches (7.62 cm), provided that the net is attached to the boat and fished in the upper two thirds of the water column, the net is marked, there is no retention of regulated species, and there is no other gear onboard capable of catching NE multispecies.'' The HPTRP regulations include an exception for single pelagic gillnets or baitnets.

Comment 17: One commenter noted that the capture of harbor porpoise in mid-water trawl fisheries has not been adequately addressed within the proposed rule. The commenter stated that the mid-water trawl fishery for Atlantic herring represents the biggest increase in fishing effort and is classified as a Category II fishery. The efforts of reducing bycatch through gillnet regulations could be negated if no regulatory action is implemented for the mid-water trawl fishery for Atlantic herring.

Response: NMFS agrees that the mid-water trawl fishery for Atlantic herring has the potential to take small cetaceans. In the proposed List of Fisheries for 1999, the GOM and Mid-Atlantic herring mid-water trawl fishery are proposed as Category II, based on comparisons with other gear types known to take several species of small cetaceans and the fact that herring are an important prey item for several stocks of marine mammals. However, NMFS currently has no observed takes of harbor porpoise in this fishery, and consequently it is not included in the final HPTRP. Monitoring will continue through the Sea Sampling Observer

Program at a level consistent with the valid sampling scheme currently used by the program.

Comment 18: One commenter expressed reservations about NMFS' intent to implement the five stated non-regulatory measures recommended by the GOMTRT at its December 1997 meeting. The study to evaluate habituation and displacement has been concluded, and the results should be published. A census of the gillnet fleet should be readily available through existing reporting requirements. The commenter also felt that there has been sufficient time for NMFS to investigate options for providing support to fishermen for pinger technology. The commenter questioned why these issues are not addressed with the proposed rule. The commenter noted that NMFS will need to have a pinger training course available at all times so as not to prevent potential fishermen access into the gillnet fishery.

Response: One study to evaluate habituation and displacement took place during the summer of 1998, but a final report was not available at the time of the proposed rule. Results of this study will be published as soon as possible. The implications of this study for the HPTRP will be discussed at the next meeting of the TRTs in 1999.

A census of the gillnet fleet using existing reporting measures is expected to occur in the near future. When the census is complete, the results will be reported.

NMFS has investigated the potential for support for fishermen to purchase pingers but no viable options are available at this time.

The certification program for fishermen using pingers is expected to be available as needed.

Comment 19: One commenter suggested that NMFS track harbor porpoise by radar to alert fishermen and thereby give fishermen the opportunity to move nets. Another commenter suggested daily tracking of harbor porpoise to regulate fishing that day.

Response: Given current technologies, it would not be feasible for harbor porpoise to be tracked by radar. Radar tracking poses significant difficulties with small cetaceans, both technically and practically. Additionally, because of the nature of the gillnet fishery, it would be impractical for fishermen to retrieve their nets when harbor porpoise are in the area without significantly reducing their catch. Daily regulations of fishing would be nearly impossible to administer and impractical for fishermen to comply with.

Comment 20: One commenter suggested making the gillnets smaller.

Response: If the comment refers to the actual size of the deployed nets, this approach is part of the reasoning behind the reduced floatline lengths in the Mid-Atlantic component of the HPTRP.

Comment 21: One commenter suggested that fishermen should not be allowed to fish in the same area where harbor porpoise eat.

Response: Although the NE multispecies and Mid-Atlantic fisheries are not necessarily targeting harbor porpoise prey, they do use many of the same feeding areas as harbor porpoise. Since restricting fishing away from areas of harbor porpoise feeding would severely restrict fishing opportunity and because it is unclear exactly where and if harbor porpoise feed on a regular basis, the intent of the pinger requirements is to allow fishermen to be in the same general area as harbor porpoise while minimizing interactions.

Comment 22: One commenter suggested closing certain areas to fishermen, particularly during harbor porpoise mating seasons. Another commenter suggested generally implementing special fishing times.

Response: The intention of the HPTRP is to close certain areas to fishing during times of high bycatch, i.e., when chances of interaction between harbor porpoise and gillnet fisheries are high. However, because all areas cannot be closed if a viable fishery is to exist, fishing during times and areas adjacent to closures can only be allowed if pingers are used.

Comment 23: One commenter recommended that no fishing be allowed when harbor porpoise are in Maine.

Response: The HPTRP closed the NE area, in Maine, from August 15 to September 13, the time period when harbor porpoise are most common in Maine waters.

Comment 24: One commenter recommended that the MMPA and ESA be strengthened.

Response: NMFS will reevaluate the effectiveness of the HPTRP management measures and the effectiveness of the MMPA to achieve harbor porpoise conservation in 1999. NMFS will not reevaluate the ESA with regard to TRPs because NMFS regards the MMPA measures sufficient for conservation of harbor porpoise.

Comment 25: One commenter suggested that NMFS list harbor porpoise as threatened.

Response: In 1993, NMFS proposed listing the harbor porpoise as threatened under the ESA in response to a petition by Sierra Club Legal Defense Fund on behalf of 13 other organizations. NMFS' research findings at that time indicated that the rate of bycatch of harbor porpoise in gillnet fisheries might reduce the population to the point where it would become threatened and that the regulatory measures in place to reduce this bycatch were inadequate. NMFS has not yet issued a final listing determination. New data, new regulations, and this rule to implement the HPTRP provide substantial new information for consideration by NMFS and the public. The proposed rule to list the GOM harbor porpoise as threatened under the ESA was reopened for public comment on October 22, 1998. The public comment period closed on November 23, 1998. NMFS plans to make a listing determination in the near future based on the new information and public comment on the proposed rule.

Comments on Data and Research

Comment 26: One commenter recommended that the PBR formula be re-assessed during the next re-authorization of the MMPA because the default safety parameters in the model are inaccurate and contrary to the available science, which indicates that harbor porpoise have an extremely short life span, early maturation, and a very high, successful reproductive rate, compared to other odontocete species.

Response: NMFS is unaware of new scientific information that could be used to re-assess the default parameters. Any new, valid scientific information would be welcome, evaluated, and incorporated, as appropriate, into these assessments. However, in the absence of other information, the default model parameters used in the PBR formula represent the best available scientific information on this topic. The life history of harbor porpoise, among other related issues, was discussed in length at a meeting in 1996, the results of which are published by Wade and Angliss, 1997, in ''Guidelines for assessing marine mammal stocks: report of the GAMMS workshop April 3–5, 1996, Seattle Washington.'' A peer-reviewed scientific article that describes some of the work that went into defining the parameters is summarized by Wade, 1998, in ''Calculating limits to the allowable human-caused mortality of cetaceans and pinnipeds.''

Comment 27: One commenter noted that the PBR level based on population dynamics continues to be ultraconservative and asked if NMFS considered a peer-review debate on choosing to use this conservative reproductive estimate. Many scientists feel that this may be too conservative.

Response: NMFS has used peer reviewed information to choose the

population dynamic parameters in the evaluation of the PBR calculation. See comment number 26 for references to the peer-reviewed work in this area.

Comment 28: One commenter expressed concern about methods used to estimate harbor porpoise bycatch because calculations are based on takes per haul as the unit of effort and not the number of takes per net. This commenter also expressed concern about weighout landings as the multiplier and recommended a review of this process for an alternative with more precision. Another commenter stated that NMFS is unwilling and unable to correct and adjust estimates of fleet size and methods of extrapolation used to determine effort and that NMFS has never had reliable fleet size information to measure effort. A third commenter stated that NMFS' bycatch calculations, based on what the gillnet fishery catches, are incorrect. This commenter noted that, despite continuous requests to adjust this approach to a more practical and realistic method, NMFS continues to do it the wrong way. This commenter recommended that units of fishing effort are more appropriate means of calculating and estimating harbor porpoise bycatch.

Response: The current method used to estimate harbor porpoise bycatch does not rely on fleet size. Therefore, obtaining the most up-to-date estimates of fleet size would not change the bycatch estimate.

Choosing the most appropriate unit of effort for the bycatch estimate is a two-step process, and both steps must be accurate and reliable before another unit of effort can be used. Step one is choosing the best unit of effort using the Sea Sampling data, and step two is calculating that unit of effort for the entire fishery.

By definition, the most appropriate theoretical unit of ''effort'' needed in any bycatch estimate is a unit of ''effort'' that is expected to relate directly to the number of harbor porpoise that are caught and to increase proportionally as the number of harbor porpoise takes increase. Therefore, even on a theoretical basis, that unit of ''effort'' does not have to be a unit that is typically thought of as fishing effort, such as days fished or number of boats. Other possible acceptable units of ''effort'' could be hours nets are soaked multiplied by the number of nets, or pounds of fish species ''X'' caught in the net. Again, for the areas and times when there are both harbor porpoise and fishing, what is needed is a unit such that as the level of that unit increases so does the number of caught harbor porpoise.

After that unit is chosen, it is essential that NMFS estimate the total amount of that unit for the entire fishery. So, for example, if hours of net soak time represented the best unit of ''effort'' then it would be necessary to calculate the total number of hours soaked by all nets used by the entire fishery, by the time and areas that are appropriate. Data in the fisher trip logbooks could be used to calculate this information. However, even in 1997, many of the data fields in the logbooks were left blank. Until the logbooks are completely and accurately filled out all of the time, it is impossible to use net soak time to calculate the total level of ''effort.''

NMFS is willing to investigate other possible units of ''effort'' but, until the total amount of a unit for the whole fishery is available and accurate, it is not possible to use any other unit of ''effort'' except that already being used—tons of fish landed from the dealers.

Comment 29: Two commenters asked how there could be insufficient data to determine population trends for this species, but enough information to determine a specific PBR point estimate.

Response: By definition, PBR requires one abundance estimate and the level of confidence associated with that estimate. This information is available, so PBR can be calculated. However, determining population trends require several abundance estimates within a long time series. At present we have three abundance estimates taken during 5 years (1991, 1992, and 1995). Three abundance estimates with Coefficient of Variation's in the 20 percent range during such a short time period are not sufficient to accurately determine if there is a trend. However, another abundance survey is scheduled for the summer of 1999. The NEFSC is intending to use the four abundance estimates (1991, 1992, 1995, and 1999) taken from the resulting 9 years (1991–1999) to investigate whether a trend can be determined and the level of accuracy of that conclusion.

Comment 30: One commenter noted that the proposed rule stated that the Assistant Administrator will review, on an annual basis, the effort and bycatch data to see if the HPTRP is achieving the PBR goal. The commenter then drew the conclusion that, if the HPTRP is effective, the number of harbor porpoise should increase each year. NMFS indicated in that same rule that sufficient data are not currently available to determine trends in harbor porpoise stock size. The commenter then asked that the harbor porpoise stock size be assessed to see if it does increase with TRP efforts.

Response: Harbor porpoise stock size will continue to be assessed by conducting sighting surveys every few years. There is a survey scheduled for the summer of 1999. The frequency of future surveys will be determined by considering the level of accuracy of each individual estimate and the need to get accurate abundance estimates of all marine mammals found in U.S. waters. At the present time, it has been suggested that conducting surveys every 4 years would be adequate.

The HPTRP will be assessed by monitoring the level of by-catch. This monitoring program will be on a quarterly basis, at least for the next few years.

Comment 31: One commenter requested that NMFS undertake research on pingers to evaluate displacement and habituation of harbor porpoise, and long-term effects of pinger use on the ecosystem.

Response: Research has started on this topic and will be continuing. Specifically, during the summer of 1998, research was conducted that investigated the small-scale distribution and relative abundance of harbor porpoise near and around pingers and herring weirs. This project will provide information on displacement and short-term habituation (on a monthly scale). Another project will be conducted during January to May 1999 and will investigate displacement, short-term habituation, and short-term effects on the ecosystem. This project will involve monitoring the spatial distribution and relative abundance of harbor porpoise, other marine mammals, herring, and other fish in areas and times with and without pingers.

Comment 32: One commenter stated that the plan appears to contain a number of discrepancies between some numbers in the tables and text of the EA that call into question the rigor of the underlying assumptions of reductions in mortality; for example, mortality reductions calculated based on use of pingers in areas or times where pinger use is not required.

Response: NMFS has thoroughly reviewed the calculations in the draft EA with respect to the final rule and has updated the EA. Some of the confusion is a result of the complexity of the data and of the difficulties in its presentation, rather than actual errors. The shaded area in Table 4 of the draft EA represents areas where reductions *can* be made, not necessarily those made by the HPTRP. Discrepancies between the text and the charts have been re-evaluated and corrections made

as appropriate in the final EA. NMFS disagrees that the discrepancies call into question the rigor of the underlying assumptions of reductions in mortality. The discrepancies were relative to 1994 and 1995 data that were not available in the 1996 data format, and consequently the estimates of reduction were less accurate. The impact of Framework 25 could not be incorporated. Because of the nature of available data, calculations of plan effectiveness on years prior to 1996 were not as accurate. These data are provided at the request of many GOMTRT members for comparison purposes, but the 1996 data, with the analysis of Framework 25, are primarily what are used to support the conclusion this plan will reach its goal.

Comment 33: One commenter challenges the information that establishes the PBR of 483 animals although specifics were not given.

Response: The value of the PBR for the Gulf of Maine/Bay of Fundy harbor porpoise has been accepted by the Atlantic Scientific Review Group. This is a group of non-government scientists that were formed under the MMPA and whose purpose is to review, correct, and monitor the data going into the assessments of all the marine mammals (see also response to comment 26).

Comment 34: The commenter stated that their understanding was that the bycatch information reflected in the proposed rule was based on a ''5 year (1990–1995) average mortality estimate'' and then questioned how NMFS can justify the expansion of regulatory conditions without current information, i.e., later than 1995.

Response: Information used to evaluate the proposed regulation was the most recent available at the time, through 1996 verified and complete, and initial estimates for spring of 1997. Therefore, data more recent than 1995 were used. Secondly, the impact of the proposed regulations were evaluated with respect to the most recent fishery management measures, including Framework 25 to the NE Multispecies FMP. The average referenced in the preamble was solely to illustrate the trend over the years of available data; it was not used to justify any regulatory components of the plan, the most recent complete data was used (1996). The years 1994 and 1995 were also provided for comparison.

Comment 35: One commenter suggested that it is time to think about opening up some of the closure areas with pinger use now, not expanding them. The commenter stated that effort and migration does not necessarily equal entanglement due to absence or presence of feed fish and that this was accepted by the NEFMC in deciding the appropriate closure for Massachusetts Bay.

Response: Clearly the Massachusetts Bay Closure was not effective because bycatch occurred just outside the closure time/areas. Fishing effort and the presence of harbor porpoise does increase the probability of entanglement. NMFS agrees that there is inter-annual variability in porpoise distribution often based on prey distribution; however, that justifies, not contradicts, the strategy for expanded pinger times and areas.

Comment 36: One commenter recommended expanding the observer program to ensure accurate bycatch estimates under the new management regime.

Response: When applying observer coverage under the new management regime, NMFS attempts to insure the best possible, unbiased, and accurate harbor porpoise bycatch estimate, given available resources and recognizing the need for accurate information on other marine mammal stocks. This is just one component of an overall fishery observer program.

Comment 37: One commenter recommended that NMFS provide the GOMTRT with a detailed description of its planned scientific research and request its comments on those studies.

Response: NMFS will provide descriptions of planned research to the GOMTRT and consider comments as appropriate.

Comment 38: For the Mid-Atlantic, three commenters felt that despite substantial fishery-dependent observer data for other gillnet fisheries which indicate little or no harbor porpoise interaction and the recommendation by the MATRT which focused only on monkfish and dogfish fisheries, NMFS has unfairly expanded the HPTRP to include all fishing with gillnets in inshore and offshore waters of the Mid-Atlantic. One commenter felt that the small mesh gillnet fishery should have a minimum mesh size limit of 5 inches.

Response: NMFS agrees that during the deliberations of the MATRT, the Team focused its recommendations on subfisheries rather than all Mid-Atlantic gillnet fisheries, as defined in the List of Fisheries. The MATRT was warned, however, that analysis of bycatch data by subfisheries under the constraints of limited sample sizes required highly speculative assumptions. Due to this factor as well as enforcement concerns and the lack of FMPs for those fisheries, NMFS expanded the definition of Mid-Atlantic fisheries covered by the HPTRP to large and small mesh fisheries.

However, NMFS has excluded mesh sizes of 5 inches (12.7 cm) and less from the small mesh regulations at this time. The reasons for this is the limited number of observed takes in these mesh sizes currently available in the data and because the fishermen typically using this gear in the nearshore Mid-Atlantic fishery, while present at the start of the TRT process, did not participate once the TRT agreed to address only the monkfish and dogfish subfisheries. This does not mean the evidence of potential interactions in this sector of the gillnet fishery will be ignored. Although the number of observed takes in mesh sizes of 5 inches (12.7 cm) or less is small, takes have been documented that were not ''dogfish-targeted'' trips. There were 3 takes in the menhaden fishery in 1997 in New Jersey and there was a take in the southern Mid-Atlantic shad fishery in 1996. Therefore it is likely that takes do occur in small mesh fisheries. Given this concern, NMFS will reevaluate the observer data (particularly through the expanded observer program and alternative platforms) and stranding data for these fisheries in the spring, 1999, and reconsider if management measures to reduce bycatch are needed.

Comment 39: One commenter stated that NMFS made assumptions about bycatch in the Mid-Atlantic that are erroneous. The EA specifies that it was assumed that no mortality occurred in fisheries other than those for monkfish and dogfish, which is incorrect. The EA also assumed that no porpoise can ever be caught in waters off Virginia and Delaware, which is unlikely based on co-occurrence of animals and gillnet fisheries in those areas.

Response: NMFS agrees that harbor porpoise mortalities occur in fisheries other than monkfish and dogfish. The assumptions alluded to are just some of a number of assumptions that were made in order to provide the models that could evaluate specific gear parameters for bycatch reduction potential for the MATRT meetings. The regulations themselves address small and large mesh gillnet fisheries with specified parameters and do not exclude Virginia and Delaware.

Comment 40: One commenter recommended that NMFS reexamine the validity and accuracy of its bycatch estimates in the Mid-Atlantic in light of unlikely assumptions, incomplete observer coverage in the past and available information on bycatch levels for 1997. The commenter recommended that if bycatch estimates are determined to be higher than those assumed in the proposed measures, the proposed time/area closures should be expanded to account for additional bycatch.

Response: The final regulations cover nearly the entire time and areas where the 1997 takes occurred. The rule includes times and areas where the observer coverage in the past was low. Observer coverage will be provided in the Mid-Atlantic at appropriate levels to evaluate whether or not the plan is meeting its goals. After HPTRP implementation, bycatch estimates will be reviewed; if they are higher than expected, NMFS and the TRTs will need to discuss what further measures might be necessary.

Comments on Pingers: Specifications, Options, Implementation Issues

Comment 41: One commenter stated that pingers are not the only option in the Gulf of Maine. In the Mid-Atlantic, it has been proven that the use of heavier gauge monofilament prevents mammal takes in gillnets. Many fishermen in southern New England are already using heavier gauge twine. Those fishermen should have the same option as the Mid-Atlantic fishermen and NMFS should review the data and present them to the TRT.

Response: Data reviewed by the MATRT on harbor porpoise takes in gillnet sets using heavier gauge monofilament appear to show a difference in the level of harbor porpoise takes when compared to finer twine sizes in sets for monkfish and dogfish. Most of the observed sets evaluated in these data were from NJ south. Data has not been analyzed for these gear options in the Gulf of Maine and they were not considered as a bycatch reduction option by the GOMTRT. In addition, because of the level of data available, and the assumptions necessary to model these variables, NMFS does not want to expand this mitigation measure to a much larger geographic area. In addition, NMFS has developed these regional strategies based on TRT recommendations. The majority of the New England fishery is diverse and no correlations in the data for gear parameters were apparent to TRT members; consequently they chose to use a tested take reduction strategy, i.e., pingers. As with many fishery management measures, lines are drawn to identify where measures change. While it is true that fisheries adjacent to but divided by such a management line may show more similarity than with fisheries within their appropriate sector, the line chosen represents the point where an overall change in the fishery occurs.

Discussion in the MATRT with respect to pingers as a management option was rejected for some of the same reasons that gear modifications were not applied in the GOM. While pingers have shown success in experimentation, they have not been evaluated (''proven'') under widespread use. In addition, pingers are not passive and other environmental effects are yet to be evaluated. Harbor porpoise may also behave differently while in the southern portion of their range. With regard to experimentation with pingers, the character of the fishery is much different in the Mid-Atlantic, being more spread out than in the Gulf of Maine. Therefore, an experiment in the Mid-Atlantic would have to be of such magnitude that the cost and years of effort do not seem justified when other options (gear modifications) that have not been tested are available. Therefore, the precautionary approach justifies limiting these two strategies geographically until further data are available. In the future, based on the results of implementation of the HPTRP, NMFS will consider, in conjunction with the advice of the TRT, whether other strategies are viable for either the GOM or the Mid-Atlantic. NMFS will analyze available data from the southern New England area and provide that information for review at the next meeting of the TRT.

Comment 42: One commenter recommended that NMFS should require that vessels carry four spare pingers in the event that there is a pinger malfunction. NMFS' own observer data does not support that fishermen are diligently maintaining their pingers, but instead indicates that in actual use, pinger effectiveness levels are significantly less than those in controlled experiments.

Response: NMFS disagrees and maintains its position that both manufacturers and fishermen will be aware of the importance of technically correct and properly maintained pingers. This is one of the primary objectives of the pinger certification training and outreach program, which began in September 1998 and will continue, as needed, after implementation of the final rule. Under the HPTRP certification is mandatory, as was recommended by the GOMTRT, for the very reason of removing some of the uncertainty surrounding the results of the experimental fisheries. Since this type of outreach was not in place for the experimental fisheries, the results of future commercial use of pingers are expected to be more positive. In addition, the results of the Pacific TRP are now available, which show high effectiveness of pingers under commercial conditions; that plan also incorporated a strategy of mandatory skipper education workshops which is partially credited for the success.

Comment 43: One commenter objected to rigid specifications for pingers as proposed in the rule, because it limits future pinger development. The concerns about the frequency of 10 kHz are about limited availability from a single manufacturer and that the specified frequency is within seal hearing range and acts as a ''dinner bell'' for seals in the area of the gillnets. Concern was also expressed that the specified decibel range (132 dB) limits development of a stronger pinger that may require less pingers on the net which would decrease costs to fishermen.

Response: NMFS recognizes that the current specifications may limit somewhat technological development on pingers. However, the pinger specifications need to remain limited during the first year of plan implementation. The only pinger for which there is currently sufficient scientific documentation regarding effectiveness in the GOM for harbor porpoise is the one specified in this rule. The best approach at this time is to implement this plan with tested technology and then entertain ideas on improving that technology or investigating different options after the plan meets its initial goal.

Comment 44: One commenter recommended that NMFS evaluate the pinger (PDM[PICE]) which has been tested in Europe and possibly incorporate its specifications. Another commenter stated that although the European pinger may be technically superior to the Dukane unit its sonic profile is very different from that of the Dukane pinger and, as such, would not be approved under the specifications in the proposed rule. This commenter urged NMFS to approve the use of pingers with the sonic output specifications of the European unit. In addition, NMFS should undertake focused experiments to develop a range of approved sonic profiles.

Response: While NMFS agrees that eventually pinger specifications may need to be revised based on new technology, new pinger specifications are not incorporated into this final rule (see response to previous comment 43).

Comment 45: One commenter recommended that NMFS examine all experience to date in use of pingers by fishermen, adopt a more conservative approach to reflect uncertainties and reality, and after the first year of the HPTRP reexamine the assumed rate of effectiveness based on observed bycatch rates. Another commenter stated that bycatch and bycatch reductions should

be projected using a realistic estimate of pinger effectiveness by time and area, relying on NMFS data rather than an optimistic region-wide estimate of 80 percent effectiveness. These two commenters, in general, felt that pingers are projected to be more efficient in reducing bycatch than data can support.

Response: NMFS has examined all experience to date in the use of pingers by fishermen in the GOM. The results of the two scientific experiments conducted in the fall of 1994 and in spring of 1997 were between 80 percent to 100 percent effectiveness. NMFS data indicate that for experimental fisheries in some times and areas, pinger efficiency was greater than 80 percent while in other times and areas the efficiency was less than 80 percent. The EA details the specifics on each of the experiments and experimental fisheries. The spring 1997 experiment was conducted based on GOMTRT recommendations, primarily because of the discrepancy in the results of various experimental fisheries, in order to remove the uncertainty over the technology's effectiveness. The TRT recommended in both the draft GOMTRP (August 1996) and at the subsequent GOMTRT meeting in December, 1997, that in order to avoid any reduction in effectiveness during commercial fishing conditions, training of fishermen should be mandatory. Certification of fishermen is occurring and is expected to remove problems with improper use and maintenance that may have caused disparate results in the experimental fisheries. The data currently support the choice of an average region-wide 80 percent efficiency, based on controlled experimental results, but allowing for some discrepancy in levels of effectiveness under actual fishing conditions.

Comment 46: One commenter recommended that because bycatch estimates will go up if a more conservative pinger effectiveness estimate is used, and because NMFS has not fully accounted for effort displacement outside of time/area management zones, NMFS should adopt a blanket provision that requires all gillnets in New England be equipped with pingers except at those times when, and in those areas where, harbor porpoise are highly unlikely to occur (e.g., Massachusetts Bay or Cape Cod South from June 1 to Sept 15).

Response: NMFS agrees that inter-annual variability in both fishing effort and harbor porpoise distribution has been a problem for bycatch reduction strategies. However, NMFS has chosen its strategy (discrete areas of pinger use) with respect to pinger requirements for several reasons. Pingers have not been used in widespread application and a number of questions remain such as overall environmental effects and habituation and displacement of harbor porpoise or other species. The times and area are currently large enough to demonstrate, based on available data, that the plan will reach its goal without the additional burden on the fishery that such a blanket provision would entail. Should monitoring reveal that bycatch indeed shifts to areas outside the closures and should research provide answers to address these remaining questions, complete implementation of pingers in the fishery would be considered along with other options.

Comments on the Gulf of Maine Component—Proposed Schedule of Closures and Pinger Use

Comment 47: One commenter stated that in general, closures are insufficient in time and space.

Response: Detailed responses to comments on time/area closures are provided in later comment responses. The EA analyzes the current plan based on available data. NMFS has determined that the plan will reach MMPA goals.

Comment 48: One commenter stated that Framework 25 will provide greater harbor porpoise conservation than considered by NMFS. This includes the 12-month closure and the rolling closures.

Response: NMFS did evaluate the additional bycatch reduction that would be achieved by Framework 25 (see Table 4 in the final EA and text of the final EA) and concluded that Framework 25 measures amounted to about a 46 percent reduction in bycatch before accounting for bycatch reduction from MMPA harbor porpoise measures. This reduction was considered together with the HPTRP expected reductions to estimate the overall bycatch reduction based on data for 1996.

Comment 49: One commenter stated that NMFS has failed to analyze the benefits of a number of measures under Amendment 7. For example, NMFS failed to consider the benefits to harbor porpoise of the net restrictions under Amendment 7 and the limits on directed catches of cod which further reduce the number of nets deployed by the gillnet sector. The cod catch limit was further reduced in Framework 25 which has resulted in reduced number of nets deployed. Also the Days-At-Sea restrictions have taken a lot of effort out of the fishery. These and other fishery management measures have resulted in substantial reductions in gillnet fishing effort which translate into lower probability of harbor porpoise interactions.

Response: NMFS now has 1997 data available which indicate that these measures have had no effect on the total bycatch of harbor porpoise in the GOM, although the distribution of takes geographically has shown interannual variability.

Comment 50: One commenter stated that there is no consistency within the regulation or the explained rationale to support the differences in regulations among areas. For example, the Mid-Coast is closed for seven plus months except for pinger use and the Northeast is only closed for 28 days. They are geographically adjacent. The commenter also questioned why there is only a four month regulatory condition in the Massachusetts Bay area and stated that NMFS does not account for the seasonal variability in the areas occupied by transiting harbor porpoise and fails to recognize the value of dynamic management.

Response: The regulations were developed based on GOMTRT recommendations and existing data. The areas are not managed the same because harbor porpoise bycatch varies between areas. Therefore, different measures are appropriate for different areas and the GOMTRT agreed with this approach. The Massachusetts Bay closure is longer than four months; it has been extended in the final regulation to include the months of December and January. This change is discussed in detail under comment number 60. As discussed during the GOMTRT deliberations, the strategy of small discrete complete closures surrounded by longer time/area closures where pingers are required was developed to account for the inter-annual variability in distribution of harbor porpoise and changes in fishing effort.

Comment 51: One commenter noted with approval that take reduction goals for the Northeast and Mid-Coast areas are already being met by measures currently in place and that no further restrictions are being proposed.

Response: Bycatch reduction has occurred within discrete closure areas, but the data show that bycatch overall has remained the same, most likely due to shifted fishing effort and inter-annual variability in harbor porpoise distribution. Therefore, these areas need to continue to achieve the same amount of bycatch reduction and the bycatch that has shifted elsewhere must be dealt with through other bycatch reduction measures as provided in the regulations.

Comments on the Gulf of Maine Component—Area-Specific Measures

Comment 52: One commenter supported maintaining the closure of the Northeast area for August 15 through September 15, citing its effectiveness.

Response: NMFS agrees and the Northeast Closure will remain in effect.

Comment 53: Two commenters requested that the plan maintain the spring (March 25 through April 25) NEFMC harbor porpoise closure in the Mid-Coast area. In addition, the commenter recommended amending the HPTRP to include a time and area closure specifically to protect harbor porpoise in the Mid-Coast during May and June because the rolling closure would not be effective during those months for reducing harbor porpoise bycatch. Another commenter recommended a complete closure during March and April.

Response: The Mid-Coast area has historically had high fishing effort and high harbor porpoise bycatch. This area was one of the first areas affected by efforts of the NEFMC to reduce harbor porpoise bycatch as a result of the NE Multispecies FMP. However, the limited one-month closure March 25 through April 25 was ineffective at reducing bycatch overall because it simply shifted fishing effort to other months and areas outside the closure where bycatch increased. Fishermen from this area are to be commended on efforts to develop mitigation measures for harbor porpoise bycatch and have been instrumental in development and experimentation with pingers as a management option. In fact, bycatch overall in the Mid-Coast area has decreased since 1994. Pingers have shown a very high effectiveness rate in the Mid-Coast in scientific experiments in both spring (1997) and fall (1994), although experimental fisheries in spring have shown mixed success. Harbor porpoise distribution and abundance as well as fishing effort show inter-annual variability. However, because Framework 25 provides for periods of complete closures in portions of the Mid-Coast area in the months of April, May and June and with the addition of the extensive pinger requirements under the HPTRP, a complete closure of the entire area during March and April is not considered necessary. The overall HPTRP strategy for the GOM is a series of short, discrete, complete closures in combination with much larger time/area closures where pinger use would be allowed to account for the changes in harbor porpoise and fishing effort that may shift bycatch elsewhere. The strategy for the Mid-Coast, including requirements for pingers under the MMPA, and closures under the Magnuson-Stevens Act are expected to achieve adequate results without additional closures.

Comment 54: Many commenters recommended adopting Framework 25 closures as harbor porpoise closures under MMPA. One commenter specifically suggested that it was inappropriate to rely on NEFMC groundfish closures to provide harbor porpoise protection. If the NEFMC makes any shifts or lifts closures the resulting harbor porpoise bycatch reduction is lost. Consequently, these same closures should be adopted under the MMPA regulations.

Response: NMFS recognizes its responsibility to protect harbor porpoise, but disagrees that these efforts need to be restricted to MMPA regulations if measures in effect under other statutes will help to achieve that goal. The NEFMC has as a stated objective in the NE multispecies FMP under Magnuson-Stevens Act that it must reduce the bycatch of harbor porpoise in this fishery and as such are also mandated to achieve bycatch reduction in this fishery. Adding additional closures in the Mid-Coast area on top of the Framework 25 Multispecies closures would create an undue burden on one segment of the fishery when the bycatch reduction for the plan overall meets MMPA objectives without such an action.

Comment 55: One commenter recommended closure of the entire Mid-Coast area (including Inshore areas II, III, IV under Framework 25) from March 25 through May 31. This commenter suggested that fishermen will just move from Area III to Area II, for example, and there would consequently be no net bycatch reduction.

Response: As noted above, the overall HPTRP strategy for the GOM is a series of short, discrete, complete closures in combination with much larger time/area closures where pinger use would be allowed. This is specifically to compensate for the inter-annual variability of both harbor porpoise and fishing effort that may shift bycatch elsewhere. Simply closing the entire Mid-Coast area from March 25 through May 31 would have the same inherent problems as the closures that have been in place under the Magnuson-Stevens Act for several years. Fishing effort would likely concentrate in January through March 24 or move just outside the Mid-Coast boundaries or into the Offshore area. NMFS disagrees that no net bycatch reduction will result from the proposed strategy because pingers are required in all of the months not covered by closure under Framework 25 surrounding the Area II, III, and IV closure months. Pingers were accepted by the GOMTRT as a viable bycatch reduction management alternative to time/area closures.

Closing the entire Mid-coast area would have an economic impact to the gillnet fleet would be $170,000 dollars in foregone revenue and it would impact 26 vessels. This is in addition to those costs already estimated for the Mid-Coast area. Given the extensive pinger requirement and a series of closures of Inshore Areas I through IV in Framework 25, a March 25 through May 31 closure is unwarranted.

Comment 56: Many commenters recommended extending the Mid-Coast Closure Area to include closure of Areas II and III for the months of April and May.

Response: See response to comment 53. This closure would cost the fleet $116 thousand dollars in foregone revenue and would affect 23 vessels. The overall plan is expected to reach MMPA goals without additional complete closures that exact such a cost to the fleet. NMFS has concluded that such a closure is currently unjustified.

Comment 57: One commenter recommended that the Mid-Coast be closed from September 15 through March 25 except for vessels using pingers.

Response: The Mid-Coast is closed in the final rule to vessels except those fishing with pingers from September 15 through May 31.

Comment 58: One commenter noted that the GOMTRT agreed there was a need to extend the boundary of Mid-Coast to the south to include a portion of Massachusetts Bay in the Mid-Coast closure area because of displacement.

Response: NMFS agrees that the GOMTRT discussed the need for dealing with the displaced fishing effort during the Mid-Coast closure period, March 25 through April 25, which in past years appears to have partially shifted into northern Massachusetts Bay. The final HPTRP extended the closure period in Massachusetts Bay when pingers are required to include the months of December through May. The HPTRP is based on a overall bycatch reduction scenario that is intended to spread the bycatch reduction effort throughout the fishery where bycatch occurs. This means that a bycatch reduction measure is in place (although not a complete closure) during the time period effort shifts might occur. Additionally Framework 25 closes the area from March 1 through March 31, the period

previously closed for harbor porpoise protection under the Magnuson-Stevens Act. Allowing the use of pingers in the Mid-Coast, instead of prohibiting them from the area, allows fishermen to fish, making it less attractive and/or necessary to travel to the southern border to escape the closure. Therefore, the need to address bycatch in the northern portion of Massachusetts Bay is covered as part of the overall HPTRP strategy.

Comment 59: One commenter noted that the current proposal was beyond GOMTRT consensus and reasonable justification for pinger use in the Mid-Coast area. Instead, the commenter recommended pingers be required March 25 through April 25, October 1 through December 31, and that no complete closures be included.

Response: NMFS agrees that these measures are beyond the GOMTRT's recommended consensus plan as submitted in August, 1996. However, these measures were based, in part, on the recommendations of GOMTRT members at an additional meeting that was held in 1997. Since the GOMTRT's proposed plan was very similar to the closures in effect under the Magnuson-Stevens Act, both NMFS and many GOMTRT members concluded that the plan as originally proposed would not bring bycatch to below PBR as required by the MMPA. Therefore, more expansive measures were required. Because the Mid-Coast area has historically had high bycatch, a short closure both geographically and temporally that allowed pingers would provide limited bycatch reduction. Particularly, since pinger use has been more widespread in the Mid-Coast, NMFS agrees that bycatch has decreased. This further supports the requirement for continued closure with pingers in such a high bycatch area.

Comment 60: One commenter suggested that the months of December and January be added to the time period when pingers are required in Massachusetts Bay.

Response: NMFS agrees that adding the months of December and January to the Massachusetts Bay closure would provide additional bycatch reduction. Both the first proposed rule (August 13, 1997) and the December 16–17, 1997 GOMTRT meeting recommended that Massachusetts Bay be closed from February through May. Since the HPTRP relies on each of its components working together collectively to reach MMPA goals, it is possible to shift some of the time/area measures where data are less consistent and still meet the overall objectives. NMFS therefore decided to add the months of December and January to Massachusetts Bay which creates little additional burden on the fishermen who already have to purchase pingers.

Comment 61: One commenter agreed with the March closure and recommended that pingers be expanded to October through January in addition to the proposed time period of February through May. Table 4 in the draft EA shows that the bycatch reduction appears to be calculated based on the use of pingers in Massachusetts Bay in the Fall, yet the plan does not stipulate their use during those months.

Response: The shaded areas in Table 4 of the draft EA represent areas where pingers could be applied because they are areas that do not represent complete closures under the Magnuson-Stevens Act; they were selectively included in the calculations.

Bycatch has been high in the fall in Massachusetts Bay in previous years, but in more recent years (1996, 1997) bycatch has decreased significantly during that period. This final rule has extended the Massachusetts Bay pinger closure two months earlier than recommended by the GOMTRT and the proposed rule to include both January and December; this will gain further bycatch reduction in this area and will deflect some of the observed shifts in effort out of the Mid-Coast into the northern portion of Massachusetts Bay. Adding the months of December and January was recommended by another commenter. Since bycatch in the most recent years in October and November has decreased, which may be a result of decreased Days-At-Sea available to fishermen from fishery management measures, or to pinger use in the Mid-Coast which prevented some shifting of effort south into Massachusetts Bay, extending the requirement further into the fall is unwarranted at this time given the measures in the overall HPTRP.

Comment 62: One commenter recommended closing the area south of Cape Cod during May except to pingers, noting that bycatch was high in 1994 in this area and that it was recommended by the GOMTRT in December, 1997. This commenter also supported the March 1 through 31 closure and the September 15 through February and February through April pinger requirement.

Response: NMFS agrees with extending the spring pinger requirement into May. The recommended closure in the proposed rule addressed concern by the GOMTRT that observer coverage has been low in the Cape Cod South area. However, since zero takes have been observed in the September though November time period and additional bycatch reduction is expected in May, this will more than offset the fall period. Therefore in the final rule NMFS has changed the closure period in Cape Cod South to December through May.

Comment 63: One commenter requested that by June, 1999, NMFS analyze use of larger twine and other gear characteristics as a mechanism for reducing bycatch in the Cape Cod South area. Based on current information, this commenter recommended that pingers be required for December 1 through the end of February, instead of September 15 through April 30.

Response: NMFS agrees that gear characteristics should be analyzed for the Cape Cod South area and will provide that information when the GOMTRT meets in mid-1999. NMFS agrees that the start of the fall pinger requirement should be December 1, but disagrees that it should not be extended past February.

Comment 64: Many commenters recommended that the closure of Cape Cod South be expanded to include at least two weeks at the end of February and two weeks at the beginning of April, based on historically high bycatch during these periods. One commenter noted that under the current plan, fishing will be allowed without use of pingers during May, a month of high mortality in 1994. This block appears to be shaded in Table 4 of the draft EA, yet pingers are not stipulated in this area during May. This one commenter further recommended that fishing should only be permitted in May with use of pingers.

Response: See response to comment 61 with respect to shading in Table 4 of the draft EA. NMFS agrees that pingers should be used in May in Cape Cod South. NMFS also agrees that bycatch has historically been high between February and April. However, the one-month closure in March, surrounded by a closure where pingers are required (December through May) is consistent with the basic strategy of the overall plan, a complete closure surrounded by a much larger time when pingers are required. Additionally, such a closure would cost the fleet $53 thousand dollars in foregone revenue and affect 23 vessels. For all of these reasons a larger complete closure is not justified at this time.

Comment 65: One commenter recommended requiring pinger use in the entire Offshore area during the month of February instead of complete closure in February in Cashes Ledge and required pinger use for the rest of the Offshore area from September 15 through December 31. This would

eliminate the February gear closure of Cashes Ledge.

Response: NMFS disagrees with allowing pingers during February in Cashes Ledge and with shortening the pinger use period to the fall only. Bycatch has been observed in both November and in February and is estimated at 45 and 258 animals respectively (1996). Therefore, to make management of this area consistent with the other areas in the HPTRP, a one-month closure surrounded by a period of pinger use during times when bycatch is expected is the most appropriate response. This means retaining the closure in February in Cashes Ledge and extending pinger use in the Offshore area November through March. Even though NMFS agrees that pingers are effective, they are not 100 percent effective. This is the reason why the strategy for the overall HPTRP remains a combination of complete closure and pinger use.

Comment 66: One commenter recommends that additional observer coverage was needed in the Offshore area to see if a closure in the month of November should be added to allow for additional bycatch reduction.

Response: See response to comment number 65. Observer coverage of this area will continue.

Comment 67: One commenter noted that there was never a recommendation for a closure in the Offshore area during the December 1997 meeting, nor did it recommend an expanded area of pinger use of the magnitude proposed. The commenter asked NMFS to justify the Offshore closure area and expanded pinger use.

Response: NMFS agrees that the GOMTRT did not recommend a complete closure in this area. However, NMFS disagrees with the second claim; the GOMTRT members present at the December 16–17, 1997 meeting did recommend expanding areas where pingers are required. Specifically, their recommendation was for NMFS to look at the bycatch data and consider closing statistical areas ''515, 522 and maybe 521'' and require pingers in that area. The Offshore Closure Area defined in the regulations is only part of area 515 and the very northernmost section of areas 521 and 522 and encompasses the area where takes have been observed.

Comment 68: One commenter stated that the current Offshore recommendation is excessive since it is based on short time frame of data and observer coverage. The commenter recommended that Cashes Ledge be closed for the month of February unless vessels have pingers but that the expanded Offshore area should be suspended until more information is gathered.

Response: NMFS agrees that data is limited in the Offshore area, but limiting the closure to a small area for short duration has all the inherent problems that have already proven this strategy to be ineffective. In addition, there have been observed takes in other months including November in 1996 and January and May in 1997. Therefore, the proposed strategy is similar to the strategy employed in the other areas of observed bycatch in the GOM, a one month closure followed by a more extensive closure with pingers allowed. However, consistent with other minor changes to the time/area closures in the proposed rule in the fall already discussed (Cape Cod South, Massachusetts Bay), the start of the closure in the Offshore area has been delayed to November 1 in the final rule.

Comment 69: One commenter noted that the proposed closure of Cashes Ledge would affect four Maine offshore gillnet vessels that often make a few sets in this area on their way to George's Bank. However the commenter was more concerned with vessels from ports in the Mid-Coast area which do fish this area regularly. The commenter noted that the Mid-Coast area had already met or exceeded its take reduction goals. This commenter recommended that rather than closing the Cashes Ledge area in February, NMFS should leave it open to vessels with pingers and that additional reductions should come from areas which have not yet achieved the results that the Mid-Coast has, like Massachusetts Bay and South Cape Cod.

Response: NMFS agrees with the characterization of fishing in the Offshore area, but disagrees that bycatch does not need to be reduced in the Offshore area. The Mid-Coast area never had take reduction goals separate from an overall HPTRP, with the exception of goals stated in the NE Multispecies FMP, goals which have not yet been met. As stated earlier, Mid-Coast fishermen are to be commended for the innovative and expansive efforts they have undertaken to make pingers a viable bycatch reduction alternative to complete closures during some times and areas. However, the reason that the NEFMC measures have not been effective at reducing bycatch overall is that bycatch shifted out of the closed areas into new areas. Increases have been seen in several areas including Massachusetts Bay, Cape Cod South and the Offshore area. Achieving the MMPA goal will not be easy, but most certainly, the overall level of bycatch in the GOM must be reduced. It would be counter productive to allow reduction in one area to be replaced with bycatch occurring elsewhere, i.e. if you reduce the amount of harbor porpoise take in the Mid-Coast by 100, but then increase it by 100 in the Offshore area, you have a net gain of no bycatch reduction. Therefore, all areas where bycatch has historically occurred in the GOM must be part of this HPTRP. NMFS agrees that further reductions are necessary in areas other than the Offshore area; the plan does contain measures beyond the status quo to reduce observed bycatch in the Cape Cod South area and the Massachusetts Bay area.

Comment 70: One commenter stated that the importance of and difficulties in enforcement have been overlooked based on comments by NMFS and the Coast Guard. Specifically, neither enforcement body can determine whether pingers are operational. The U.S. Coast Guard has also stated that anything short of complete closures are difficult to enforce. The commenter concluded that effective mortality reduction is most likely to be achieved by closures, not by use of pingers.

Response: NMFS agrees that currently neither NMFS or the U.S. Coast Guard can determine whether or not pingers are working on deployed fishing gear. A hydrophone has been developed that can be used as an enforcement tool to determine whether or not pingers are working. The hydrophone can be towed to evaluate set gear. This will be made available to U.S. Coast Guard and NMFS Enforcement personnel. NMFS also agrees that anything short of complete closures is difficult to enforce, but not impossible.

NMFS disagrees that the closures are more likely to achieve effective mortality reduction. In fact, the closures that have been in effect under the Magnuson-Stevens Act have been ineffective primarily because of the inter-annual variability in harbor porpoise distribution and fishing effort shifts. In order for closures to be effective and to avoid these phenomena, closures would have to be so large that the impact on the fishery would be very disruptive. Such widespread closures are evaluated as an alternative in the EA, which should be consulted for the specific information. Pingers have been demonstrated to be effective, and NMFS has concluded that they are a better alternative for achieving effective mortality reduction while allowing the fishery to continue.

Comments on the Overall Mid-Atlantic Strategy

Comment 71: One commenter asked how the new expanded closures affect the harbor porpoise bycatch estimate

given that the MATRT proposal was expected to achieve a 79 percent reduction in harbor porpoise bycatch?

Response: If all assumptions of the statistical models are correct, the additional closures would likely achieve between 88 percent—99 percent reduction in takes over the entire area for all months. However, it is unlikely that all the assumptions used in the data analysis will be proven 100 percent accurate; therefore, the additional measures will help to ensure that the 79 percent reduction in harbor porpoise take is achieved. The reason the assumptions are unlikely to be 100 percent accurate appear to be borne out in the 1997 data. In that year harbor porpoise were taken in the menhaden fishery, countering the assumption that the only subfisheries that catch harbor porpoise are the monkfish and dogfish subfisheries (Palka, 1997).

Comment 72: One commenter stated that the changes from fishery-specific strategies to specific gear type strategies appear largely consistent with the MATRT proposal.

Response: NMFS agrees.

Comment 73: One commenter requested that the gillnet cap of 80 nets and tagging requirements of 2 tags per net be changed to a 160-net-cap and a 1 tag per net requirement to be consistent with the proposed Monkfish FMP requirements.

Response: NMFS disagrees with changing the 80-net-cap limit, as proposed in the HPTRP, to a net cap of 160 nets to be consistent with the proposed Monkfish FMP. The 160 net cap set by the Monkfish FMP is too high to achieve the goal of maintaining current fishing effort in the Mid-Atlantic that has historically been associated with locally prevailing practices. NMFS has followed the recommendation of the MATRT to support locally prevailing fishing practices and an 80 net cap limit reflects those practices. The average large mesh fisherman in the Mid-Atlantic employs 80 nets, therefore this average was agreed to be an appropriate limit to cap effort. By allowing 160 nets, the positive benefits expected from the HPTRP measures could be negated. Anyone wishing to fish in the Mid-Atlantic during these time periods can only have a total of 80 nets on board, hauled, or deployed. NMFS agrees with the recommendation to change the net tag requirement to one tag per net, beginning January 1, 2000, to be consistent with the net tag requirement under the Monkfish FMP. This change should not affect NMFS' ability to enforce the HPTRP measures.

Comment 74: Several commenters felt that the requirement for a twine size greater than or equal to .81 mm is unfair and uncalled for in those fisheries targeting bluefish, croaker, weakfish (i.e., some of the very small mesh fisheries) which have not been observed to take harbor porpoise. They felt that the MATRT, including NMFS, agreed that there was not enough data to support any restrictions to the small mesh fishery.

Response: NMFS did not restrict fisheries with mesh sizes 4 inches (10.2 cm) and smaller with regard to twine size regulations in the proposed HPTRP.

Based on further review and public comment, mesh sizes of 5 inches (12.7 cm) and smaller are not required to comply with the small mesh regulations at this time.

Comment 75: Two commenters questioned how the proposed rule applies to all fishing with gillnets in inshore and offshore waters of the Mid-Atlantic despite the fact that North Carolina gillnet fisheries targeting bluefish, croaker, and weakfish, have little or no interactions with harbor porpoise.

Response: NMFS agrees there were no documented observed takes with very small mesh gear in North Carolina. However, there were takes in North Carolina waters. Harbor porpoise stranding data, discussed by the MATRT but not considered part of the MATRT process for management measures, suggests that very small mesh fisheries, and fisheries in nearshore as well as offshore waters, may indeed take harbor porpoise. However, NMFS is exempting the gear that is less than 5 inches (12.7 cm) mesh size from the regulatory measures at this time. The definition of the small mesh gear that must comply with the management measures has been changed. Only mesh sizes of greater than 5 inches (12.7 cm) to less than 7 inches (17.78 cm) must comply with the small mesh management measures.

Comment 76: One commenter felt that the small mesh fishery in North Carolina should be classified as a Category III fishery. If not designated as Category III, then they felt that the restrictions on small mesh should only apply north of the North Carolina/Virginia border and not include North Carolina waters. If small mesh restrictions were to be implemented for North Carolina waters, those restrictions should absolutely not apply south of Cape Hatteras.

Response: Until NMFS gets additional information, the small mesh fishery is still categorized as part of the Mid-Atlantic coastal gillnet fishery. As discussed in the Final List of Fisheries for 1998 (63 FR 5748), the information currently available on the composition and distribution of the Mid-Atlantic coastal gillnet fishery and on its incidental take levels is insufficient to identify distinct subcomponents of this fishery. NMFS has allocated funding in 1998 to expand its observer coverage of this fishery and to obtain a better characterization of the individual subcomponents that comprise it.

Regarding the geographic application of the small mesh measures to North Carolina waters, the final rule will continue to apply to all waters off North Carolina, including waters south of Cape Hatteras to the South Carolina border. The geographic application of the HPTRP is consistent with the MATRT report (RESOLVE, 1997). Additionally, although there were takes in North Carolina waters with large mesh gear but no documented observed takes with small mesh gear, this does not preclude the likelihood that takes may occur in North Carolina waters in small mesh gear (see response to comment 38).

Comment 77: One commenter felt that the statement on page 48678 of the proposed rule distorts the consensus agreement of the MATRT because there was never an assumption that the only subfisheries that could potentially ever catch harbor porpoise are dogfish and monkfish.

Response: NMFS did not intend to distort the consensus agreement of the MATRT. The assumption that harbor porpoise are only caught in dogfish and monkfish fisheries was discussed at the MATRT meetings and is outlined in the paper by Palka (handout at the August 4–6 meeting of the MATRT, Page 8) and used in the statistical analysis presented at the MATRT. Because of the nature of the assumptions in that analysis, discussed in detail in the EA/HPTRP, NMFS felt additional regulatory measures were appropriate.

Comment 78: Several commenters were concerned that NMFS had not considered the difficulty for small mesh fishermen in ordering and rigging the new gear. Mesh sizes used to target weakfish and croaker are normally not stocked by local net shops in .81 twine size. The time to order, receive and hang webbing would be as long as six months. Fishermen need 180 days advanced public notice or fishermen would lose out on whole season. So .81 mm should only apply to gill nets greater than 5 inches (12.7 cm) and less than 7 inches (17.78 cm) stretched mesh.

Response: In the final rule, NMFS changed the requirements for the small mesh fisheries so that the requirements apply only to mesh sizes of greater than

5 inches (12.7 cm) to less than 7 inches (17.78 cm). Fisheries which use greater than 5 inches (12.7 cm) to less than 7 inch (17.78 cm) mesh sizes should be able to buy the gear and re-rig in the allotted time. Southern Mid-Atlantic fishermen would have more time to buy and re-rig because measures do not go into effect in the southern Mid-Atlantic until February 1, 1999.

Comments on the Mid-Atlantic Area and Gear Specific Measures

Comment 79: One commenter asked why NMFS expanded the closure in the Mudhole from February 15 through March 15, as recommended by the MATRT, to an additional closure from April 1 through April 20.

Response: The HPTRP calls for closures in the Mudhole from February 15 through March 15 for small mesh and large mesh gear, and April 1 through April 20 for large mesh gear. This differs from the MATRT report, which only recommended closures in the Mudhole from February 15 through March 15 for monkfish (large mesh). NMFS added a closure to New Jersey for large mesh gear in April. Given the considerable assumptions inherent in the subfishery bycatch analysis, NMFS determined that additional regulatory measures would be prudent to realistically achieve the bycatch reduction goals of the HPTRP. For New Jersey, January and April are the months of highest bycatch. Since a closure in January would be very costly for the fishermen, as discussed by the MATRT, NMFS chose to limit fishing opportunity in April instead of January. A closure in April would still afford significant harbor porpoise conservation benefits, still be consistent with the proposed Monkfish FMP regulations and not cause undue impact on fishermen. The Mudhole is part of New Jersey waters.

Comment 80: One commenter asked that NMFS explain the reason for expansions of the original 20-day monkfish closure for the southern Mid-Atlantic, as proposed by the MATRT, to a one month closure for large mesh fishery.

Response: The MATRT recommended a 20-day floating closure in the southern Mid-Atlantic, sometime between February and April, for the monkfish (i.e., large mesh) fishery. The exact 20 days would be chosen by the individual fishermen. This proposal was changed by NMFS in two ways: (1) The proposal for a floating closure was rejected in favor of a fixed closure and (2) the 20-day closure was expanded by 10 days to a full one month closure.

NMFS changed the floating closure because an FMP and associated permit system will not be in place for the spring 1999 fishery, thereby making it extremely difficult to enforce and administer a call-in system for this fishery. Therefore, a set period for the closure was favored.

The 20-day closure recommended by the MATRT was expanded to 30 days as a way to more strongly address the harbor porpoise bycatch in the southern Mid-Atlantic during this time period by avoiding a 10-day window of possible fishing effort displacement.

Comment 81: One commenter proposed that NMFS move the southern border of the area defined as the Mudhole to 39°50′ N. Latitude, instead of 40°05′ N. Latitude, to include documented take of harbor porpoise.

Response: NMFS disagrees that any changes are needed in the Mudhole definition at this time. The definition of the Mudhole is based on topographic features that support concentrations of target fish species at certain times of the year. Since the majority of takes that occur just south of the Mudhole occur in April in the large mesh fishery, this area has been included in the closure from April 1 through 20 for large mesh gear only. During February, another time of high bycatch inside the Mudhole for both large and small mesh gear, the Mudhole will be closed to both small and large mesh gear. There is little bycatch of harbor porpoise outside the boundaries of the Mudhole, in the rest of New Jersey, during February and March. It is possible that effort could shift outside the Mudhole boundaries during this time period, but gear modifications will be in effect for all areas in New Jersey outside of the Mudhole. This means that a bycatch reduction measure, although it is not a complete closure, is in place for the area outside the Mudhole closure. This is consistent with the overall HPTRP strategy.

Comment 82: One commenter questioned the conclusion that the entire state of North Carolina should have a time/area closure. The commenter noted that 250 observer trips on North Carolina boats between 1993 and 1997 using small mesh gear with no reports of harbor porpoise takes and 95 trips with North Carolina Division of Marine Fisheries on striped bass, and 30 more in 1991 on weakfish and no harbor porpoise takes. The commenter objected to the changes in closures for North Carolina for the following reasons: there is no documented bycatch of harbor porpoise in small mesh, the take of 5 harbor porpoise in monkfish and dogfish does not equal high harbor porpoise bycatch, the proposed closure is 50 percent longer than what was recommended by MATRT, the monkfish fishery will no longer exist off North Carolina, and no observer data for areas south of Ocracoke, North Carolina. The commenter then concluded that for all those reasons, time/area closures should not apply to waters south of the North Carolina/Virginia border. The definition of southern Mid-Atlantic includes the North Carolina/South Carolina border, but the commenter recommended that under no circumstances should south of Cape Hatteras be closed to small mesh gillnets. Several commenters noted that observer data does not justify extending small mesh restrictions to the North Carolina/South Carolina border.

Response: The time/area closure applies to the large mesh fishery for one month in the southern Mid-Atlantic. Between 1995 and 1996 there were 89 takes in North Carolina in the large mesh fishery, warranting the need for a closure during times of high bycatch. The small mesh fishery is closed for one month in the New Jersey Mudhole, but not in the southern Mid-Atlantic.

Although 5 observed takes does not appear to equal a high harbor porpoise bycatch, when estimated for the entire fishery it does appear to be a significant number of takes, resulting in an estimated take of 132 for the North Carolina fishery in 1996.

The proposed large mesh closure is 10 days longer than what was recommended by the MATRT as explained in response to comment number 80.

Although monkfish may not be able to be legally fished off North Carolina in the future, the mesh size (i.e, greater than 7 inch (17.78 cm) mesh) may be used to fish for other species. As mentioned previously, it is the type of gear and not the target species that is of concern to harbor porpoise bycatch reduction.

There are observer data south of Ocracoke, in fact, observer data span the entire North Carolina coast. NMFS agrees that observer data through 1996 shows that there are no observed takes from January through April south of Cape Hatteras. However, this is the boundary that was agreed to by the MATRT and is documented in the MATRT report. Additionally, even though stranding data were not used in developing the plan, stranding data do indicate that there is a gillnet fishery interaction problem south of Cape Hatteras. Primarily because it was a MATRT recommendation, NMFS is retaining the boundary of the plan at the North Carolina/South Carolina boundary.

Comment 83: One commenter supported a 30-day closure from mid-

February through mid-March rather than allowing individual fishermen to determine the 30-day block.

Response: The final rule implements the 30-day closure from mid-February to mid-March.

Comment 84: One commenter noted that the MATRT was generally supportive of a pinger study in the Mid-Atlantic. If pingers are effective in New England, they should also be effective in the Mid-Atlantic. The commenter questioned why NMFS is only proposing time/area closures and gear modifications and not supporting a pinger study in the Mid-Atlantic. Several commenters stated that the industry has indicated support for experimental pinger studies, and questioned why NMFS suggests only time/area closures to achieve goals and recommended that Mid-Atlantic fishermen should be given the option of choosing between gear modifications and time/area closures and participating in experimental fisheries using pingers. Two commenters stated that no consensus was reached in the MATRT because of the unjustified objections of one scientist/advocate and a small number of conservation members.

Response: See response to comment 41 for a discussion of why pingers were not chosen as an alternative in the Mid-Atlantic. NMFS agrees that the industry indicated support for a pinger study in the Mid-Atlantic but disagrees that objections were of lesser magnitude or lesser justification. Both points of view were strongly supported by respective advocates.

Comment 85: One comment supported the determination not to use pingers in the Mid-Atlantic.

Response: This component of the plan differs from the GOM component because rather than using a series of time and areas closed to fishing and times and areas where acoustic deterrents are required, the Mid-Atlantic portion requires a suite of gear modifications. The distinction in management measures between the two regions is appropriate in this case for a number of reasons. The regions differ markedly in stages of development with regard to harbor porpoise conservation. Whereas the GOMTRT and similar groups have been meeting and proposing various bycatch reduction measures for the GOM for many years, the MATRT has only met in the last two years. The GOMTRT proposed a number of measures initially which did not include mandated pinger use prior to the current recommendation. Based on new information, those measures were determined to be unsuccessful in achieving the PBR level. With regard to the use of pingers as an appropriate management measure in the GOM, no data exist to support other options, except for total closure to sink gillnet fishing. In the Mid-Atlantic, data indicated other options in the form of gear modifications might be successful in reducing bycatch without some of the uncertainties surrounding widespread pinger use.

For the Mid-Atlantic area, the HPTRP would institute the first set of management measures to reduce harbor porpoise bycatch in that region. Since a number of options are available which may be successful, NMFS would implement non-acoustic measures before proposing pinger testing. Additionally, the MATRT did not fully support a pinger experiment in the Mid-Atlantic area at this time. The gear modifications and time/area closures recommended by the MATRT and included in this final rule are expected to be sufficient.

Comment 86: One commenter questioned the justification for the prohibition of tie downs in the small mesh gillnet fisheries for the sole purpose of avoiding the potential for effort shifts (i.e., into the monkfish fishery). The commenter stated that this is inconsistent with NMFS' stated intent to avoid subfishery-specific regulations, it is a regional council issue, and it is non-substantive since inshore gillnet fishermen do not tie down their nets because that would decrease harvest efficiency. Another commenter argued that given the monkfish and dogfish proposed management measures under the FMPs, it is highly unlikely that individual fishermen will try to circumvent the monkfish regulations and land monkfish through tieing down their nets.

Response: It is difficult to speculate what fishermen will do. While it is true that this overall plan is meant to avoid the sub-fishery specific regulations and while the potential for effort shifts is speculative, removing this uncertainty is important to this HPTRP being able to reach its goals. It is unclear why the prohibition would be a problem to fishermen since the commenter states that inshore fishermen do not tie-down their nets for any other reason.

Comment 87: One commenter noted that the proposed rule responded to their comment addressing concern over the boundary line between the GOM and Mid-Atlantic, but they were still not satisfied with where the line was drawn. The recommendation is to use the boundary between the New England and Mid-Atlantic FMCs as specified in the Magnuson-Stevens Act, with the exception of the GOM closed area south of Cape Cod that is slightly west of the two Councils. Further the commenter recommended that vessels employing small mesh less than 5 inches (12.7 cm) should not be subject to twine size modification requirements and noted that all small mesh less than 7 inches (17.78 cm) will still have to comply with the closure in the New Jersey Mudhole from February 15 through March 15 and other requirements.

Response: NMFS maintains the position as stated in the proposed rule, that the line used to separate the two plans indicates the area where the characteristics of the fisheries on either side of that line diverge; it is a line already familiar to fishermen because it is used for fishery management purposes, and is overall a more appropriate boundary than a purely administrative boundary.

NMFS has changed the requirements for the small mesh fishery. Mesh sizes of 5 inches (12.7 cm) and less will not have to comply with the management measures at this time.

Comment 88: One commenter stated that NMFS should commit to providing observer coverage to small mesh fishery because data are lacking.

Response: NMFS has already provided observer coverage during 1998 to the Mid-Atlantic small mesh fishery and plans to continue such coverage in the future.

Comments on Enforcement

Comment 89: One commenter stated that enforcement of fishing in closed areas or fishing without pingers must be enforced.

Response: NMFS agrees and is currently investigating information concerning noncompliance.

Comment 90: Two commenters suggested that NMFS can address the difficulty in inspecting pingers by requiring that working pingers be on all nets at all times, except for the summer months when porpoise are not interacting with the fishery. This may also facilitate dockside inspection and remove some of the enforcement concerns.

Response: NMFS is addressing the difficulty in inspecting pingers by developing an enforcement hydrophone. NMFS is not proposing deployment of pingers on every gillnet in the Gulf of Maine during the time harbor porpoise are interacting with the fishery for several reasons. First, the overall environmental effects of widespread pinger use cannot be predicted with current information and research is just beginning at this point. Habituation and displacement of harbor porpoise and questions of pingers attracting seals are

still being evaluated. Second, the plan appears to be able to reach its bycatch reduction goal by a more limited approach. Requiring pingers on every net would increase the economic burden to fishermen, when a more limited version that will achieve plan goals is available.

Comment 91: One commenter recommended that NMFS expand the HPTRP and the EA to provide a thorough description of the steps that could be taken to ensure that pingers are properly deployed and maintained.

Response: The HPTRP requires fishermen to attend a certification program in order to fish with pingers in areas that otherwise are closed by the HPTRP. In addition, outreach and education will be ongoing during plan implementation and will include information on proper deployment and maintenance of pingers.

Comment 92: One commenter recommended that NMFS provide regulatory guidance as to how NMFS intends to certify and enforce proposed pinger parameters.

Response: The regulations include specifications for pingers that are required to be used in the NE multispecies gillnet fishery. All pingers used in this fishery must meet those specifications. Pinger manufacturers would need to provide documentation to consumers that their pingers meet the specifications of these regulations. NMFS is not requiring that these manufacturers have their pingers certified by an independent company to ensure that they meet the specifications. NMFS will be periodically monitoring whether the pingers used by the fishery meet the specifications.

Because the harbor porpoise bycatch rate will be carefully monitored, NMFS expects that both manufacturers and fishermen will be aware of the importance of technically correct and properly maintained pingers. If bycatch goals are not achieved because of improper pinger use or non-effective acoustics, more restrictive measures to reduce bycatch may be warranted. Additionally, a specific research program begins with rule implementation that will monitor pingers during normal use to ensure that the acoustics of pingers do not change with time, and that they maintain the acoustical characteristics specified by the manufacturer.

Comment 93: Two commenters felt that rather than focusing on subfisheries according to the MATRT recommendations, NMFS has extended the regulations to all gillnet activity because of enforcement concerns. One commenter suggested that the basis for NMFS differing with the MATRT's ''solution'' was that NMFS does not have enough manpower to enforce the regulations. Those fisheries without interaction should not be penalized for NMFS' lack of enforcement staff.

Response: Enforcement of regulations is a valid concern but the enforcement issues with regard to the HPTRP are not just a matter of adequate staff. A regulation must be legally as well as administratively enforceable. For example, a call-in system, which was recommended by the MATRT, is very difficult to enforce because there is no defined monkfish fishery or dogfish fishery at this time, so no one is legally defined as a monkfisherman or a dogfisherman. To do so under this rule, being promulgated under the MMPA, would go well beyond the scope of this plan. NMFS did not contemplate instituting a permit system of the dogfish and monkfish fisheries pending the development of permit systems under the Magnuson-Stevens Act system. Without a permit system, a fisherman can say they are targeting any number of species and still use the same gear that will take harbor porpoise. NMFS' intent in this HPTRP is to avoid the opportunity to take harbor porpoise because of the gear employed.

Classification

The Assistant Administrator, NMFS, determined that the TRP is necessary for the conservation of harbor porpoise and is consistent with the MMPA and other laws.

This rule has been determined to be significant for purposes of E.O. 12866.

NMFS prepared an FRFA that describes the impact of this rule on small entities. The need for, and objectives of this rule and a summary of the significant issues are described elsewhere in this preamble. Comments on the economic aspects of the proposed rule (comments 55, 56, 64) and NMFS' responses to those comments stated in the preamble to the final rule are incorporated in the FRFA. The GOM sink gillnet and Mid-Atlantic coastal gillnet fisheries are directly affected by the action and are composed primarily of small business entities.

In formulating this action, NMFS considered a number of alternatives: Alternative 1, the proposed action or Preferred Alternative; Alternative 2, no action; Alternative 3, wide-spread use of pingers; and Alternative 4, wide-spread time and area closures. In addition, a number of alternatives suggested in the comments were also considered. These alternatives were discussed in comments 19, 20, 21, 22, 23 and 41 above.

Alternative 1, a combination of area closures, pinger requirements, and gear modifications, is the preferred alternative because it will achieve the goals of the MMPA while minimizing the overall economic impact to the affected fisheries.

Under Alternative 1, it is estimated that 95 vessels (35 percent of total, 54 percent of impacted) would see their total costs increase more than 5 percent. The cost increase is due to purchasing new gear or pingers, and the cost of gear marking requirements. Vessels could avoid these cost increases by not fishing during the time periods when they would have to modify their gear or by using pingers. However, they would then lose some percentage of their yearly profit. The total economic losses of the Preferred Alternative to the GOM and the Mid-Atlantic regions are estimated to be between $609 thousand dollars and $4.5 million dollars, depending on the number of vessels that can shift their effort to open areas and the number that use pingers.

The costs associated with this rule are not related to reporting requirements. To the extent that the rule would allow fishery participants to select whether to acquire a new gear type or to avoid the time/area closures, performance requirements can be substituted for design requirements at the participant's discretion. Since most of the affected entities are small entities, providing an exemption for small entities would not enable the agency to meet the conservation and management goals of the MMPA.

Currently, the NE Multispecies sink gillnet fishery is subject to regulations under the NE Multispecies FMP. Recent groundfish conservation measures for the Gulf of Maine were proposed under Framework Adjustment 25 to the NE Multispecies FMP. The predominant Mid-Atlantic gillnet fisheries are not subject to regulations under an FMP at this time. The final rule is designed to complement Framework 25 and other fishery management regulations. The recommendations of the GOMTRT were modified by NMFS to take into consideration the combined effect of Framework 25 and the HPTRP on Gulf of Maine fishermen.

Under Alternative 2, there would be no additional costs to the fleet either through gear modifications and purchase of pingers or through losses in surplus due to time and area closures. Therefore, based on costs which the fleet would incur, this alternative is the least costly when compared with the Preferred Alternative or non-preferred alternatives. However, there is a much larger cost in terms of foregone harbor

porpoise protection. Based on the contingent valuation study conducted by the University of Maryland (Strand, *et al.,* 1994), households in Massachusetts were willing to pay between $176 and $364 to eliminate human induced mortality of 1,000 harbor porpoise. Using the lower figure of $176 multiplied by the number of Massachusetts households, and amortizing the total using a 7 percent rate yielded a yearly value of roughly $28 million. This means that decreasing mortality by 1,000 animals would increase consumer surplus by $28 million. Therefore, when compared against the other alternatives, the status quo is far inferior because it does not achieve the same level of consumer surplus due to a higher level of harbor porpoise mortality.

Alternative 3 would require all vessels fishing between September and May in the Gulf of Maine and between January and April in the Mid-Atlantic to use pingers. Each vessel owner would decide whether to purchase pingers based on his or her own set of circumstances. Each pinger was estimated to cost $50 dollars based on information obtained from NMFS Sea Sampling personnel. It is assumed that there would be one pinger required per net, and one on each buoy line. Using the average number of nets and strings fished in each region, a weighted average $3,437 dollars per vessel was estimated for the cost of pingers which translates into a total fleet cost of $608 thousand dollars.

The cost of pingers was estimated to be $608 thousand dollars if all vessels purchase pingers. However, some vessels may be unable to afford pingers. This would increase the total losses because vessels that were unable to afford pingers would have to stay tied up at the dock and, therefore, lose revenue. It is assumed that losses in producer surplus are linearly related to the percent of vessels that purchase pingers. For example, if 50 percent of the vessels use pingers, then the losses in producer surplus and crew rents will be reduced by 50 percent. Total pinger costs are also estimated based on the percent of vessels which purchase pingers. Losses calculated using these assumptions are estimated to be between zero and $7.4 million dollars.

In reality, vessels can either purchase pingers and continue to fish and shift their effort to other areas, or elect not to purchase pingers and stay tied up at the dock. Because the time and areas where pingers are required are quite extensive, it is unlikely that vessels will be able to switch areas and continue fishing without pingers. Without a more formal model, it is not possible to predict the number of vessels which will adopt either strategy.

This alternative is not preferred because it is unclear whether it could achieve the bycatch reduction goals, particularly in the Mid-Atlantic, because pingers have not been proven to be effective in this area. In addition, there are a number of scientific concerns regarding the impacts of widespread pinger use on harbor porpoise and other marine organisms. This alternative is not preferred given that more data is needed on the ecosystem effects of widespread pinger and given that other methods are available in the Mid-Atlantic to reduce harbor porpoise bycatch.

Alternative 4 would result in a total loss in producer surplus and crew rents for both regions of $7.4 million dollars. Overall, 177 vessels would be impacted for a per vessel loss of roughly $42 thousand dollars. As described in the FRFA, the cost to the fishery in terms of economic impacts would vary by area closure. Refer to the FRFA for a discussion of the impacts of this alternative based on the closure variations.

Vessels could shift their operations to other areas and make up for any revenue loss. This puts bounds on the losses of between zero, if revenue was totally replaced in other areas, and $7.4 million dollars. For this alternative, it will be more difficult for vessels to shift to other times and areas because the areas are all closed at the same time. There is the opportunity for vessels from New England to move to the Mid-Atlantic in the fall or to the NE closure area. Some may do so, but it is likely that most would not be able to switch. Gillnet vessels have traditionally fished in certain times and areas depending on many factors, including the vessels homeport. Because these times and areas are so extensive, it is unlikely that many vessels will be able to shift their operations and replace lost revenue.

Because the times and areas designated for closure are so extensive, it is likely that this alternative would reduce harbor porpoise mortality to close to zero. The trade-off for this reduction would be a much higher cost to the fishing fleet and possibly a higher likelihood of business failure; therefore this alternative is not preferred. However, it is not possible to evaluate the trade-off between reduced harbor porpoise mortality and increased costs. Based on the contingent valuation study discussed earlier (Strand *et al.,* 1994), harbor porpoise are highly valued by consumers.

The potential losses of the Preferred Alternative discussed above depend on assumptions about how individual vessels will react to the regulations. In most cases, these assumptions were very conservative in order to estimate the maximum possible losses. Non-Preferred Alternative 4 has the potential to cost more than either the Preferred Alternative, Non-Preferred Alternative 2 and Non-Preferred Alternative 3. This is because the area closures are large, and last for multiple months. The losses for Alternative 4 are expected to be $7.4 million dollars, and it is unlikely that vessels would be able to fish elsewhere to offset their losses. Allowing the use of pingers in the Preferred Alternative will lower the cost to the fleet, even with the price of pingers included. The provisions in the plan which allows the use of pingers in the New England region lowers the losses in the Preferred Alternative for New England vessels to $0.49 million dollars if all vessels elected to use pingers. The actual losses which will occur depend on which strategy vessels adopt to continue operating in the face of these regulations. Clearly, allowing pingers to be used will lower the cost to the fleet because it gives vessels added flexibility.

Non-Preferred Alternative 2 is lower in cost than any of the alternatives in terms of losses the fleet will incur. However, the losses in consumer surplus because of high harbor porpoise mortality are likely to be far greater than the losses in producer surplus and crew rents. If the contingent valuation study conducted by the University of Maryland is accurate, then the value of losses from harbor porpoise mortality would be far greater than any of the other options.

Non-Preferred Alternative 3 is the least costly alternative if all vessels impacted by the plan chose to fish with pingers. To the extent that some vessels would not be able to afford pingers, the costs will increase. Implicit in the analysis of this alternative was the assumption that the mortality reduction was the same as the Preferred Alternative. This assumption may not be true because pingers have not been formally tested in some of the times and areas where they would be allowed under this alternative. If mortality was higher, gains in consumer surplus would not be as high as under the Preferred Alternative, which means this alternative would have lower benefits than the Preferred Alternative.

In response to public comments, NMFS shortened the time periods when pingers would be required in certain areas, and reduced the number of net

tags required in the Mid-Atlantic region. This lowered the estimated costs by approximately $613,000 from the proposed rule which was submitted.

In summary, Alternative 1 will allow NMFS to achieve MMPA goals, reduction of harbor porpoise bycatch to acceptable levels, while minimizing the overall impact to affected fisheries, compared to the other available alternatives. Alternative 1 accomplishes this by placing carefully considered time-area closures in place, and allowing the use of bycatch reduction devices instead of total closures. This allows fishermen to continue to generate revenue. Further, Alternative 1 is less costly than other alternatives that would require pingers in the Gulf of Maine the entire time harbor porpoise are present there. A copy of this analysis is available from NMFS (see **ADDRESSES**).

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA). The collection of this information has been approved by the Office of Management and Budget, OMB control number 0648–0357.

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

The final rule requires nets in the Mid-Atlantic region to be marked in order to identify the vessel and enforce net cap provisions. It is estimated that each tag will take 1 minute to attach to the net, and each net requires one net tag. The total number of nets which will need to be tagged is estimated by assuming that combination gillnet vessels are, on average, fishing 60 nets, and all other vessels are, on average, fishing 30 nets. This gives a weighted average of 49 nets per vessel. Using these figures, the total burden hours is estimated to be 49 minutes per vessel.

The 76 vessel owner/operators will have to order net tags, estimated at 2 minutes per request. Depending on whether net tags are lost or damaged, vessels are expected to only have to comply once over three years. The annual average over the 3 years would be 25.3 vessels affected.

Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS and OMB (see **ADDRESSES**).

An informal consultation under the ESA was concluded for the HPTRP on November 12, 1998. As a result of the informal consultation, the Assistant Administrator determined that these actions are not likely to adversely affect endangered or threatened species or their critical habitat.

The 30-day delayed effectiveness requirement under the Administrative Procedure Act has been shortened in part. The requirements in 50 CFR 229.33(a)(2), the Mid-Coast Closure Area, become effective immediately upon publication; the requirements in 50 CFR 229.33(a)(5), the Offshore Closure Area, become effective December 8, 1998; and 50 CFR 229.33 (a)(3), (a)(4), the Massachusetts Bay and Cape Cod South Closure Areas become effective December 16, 1998. For all other components of the HPTRP, the requirements become effective January 1, 1999. The shortened time periods are necessary to reduce take of harbor porpoise at the beginning of the high-take season. The areas identified have different effective dates based on the need to have take reduction measures in place for harbor porpoise and on the ability of fishermen in that area to acquire additional pingers. Specifically, the current closure in the Mid-Coast area under the Magnuson-Stevens Act allows fishermen to fish with pingers in the closed area from November 1 through December 31. In addition, experimental fisheries have occurred in this area from September 15 through October 31 and again also during the March 25 through April 25 Magnuson-Stevens Act harbor porpoise closure. Therefore, most of the Mid-Coast fleet that intends to fish in December already has gear outfitted with pingers. A limited number of fishermen in both the Cape Cod South and Massachusetts Bay areas already have pingers from limited experimental fisheries that occurred in those areas. This means that fishermen that will need to purchase pingers in December are those fishing in the Cape Cod South, Offshore, and Massachusetts Bay Closure areas. NMFS has inquired and believes that enough pingers will be available to supply fishermen that choose to fish at that time. These areas will have a week to two weeks, depending on the area, to purchase the pingers and deploy them on the nets. Providing a delayed effectiveness period for requiring pingers in the Offshore Closure area a week later than the Mid-Coast area is justified because bycatch is known to be consistently high in the Mid-Coast area at the time this rule will be effective. Shortening the delay of effectiveness period for requiring pingers in the Offshore Closure area to a week less than other areas is justified because less than 10 fishermen are known to use the Offshore Closure area year round, and moreover, it is an area of high bycatch. Accordingly, the Assistant Administrator finds that there is good cause to shorten the 30-day delayed effectiveness period under 5 U.S.C. 553(d)(3) regarding pinger requirements.

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List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: November 25, 1998.

Andrew A. Rosenberg,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 229 is amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

1. The authority citation for part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

2. In § 229.2, definitions for ''Large mesh gillnet'', ''Mesh size'', ''Mudhole'', ''Small mesh gillnet'', ''Southern Mid-Atlantic waters'', ''Stowed'', ''Tie-down'', and ''Waters off New Jersey'' are added, in alphabetical order, to read as follows:

§ 229.2 Definitions.

* * * * *

Large mesh gillnet means a gillnet constructed with a mesh size of 7 inches (17.78 cm) to 18 inches (45.72 cm).

* * * * *

Mesh size means the distance between inside knot to inside knot. Mesh size is measured as described in § 648.80(f)(1) of this title.

* * * * *

Mudhole means waters off New Jersey bounded as follows: From the point 40°30′ N. latitude where it intersects with the shoreline of New Jersey east to its intersection with 73°20′ W. longitude, then south to its intersection with 40°05′ N. latitude, then west to its intersection with the shoreline of New Jersey.

* * * * *

Small mesh gillnet means a gillnet constructed with a mesh size of greater than 5 inches (12.7 cm) to less than 7 inches (17.78 cm).

* * * * *

Southern Mid-Atlantic waters means all state and Federal waters off the States of Delaware, Maryland, Virginia, and North Carolina, bounded on the north by a line extending eastward from the northern shoreline of Delaware at 38°47′ N. latitude (the latitude that corresponds with Cape Henlopen, DE), east to its intersection with 72°30′ W. longitude, south to the 33°51′ N. latitude (the latitude that corresponds with the North Carolina/South Carolina border), and then west to its intersection with the shoreline of the North Carolina/South Carolina border.

* * * * *

Stowed means nets that are unavailable for use and that are stored in accordance with the regulations found in § 648.81(e) of this title.

* * * * *

Tie-down refers to twine used between the floatline and the lead line as a way to create a pocket or bag of netting to trap fish alive.

* * * * * *

Waters off New Jersey means all state and Federal waters off New Jersey, bounded on the north by a line extending eastward from the southern shoreline of Long Island, NY at 40°40′ N. latitude, on the south by a line extending eastward from the northern shoreline of Delaware at 38°47′ N. latitude (the latitude that corresponds with Cape Henlopen, DE), and on the east by the 72°30′ W. longitude. This area includes the Mudhole.

* * * * *

3. In § 229.3, paragraphs (k) through (p) are added to read as follows:

§ 229.3 Prohibitions.

* * * * *

(k) It is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies, from the areas and for the times specified in § 229.33 (a)(1) through (a)(6), except with the use of pingers as provided in § 229.33 (d)(1) through (d)(4). This prohibition does not apply to the use of a single pelagic gillnet (as described and used as set forth in § 648.81(f)(2)(ii) of this title).

(l) It is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any gillnet gear from the areas and for the times as specified in § 229.34 (b)(1) (ii) or (iii) or (b)(2)(ii).

(m) It is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh or small mesh gillnet gear from the areas and for the times specified in § 229.34 (c)(1) through (c)(4) unless the gear complies with the specified gear restrictions set forth in those provisions.

(n) Beginning on January 1, 1999, it is prohibited to fish with, set, or haul back sink gillnets or gillnet gear, or leave such gear in closed areas where pingers are required, as specified under § 229.33 (c)(1) through (c)(4), unless a person on board the vessel during fishing operations possesses a valid pinger certification training certificate issued by NMFS.

(o) Beginning on January 1, 2000, it is prohibited to fish with, set, haul back, or possess any large mesh or small mesh gillnet gear in Mid-Atlantic waters in the areas and during the times specified under § 229.34(d), unless the gear is properly tagged in compliance with that provision and unless a net tag certificate is on board the vessel. It is prohibited to refuse to produce a net tag certificate or net tags upon the request of an authorized officer.

(p) *Net tag requirement.* Beginning on January 1, 2000, all gillnets fished, hauled, possessed, or deployed during the times and areas specified below must have one tag per net, with one tag secured to every other bridle of every net and with one tag secured to every other bridle of every net within a string of nets. This applies to small mesh and large mesh gillnet gear in New Jersey waters from January 1 through April 30 or in southern Mid-Atlantic waters from February 1 through April 30. The owner or operator of fishing vessels must indicate to NMFS the number of gillnet tags that they are requesting up to the maximum number of nets allowed in those paragraphs and must include a check for the cost of the tags. Vessel owners and operators will be given notice with instructions informing them of the costs associated with this tagging requirement and directions for obtaining tags. Tag numbers will be unique for each vessel and recorded on a certificate. The vessel operator must produce the certificate and all net tags upon request by an authorized officer.

4. In subpart C, new §§ 229.33 and 229.34 are added to read as follows:

§ 229.33 Harbor Porpoise Take Reduction Plan Implementing Regulations—Gulf of Maine.

(a) *Restrictions*—(1) *Northeast Closure Area.* From August 15 through September 13 of each fishing year, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies, from Northeast Closure Area. This prohibition does not apply to a single pelagic gillnet (as described and used as set forth in § 648.81(f)(2)(ii) of this title). The Northeast Closure Area is the area bounded by straight lines connecting the following points in the order stated:

NORTHEAST CLOSURE AREA

Point	N. Lat.	W. Long.
NE1	(1)	68°55.0′
NE2	43°29.6′	68°55.0′
NE3	44°04.4′	67°48.7′
NE4	44°06.9′	67°52.8′
NE5	44°31.2′	67°02.7′
NE6	(1)	67°02.7′

[1] Maine shoreline.

(2) *Mid-coast Closure Area.* From September 15 through May 31, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies. This prohibition does not apply to a single pelagic gillnet (as described and used as set forth in § 648.81(f)(2)(ii) of this title). The Mid-

Coast Closure Area is the area bounded by straight lines connecting the following points in the order stated:

MID-COAST CLOSURE AREA

Point	N. Lat.	W. Long.
MC1	42°30′	(1)
MC2	42°30′	70°15′
MC3	42°40′	70°15′
MC4	42°40′	70°00′
MC5	43°00′	70°00′
MC6	42°00′	69°30′
MC7	43°30′	69°30′
MC8	43°00′	69°00′
MC9	(2)	69°00′

1 Massachusetts shoreline.
2 Maine shoreline.

(3) *Massachusetts Bay Closure Area.* From December 1 through May 31, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies from the Massachusetts Bay Closure Area, except with the use of pingers as provided in paragraph (d)(2) of this section. This prohibition does not apply to a single pelagic gillnet (as described in § 648.81(f)(2)(ii) of this title). The Massachusetts Bay Closure Area is the area bounded by straight lines connecting the following points in the order stated:

MASSACHUSETTS BAY CLOSURE AREA

Point	N. Lat.	W. Long.
MB1	42°30′	(1)
MB2	42°30′	70°30′
MB3	42°12′	70°30′
MB4	42°12′	70°00′
MB5	(2)	70°00′
MB6	42°00′	(2)
MC7	42°00′	(1)

1 Massachusetts shoreline.
2 Cape Cod shoreline.

(4) *Cape Cod South Closure Area.* From December 1 through May 31, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies from Cape Cod South Closure Area, except with the use of pingers as provided in paragraph (d)(3) of this section. This prohibition does not apply to a single pelagic gillnet (as described in § 648.81(f)(2)(ii) of this title). The Cape Cod South Closure Area is the area bounded by straight lines connecting the following points in the order stated:

CAPE COD SOUTH CLOSURE AREA

Point	N. Lat.	W. Long.
CCS1	(1)	71°45′
CCS2	40°40′	71°45′
CCS3	40°40′	70°30′
CCS4	(2)	70°30′

1 Rhode Island shoreline.
2 Massachusetts shoreline.

(5) *Offshore Closure Area.* From November 1 through May 31, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies from Offshore Closure Area, except for the use of pingers as provided in § 229.33(d)(4). This prohibition does not apply to a single pelagic gillnet (as described in § 648.81(f)(2)(ii) of this title). The Offshore Closure Area is the area bounded by straight lines connecting the following points in the order stated:

OFFSHORE CLOSURE AREA

Point	N. Lat.	W. Long.
OFS1	42°50′	69°30′
OFS2	43°10′	69°10′
OFS3	43°10′	67°40′
OFS4	42°10′	67°40′
OFS5	42°10′	69°30′

(6) *Cashes Ledge Closure Area.* For the month of February of each fishing year, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove sink gillnet gear or gillnet gear capable of catching multispecies from the Cashes Ledge Closure Area. This prohibition does not apply to a single pelagic gillnet (as described in § 648.81(f)(2)(ii) of this title). The Cashes Ledge Closure Area is the area bounded by straight lines connecting the following points in the order stated:

CASHES LEDGE CLOSURE AREA

Point	N. Lat.	W. Long.
CL1	42°30′	69°00′
CL2	42°30′	68°30′
CL3	43°00′	68°30′
CL4	43°00′	69°00′
CL5	42°30′	69°00′

(b) Pingers—(1) *Pinger specifications.* For the purposes of this subpart, a pinger is an acoustic deterrent device which, when immersed in water, broadcasts a 10 kHz (±2 kHz) sound at 132 dB (±4 dB) re 1 micropascal at 1 m, lasting 300 milliseconds (±15 milliseconds), and repeating every 4 seconds (±.2 seconds).

(2) *Pinger attachment.* An operating and functional pinger must be attached at the end of each string of the gillnets and at the bridle of every net within a string of nets.

(c) *Pinger training and certification.* Beginning on January 1, 1999, the operator of a vessel may not fish with, set or haul back sink gillnets or gillnet gear, or allow such gear to be in closed areas where pingers are required as specified under paragraph (b) of this section, unless the operator has satisfactorily completed the pinger certification training program and possesses on board the vessel a valid pinger training certificate issued by NMFS. Notice will be given announcing the times and locations of pinger certification training programs.

(d) *Use of pingers in closed areas*—(1) Vessels, subject to the restrictions and regulations specified in paragraph (a)(2) of this section, may fish in the Mid-coast Closure Area from September 15 through May 31 of each fishing year, provided that pingers are used in accordance with the requirements of paragraphs (b) (1) and (2) of this section.

(2) Vessels, subject to the restrictions and regulations specified in paragraph (a)(3) of this section, may fish in the Massachusetts Bay Closure Area from December 1 through the last day of February and from April 1 through May 31 of each fishing year, provided that pingers are used in accordance with the requirements of paragraphs (b) (1) and (2) of this section.

(3) Vessels, subject to the restrictions and regulations specified in paragraph (a)(4) of this section, may fish in the Cape Cod South Closure Area from December 1 through the last day of February and from April 1 through May 31 of each fishing year, provided that pingers are used in accordance with the requirements of paragraphs (b) (1) and (2) of this section.

(4) Vessels, subject to the restrictions and regulations specified in paragraph (a)(5) of this section, may fish in the Offshore Closure Area from November 1 through May 31 of each fishing year, with the exception of the Cashes Ledge Closure Area. From February 1 through the end of February, the area within the Offshore Closure Area defined as ''Cashes Ledge'' is closed to all fishing with sink gillnets. Vessels subject to the restrictions and regulation specified in paragraph (a)(5) of this section may fish in the Offshore Closure Area outside the Cashes Ledge Area from February 1 through the end of February provided that pingers are used in accordance with the requirements of paragraphs (b) (1) and (2) of this section.

(e) *Other special measures.* The Assistant Administrator may revise the requirements of this section through notification published in the **Federal Register** if:

(1) After plan implementation, NMFS determines that pinger operating effectiveness in the commercial fishery is inadequate to reduce bycatch to the PBR level with the current plan.

(2) NMFS determines that the boundary or timing of a closed area is inappropriate, or that gear modifications (including pingers) are not reducing bycatch to below the PBR level.

§ 229.34 Harbor Porpoise Take Reduction Plan—Mid-Atlantic.

(a)(1) *Regulated waters.* The regulations in this section apply to all waters in the Mid-Atlantic bounded on the east by 72°30′ W. longitude and on the south by the North Carolina/South Carolina border (33°51′ N. latitude), except for the areas exempted in paragraph (a)(2) of this section.

(2) *Exempted waters.* All waters landward of the first bridge over any embayment, harbor, or inlet will be exempted. The regulations in this section do not apply to waters landward of the following lines:

New York

40° 45.70′ N 72° 45.15′ W TO 40° 45.72′ N 72° 45.30′ W (Moriches Bay Inlet)
40° 37.32′ N 73° 18.40′ W TO 40° 38.00′ N 73° 18.56′ W (Fire Island Inlet)
40° 34.40′ N 73° 34.55′ W TO 40° 35.08′ N 73° 35.22′ W (Jones Inlet)

New Jersey

39° 45.90′ N 74° 05.90′ W TO 39° 45.15′ N 74° 06.20′ W (Barnegat Inlet)
39° 30.70′ N 74° 16.70′ W TO 39° 26.30′ N 74° 19.75′ W (Beach Haven to Brigantine Inlet)
38° 56.20′ N 74° 51.70′ W TO 38° 56.20′ N 74° 51.90′ W (Cape May Inlet)
39° 16.70′ N 75° 14.60′ W TO 39° 11.25′ N 75° 23.90′ W (Delaware Bay)

Maryland/Virginia

38° 19.48′ N 75° 05.10′ W TO 38° 19.35′ N 75° 05.25′ W (Ocean City Inlet)
37° 52.′ N 75° 24.30′ W TO 37° 11.90′ N 75° 48.30′ W (Chincoteague to Ship Shoal Inlet)
37° 11.10′ N 75° 49.30′ W TO 37° 10.65′ N 75° 49.60′ W (Little Inlet)
37° 07.00′ N 75° 53.75′ W TO 37° 05.30′ N 75° 56.′ W (Smith Island Inlet)

North Carolina

All marine and tidal waters landward of the 72 COLREGS demarcation line (International Regulations for Preventing Collisions at Sea, 1972), as depicted or noted on nautical charts published by NOAA (Coast Charts 1:80,000 scale), and as described in 33 CFR part 80.

(b) *Closures*—(1) *New Jersey waters.* From April 1 through April 20, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh gillnet gear from the waters off New Jersey.

(2) *Mudhole.* From February 15 through March 15, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh or small mesh gillnet gear from the waters off New Jersey known as the Mudhole.

(3) *Southern Mid-Atlantic waters.* From February 15 through March 15, it is prohibited to fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh gillnet gear from the southern Mid-Atlantic waters.

(c) Gear requirements and limitations—(1) *Waters off New Jersey—large mesh gear requirements and limitations.* From January 1 through April 30 of each year, no person may fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh gillnet gear in waters off New Jersey, unless the gear complies with the specified gear characteristics. During this period, no person who owns or operates the vessel may allow the vessel to enter or remain in waters off New Jersey with large mesh gillnet gear on board, unless the gear complies with the specified gear characteristics or unless the gear is stowed. In order to comply with these specified gear characteristics, the gear must have all the following characteristics:

(i) *Floatline length.* The floatline is no longer than 4,800 ft (1,463.0 m), and, if the gear is used in the Mudhole, the floatline is no longer than 3,900 ft (1,188.7 m).

(ii) *Twine size.* The twine is at least 0.04 inches (0.090 cm) in diameter.

(iii) *Size of nets.* Individual nets or net panels are not more than 300 ft (91.44 m, or 50 fathoms), in length.

(iv) *Number of nets.* The total number of individual nets or net panels for a vessel, including all nets on board the vessel, hauled by the vessel or deployed by the vessel, does not exceed 80.

(v) *Tie-down system.* The gillnet is equipped with tie-downs spaced not more than 15 ft (4.6 m) apart along the floatline, and each tie-down is not more than 48 inches (18.90 cm) in length from the point where it connects to the floatline to the point where it connects to the lead line.

(vi) *Tagging requirements.* Beginning January 1, 2000, the gillnet is equipped with one tag per net, with one tag secured to each bridle of every net within a string of nets.

(2) *Waters off New Jersey—small mesh gillnet gear requirements and limitations.* From January 1 through April 30 of each year, no person may fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any small mesh gillnet gear in waters off New Jersey, unless the gear complies with the specified gear characteristics. During this period, no person who owns or operates the vessel may allow the vessel to enter or remain in waters off New Jersey with small mesh gillnet gear on board, unless the gear complies with the specified gear characteristics or unless the gear is stowed. In order to comply with these specified gear characteristics, the gear must have all the following characteristics:

(i) *Floatline length.* The floatline is less than 3,000 ft (914.4 m).

(ii) *Twine size.* The twine is at least 0.031 inches (0.081 cm) in diameter.

(iii) *Size of nets.* Individual nets or net panels are not more than 300 ft (91.4 m or 50 fathoms) in length.

(iv) *Number of nets.* The total number of individual nets or net panels for a vessel, including all nets on board the vessel, hauled by the vessel or deployed by the vessel, does not exceed 45.

(v) *Tie-down system.* Tie-downs are prohibited.

(vi) *Tagging requirements.* Beginning January 1, 2000, the gillnet is equipped with one tag per net, with one tag secured to each bridle of every net within a string of nets.

(3) *Southern Mid-Atlantic waters—large mesh gear requirements and limitations.* From February 1 through April 30 of each year, no person may fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any large mesh gillnet gear in Southern Mid-Atlantic waters, unless the gear complies with the specified gear characteristics. During this period, no person who owns or operates the vessel may allow the vessel to enter or remain in Southern Mid-Atlantic waters with large mesh sink gillnet gear on board, unless the gear complies with the specified gear characteristics or unless the gear is stowed. In order to comply with these specified gear characteristics, the gear must have all the following characteristics:

(i) *Floatline length.* The floatline is no longer than 3,900 ft (1,188.7 m).

(ii) *Twine size.* The twine is at least 0.04 inches (0.090 cm) in diameter.

(iii) *Size of nets.* Individual nets or net panels are not more than 300 ft (91.4 m or 50 fathoms) in length.

(iv) *Number of nets.* The total number of individual nets or net panels for a vessel, including all nets on board the vessel, hauled by the vessel or deployed by the vessel, does not exceed 80.

(v) *Tie-down system*. The gillnet is equipped with tie-downs spaced not more than 15 ft (4.6 m) apart along the floatline, and each tie-down is not more than 48 inches (18.90 cm) in length from the point where it connects to the floatline to the point where it connects to the lead line.

(vi) *Tagging requirements*. Beginning January 1, 2000, the gillnet is equipped with one tag per net, with one tag secured to each bridle of every net within a string of nets.

(4) *Southern Mid-Atlantic waters—small mesh gillnet gear requirements and limitations*. From February 1 through April 30 of each year, no person may fish with, set, haul back, possess on board a vessel unless stowed, or fail to remove any small mesh gillnet gear in waters off New Jersey, unless the gear complies with the specified gear characteristics. During this period, no person who owns or operates the vessel may allow the vessel to enter or remain in Southern Mid-Atlantic waters with small mesh gillnet gear on board, unless the gear complies with the specified gear characteristics or unless the gear is stowed. In order to comply with these specified gear characteristics, the gear must have all the following characteristics:

(i) *Floatline length*. The floatline is no longer than 2118 ft (645.6 m).

(ii) *Twine size*. The twine is at least 0.03 inches (0.080 cm) in diameter.

(iii) *Size of nets*. Individual nets or net panels are not more than 300 ft (91.4 m or 50 fathoms) in length.

(iv) *Number of nets*. The total number of individual nets or net panels for a vessel, including all nets on board the vessel, hauled by the vessel or deployed by the vessel, does not exceed 45.

(v) *Tie-down system*. Tie-downs are prohibited.

(vi) *Tagging requirements*. Beginning January 1, 2000, the gillnet is equipped with one tag per net, with one tag secured to each bridle of every net within a string of nets.

(d) *Other special measures*. The Assistant Administrator may revise the requirements of this section through notification published in the **Federal Register** if:

(1) After plan implementation, NMFS determines that pinger operating effectiveness in the commercial fishery is inadequate to reduce bycatch to the PBR level with the current plan.

(2) NMFS determines that the boundary or timing of a closed area is inappropriate, or that gear modifications (including pingers) are not reducing bycatch to below the PBR level.

[FR Doc. 98–31957 Filed 11–25–98; 4:21 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 630

[I.D. 111698C]

Atlantic Swordfish Fishery; Quota Adjustment

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

ACTION: Notification of quota adjustment.

SUMMARY: NMFS adjusts the 1998 North Atlantic swordfish fishery quota to carryover the unharvested portion of the 1997 quota.

DATES: Effective December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Jill Stevenson, 301–713–2347.

SUPPLEMENTARY INFORMATION: The U.S. Atlantic swordfish fishery is managed under the Fishery Management Plan for Atlantic Swordfish. Regulations at 50 CFR part 630 are issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (codified at 16 U.S.C. 1801 *et seq*.) and the Atlantic Tunas Convention Act (ATCA) (codified at 16 U.S.C. 971 *et seq*.). Regulations issued under the authority of ATCA implement the recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT).

NMFS recently revised quota adjustment procedures for the Atlantic swordfish fishery in a final rule published on September 29, 1998 (63 FR 51856). These revised procedures allow for carryover of unharvested quota from one fishing year to the next, provided such carryover is consistent with the applicable recommendation of ICCAT. Current ICCAT recommendations provide for carryover from 1997 to 1998 of unharvested swordfish quota from the North Atlantic stock but not the South Atlantic stock. Therefore, this quota adjustment pertains to the 1998 quota for the North Atlantic swordfish stock only.

For both semiannual periods of the 1997 fishing year, NMFS closed the longline/harpoon directed fishery for North Atlantic swordfish based on projections of when the quota for each semiannual period would be caught. The closures were effective October 12, 1997, for the first semiannual period and March 31, 1998, for the second. When NMFS tallied actual catches for both periods, NMFS determined that the entire 1997 longline/harpoon quota of 2121.2 metric tons dressed weight was not harvested, leaving 224.6 metric tons available for carryover. Additionally, the entire 1997 directed fishery quota of 42.8 mt allocated to driftnet gear remained unharvested due to a year long emergency closure of that fishery issued under authority of the Magnuson-Stevens Act (62 FR 30775, June 5, 1997) and the Endangered Species Act (62 FR 63467, December 1, 1997). Finally, out of the 1997 incidental catch quota of 300 mt, a total of 232.1 mt of swordfish were taken incidentally in fisheries targeting other species (e.g., yellowfin tuna, bigeye tuna, squid) including longline landings after the directed fishery closures. This leaves 335.3 mt (224.6 + 42.8 + 67.9) available for carryover to the 1998 fishing year.

Regulations on adjustment procedures require that any underharvest from the prior fishing year be apportioned equally between the two semiannual fishing periods and be allocated so that the new directed fishery gear quotas represent the same proportion of the adjusted quota as they did before the quota adjustment. Given that the first 1998 semiannual period will end on November 30, 1998, that the driftnet fishery remains closed for the remainder of the 1998 fishing year, and that NMFS has published a proposed rule to prohibit further use of driftnet gear in the North Atlantic swordfish fishery (63 FR 55998, October 20, 1998), NMFS has decided to allocate the entire amount of the 1997 underharvest (335.3 mt) to the 1998 second semiannual directed fishery for longline and harpoon gear.

In addition to the 1997 carryover adjustment, NMFS also makes inseason adjustments to the 1998 North Atlantic swordfish allocations. According to the regulations, if NMFS determines it is necessary to close a directed fishery, any estimated underharvest of that directed fishery quota will be used to adjust the annual incidental catch quota. In 1998, a closure based on catch projections (63 FR 41205, August 3, 1998) resulted in an underharvest of the 1998 North Atlantic swordfish driftnet quota (14.6 mt remaining). NMFS did not reopen this fishery due to protected species bycatch concerns. Therefore, NMFS allocates the unharvested 14.6 mt of the 1998 driftnet quota to the 1998 North Atlantic swordfish incidental catch category.

The quotas for the 1998 North Atlantic swordfish fishery were previously established (62 FR 55357, October 24, 1997) to provide 1028.5 mt for each semiannual period in the directed (longline/harpoon) fishery, 41.6

mt for the driftnet fishery, and 300 mt reserved for incidental catch. Given the regulatory requirements on carryover and inseason reallocation, NMFS adjusts the 1998 second semiannual directed North Atlantic swordfish quota to 1363.8 mt (1028.5 + 335.3) and adjusts the 1998 incidental catch quota to 314.6 mt (300.0 + 14.6).

Classification

This action is taken under 50 CFR 630.24(e) and (f) and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.* and 16 U.S.C. 971 *et seq.*

Dated: November 25, 1998.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–32017 Filed 11–27–98; 1:13 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 63, No. 231
Wednesday, December 2, 1998

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 Part 31

RIN 3150—AG06

Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material To Provide Requested Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes amending its regulations to add an explicit requirement that general licensees who possess certain measuring, gauging, or controlling devices that contain byproduct material provide the NRC with information concerning these devices. The NRC intends to use this provision to request information concerning devices that present a comparatively higher risk of exposure to the public or property damage. The proposed rule is intended to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded.

DATES: Submit comments by February 16, 1999. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments by mail to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415–5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6264, or e-mail at CRM@nrc.gov; or Jayne McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415–6219, or e-mail at JMM2@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission (AEC) amended its regulations to provide a general license for the use of byproduct material contained in certain measuring, gauging, or controlling devices (10 CFR 30.21(c)). Under current regulations (10 CFR 31.5), certain persons may receive and use a device containing byproduct material under this general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license authorizing distribution of generally licensed devices is issued if a regulatory authority determines that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee must comply with requirements for labeling, instructions for use, and proper storage or disposition of the device. For some devices, the general licensee must also comply with leak testing requirements. The general licensee is also subject to the terms and conditions in 10 CFR 31.2 concerning general license requirements, transfer of byproduct material, reporting and recordkeeping, and inspection. The general licensee must comply with the safety instructions contained in or referenced on the label of the device and must have the testing or servicing of the device performed by an individual who is authorized to manufacture, install, or service these devices.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the general license is meant to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

There are about 45,000 general licensees under 10 CFR 31.5 who possess about 600,000 devices that contain byproduct material. In the past, the NRC has not contacted general licensees on a regular basis because of the relatively small radiation exposure risk posed by these devices and the very large number of general licensees.

However, there have been a number of occurrences where generally licensed devices containing radioactive material have not been properly handled or properly disposed of. In some cases, this has resulted in radiation exposure to the public and contamination of property. For example, when a source is accidentally melted in a steel mill, considerable contamination of the mill, the steel product, and the wastes from the process, the slag and the baghouse dust, can result.

Because of these incidents, the NRC conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program and to determine whether there was an accounting problem with generally licensed device users and, if so, what action could be taken. The sampling revealed several areas of concern regarding the use of radioactive material under the general license provisions of 10 CFR 31.5. The NRC concluded that—(1) Many general licensees are not aware of the appropriate regulations, and (2) Generally licensed devices are inadequately handled and accounted for.

Approximately 15 percent of all general licensees sampled could not account for all of their generally

licensed devices. The NRC concluded that these problems could be remedied by more frequent and timely contact between the general licensee and the NRC.

On December 27, 1991 (56 FR 67011), the NRC published a notice of proposed rulemaking concerning the accountability of generally licensed devices. The proposed rule contained a number of provisions, including a requirement for general licensees under 10 CFR 31.5 to provide information to the NRC upon request, through which a device registry could be developed. The proposed rule also included requirements in 10 CFR 32.51a and 32.52 for the specific licensees who manufacture or initially transfer generally licensed devices. Although the public comments received were reviewed and a final rule developed, a final rule was not issued because the resources to implement the proposed rule properly were not available.

The NRC has continued to consider the issues related to the loss of control of generally licensed, as well as specifically licensed, sources of radioactivity. In July 1995, the NRC, with assistance from the Organization of Agreement States, formed a working group to evaluate these issues. The working group consisted of both NRC and Agreement State personnel and encouraged the involvement of all persons having a stake in the process and its final recommendations. All working group meetings were open to the public. A final report was completed in July 1996 and published in October 1996 as NUREG–1551, ''Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices.''

In considering these recommendations, the NRC has decided, among other things, to initiate an annual registration program of devices generally licensed under 10 CFR 31.5 that would be similar to the program originally proposed in the December 27, 1991, proposed rule. However, the NRC has decided to do so only for those devices that present a higher risk (compared to other generally licensed devices) of potential exposure to the public and property loss if control of the device is lost. Initially, the NRC will use the criteria developed by the working group to determine which devices should be registered.

This proposed rule presents the proposed addition of an explicit requirement to provide information in response to requests made by the NRC for a second round of comment. While the proposed rule would apply to all 10 CFR 31.5 general licensees, the NRC plans to contact only those general licensees identified by the working group for the purpose of the registration program.

The NRC is withdrawing the December 27, 1991, proposed rule. The NRC plans to review the other provisions contained in the December 27, 1991, proposed rule and the recommendations of the working group and develop additional requirements in a separate rulemaking.

Discussion

The Atomic Energy Act of 1954 (AEA), as amended, authorizes the NRC to request appropriate information from its licensees concerning licensed activities. However, the Commission has not included such an explicit provision in the regulations governing 10 CFR 31.5 general licensees. Although 10 CFR 2.204, 30.34(e), and 30.61(a) require information from licensees by order or demand, these provisions are not considered appropriate for the initiation of a routine registration program. In a previous rulemaking, the Commission (then AEC) had proposed the inclusion of a registration requirement for generally licensed devices before receipt of devices (February 5, 1974; 39 FR 4583). In response to comment on that proposal, the Commission decided not to institute a registration requirement as part of the final rulemaking on that action (December 16, 1974; 39 FR 43531). Given this history, establishing a device registration program without a rulemaking process is also considered inappropriate.

This proposed rule would add an explicit requirement to 10 CFR 31.5 that would require general licensees to respond to written requests from the NRC for information concerning products that they have received for use under a general license in a timely way.

The proposed rule would require a response to requests within 30 days or such other time as specified in the request. For routine requests for information, 30 days should be adequate in most instances, and an extension can be obtained for good cause. If more complicated requests are made or circumstances recognized that may require a longer time, the Commission may provide a longer response time. In the unusual circumstance of a significant safety concern, the Commission could demand information in a shorter time. The NRC is specifically soliciting comments on this time period. Also, a phone number will be provided in the request for information in case additional guidance is necessary.

The NRC intends to use this provision primarily to institute an annual registration program for devices using certain quantities of specific radionuclides. The registration program is primarily intended to ensure that general licensees are aware of and understand the requirements for the possession of devices containing byproduct material. The registration process would allow NRC to account for devices that have been distributed for use under the general license. The NRC believes that if general licensees are aware of their responsibilities they would comply with the requirements for proper handling and disposal of generally licensed devices. This would help reduce the potential for incidents that could result in unnecessary radiation exposure to the public as well as contamination of property.

The general licensees covered by the registration program would be asked to account for the devices in their possession and to verify, as well as certify, information concerning:

1. The identification of devices, such as the manufacturer, model and serial numbers;
2. The persons responsible for compliance with the regulations;
3. The disposition of the devices; and
4. The location of the devices.

While the proposed rule would apply to all 10 CFR 31.5 general licensees (about 45,000), the NRC would only contact, for purposes of registration, approximately 6000 general licensees, possessing about 24,000 devices. This estimate is based on the criteria recommended by the working group for determining which sources should have increased oversight. Requests for information would be sent to general licensees who are expected, based on current NRC records, to possess devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of any transuranic (at this time, the only generally licensed devices meeting this criterion contain americium-241). The majority of the devices meeting these criteria are used in commercial and industrial applications measuring thickness, density, or chemical composition in petrochemical and steel manufacturing industries. The requests will include the information contained in NRC records concerning the possession of these devices. The licensees will be asked to verify, correct, and add to that information. The NRC records are based on information provided to NRC by distributors under 10 CFR 32.52(a) and from general licensees as required by 10 CFR

31.5(c)(8) or (9). If a general licensee no longer possesses devices meeting the criteria, it would be expected to provide information about the disposition of the devices previously possessed. Errors in current NRC records concerning these general licensees could be the result of: (1) errors made in the quarterly reports of manufacturers or initial distributors, (2) general licensees not reporting transfers, or (3) errors made by NRC or its contractors in recording transfer information.

In addition to the 6000 general licensees identified for registration, the NRC may occasionally request information from other general licensees on a case-by-case basis as necessary or appropriate. For example, this might involve investigating the extent that other users have experienced a problem that has been identified with the design of a particular device model. However, significant modifications to the registration program to include a larger class of licensees would be done through rulemaking.

Although the proposed amendment would impose some additional costs on licensees, the NRC has estimated these costs to be minimal. This cost is the estimated administrative cost expended by general licensees to verify the information requested by the NRC regarding licensed devices. The NRC believes that the proposed rule's intended effect of increased compliance by general licensees with regulatory requirements and resulting NRC and public confidence in the general license program potentially afforded by these new requirements outweigh this nominal administrative cost.

The NRC is currently considering additional rulemaking concerning the control and accountability of devices generally licensed under 10 CFR 31.5. The recommendations made in NUREG–1551 will be considered at that time. That anticipated rule would address fees for registration, additional labeling requirements for 10 CFR 32.51 licensees, and compatibility of Agreement State regulations in this area. Public comments on this current proposed rule should only address the requirements proposed in this action. Comments concerning possible future rulemaking and the possible imposition of fees will not be addressed in any rule resulting from this proposed action.

Public Comments on the Original Proposed Rule

The NRC reviewed the comments received on the December 27, 1991, proposed rule. There were 26 comment letters received from a variety of sources including private and publicly held corporations, private citizens, citizens groups, the Armed Forces, and State governments. These comments have been considered to the extent applicable to this more limited proposed rule and will be considered in the development of a subsequent rulemaking concerning the accountability of devices generally licensed under 10 CFR 31.5. A detailed analysis of the comments received on the December 27, 1991, proposed rule will not be presented in either action as many of the specific comments pertain to specific provisions that have been withdrawn, much time has passed since these comments were made, and additional opportunity for comment is being provided.

Comments received on the December 27, 1991, proposed rule demonstrated that there was considerable opposition to the rule as proposed, some of it specifically concerning a registration requirement. Most of this opposition was related to the breadth of the proposal which would have made the registration program applicable to all of the 10 CFR 31.5 general licensees, accounting for as many as 600,000 devices. Some respondents questioned whether this was justified or cost effective. Some thought the impacts were underestimated, particularly for general licensees possessing many devices, and that the provision would have serious impacts on certain industries. Registration was specifically opposed for devices used by the airline industry, self-luminous signs, static eliminators, and some other devices which present relatively low risks.

The NRC found the working group process valuable in identifying criteria for categorizing devices that are more likely to present a significant risk by exposure of the public or through contamination of property. Therefore, the registration of devices under this proposed rulemaking would be limited to those devices meeting the criteria recommended by the working group. For the most part, general licensees using devices meeting these criteria have a limited number of devices that would require registration. The NRC is exploring approaches to minimize the administrative effort for both general licensees and the NRC in implementing this requirement.

This proposal includes a provision to request an extension to the time interval to provide a complete response to requests for information, if the general licensee is having difficulty in meeting the time limit. This provision was included in response to comments on the December 27, 1991, proposed rule. Although this difficulty is much less likely to arise within the limited population of general licensees covered by the current proposal, the Commission believes that the additional flexibility is desirable.

Interim Enforcement Policy

As had been planned at the time of the 1991 proposed rule, the Commission intends to establish an interim enforcement policy for violations of 10 CFR 31.5 that licensees discover and report during the initial cycle of the registration program. This policy will supplement the normal NRC Enforcement Policy in NUREG–1600, Rev. 1. It will be issued in the near future and will remain in effect through one complete cycle of the registration program.

Under the current NRC Enforcement Policy, significant violations, such as those involving lost sources, may result in escalated enforcement action including civil penalties. The interim policy would provide that enforcement action normally would not be taken for violations identified by a licensee and reported to the NRC if appropriate corrective action is taken. For the period that the interim policy is in effect, it would also apply to general licensees not subject to the registration requirement if they identify and report violations and take appropriate corrective action. This change from the current NRC Enforcement Policy is intended to remove any disincentive to identify deficiencies that might be caused by a concern over potential enforcement action. This action would encourage general licensees to search their facilities to ensure sources are located, to determine if applicable requirements have been met, and to develop appropriate corrective action when deficiencies are found. A Notice of Violation (NOV) without a civil penalty still may be issued if the NRC staff believes that taking this action is justified by the safety significance of the violation or the need to record and document the general licensee's corrective action in the formal manner required in a response to an NOV.

In addition, escalated enforcement action still will be considered for violations involving failure to provide the information requested, failure to take appropriate corrective action, or for willful violations including the submittal of false information. Sanctions in those situations may include significant civil penalties as well as orders to limit or revoke the authority to possess radioactive sources under a general license.

The Commission also intends to increase the civil penalty amounts specified in its current Enforcement

Policy in NUREG–1600, Rev. 1, for violations involving lost or improperly disposed sources or devices. This is to ensure that such civil penalties are significantly higher than the costs avoided by the failure to properly dispose of the source or device.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997 (62 FR 46517), this proposed rule is classified as Compatibility Category D. Category D means the provisions are not required for purposes of compatibility; however, if adopted by the State, the provisions should not create any conflicts, duplications, or gaps in the regulation of AEA material. Ultimately an enhanced oversight program is expected to include provisions that will require a higher degree of compatibility. This will be considered in a subsequent rulemaking to add more explicit requirements for the registration program and additional provisions concerning accountability of generally licensed devices.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in the categorical exclusion 10 CFR 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden for this information collection is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing the burden, to the Records Management Branch (T–6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150–0016), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the **Federal Register**). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis for this proposed regulation. The analysis examines the cost and benefits of the alternatives considered by the NRC. The comments received on the earlier draft regulatory analysis have been considered to the extent that they apply to this more limited action. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained by calling Jayne McCausland, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC, 20555–0001; telephone (301) 415–6219; or e-mail at JMM2@nrc.gov.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would require general licensees who have received specific devices to respond to requests for information from NRC. The proposed rule would apply to the approximately 45,000 persons using products under an NRC general license, many of whom may be classified as small entities. However, the NRC intends to request registration information from only approximately 6000 of these general licensees about the identification of the devices, accountability for the devices, the persons responsible for compliance with the regulations, and the disposition of the devices. The NRC believes that the economic impact of the proposed requirements on any general licensee would be a negligible increase in administrative burden. The proposed rule is intended to ensure that general licensees understand and comply with regulatory responsibilities regarding the generally licensed radioactive devices in their possession.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, a backfit analysis is not required because these amendments would not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 31

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 31.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

1. The authority citation for Part 31 continues to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Section 31.6 also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

2. Section 31.5 is amended by adding paragraph (c)(11) to read as follows:

10 CFR 31.5 Certain measuring, gauging, or controlling devices.[2]

* * * * *

(c) * * *

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 and provide written justification as to why it cannot comply.

* * * * *

Dated at Rockville, Maryland, this 19th day of November, 1998.

For the Nuclear Regulatory Commission.

Malcolm R. Knapp,

Acting Executive Director for Operations.

[FR Doc. 98–32113 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150–AC42

Comprehensive Quality Assurance in Medical Use and a Standard of Care

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPRM) that requested public comments on questions related to comprehensive quality assurance and a standard of care in medical uses of byproduct material. The Commission has decided to withdraw this ANPRM because of the effective implementation of the ''Quality Management Program and Misadministrations'' rule and the NRC's current efforts in revising the existing regulation for medical uses of byproduct material into a more risk-informed and performance-based regulation.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012–7082, telephone: (202) 512–2249.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6219, e-mail jmm2@nrc.gov.

SUPPLEMENTARY INFORMATION:

On October 2, 1987, the Commission published two notices in the **Federal Register** regarding medical use of byproduct material. The first notice was the proposed rulemaking entitled ''Basic Quality Assurance in Radiation Therapy'' (52 FR 36942), that proposed a requirement for medical use licensees to implement some specific basic quality assurance practices to reduce the number of therapy misadministrations involving byproduct material. The second notice was an ANPRM entitled ''Comprehensive Quality Assurance in Medical Use and a Standard of Care'' (52 FR 36949), that requested public comments on the extent to which a comprehensive quality assurance program requirement was needed. The NRC believed that this two-pronged approach to the misadministrations problem would provide the best balance between assuring public health and safety and avoiding inadvertent interference in the delivery of quality medical care.

On July 25, 1991 (56 FR 34104), the NRC published a final rule entitled ''Quality Management Program and Misadministrations'' (the QM Rule) which was based on the above-mentioned 1987 proposed rule. During the implementation of the final rule, the NRC decided to assess the effectiveness of the rule and, based on the results of the assessment, to determine the need for a rulemaking on comprehensive quality management.

Subsequently, a Commission SRM on SECY–97–115 dated June 30, 1997, approved subsuming several Part 35 rulemakings into one major revision to 10 CFR Part 35 rulemaking activity. The proposed rulemaking entitled ''Medical Use of Byproduct Material,'' was published in the **Federal Register** (RIN 3150–AF74) (August 13, 1998; 63 FR 43516). The NRC is in the process of developing the final rule governing medical use of byproduct material into a more risk-informed and performance-based regulation. This overall revision includes a consideration as to whether or not the regulation on the quality management program should be revised to become more risk-informed and performance-based. For this reason, the Commission is withdrawing the ANPRM.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–32108 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AF04

Steam Generator Tube Integrity for Operating Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPRM) that was published to request public comment on the Commission's regulations pertaining to steam generator (SG) tube integrity. The proposed rule would have implemented a more flexible regulatory framework for steam generator surveillance and maintenance activities that would maintain adequate assurance of tube integrity while allowing a degradation-specific management approach. Because the NRC has concluded that the regulatory objectives set forth for this effort can be achieved by equally effective regulatory alternatives, the ANPR is being withdrawn.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012–7082, telephone: (202) 512–2249.

FOR FURTHER INFORMATION CONTACT: Tim Reed, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1462, e-mail tar@nrc.gov.

SUPPLEMENTARY INFORMATION:

On September 19, 1994 (59 FR 47817), the Commission published an ANPRM that requested comments, advice, and recommendations from interested parties on the proposed steam generator rule. In response to the ANPRM, two

[2] Persons possessing byproduct material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.

public comments were received. The primary comment was a coordinated industry response submitted by the Nuclear Energy Institute (NEI). The remaining comment, submitted by Virginia Power, endorsed the NEI comment. Subsequently, the NRC staff developed a draft rule and draft regulatory guide intended to implement a performance-based regulatory structure that provides for the development and implementation of appropriate measures to ensure the consistency and quality of inspection methods, repair criteria, and tube condition assessment, while giving appropriate consideration to risk. As part of the rulemaking process, the NRC staff estimated the risk associated with SG tube degradation and used the results to provide the insights required for performing a regulatory analysis of the proposed rulemaking approach.

In COMSECY–97–013, dated May 23, 1997, the NRC staff provided a risk assessment summary and major conclusions from a regulatory analysis. Based on these results, the NRC staff reassessed whether a rulemaking is the appropriate regulatory vehicle for addressing the problems associated with SG tube integrity. It should be recognized that the NRC staff found that the current regulations governing SG tube integrity provide an adequate basis to ensure public health and safety due to SG operation. However, the NRC staff concluded that further guidance is needed for the industry to continue to effectively meet these regulations. Issues involving a plant's technical specifications (TS) are amenable to a generic letter approach. Given these considerations, the NRC staff informed the Commission that it planned to pursue the following approach in lieu of a new steam generator rulemaking: (1) Complete development of a SG tube integrity regulatory guide which describes an acceptable performance-based program for ensuring adequate tube inspection, monitoring, and assessment; (2) request licensees, through a generic letter, to propose performance-based technical specification changes to address the issues regarding inspection, monitoring, and assessment of SG tube condition to ensure that SG tube integrity is maintained consistent with the plant licensing basis; (3) provide licensees with an option to change current SG tube repair criteria and implement a degradation-specific management approach, if it can be demonstrated that risk will be maintained at an acceptable level. An application-specific regulatory guide would provide guidance on acceptable approaches for proposing changes to SG tube integrity criteria and assessing changes in risk associated with relaxation of tube integrity criteria. Licensees would not be able to implement alternate repair criteria until an appropriate risk assessment is submitted and found acceptable by the NRC staff; and (4) as part of the IPE follow-up program, the NRC staff will evaluate pressurized water reactors (PWRs) that appear to have a high potential for core damage sequences that can challenge SG tubes. Any additional requirements would be imposed consistent with the backfit requirements of § 50.109.

The SRM on COMSECY–97–013, dated June 30, 1997, approved the revised approach. The SRM also directed the NRC staff to seek industry input, as appropriate, in developing the technical basis for the proposed TS changes to ensure that the proposed changes are consistent with current steam generator tube degradation modes. In support of this commitment, the NRC staff developed a proposed generic letter that: (1) informs PWR licensees that plant TSs for maintaining SG tube integrity do not alone provide the needed assurance that SG tube integrity is being adequately monitored and maintained in accordance with NRC regulations and plant licensing bases; (2) advises licensees that they may request license amendments to their plant TSs to implement the model TSs attached to the generic letter for maintaining SG tube integrity, or justify alternate approaches for ensuring that SG tube integrity; and (3) requires that licensees submit to the NRC written responses that describe their ongoing or planned activities to monitor and maintain SG tube integrity. By letter dated December 16, 1997, the NRC staff was informed that the industry, through the NEI Nuclear Strategic Issues Advisory Committee, had voted to adopt NEI 97–06. The chief objective of the industry initiative is for PWR licensees to evaluate their existing SG programs and, where necessary, to revise or strengthen program attributes to meet the intent of the NEI 97–06 guidelines. The NEI 97–06 guidelines are intended to improve both the quality and the consistency of SG programs throughout the industry. Consistent with Direction Setting Issue (DSI) 13, the NRC staff's preferred approach is to endorse an industry initiative that addresses all NRC staff and stakeholder concerns, rather than issue a generic letter. As a result, the NRC staff has temporarily deferred issuing the proposed generic letter for public comment while it works with industry to resolve issues associated with NEI 97–06, with the objective of endorsing NEI 97–06 in a regulatory guide.

Whether the NRC staff ultimately endorses the NEI 97–06 guidance or continues with its efforts to issue a generic letter addressing SG tube integrity, the NRC has concluded that equally effective regulatory alternatives to rulemaking are available to address the issue of SG tube integrity. Therefore, the proposed rule is not required and is being withdrawn.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–32107 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AF33

Reporting Reliability and Availability Information for Risk-Significant Systems and Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing a notice of proposed rulemaking that solicited comments on proposed amendments to its regulations that would have required licensees for commercial nuclear power reactors to report to the NRC, plant-specific summary reliability and availability data for certain risk-significant systems and equipment. The proposed rule would have also required licensees to maintain onsite, and to make available for NRC inspection, records and documentation that provide the basis for the summary data reported to the NRC. The systems and equipment for which data would be provided are a subset of the systems and equipment within the scope of the NRC's maintenance rule. The Commission has decided to accept industry's proposed alternative to the rule to voluntarily provide reliability and availability information for risk-significant systems and equipment and, therefore, withdraws this rulemaking.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room

located at 2120 L Street NW. (Lower Level), Washington, DC 20012–7082, telephone: (202) 512–2249.

FOR FURTHER INFORMATION CONTACT: Dennis Allison, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6835, e-mail dpa@nrc.gov.

SUPPLEMENTARY INFORMATION:

On February 12, 1996 (61 FR 5318), the NRC published in the **Federal Register** proposed amendments to 10 CFR Part 50 that would have required operating reactor licensees to report reliability and availability information for certain risk-significant systems and equipment. The reporting requirements would have applied to the event-mitigating systems and equipment that have or could have a significant effect on risk in terms of avoiding core damage accidents or preserving containment integrity. The data that would have been reported would have included: the number of demands and the number of failures to start associated with those demands, along with additional descriptive information; the number of hours of operation following each successful start including whether or not the run was terminated by equipment failure, along with additional descriptive information; the number of hours equipment is unavailable, along with additional descriptive information; for each period equipment is unavailable due to component failure, descriptive information on that failure; and the number of hours when two or more trains from the same or different systems were concurrently unavailable, along with additional descriptive information.

The public comment period closed on June 11, 1996. The NRC received 31 comment letters. One comment letter supported the rule, stating that the public and industry could expect significant benefits. Most of the remaining comments opposed the rule, stating that the proposed reporting requirements costs were underestimated, benefits were overestimated, the rule would be overly burdensome, the rule would be premature, and that the rule is not justified.

The Commission SRM dated June 28, 1995, issued in response to SECY–95–129, and the SRM on SECY–95–215 dated October 24, 1995, directed the NRC staff to continue to work with industry on voluntary submittal of reliability data under a program that will meet the needs of all parties. On October 1, 1996, the Institute of Nuclear Power Operations (INPO) provided the NRC with a sample of data available from its Safety System Performance Indicator (SSPI) system, as part of a voluntary nuclear industry data sharing initiative. A revised Memorandum of Agreement (MOA) between INPO and the NRC was signed on December 24, 1996, providing NRC with access to SSPI data. In addition, on March 21, 1997, the Nuclear Energy Institute (NEI) provided the NRC with a description of a new INPO data collection system, Equipment Performance and Information Exchange (EPIX). Based upon a review of data available in SSPI and EPIX, as well as the information available from Licensee Event Reports and Monthly Operating Reports, the Commission has determined that under the voluntary approach, the NRC can estimate risk parameters and construct a reliability database that reflects the parameters needed for effective use in risk-informed applications. Thus, the intended benefits of the proposed rule would be realized and the main advantages of the voluntary approach (i.e., the lower cost, schedule, and industry support) outweigh any disadvantages. The NRC will continue to work with industry representatives to improve thecontent of the voluntary data. Because of industry's voluntary alternative approach to the rule, the Commission is withdrawing this proposed rulemaking.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–32106 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

RIN 3150–AC03

Elimination of Inconsistencies Between NRC Regulations and EPA High-Level Waste Standards

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing a notice of proposed rulemaking that would have eliminated several inconsistencies with the generic Environmental Protection Agency (EPA) standards to be developed for the disposal of High-Level Waste (HLW) in deep geologic repositories. Because the NRC is developing site-specific disposal regulations for Yucca Mountain, Nevada, consistent with the Energy Policy Act of 1992 (EnPA), the proposed rule is being withdrawn.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012–7082, telephone: (202) 512–2249.

FOR FURTHER INFORMATION CONTACT: Tim McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6681, e-mail tjm3@nrc.gov.

SUPPLEMENTARY INFORMATION:

On June 19, 1986 (51 FR 22288), the NRC published a notice of proposed rulemaking in the **Federal Register** that would have eliminated several inconsistencies with the EPA standards to be developed for the disposal of HLW in deep geologic repositories. The Nuclear Waste Policy Act of 1982 (NWPA) directs NRC to issue criteria for the licensing of HLW geologic repositories. Section 121(c) of this Act states that the criteria for the licensing of HLW geologic repositories must be consistent with these standards. The proposed rule was necessary to eliminate several inconsistencies with the EPA standards, thus fulfilling the statutory requirement. However, since then, Congress passed the EnPA, which requires EPA to issue radiation standards for the proposed geologic repository at Yucca Mountain, based on and consistent with the findings and recommendations of the National Academy of Sciences (NAS). Under EnPA, NRC is also required to develop site-specific disposal regulations that would apply solely to the proposed geologic repository at Yucca Mountain. NAS published its findings and recommendations in 1995.

The NRC staff has considered and is implementing a strategy for developing site-specific disposal regulations that would apply solely to the proposed geologic repository at Yucca Mountain, and is deferring the updating of 10 CFR Part 60 generic requirements to a later date. These site-specific regulations will be issued consistent with EnPA, which also requires the Environmental Protection Agency to issue radiation standards for a geologic repository at Yucca Mountain, based on and consistent with the 1995 findings and recommendations of the NAS.

The NRC staff's strategy for developing the site-specific disposal

regulations for Yucca Mountain can be found in a Commission paper, designated SECY–97–300, dated December 24, 1997. This strategy was approved by the SRM dated March 6, 1998. Because the NRC is developing site-specific disposal regulations for Yucca Mountain, Nevada, the proposed rulemaking is being withdrawn.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–32109 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket Number EE–RM–97–500]

RIN:1904–AA75

Energy Conservation Program for Consumer Products: Fluorescent Lamp Ballasts Energy Conservation Standards

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of extension of comment period.

SUMMARY: On October 30, 1998, the Department of Energy published a notice providing limited reopening of the record of its rulemaking to revise energy conservation standards for fluorescent lamp ballasts under the Energy Policy and Conservation Act (63 FR 58330). The notice announced that November 30, 1998, would be the closing date for receiving public comments regarding the Department's consideration of consumers who choose electronic ballast T–8 systems over electronic ballast T–12 systems and consumers who choose electronic ballasts over cathode cutout ballasts. On November 20, 1998, the National Electrical Manufacturers Association requested that the comment period be extended until December 15, 1998, to allow additional time for data collection and to avoid having the closing date immediately follow the Thanksgiving holiday. The Department agrees to extend the comment period closing date until December 15, 1998.

DATES: Comments must be received on or before December 15, 1998.

ADDRESSES: Written comments are welcome. Please submit 10 copies (no faxes) to: Brenda Edwards-Jones, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Energy Conservation Program for Consumer Products: Fluorescent Lamp Ballasts, Docket No. EE–RM–97–500, 1000 Independence Avenue, SW, Washington, DC 20585–0121.

FOR FURTHER INFORMATION CONTACT: Carl Adams, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–43, 1000 Independence Avenue, SW, Washington, DC 20585–0121, (202) 586–9127, or Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–9507.

Issued in Washington, DC, on November 25, 1998.

Dan W. Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 98–32120 Filed 12–1–98; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 229

[Regulation CC; Docket No. R–1027]

Availability of Funds and Collection of Checks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Board of Governors of the Federal Reserve System (the Board) is proposing to amend Regulation CC to allow banks that consummate a merger on or after July 1, 1998, and before June 1, 1999, greater time to implement software changes related to the merger.

DATES: Comments must be received by January 4, 1999.

ADDRESSES: Comments, which should refer to Docket No. R–1027, may be mailed to Ms. Jennifer Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551. Comments addressed to Ms. Johnson may also be delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m., and to the security control room at all other times. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, N.W. Comments may be inspected in room MP–500, pursuant to § 261.12 of the Board's Rules Regarding Availability of Information, between 9:00 a.m. and 5:00 p.m., except as provided in § 261.14 of those same Rules. (12 CFR 261.12 and 261.14)

FOR FURTHER INFORMATION CONTACT: Jean Anderson, Staff Attorney, Legal Division (202/452–3707). For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Diane Jenkins (202/452–3544).

SUPPLEMENTARY INFORMATION: The Board is proposing to amend Regulation CC to allow banks that consummate merger transactions on or after July 1, 1998, and before June 1, 1999, greater time to implement software changes related to the merger. The Board recognizes that banks are currently dedicating their automation resources to renovating and testing software and replacing noncompliant systems to address Year 2000 and leap year computer problems. Because a large amount of banks' automation resources may be dedicated to these efforts, banks may be challenged to make and test other programming changes, including those that may be required to comply with Regulation CC's merger transition provisions, thus potentially jeopardizing the success of their Year 2000 efforts and/or their system integration efforts due to the merger. Therefore, the Board is proposing to allow banks that consummate a merger on or after July 1, 1998, and before June 1, 1999, to be treated as separate banks until June 1, 2000. Beginning in June 1999, the normal one-year transition period will resume.

The Board requests comment on the need for this amendment and whether the proposed liberalization of the regulation's merger transition provisions is adequate to avoid contention for programming and testing resources necessary to manage banks' Year 2000 readiness efforts that otherwise would be created by these requirements.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires an agency to publish an initial regulatory flexibility analysis with any notice of proposed rulemaking. The initial regulatory flexibility analysis (5 U.S.C. 603(b)) requires an agency to describe the reasons why the proposed rule is being considered and a statement of the objectives of, and legal basis for, the proposed rule. The ''Supplementary Information'' above, contains this information. The proposed rule requires no additional reporting or recordkeeping requirements and does not overlap with other federal rules.

The initial regulatory flexibility analysis also requires a description of,

and where feasible, an estimate of the number of small entities to which the proposed rule will apply. The proposal will apply to all insured banks, as defined in section 3 of the Federal Deposit Insurance Act (12 USC 1813) as well as banks that are eligible to apply to become an insured bank under section 5 of that act (12 U.S.C. 1815). As of June 30, 1998, there were 10,712 insured banks. The proposed amendments are intended to provide relief to banks involved in mergers, including small institutions, by reducing required changes to their automation environment during the period surrounding the century rollover, and should not have a negative economic effect on small institutions.

List of Subjects in 12 CFR Part 229

Banks, banking, Federal Reserve System, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board proposes to amend Regulation CC, 12 CFR part 229 as set forth below:

PART 229—AVAILABILITY OF FUNDS AND COLLECTION OF CHECKS (REGULATION CC)

1. The authority citation for part 229 continues to read as follows:

Authority: 12 U.S.C. 4001 *et seq.*

2. In § 229.19, paragraph (g) is redesignated as paragraph (g)(1), a heading is added for newly designated paragraph (g)(1), and a new paragraph (g)(2) would be added to read as follows:

§ 229.19 Miscellaneous.

* * * * *

(g) *Effect of merger transaction.* (1) *In general.* * * *

(2) *Merger transactions on or after July 1, 1998, and before June 1, 1999.* If banks have consummated a merger transaction on or after July 1, 1998, and before June 1, 1999, the merged banks may be considered separate banks until June 1, 2000.

3. In § 229.40 the existing text is redesignated as paragraph (a), a heading is added for newly designated paragraph (a), and a new paragraph (b) would be added to read as follows:

§ 229.40 Effect of merger transaction.

(a) *In general.* * * *

(b) *Merger transactions on or after July 1, 1998, and before June 1, 1999.* If banks have consummated a merger transaction on or after July 1, 1998, and before June 1, 1999, the merged banks may be considered separate banks until June 1, 2000.

By order of the Board of Governors of the Federal Reserve System, November 25, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98–32051 Filed 12–1–98; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–ANE–02]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT8D–200 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to Pratt & Whitney JT8D–200 series turbofan engines, that currently requires periodic inspection of fan blades for locked rotors and foreign object damage (FOD), unlocking of shrouds if necessary, lubrication of fan blade shrouds, and dimensional restoration of the fan blade leading edge. In addition, that AD requires installation of improved design fan blades as terminating action for the inspections. This action would reduce the lubrication interval, and require removal of rotors that experience repeat lockups within 225 cycles in service. This proposal is prompted by reports of 7 fan blade failures since publication of the current AD. The actions specified by the proposed AD are intended to prevent fan blade failure, which can result in damage to the aircraft.

DATES: Comments must be received by February 1, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 96–ANE–02, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line. Comments may be inspected at this location between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from fan blade failure, which can result in damage to the aircraft. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Peter White, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7128, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. 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, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 summarizing each FAA-public contact concerned with the substance of this proposal 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 Number 96–ANE–02.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 96–ANE–02, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

On November 7, 1996, the Federal Aviation Administration (FAA) issued airworthiness directive AD 96–23–15, Amendment 39–9821 (61 FR 63706, December 2, 1996), applicable to Pratt & Whitney (PW) JT8D–200 series turbofan

engines, to require periodic inspection of fan blades for locked rotors and foreign object damage (FOD), unlocking of shrouds if necessary, lubrication of fan blade shrouds, and dimensional restoration of the fan blade leading edge. In addition, that AD requires installation of improved design fan blades as terminating action for the inspections. That action was prompted by the introduction into service of improved design fan blades. That condition, if not corrected, could result in fan blade failure, which can result in damage to the aircraft.

Since the issuance of that AD, the FAA has received reports of 7 additional fan blade failures on engines that had been inspected in accordance with the current AD. The fan blades are failing as a result of high cycle fatigue. Contributing factors are foreign object damage (FOD), leading edge erosion, manufacturing discrepancies, and locked fan shrouds. These fan blade failures indicate that the currently mandated fleet management plan is insufficient.

The FAA has reviewed and approved the technical contents of PW Alert Service Bulletin (ASB) No. A6241, Revision 2, dated June 29, 1998, that reduces the lubrication interval, and requires removal of rotors that experience repeat lockups within 225 cycles in service (CIS).

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 96–23–15 to reduce the lubrication interval, and require removal of rotors that experience repeat lockups within 225 cycles in service.

There are approximately 2,650 engines of the affected design in the worldwide fleet. The FAA estimates that 960 engines installed on aircraft of U.S. registry would be affected by this proposed AD, that it would take no additional work hours to perform these inspections except at a shorter lubrication interval. Rework costs for the fan blades are $275 per blade, of which approximately $140 per blade is attributable to this AD action. With the manufacturer's rebate of $50 per blade, the total cost to industry of reworking these blades is $2,750 per engine. The manufacturer estimates that it will take 19 work hours per engine to remove and reinstall the blades. Using labor costs of $60 per hour, the labor costs to remove and reinstall the blades are $1,140 per engine. Hence, the increased costs generated by this proposed AD on U.S. operators is estimated to be $3,890 per engine, or $3,734,400 to retrofit the remaining 960 engines.

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9821 (61 FR 63706, December 2, 1998) and by adding a new airworthiness directive to read as follows:

Pratt & Whitney: Docket No. 96–ANE–02. Supersedes AD 96–23–15, Amendment 39–9821.

Applicability: Pratt & Whitney (PW) Models JT8D–209, –217, –217A, –217C, and –219 turbofan engines that have not incorporated PW Service Bulletin (SB) No. 6193, dated October 31, 1994, or with fan blade, Part Numbers (P/N's) 798821, 798821–001, 808121, 808121–001, 809221, 811821, 851121, 851121–001, 5000021–02, 5000021–022, and 5000021–032 installed. These engines are installed on but not limited to McDonnell Douglas MD–80 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fan blade failure, which can result in damage to the aircraft, accomplish the following:

(a) Inspect fan blades and shrouds, unlock fan blade shrouds, lubricate fan blade shrouds, restore leading edge dimensions, and modify or install improved design fan blades in accordance with the schedule and procedures described in Parts 1, 2, and 3 of the Accomplishment Instructions of PW Alert Service Bulletin (ASB) No. A6241, Revision 2, dated June 29, 1998.

(b) Modification of fan blades to the improved design configuration or installation of improved design fan blades in accordance with Part 3 of the Accomplishment Instructions of PW ASB No. A6241, Revision 2, dated June 29, 1998, constitutes terminating action to the inspections and maintenance actions described in paragraph (a) of this AD.

(c) For the purpose of this AD, the accomplishment effective date to be used for determination of compliance intervals, as required by Section 2 of PW ASB No. A6241, Revision 2, dated June 29, 1998, is defined as the effective date of this AD.

(d) For the purpose of this AD, ''repair'' as specified in Part 3, Paragraph A.(1)(b) of the Accomplishment Instructions of PW ASB No. A6241, Revision 2, dated June 29, 1998 is defined as the refurbishment of fan blades in accordance with Part 3, Paragraph C of the Accomplishment Instructions of PW ASB No. A6241, Revision 2, dated June 29, 1998.

(e) Alternative methods of compliance that have been approved for AD 95–12–19 are applicable for this AD and additional approval is not required.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative method of compliance with this AD, if any, may be obtained from the Engine Certification Office.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to

a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on November 24, 1998.

David A. Downey,

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

[FR Doc. 98–32048 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–49]

Proposed Amendment to Class D and Class E Airspace; St. Joseph, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Class E airspace area at Rosecrans Memorial Airport, St. Joseph, MO. A review of the Class E airspace for Rosecrans Memorial Airport indicates it does not comply with the criteria for 700 feet Above Ground Level (AGL) airspace required for diverse departures as specified in FAA Order 7400.2D. The Class E airspace area has been enlarged to conform to the criteria of FAA Order 7400.2D. A revision to the Airport Reference Point (ARP) coordinates is included in this document. The intended effect of this rule is to revise the ARP coordinates, comply with the criteria of FAA Order 7400.2D, and provide additional controlled Class E airspace for aircraft operating under instrument Flight Rules (IFR). The area will be depicted on aeronautical charts to provide a reference for pilots operating under Visual Flight Rules (VFR).

DATES: Comments must be received on or before January 5, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, ACE–520, Federal Aviation Administration, Docket No. 98–ACE–49, 601 East 12th Street, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the office of the Manager, Airspace Branch, Air Traffic Division, at the address listed above.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number: (816) 426–3408.

SUPPLEMENTARY INFORMATION: .

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 98–ACE–49.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which described the procedures.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to provide additional controlled airspace for Instrument Flight Rules (IFR) at Rosecrans Memorial Airport, St. Joseph, MO. A review of the Class E airspace for Rosecrans Memorial Airport, St. Joseph, MO, indicates it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2D. The Class E airspace area has been enlarged to conform to the criteria in FAA Order 7400.2D. The criteria in FAA Order 7400.2D for an aircraft to reach 1200 feet AGL, is based on a standard climb gradient of 200 feet per mile, plus the distance from the Airport Reference Point (ARP) to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The Class D and Class E surface areas are amended to indicate the new ARP coordinates. The amendment of Rosecrans Memorial Airport will meet the criteria of FAA Order 7400.2D, revise the ARP coordinates, provide additional controlled airspace at and above 700 feet AGL, and thereby facilitate separation of aircraft operating under Instrument Flight Rules. The areas will be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures. Class D airspace areas are published in paragraph 5000; Class E airspace areas designated as an extension to a Class D or Class E surface area are published in paragraph 6004; and Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9F, dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by Reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 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.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 5000 Class D airspace

* * * * *

ACE MO D St. Joseph, MO [Revised]

Rosecrans Memorial Airport, MO
(Lat. 39°46′19″ N., long. 94°54′35″ W.)

That airspace extending upward from the surface to and including 3,300 feet MSL within a 4.2-mile radius of the Rosecrans Memorial Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6004 Class E airspace areas designated as an extension to a Class D or Class E surface area

* * * * *

ACE MO E4 St. Joseph, MO [Revised]

Rosecrans Memorial Airport, MO
(Lat. 39°46′19″ N., long. 94°54′35″ W.)
St. Joseph VORTAC
(Lat. 39°57′38″ N., long. 94°55′31″ W.)
TARIO LOM
(Lat. 39°40′33″ N., long. 94°54′25″ W.)
St. Joseph ILS
(Lat. 39°47′16″ N., long. 94°54′25″ W.)

That airspace extending upward from the surface within 1.8 miles each side of the St. Joseph ILS localizer south course extending from the 4.2-mile radius of Rosecrans Memorial Airport to the TARIO LOM and within 1.8 miles each side of the St. Joseph VORTAC 175° radial extending from the 4.2-mile radius of the airport to 5.8 miles north of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E airspace area extending upward from 700 feet or more above the surface of the earth

* * * * *

ACE MO E5 St. Joseph, MO [Revised]

Rosecrans Memorial Airport, MO
(Lat. 39°46′19″ N., long. 94°54′35″ W.)
St. Joseph VORTAC
(Lat. 39°57′38″ N., long. 94°55′31″ W.)
TARIO LOM
(Lat. 39°40′33″ N., long. 94°54′25″ W.)
St. Joseph ILS
(Lat. 39°47′16″ N., long. 94°54′25″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Rosecrans Memorial Airport and within 2.0 miles each side of the 175° radial of the St. Joseph VORTAC extending from the 6.8-mile radius to the VORTAC and within 4 miles east and 6 miles west of the St. Joseph ILS localizer south course, extending from the 6.8-mile radius to 10.5 miles south of the TARIO LOM.

* * * * *

Issued in Kansas City, MO, on November 3, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–32134 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–105170–97]

RIN 1545–AV14

Credit for Increasing Research Activities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the computation of the credit under section 41(c) and the definition of *qualified research* under section 41(d). The proposed regulations reflect changes to section 41 made by the Tax Reform Act of 1986, the Revenue Reconciliation Act of 1989, the Small Business Job Protection Act of 1996, and the Taxpayer Relief Act of 1997. The proposed regulations also provide certain technical amendments to the regulations.

DATES: Written comments must be received no later than March 2, 1999.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–105170–97), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–105170–97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option of the IRS Home Page, or by submitting comments directly to the IRS Internet site at: http://www.irs.ustreas.gov/prod/tax—regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Lisa J. Shuman or Leslie H. Finlow at (202)622–3120 (not a toll-free number); concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, La Nita Van Dyke at (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(d)). 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, OP:FS:FP, Washington, DC 20224. Comments on the collection of information should be received by March 2, 1999. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in §§ 1.41–4(a) and 1.41–8(b). The information is required by the IRS to ensure that taxpayers have engaged in qualified research and to ensure the proper computation of the credit for increasing research activities under section 41. Section 1.41–4(a) defines a process of experimentation, as required for credit eligibility, to include the recording of the results of the experiments. This requirement imposes no additional recordkeeping burden, because taxpayers engaging in a bona fide process of experimentation already record the results in any event (see discussion under Explanation of Provisions, 3. *Documentation,* in this preamble). The information required by § 1.41–8 will be used to determine if the taxpayer has elected or revoked the election to use the alternative incremental credit allowed under section 41(c)(4). The collection of information is mandatory. The likely respondents are businesses or other for-profit institutions and organizations. Responses to this collection of information are required to elect to use and to revoke the election to use the alternative incremental credit computation allowed under section 41(c)(4).

The reporting burden contained in § 1.41–8(b)(2) (relating to the election of the alternative incremental credit) is reflected in the burden of Form 6765.

Estimated total annual reporting burden under § 1.41–8(b)(3) (relating to the revocation of the election to use the alternative incremental credit): 250 hours.

Estimated average annual burden hours per respondent: 50 hours.

Estimated number of respondents: 5.

Estimated frequency of responses: On occasion.

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

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

The research credit provisions originally appeared in section 44F of the Internal Revenue Code of 1954 (the 1954 Code), as added to the 1954 Code by section 221 of the Economic Recovery Tax Act of 1981. Section 471(c) of the Tax Reform Act of 1984 redesignated section 44F as section 30. Section 231 of the Tax Reform Act of 1986 (the 1986 Act) redesignated section 30 as section 41 and substantially modified the research credit provisions. The amendments made to section 41 by the 1986 Act primarily relate to the definition of *qualified research* in section 41(d) and the computation of *basic research* payments under section 41(e). The Revenue Reconciliation Act of 1989 (the 1989 Act), the Revenue Reconciliation Act of 1993 (the 1993 Act), the Small Business Job Protection Act of 1996 (the 1996 Act), and the Taxpayer Relief Act of 1997 (the 1997 Act) also amended the research credit provisions. These amendments primarily relate to the trade or business requirement in section 41(b) and the computation of the credit under sections 41(c) and 41(f).

On May 17, 1989, the IRS published in the **Federal Register** (54 FR 21203) final regulations under section 41. The 1989 final regulations generally do not reflect the amendments to section 41 made by the 1986 Act, the 1989 Act, the 1993 Act, the 1996 Act, and the 1997 Act. The amendments proposed by this document contain rules relating primarily to the amendments to section 41(d) made by the 1986 Act. The amendments proposed by this document also contain some rules relating to amendments to section 41 made by the 1989 Act, the 1996 Act, and the 1997 Act.

On January 2, 1997, the IRS published in the **Federal Register** (62 FR 81) proposed regulations (the 1997 proposed regulations) under section 41 describing when computer software that is developed by (or for the benefit of) a taxpayer primarily for the taxpayer's internal use can qualify for the credit for increasing research activities. The 1997 proposed regulations reflect a change to section 41 made by the 1986 Act. The proposed regulations set forth in this notice of proposed rulemaking complement but otherwise do not affect the 1997 proposed regulations.

The Tax and Trade Relief Extension Act of 1998 extended the research credit from June 30, 1998 through June 30, 1999. In the Conference Report, H.R. Rep. No. 105–825, at 1547–49 (1998), the conferees address the scope of the term *qualified research,* comment on an aspect of the process of experimentation requirement, and note a lack of clarity in the interpretation of the distinction between internal-use software and other software. These proposed regulations reflect the views expressed by the conferees, as well as prior legislative history, regarding the term *qualified research* and the process of experimentation. The IRS and Treasury request comments on the distinction between internal-use software and other software.

Explanation of Provisions

1. Qualified Research

Congress enacted the research credit to encourage business firms to perform the research necessary to increase the innovative qualities and efficiency of the U.S. economy. H.R. Rep. No. 99–426, at 177 (1985); S. Rep. No. 99–313, at 694 (1986). In extending the research credit in the 1986 Act, Congress expressed concern that, in practice, taxpayers had applied the existing definition of *qualified research* too broadly and some taxpayers had claimed the credit for virtually any expense relating to product development. H.R. Rep. No. 99–426, at 178; S. Rep. No. 99–313, at 694–95. Many taxpayers claiming the credit were not in industries that involved high technology or its application in developing technologically new and improved products or methods of production. H.R. Rep. No. 99–426, at 178; S. Rep. No. 99–313, at 695.

To address these concerns, Congress narrowed the scope of the research credit by providing in the Internal Revenue Code (Code) an express definition of the term *qualified research*. In determining eligibility for the research credit, section 41(d) requires that qualified research activities satisfy a multi-part test. First, the taxpayer's expenditures must be eligible to be treated as expenses under section 174. See § 1.174–2(a)(1) (defining *research and experimental expenditures*).

Second, the expenditures must relate to research undertaken for the purpose of discovering information that is both technological in nature and the application of which is intended to be useful in developing a new or improved business component of the taxpayer. The proposed regulations provide that research is undertaken for the purpose of discovering information that is technological in nature only if the research activities are undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the particular field of technology or

science and the process of experimentation utilized fundamentally relies on principles of physical or biological sciences, engineering, or computer science. Consistent with the requirement that the research activities be undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the particular field of technology or science, the credit may be available where the technological advance sought by the taxpayer is evolutionary, and, in certain circumstances, where the taxpayer is not the first to achieve the same advance. Moreover, the credit is available regardless of whether the taxpayer succeeds or fails in achieving the desired advance.

Third, section 41(d) requires that substantially all of the activities of the research constitute elements of a *process of experimentation* that relates to a new or improved function, performance, reliability or quality. As noted in the previous paragraph, the process of experimentation utilized must fundamentally rely on principles of physical or biological sciences, engineering, or computer science.

In developing a process of experimentation rule applicable to all scientific disciplines, IRS personnel met with personnel from the National Science Foundation and the National Institute of Standards and Technology. The proposed regulation explains that a process of experimentation is a process involving the evaluation of more than one alternative designed to achieve a result where the means of achieving that result are uncertain at the outset. This requires that the taxpayer (i) develop one or more hypotheses designed to achieve the intended result; (ii) design a scientific experiment (that, where appropriate to the particular field of research, is intended to be replicable with an established experimental control) to test and analyze those hypotheses (through, for example, modeling, simulation, or a systematic trial and error methodology); (iii) conduct the experiment and record the results; and (iv) refine or discard the hypotheses as part of a sequential design process to develop or improve the business component.

The proposed regulation does not require that the results of the experiments be recorded in any specific manner. The results of the experiments should be recorded in a manner that is appropriate for the particular field of science in which the experiment is conducted and for the type of experimentation involved. In some fields, for example, experiments are recorded in lab books. When developing computer software, by contrast, the experiments might be recorded in comment lines contained in the source code.

In the 1986 Act, Congress also specified that expenditures incurred in certain research, research-related, or non-research activities are not eligible for the credit. The excluded activities are: post-production activities, adaptation, duplication, surveys and studies, research outside the United States, research in the social sciences, funded research, and research related to certain internal-use computer software.

Section 1.41–4 of this proposed regulation contains rules that clarify the definition of the term qualified research and other terms used in section 41(d). The proposed regulation also provides rules relating to activities for which the research credit is not allowed.

2. Application of Tests

In the legislative history to the 1986 Act, Congress stated that if the requirements of section 41(d) are not met for an entire product, the term *business component* means the most significant set of elements of that product for which all the requirements of section 41(d) are met. The legislative history provides that this ''shrinking back'' is to continue until either a subset of elements of the product that satisfies the requirements is reached, or the most basic element of the product is reached and such element fails to satisfy the test.

Consistent with the legislative history, § 1.41–4(b) of the proposed regulation explains that the ''shrinking-back'' concept is the method for applying the tests in section 41(d) to a business component.

3. Documentation

Taxpayers must (a) record the results of their scientific experiments (in a manner that is appropriate for the particular field of science in which the experiment is conducted and for the type of experiment involved) and (b) comply with the recordkeeping requirements of section 6001 and the regulations thereunder. The requirement that taxpayers record the results of their scientific experiments is not intended to cause taxpayers to create records that otherwise would not be created. Rather, the recording of results is inherent in a process of experimentation to discover information that is technological in nature. Limiting the availability of the credit to taxpayers who record the results of their scientific experiments is not intended to change taxpayer behavior, but to identify taxpayers who engage in a bona fide process of experimentation and thus may be eligible for the credit.

4. Election of the Alternative Incremental Credit

The notice of proposed rulemaking provides rules for electing the alternative incremental credit, which may be elected under section 41(c)(4). Section 1.41–8 of the proposed regulation provides that the election is made on Form 6765, ''Credit for Increasing Research Activities,'' and that the completed form must be attached to the taxpayer's timely filed original return (including extensions) for the taxable year to which the election applies.

Proposed Effective Date

In general, the regulations are proposed to be effective for expenditures paid or incurred on or after the date final regulations are published in the **Federal Register**. The regulations addressing the base amount are proposed to be effective for taxable years beginning on or after the date final regulations are published in the **Federal Register**. The regulations providing for the election and revocation of the alternative incremental credit are proposed to be effective for taxable years ending on or after the date final regulations are published in the **Federal Register**. No inference should be drawn from the proposed effective date concerning the application of section 41 to expenditures paid or incurred or the computation of the base amount before the proposed effective date.

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) does not apply to these regulations. It is hereby certified that the collection of information contained in these regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. This certification is based on the information that follows. The economic impact of the collection of information contained in these regulations on any small entity would result from the entity being required: to (1) Record the results of experiments related to its qualified research activities, (2) elect on Form 6765 to use the alternative incremental credit if the

entity desires to use that method, and (3) obtain permission to revoke the alternative incremental credit election, if so desired. Because taxpayers record results in conducting their research activities in any event (see discussion under Explanation of Provisions, 3. *Documentation*, in this preamble), the economic impact of the recordkeeping requirement in the regulation would not be significant. The economic impact of electing the alternative incremental credit on Form 6765 also would not be significant because the election is made on the same form and is based on the same information that is used to claim the research credit. Pursuant to section 7805(f), 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 (preferably a signed original and eight (8) copies) that are submitted timely (in the manner described in the **ADDRESSES** portion of this preamble) to the IRS. Submissions might include comments on the definition of gross receipts, comments regarding the exclusion for post-production activities, comments on whether and how the definition of a process of experimentation should be refined to ensure that it is appropriate for all scientific fields, and comments on the interaction of the discovery requirement and the duplication exclusion and the effect of such interaction on specific industries. Also, submissions might include comments on clarifying the distinction between internal-use software (i.e., software described in section 41(d)(4)(E)) and other software. All comments will be available for public inspection and copying.

A public hearing will be scheduled in the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The IRS recognizes that persons outside the Washington, DC area also may wish to testify at the public hearing through teleconferencing. Requests to include teleconferencing sites must be received by January 16, 1999. If the IRS receives sufficient indications of interest to warrant teleconferencing to a particular city, and if the IRS has teleconferencing facilities available in that city on the date the public hearing is to be scheduled, the IRS will try to accommodate the requests.

The IRS will publish the time and date of the public hearing and the locations of any teleconferencing sites in an announcement in the **Federal Register**. The announcement will include the date by which persons that wish to present oral comments at the hearing must submit requests to speak, outlines of the topics to be discussed, and the time to be devoted to each topic.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information. The principal authors of these proposed regulations are Lisa J. Shuman and Leslie H. Finlow of the Office of the Assistant Chief Counsel (Passthroughs and Special Industries). However, personnel from other offices of the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows.

(**Note**: These proposed amendments complement the proposed amendments published at 62 FR 83, January 2, 1997.)

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. Revise the undesignated centerheading immediately before § 1.30–1 to read as follows:

Credits Allowable Under Section 30 through 44B

Par. 3. Remove the undesignated centerheading immediately before § 1.41–0.

Par. 4. Section 1.41–0 is revised to read as follows:

§ 1.41–0 Table of contents.

This section lists the paragraphs contained in §§ 1.41–0 through 1.41–8.

(6) Internal-use computer software.
(7) Activities outside the United States.
(i) In general.
(ii) Apportionment of in-house research expenses.
(iii) Apportionment of contract research expenses.
(8) Research in the social sciences, etc.
(9) Research funded by any grant, contract, or otherwise.
(10) Illustrations.
(d) Documentation.

§ 1.41–5 Basic research for taxable years beginning after December 31, 1986. [Reserved]

§ 1.41–6 Aggregation of expenditures.

(a) Controlled group of corporations; trades or businesses under common control.
(1) In general.
(2) Definition of trade or business.
(3) Determination of common control.
(4) Examples.
(b) Minimum base period research expenses.
(c) Tax accounting periods used.
(1) In general.
(2) Special rule where timing of research is manipulated.
(d) Membership during taxable year in more than one group.
(e) Intra-group transactions.
(1) In general.
(2) In-house research expenses.
(3) Contract research expenses.
(4) Lease payments.
(5) Payment for supplies.

§ 1.41–7 Special rules.

(a) Allocations.
(1) Corporation making an election under subchapter S.
(i) Pass-through for taxable years beginning after December 31, 1982, in the case of an S corporation.
(ii) Pass-through, for taxable years beginning before January 1, 1983, in the case of a subchapter S corporation.
(2) Pass-through in the case of an estate or trust.
(3) Pass-through in the case of a partnership.
(i) In general.
(ii) Certain expenditures by joint ventures.
(4) Year in which taken into account.
(5) Credit allowed subject to limitation.
(b) Adjustments for certain acquisitions and dispositions—Meaning of terms.
(c) Special rule for pass-through of credit.
(d) Carryback and carryover of unused credits.

§ 1.41–8 Special rules for taxable years ending on or after the date final regulations are published in the **Federal Register**.

(a) Alternative incremental credit.
(b) Election.
(1) In general.
(2) Time and manner.
(3) Revocation.

Par. 5. Section 1.41–1 is revised to read as follows:

§ 1.41–1 Credit for increasing research activities.

(a) *Basic principles.* Section 41 provides a credit for increasing research activities. The credit is intended to encourage business firms to perform the technological research necessary to increase the innovative qualities and efficiency of the U.S. economy. The credit provides an incentive for business firms to increase their expenditures for research to obtain new knowledge through a scientific process of experimentation. Consequently, the credit is not to be applied too broadly or in a manner such that virtually any expense relating to the development of a product is eligible for the credit, even if some portion of the expense of developing the product does qualify for the credit. Similarly, the credit is not available for an expenditure merely because the expenditure may be treated as an expense under section 174. On the other hand, the credit may be available even though the technological advance sought by the taxpayer is evolutionary, and, in certain circumstances, even if another taxpayer has previously achieved the same advance. Moreover, the credit is available regardless of whether the taxpayer succeeds or fails in achieving the desired advance. The credit is limited to eligible expenditures paid or incurred for qualified research, as defined in section 41(d) and § 1.41–4.

(b) *Amount of credit.* The amount of a taxpayer's credit is determined under section 41(a). For taxable years beginning after June 30, 1996, and at the election of the taxpayer, the portion of the credit determined under section 41(a)(1) may be calculated using the alternative incremental credit set forth in section 41(c)(4).

(c) *Introduction to regulations under section 41.* (1) Sections 1.41–2 through 1.41–8 and 1.41–3A through 1.41–5A address only certain provisions of section 41. The following table identifies the provisions of section 41 that are addressed, and lists each provision with the section of the regulations in which it is covered.

Section of the regulation	Section of the Internal Revenue Code
§ 1.41–2	41(b)
§ 1.41–3	41(c)
§ 1.41–4	41(d)
§ 1.41–5	41(e)
§ 1.41–6	41(f)
§ 1.41–7	41(f)
	41(g)
§ 1.41–8	41(c)
§ 1.41–3A	41(c) (taxable years beginning before January 1, 1990)
§ 1.41–4A	41(d) (taxable years beginning before January 1, 1986)
§ 1.41–5A	41(e) (taxable years beginning before January 1, 1987)

(2) Section 1.41–3A also addresses the special rule in section 221(d)(2) of the Economic Recovery Tax Act of 1981 relating to taxable years overlapping the effective dates of section 41. Section 41 was formerly designated sections 30 and 44F. Sections 1.41–0 through 1.41–8 and 1.41–0A through 1.41–5A refer to these sections as section 41 for conformity purposes. Whether section 41, former section 30, or former section 44F applies to a particular expenditure depends upon when the expenditure was paid or incurred.

§ 1.41–2 [Amended]

Par. 6. Section 1.41–2 is amended as follows:

1. The last sentence of paragraph (a)(3)(i) is amended by removing the language ''§ 1.41–5(d)(2)'' and adding ''§ 1.41–4A(d)(2)'' in its place.

2. The last sentence of paragraph (a)(3)(ii) is amended by removing the language ''§ 1.41–5(d)(3)'' and adding ''§ 1.41–4A(d)(3)'' in its place.

3. The last sentence of paragraph (a)(4)(ii)(F) is amended by removing the language ''§ 1.41–9(a)(3)(ii)'' and adding ''§ 1.41-7(a)(3)(ii)'' in its place.

4. Paragraph (e)(1)(i) is amended by removing the language ''§ 1.41–5'' and adding ''§ 1.41–4 or 1.41–4A, whichever is applicable'' in its place.

Par. 7. An undesignated centerheading is added immediately following § 1.44B–1 to read as follows:

Research Credit—For Taxable Years Beginning Before January 1, 1990

§ 1.41–3 [Redesignated as § 1.41–3A]

Par. 8. Section 1.41–3 is redesignated as § 1.41–3A and added under the new undesignated centerheading ''Research Credit—For Taxable Years Beginning Before January 1, 1990.''

Par. 9. New § 1.41–3 is added to read as follows:

§ 1.41–3 Base amount for taxable years beginning on or after the date final regulations are published in the Federal Register.

(a) and (b) [Reserved]

(c) *Definition of gross receipts*—(1) *In general.* For purposes of section 41, gross receipts means the total amount, as determined under the taxpayer's method of accounting, derived by the taxpayer from all its activities and from all sources (e.g., revenues derived from

the sale of inventory before reduction for cost of goods sold).

(2) *Amounts excluded.* For purposes of this paragraph (c), gross receipts do not include amounts representing—

(i) Returns or allowances;

(ii) Receipts from the sale or exchange of capital assets, as defined in section 1221;

(iii) Repayments of loans or similar instruments (e.g., a repayment of the principal amount of a loan held by a commercial lender);

(iv) Receipts from a sale or exchange not in the ordinary course of business, such as the sale of an entire trade or business or the sale of property used in a trade or business as defined under section 1221(2); and

(v) Amounts received with respect to sales tax or other similar state and local taxes if, under the applicable state or local law, the tax is legally imposed on the purchaser of the good or service, and the taxpayer merely collects and remits the tax to the taxing authority.

(3) *Foreign corporations.* For purposes of section 41, in the case of a foreign corporation, gross receipts include only gross receipts that are effectively connected with the conduct of a trade or business within the United States. See section 864(c) and applicable regulations thereunder for the definition of *effectively connected income.*

(d) *Consistency requirement*—(1) *In general.* In computing the credit for increasing research activities for taxable years beginning after December 31, 1989, qualified research expenses and gross receipts taken into account in computing a taxpayer's fixed-base percentage and a taxpayer's base amount must be determined on a basis consistent with the definition of qualified research expenses and gross receipts for the credit year, without regard to the law in effect for the taxable years taken into account in computing the fixed-base percentage or the base amount. This consistency requirement applies even if the period for filing a claim for credit or refund has expired for any taxable year taken into account in computing the fixed-base percentage or the base amount.

(2) *Illustrations.* The following examples illustrate the application of the consistency rule of paragraph (d)(1) of this section:

Example 1. (i) X, an accrual method taxpayer using the calendar year as its taxable year, incurs qualified research expenses in 1990. X wants to compute its research credit under section 41 for the tax year ending December 31, 1990. As part of the computation, X must determine its fixed-base percentage, which depends in part on X's qualified research expenses incurred during the fixed-base period, the taxable years beginning after December 31, 1983, and before January 1, 1989.

(ii) During the fixed-base period, X reported the following amounts as qualified research expenses on its Form 6765:

1984	$100x
1985	120x
1986	150x
1987	180x
1988	170x
Total	$720x

(iii) For the taxable years ending December 31, 1984, and December 31, 1985, X based the amounts reported as qualified research expenses on the definition of qualified research in effect for those taxable years. The definition of qualified research changed for taxable years beginning after December 31, 1985. If X used the definition of qualified research applicable to its taxable year ending December 31, 1990, the credit year, its qualified research expenses for the taxable years ending December 31, 1984, and December 31, 1985, would be reduced to $80x and $100x, respectively. Under the consistency rule in section 41(c)(5) and paragraph (d)(1) of this section, to compute the research credit for the tax year ending December 31, 1990, X must reduce its qualified research expenses for 1984 and 1985 to reflect the change in the definition of qualified research for taxable years beginning after December 31, 1985. Thus, X's total qualified research expenses for the fixed-base period (1984–1988) to be used in computing the fixed-base percentage is $80 + 100 + 150 + 180 + 170 = $680x.

Example 2. The facts are the same as in *Example 1,* except that, in computing its qualified research expenses for the taxable year ending December 31, 1999, X claimed that a certain type of expenditure incurred in 1999 was a qualified research expense. X's claim reflected a change in X's position, because X had not previously claimed that similar expenditures were qualified research expenses. The consistency rule requires X to adjust its qualified research expenses in computing the fixed-base percentage to include any similar expenditures not treated as qualified research expenses during the fixed-base period, regardless of whether the period for filing a claim for credit or refund has expired for any year taken into account in computing the fixed-base percentage.

Par. 10. Section 1.41–4 is revised to read as follows:

§ 1.41–4 Qualified research for expenditures paid or incurred on or after the date final regulations are published in the Federal Register.

(a) *Qualified research*—(1) *General rule.* Research activities related to the development or improvement of a business component constitute qualified research only if the research activities meet all of the requirements of section 41(d)(1) and this section, and are not otherwise excluded under section 41(d)(3)(B) or (4), or this section.

(2) *Requirements of section 41(d)(1).* Research constitutes qualified research only if it is research—

(i) With respect to which expenditures may be treated as expenses under section 174, see § 1.174–2;

(ii) That is undertaken for the purpose of discovering information that is technological in nature, and the application of which is intended to be useful in the development of a new or improved business component of the taxpayer; and

(iii) Substantially all of the activities of which constitute elements of a process of experimentation that relates to a new or improved function, performance, reliability or quality.

(3) *Discovering information.* For purposes of section 41(d) and this section, the term *discovering information* means obtaining knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in a particular field of technology or science.

(4) *Technological in nature.* For purposes of section 41(d) and this section, information is technological in nature if the process of experimentation used to discover such information fundamentally relies on principles of physical or biological sciences, engineering, or computer science.

(5) *Process of experimentation.* For purposes of section 41(d) and this section, a process of experimentation is a process to evaluate more than one alternative designed to achieve a result where the means of achieving that result are uncertain at the outset. A process of experimentation in the physical or biological sciences, engineering, or computer science requires that the taxpayer—

(i) Develop one or more hypotheses designed to achieve the intended result;

(ii) Design a scientific experiment (that, where appropriate to the particular field of research, is intended to be replicable with an established experimental control) to test and analyze those hypotheses (through, for example, modeling, simulation, or a systematic trial and error methodology);

(iii) Conduct the experiment and record the results; and

(iv) Refine or discard the hypotheses as part of a sequential design process to develop or improve the business component.

(6) *Substantially all requirement.* The substantially all requirement of section 41(d)(1)(C) and paragraph (a)(2)(iii) of this section is satisfied only if 80 percent or more of the research activities, measured on a cost or other

consistently applied reasonable basis, constitute elements of a process of experimentation for a purpose described in section 41(d)(3). The substantially all requirement is applied separately to each business component.

(7) *Use of computers and information technology.* The employment of computers or information technology, or the reliance on principles of computer science or information technology to store, collect, manipulate, translate, disseminate, produce, distribute, or process data or information, and similar uses of computers and information technology does not itself establish that qualified research has been undertaken.

(8) *Illustrations.* The following examples illustrate the application of paragraph (a) of this section:

Example 1. (i) *Facts.* X undertakes to develop for sale a tool that would improve its suite of application development products. The desired tool would handle connectivity problems for software application developers by providing data access via a layer of software that is more effective than existing software at finding data in various locations and forms within a network, translating it if need be, and then delivering the result to whatever application or user requested it. The means of developing such versatile database access middleware are not in the common knowledge of skilled professionals in the relevant technological fields. In order to determine whether it can successfully develop the desired tool, X develops, tests, and discards or refines various algorithms and protocols.

(ii) *Conclusion.* X's activities to develop the technology to build the new software development tool may be qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section. In developing the technology, X undertook to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 2. (i) *Facts.* X acquired a new software environment, including a new operating system and a new database management system with related tools. X undertook a project to redeploy its data processing systems to the new software environment. X anticipated that, relative to the old system, the new system would significantly increase the time-sharing capabilities of its computer system. The project activities included redesign of databases and user interfaces, and translation of code from one programming language to another. In migrating to the new software environment, X relied on techniques and approaches that were within the common knowledge of skilled professionals in the relevant technological fields.

(ii) *Conclusion.* X's activities to redeploy its data processing systems to the new software environment are not qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section. X did not undertake to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 3. (i) *Facts.* X operates a computer system that does not recognize dates beginning in the year 2000. In order to ensure that its computer system will not malfunction in the year 2000, X incurs substantial costs having its employees manually search its computer programs to find all date fields used in the programs and replace all of the date fields with year 2000 compliant date fields.

(ii) *Conclusion.* Because the activities of X's employees were not undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields and do not involve a process of experimentation, the activities are not qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section.

Example 4. (i) *Facts.* X is engaged in the business of developing and manufacturing widgets. X wants to manufacture an improved widget made out of a material that X has not previously used. Although X is uncertain how to use the material to manufacture an improved widget, the viability and means of using the material to manufacture such widgets are within the common knowledge of skilled professionals in the relevant technological fields.

(ii) *Conclusion.* Even though X's expenditures for the activities to resolve the uncertainty in manufacturing the improved widget may be treated as expenses for research activities under section 174 and § 1.174–2, X's activities to resolve the uncertainty in manufacturing the improved widget are not qualified research within the meaning of section 41(d) and paragraph (a) of this section. Although X's activities were intended to eliminate uncertainty, the activities were not undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 5. (i) *Facts.* X desires to build a bridge that can sustain greater traffic flow without deterioration than can existing bridges. The technology used to build such a bridge is not in the common knowledge of skilled professionals in the relevant technological fields. X eventually abandons the project after attempts to develop the technology prove unsuccessful.

(ii) *Conclusion.* X's activities to develop the technology to build the bridge may be qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section, regardless of the fact that X did not actually succeed in developing that technology. In seeking to develop the technology, X undertook to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 6. (i) *Facts.* The facts are the same as in *Example 5*, except that Y successfully builds a bridge that can sustain the greater traffic flow. Thereafter, Z seeks to build a bridge that can also sustain such greater traffic flow. The technology used by Y to build its bridge is a closely guarded secret that is not known to Z and remains beyond the common knowledge of skilled professionals in the relevant technological fields.

(ii) *Conclusion.* Z's activities to develop the technology to build the bridge may be qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section, even if it so happens that the technology used by Z to build its bridge is similar or identical to the technology used by Y. In developing the technology, Z undertook to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 7. (i) *Facts.* X and other manufacturing companies have previously designed and manufactured a particular kind of machine using Material S. Material T is less expensive than Material S. X wishes to design a new machine that appears and functions exactly the same as its existing machines, but that is made of Material T instead of Material S. The technology necessary to achieve this objective is not within the common knowledge of skilled professionals in the relevant technological fields.

(ii) *Conclusion.* X's activities to design the new machine using Material T may be qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section. In seeking to design the machine, X undertook to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

Example 8. (i) *Facts.* X, a tire manufacturer, seeks to build a tire that will not deteriorate as rapidly under certain conditions of high speed and temperature as do existing tires. The design of such a tire is not within the common knowledge of skilled professionals in the relevant technological fields. X commences laboratory research on January 1. On April 1, X determines in the laboratory that a certain combination of materials and additives can withstand higher rotational speeds and temperatures than the combination of materials and additives used in existing tires. On the basis of this determination, X undertakes further research activities to determine how to design a tire using those materials and additives, and to determine whether such a tire functions outside the laboratory as intended under various actual road conditions. By September 1, but not prior to September 1, X's research has progressed to the point where, applying X's knowledge to date, both the viability and means of producing the desired tire would be within the common knowledge of skilled professionals in the relevant technological fields. However, X continues to engage in certain research activities related to the tire after September 1, and until the first tire rolls off the assembly line on December 1.

(ii) *Conclusion.* Some or all of X's research activities until September 1 may be qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section. In seeking to design the tire, X undertook to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological

fields. The activities conducted after September 1 are not qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section, because those activities were not undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in the relevant technological fields.

(b) *Application of requirements for qualified research—(1) In general.* The requirements for qualified research in section 41(d)(1) and paragraph (a) of this section, must be applied separately to each business component, as defined in section 41(d)(2)(B). In cases involving development of both a product and a manufacturing or other commercial production process for the product, research activities relating to development of the process are not qualified research unless the requirements of section 41(d) and this section are met for the research activities relating to the process without taking into account the research activities relating to development of the product. Similarly, research activities relating to development of the product are not qualified research unless the requirements of section 41(d) and this section are met for the research activities relating to the product without taking into account the research activities relating to development of the manufacturing or other commercial production process.

(2) *Shrinking-back rule.* The requirements of section 41(d) and paragraph (a) of this section are to be applied first at the level of the discrete business component to be held for sale, lease or license, or used by the taxpayer in a trade or business of the taxpayer. If all aspects of the requirements are not met at the first level, the requirements are to be applied at the next most significant subset of elements of the business component. The shrinking-back of the applicable business component continues until a subset of elements of the business component satisfies the requirements of section 41(d) and paragraph (a) of this section (treating that subset of elements as a business component) or the most basic element fails to satisfy the requirements.

(3) *Illustration.* The following example illustrates the application of this paragraph (b):

Example. X, a motorcycle engine builder, develops a new carburetor for use in a motorcycle engine. X also modifies an existing engine design for use with the new carburetor. Under the shrinking-back rule, the requirements of section 41(d)(1) and paragraph (a) of this section are applied first to the engine. If the modifications to the engine when viewed as a whole, including the development of the new carburetor, do not satisfy the requirements of section 41(d)(1) and paragraph (a) of this section, those requirements are applied to the next most significant subset of elements of the business component. For purposes of this example, it is assumed that the new carburetor is the next most significant subset of elements of the business component. The research activities in developing the new carburetor may constitute qualified research within the meaning of section 41(d)(1) and paragraph (a) of this section.

(c) *Excluded activities*—(1) *In general.* Qualified research does not include any activity described in sections 41(d)(3)(B) and (4), this paragraph (c), and paragraph (e) of this section.

(2) *Research after commercial production*—(i) *In general.* Activities conducted after the beginning of commercial production of a business component are not qualified research. Activities are conducted after the beginning of commercial production of a business component if such activities are conducted after the component is developed to the point where it is ready for commercial sale or use, or meets the basic functional and economic requirements of the taxpayer for the component's sale or use.

(ii) *Certain additional activities related to the business component.* The following activities are deemed to occur after the beginning of commercial production of a business component—

(A) Preproduction planning for a finished business component;

(B) Tooling-up for production;

(C) Trial production runs;

(D) Trouble shooting involving detecting faults in production equipment or processes;

(E) Accumulating data relating to production processes; and

(F) Debugging or correcting flaws in a business component.

(iii) *Activities related to production process or technique.* In cases involving development of both a product and a manufacturing or other commercial production process for the product, the exclusion described in section 41(d)(4)(A) and paragraphs (c)(2)(i) and (ii) of this section applies separately for the activities relating to the development of the product and the activities relating to the development of the process. For example, even after a product meets the taxpayer's basic functional and economic requirements, activities relating to the development of the manufacturing process still may constitute qualified research, provided that the development of the process itself separately satisfies the requirements of section 41(d) and this section, and the activities are conducted before the process meets the taxpayer's basic functional and economic requirements or is ready for commercial use.

(3) *Adaptation of existing business components.* Activities relating to adapting an existing business component to a particular customer's requirement or need are not qualified research. This exclusion does not apply merely because a business component is intended for a specific customer.

(4) *Duplication of existing business component.* Activities relating to reproducing an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information about the business component are not qualified research. This exclusion does not apply merely because the taxpayer inspects an existing business component in the course of developing its own business component.

(5) *Surveys, studies, research relating to management functions, etc.* Qualified research does not include activities relating to—

(i) Efficiency surveys;

(ii) Management functions (except for the direct supervision of qualified research as defined in § 1.41–2(c)(2)) or techniques, including such items as preparation of financial data and analysis, development of employee training programs and management organization plans, and management-based changes in production processes (such as rearranging work stations on an assembly line);

(iii) Market research, testing, or development (including advertising or promotions);

(iv) Routine data collections; or

(v) Routine or ordinary testing or inspections for quality control.

(6) *Internal-use computer software.* [Reserved] [1]

(7) *Activities outside the United States*—(i) *In general.* Research conducted outside the United States, as defined in section 7701(a)(9), does not constitute qualified research.

(ii) *Apportionment of in-house research expenses.* In-house research expenses paid or incurred for qualified services performed both in the United States and outside the United States must be apportioned between the services performed in the United States and the services performed outside the United States. Only those in-house research expenses apportioned to the

[1] Section 1.41–4(e), proposed on January 2, 1997 (62 FR 83), including any revisions to that proposed rule will be incorporated as this paragraph (c)(6) in the final rule.

services performed within the United States are eligible to be treated as qualified research expenses, unless the in-house research expenses are wages and the 80 percent rule of § 1.41–2(d)(2) applies.

(iii) *Apportionment of contract research expenses.* If contract research is performed partly in the United States and partly outside the United States, only 65 percent (or 75 percent in the case of amounts paid to qualified research consortia) of the portion of the contract amount that is attributable to the research activity performed in the United States may qualify as a contract research expense (even if 80 percent or more of the contract amount is for research performed in the United States).

(8) *Research in the social sciences, etc.* Qualified research does not include research in the social sciences (including economics, business management, and behavioral sciences), arts, or humanities.

(9) *Research funded by any grant, contract, or otherwise.* Qualified research does not include any research to the extent funded by any grant, contract, or otherwise by another person (or governmental entity). To determine the extent to which research is so funded, § 1.41–4A(d) applies.

(10) *Illustrations.* The following examples illustrate provisions contained in paragraphs (c)(1) through (9) of this section. No inference should be drawn from these examples concerning the application of section 41(d)(1) and paragraph (a) of this section to these facts:

Example 1. (i) *Facts.* X, a pharmaceutical company, performs additional clinical tests on one of its products after that product has been approved for a specific therapeutic use by the FDA and is ready for commercial production and sale. The clinical tests study the drug's long-term morbidity and mortality profile, and are undertaken to develop information to use in the marketing materials for the drug.

(ii) *Conclusion.* Because the additional tests are performed after the drug is ready for commercial sale, X's activities in connection with the tests are excluded from the definition of qualified research under section 41(d)(4)(A) and paragraph (c)(2) of this section.

Example 2. (i) *Facts.* The facts are the same as in *Example 1*, except that, while studying the long-term morbidity and mortality profile of the drug product, X discovers that the product may be useful in treating a different medical condition. X begins new clinical studies to establish the compound's new potential therapeutic use.

(ii) *Conclusion.* Because the new clinical studies are performed to establish a new therapeutic use of the drug product, the additional clinical studies performed to establish the new therapeutic use are not excluded from the definition of qualified research under section 41(d)(4)(A) and paragraph (c)(2) of this section.

Example 3. (i) *Facts.* X, a domestic corporation that manufactures paper, develops and markets a new type of paper containing a different chemical composition than the paper generally available for commercial sale. Prior to manufacturing the paper, X conducts preproduction planning for the finished paper product, tools up for production, conducts trial production runs, engages in trouble shooting involving detecting problems in production equipment, accumulates production process data, and debugs the product.

(ii) *Conclusion.* X's activities of preproduction planning, tooling up for production, trial production runs, trouble shooting, accumulation of production process data, and product debugging do not constitute qualified research with respect to development of the paper product because the activities are deemed to occur after the beginning of commercial production of the product. Whether any activities engaged in by X to develop a process for manufacturing the paper constitute qualified research depends on whether the development of the process itself separately satisfies the requirements of section 41(d) and this section, and whether the process meets the taxpayer's basic functional and economic requirements or is ready for commercial use.

Example 4. (i) *Facts.* X, a computer software development firm, owns all substantial rights in a general ledger accounting software core program that X markets and licenses to customers. After entering into a contractual agreement with a customer, X incurs expenditures in modifying the core software program to adapt the program to the customer's requirement or need.

(ii) *Conclusion.* Because X's activities represent activities to modify an existing software program to adapt the program to a particular customer's requirement, X's activities are excluded from the definition of qualified research under section 41(d)(4)(B) and paragraph (c)(3) of this section.

Example 5. (i) *Facts.* An existing gasoline additive is manufactured by Y using three ingredients, A, B, and C. X seeks to develop and manufacture its own gasoline additive that appears and functions in a manner similar to Y's additive. To develop its own additive, X first inspects the composition of Y's additive, and uses knowledge gained from the inspection to reproduce A and B in the laboratory. Any differences between ingredients A and B that are used in Y's additive and those reproduced by X are insignificant and are not material to the viability, effectiveness, or cost of A and B. X desires to use with A and B an ingredient that has a materially lower cost than ingredient C. Accordingly, X engages in a process of experimentation to discover potential alternative formulations of the additive (i.e., the development and use of various ingredients other than C to use with A and B).

(ii) *Conclusion.* X's activities in analyzing and reproducing ingredients A and B involve duplication of existing business components and are excluded from qualified research under section 41(d)(4)(C) and paragraph (c)(4) of this section. X's experimentation activities to discover potential alternative formulations of the additive do not involve duplication of an existing business component and are not excluded from qualified research under section 41(d)(4)(C) and paragraph (c)(4) of this section.

Example 6. (i) *Facts.* X, an appliance manufacturer, rearranges employee work stations in its manufacturing assembly line and develops a new employee training program to train employees for the rearranged work stations.

(ii) *Conclusion.* X's activities associated with rearranging the work stations and developing a new employee training program represent activities related to management functions or techniques and are excluded from qualified research under section 41(d)(4)(D) and paragraph (c)(5) of this section.

Example 7. (i) *Facts.* X, an insurance company, develops a new life insurance product. In the course of developing the product, X engages in research with respect to the effect of pricing and tax consequences on demand for the product, the expected volatility of interest rates, and the expected mortality rates (based on published data and prior insurance claims).

(ii) *Conclusion.* X's activities related to the new product represent research in the social sciences, and are thus excluded from qualified research under section 41(d)(4)(G) and paragraph (c)(7) of this section.

(d) *Documentation.* See section 6001 and the regulations thereunder for the recordkeeping requirements that must be satisfied.

§ 1.41–5 [Redesignated as § 1.41–4A, and Amended]

Par. 11. Section 1.41–5 is redesignated as § 1.41–4A, and the last sentence of paragraph (d)(1) is amended by removing the language ''§ 1.41–8(e)'' and adding ''§ 1.41–6(e)'' in its place.

§ 1.41–6 [Redesignated as § 1.41–5 and Amended]

Par. 12. Section 1.41–6 is redesignated as § 1.41–5 and the section heading is amended by removing the language ''December 31, 1985'' and adding ''December 31, 1986'' in its place.

§ 1.41–7 [Redesignated as § 1.41–5A, and Amended]

Par. 13. Section 1.41–7 is redesignated as § 1.41–5A, and amended as follows:

1. The section heading is amended by removing the language ''January 1, 1986'' and adding ''January 1, 1987'' in its place.

2. Paragraph (e)(2) is amended by removing the language ''§ 1.41–5(c)'' and adding ''1.41–4A(c)'' in its place.

§ 1.41–8 [Redesignated as § 1.41–6, and Amended]

Par. 14. Section 1.41–8 is redesignated as § 1.41–6, and the last sentence of paragraph (c) is amended by removing the language ''§ 1.41–3, except that § 1.41–3(c)(2)'' and adding ''§ 1.41–3A, except that § 1.41–3A(c)(2)'' in its place.

§ 1.41–9 [Redesignated as § 1.41–7]

Par. 15. Section 1.41–9 is redesignated as § 1.41–7.

Par. 16. New § 1.41–8 is added to read as follows:

§ 1.41–8 Special rules for taxable years ending on or after the date final regulations are published in the Federal Register.

(a) *Alternative incremental credit.* At the election of the taxpayer, the credit determined under section 41(a)(1) equals the amount determined under section 41(c)(4).

(b) *Election*—(1) *In general.* A taxpayer may elect to apply the provisions of the alternative incremental credit in section 41(c)(4) for any taxable year of the taxpayer beginning after June 30, 1996. If a taxpayer makes an election under section 41(c)(4), the election applies to the taxable year for which made and all subsequent taxable years.

(2) *Time and manner of election.* An election under section 41(c)(4) is made by completing the portion of Form 6765, ''Credit for Increasing Research Activities,'' relating to the election of the alternative incremental credit, and attaching the completed form to the taxpayer's timely filed original return (including extensions) for the taxable year to which the election applies.

(3) *Revocation.* An election under this section may not be revoked except with the consent of the Commissioner. A taxpayer must attach the Commissioner's consent to revoke an election under section 41(c)(4) to the taxpayer's timely filed original return (including extensions) for the taxable year of the revocation.

Par. 17. Section 1.41–0A is added under the new undesignated centerheading ''Research Credit—For Taxable Years Beginning Before January 1, 1990'' to read as follows:

§ 1.41–0A Table of contents.

This section lists the paragraphs contained in §§ 1.41–0A, 1.41–3A, 1.41–4A and 1.41–5A.

§ 1.41–0A Table of contents.

§ 1.41–3A Base period research expenses.

(a) Number of years in base period.
(b) New taxpayers.
(c) Definition of base period research expenses.
(d) Special rules for short taxable years.
(1) Short determination year.
(2) Short base period year.
(3) Years overlapping the effective dates of section 41 (section 44F).
(i) Determination years.
(ii) Base period years.
(4) Number of months in a short taxable year.
(e) Examples.

§ 1.41–4A Qualified research for taxable years beginning before January 1, 1986.

(a) General rule.
(b) Activities outside the United States.
(1) In-house research.
(2) Contract research.
(c) Social sciences or humanities.
(d) Research funded by any grant, contract, or otherwise.
(1) In general.
(2) Research in which taxpayer retains no rights.
(3) Research in which the taxpayer retains substantial rights.
(i) In general.
(ii) Pro rata allocation.
(iii) Project-by-project determination.
(4) Independent research and development under the Federal Acquisition Regulations System and similar provisions.
(5) Funding determinable only in subsequent taxable year.
(6) Examples.

§ 1.41–5A Basic research for taxable years beginning before January 1, 1987.

(a) In general.
(b) Trade or business requirement.
(c) Prepaid amounts.
(1) In general.
(2) Transfers of property.
(d) Written research agreement.
(1) In general.
(2) Agreement between a corporation and a qualified organization after June 30, 1983.
(i) In general.
(ii) Transfers of property.
(3) Agreement between a qualified fund and a qualified educational organization after June 30, 1983.
(e) Exclusions.
(1) Research conducted outside the United States.
(2) Research in the social sciences or humanities.
(f) Procedure for making an election to be treated as a qualified fund.

§ 1.218–0 [Removed]

Par. 18. Section 1.218–0 is removed.

§ 1.482–7 [Amended]

Par. 19. In § 1.482–7, the sixth sentence of paragraph (h)(1) is amended by removing the language ''§ 1.41–8(e)'' and adding ''§ 1.41–6(e)'' in its place.

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

[FR Doc. 98–31528 Filed 12–01–98; 8:45 am]

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FEDERAL MARITIME COMMISSION

46 CFR Parts 502, 545 and 571

[Docket No. 98–21]

Miscellaneous Amendments to Rules of Practice and Procedure

AGENCY: Federal Maritime Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Maritime Commission intends to make corrections and changes to existing regulations to update and improve them, and to conform them to and implement the Ocean Shipping Reform Act of 1998. At the same time, the Commission is restructuring all of its rules and regulations. (See Tables herein.) This proposed rule would modify part 502 (Rules of Practice and Procedure) and part 571 (to be redesignated as part 545) (Interpretations and Statements of Policy).

DATES: Submit comments on or before January 4, 1999.

ADDRESSES: Address all comments concerning this proposed rule to: Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol St., N.W., Room 1046, Washington, D.C., 20573–0001.

FOR FURTHER INFORMATION CONTACT: Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol St., N.W., Room 1046, Washington, D.C. 20573–0001 (202) 523–5725, E-mail: secretary@fmc.gov.

SUPPLEMENTARY INFORMATION:

The Ocean Shipping Reform Act of 1998 (''OSRA''), Pub. L. 105–258, 112 Stat. 1902, which made numerous changes to the Shipping Act of 1984 (''1984 Act''), Pub. L. 98–237, 98 Stat. 67 (46 U.S.C. app. secs. 1701 through 1720), was enacted on October 14, 1998, and becomes effective on May 1, 1999. Among other things, OSRA authorizes the Commission to prescribe implementing rules and regulations. Accordingly, the Federal Maritime Commission (hereinafter referred to as the Commission) must conform all of its rules and regulations to this new statute.

In addition to changes required by OSRA, other changes will be made to improve various rules and to bring them in line with current practices, guidelines and organization. This approach will provide the Commission and the industry with the opportunity to review the Commission's rules and regulations related to ocean shipping. This review process should ultimately result in a more useful realignment of Chapter IV of Title 46 of the CFR.

The Commission takes this opportunity to inform the public of its intended general reorganization of parts 500–588. As realigned, the Commission's rules will be contained in three Subchapters. Subchapter A will continue to set forth general and administrative provisions. Subchapter B will contain all of the Commission's basic regulations concerning operations in the U.S. foreign commerce. Subchapter C will be set aside to cover matters involving the restrictive maritime practices of foreign governments and controlled carriers. Subchapter D will be removed. All rule changes will become effective May 1, 1999. An outline of the foregoing is set forth in the following tables:

FEDERAL MARITIME COMMISSION—46 CFR, CHAPTER IV.—REDESIGNATION AND DISTRIBUTION TABLE

Old part or section (§)	New part or section (§)
500	508.
501	501.
502	502.
§502.92 (Special Dockets)	§502.271.
503	503.
504	504.
505	505.
506	506.
507	507.
510	515.
§510.25 & §514.1(c)(1)(iii) (Anti-rebate Certification).	To be removed.
514	520, 525, & 565.
§514.7 & §514.17 (Service Contracts).	530.
540	540.
571	545.
572	535.
§572.301 (Agreement Exemptions).	§502.67 (All exemptions).
582	To be removed.
583	515.
585	550.
586	551.
587	560.
588	555.

FEDERAL MARITIME COMMISSION—46 CFR, CHAPTER IV.—DERIVATION TABLE

New part	Old part
(Subchapter A—General and Administrative Provisions)	
501	501.
502	502.
503	503.
504	504.
505	505.
506	506.
507	507.
508	500.
(Subchapter B—Regulations Affecting Ocean Shipping in Foreign Commerce)	
515	510, 583.
520	514.
525	514.
530	514.
535	572.
540	540.
545	571.
(Subchapter C—Regulations and Actions to Address Restrictive Foreign Maritime Practices)	
550	585.
551	586.
555	588.
560	587.
565	(Controlled Carriers—New).

In addition to providing notice of the Commission's intent to reorganize its rules, this notice of proposed rulemaking proposes various amendments to Parts 502 and 571. Changes to other parts of the Commissions' rules will be the subject of future notices of proposed rulemaking.

The OSRA, among other things, modified section 8(e) of the 1984 Act by adding authority for the Commission, upon application, to grant refund and waiver of tariff charges for errors in quoting a tariff, and eliminating tariff filing at the Commission, instead requiring common carriers to publish tariffs and make them electronically available. The OSRA also modified the standards for exemption from requirements of the 1984 Act, and changed its provisions prohibiting the refusal to negotiate with a shipper's association. In addition, the Commission's Rules of Practice and Procedure, located currently at 46 CFR 502, contain references to statutes no longer within the purview of the Commission, certain provisions are in need of modernization and clarification, and the Commission desires to change certain other provisions. The Commission now proposes to make the following modifications to Parts 502 and 571 to reflect statutory changes, and to clarify, reorganize, modernize, and improve its rules of practice and procedure. The proposed modifications will be addressed seriatim.

The authority citation would be modified to drop references to the Shipping Act, 1916 (''1916 Act''), responsibility for which has been transferred to the Surface Transportation Board (''STB'') within the Department of Transportation, and to list OSRA, Public Law 105–258, as an authority for Part 502. Similarly, § 502.1 would be modified to drop references to the 1916 Act and the Intercoastal Shipping Act, 1933 (''1933 Act''), responsibility for which also has been transferred to the STB.

To improve structure, current § 502.11(a) would be moved and become new § 502.2(e), thus leaving § 502.11 to deal only with ex parte communications. Also, the heading of § 502.21(c) would be changed to better reflect its subject matter, i.e., special appearance.

Section 502.23 would be restructured for simplification purposes, and modernized to replace references to telephone calls and telegrams with references to facsimile and e-mail. Exhibit No. 1 to subpart B of Part 502 would similarly be modified. Also, proposed § 502.23(d) would accommodate requests by attorneys to withdraw from representing a client. Some recent proceedings have involved issues concerning attempts by counsel to withdraw from representation. Current § 502.23 provides for substitution of counsel, but is silent with respect to withdrawal of counsel.

Section 502.24 would be modified to delete reference to field offices, since the Commission no longer has any field offices.

Section 502.26 would be modified to incorporate the standards of conduct set forth in the American Bar Association's Model Rules of Professional Conduct as the standards to govern conduct of attorneys practicing before the Commission.

Changes are proposed to § 502.42 to reflect the fact that the Director, Bureau of Enforcement, is not necessarily a party to proceedings involving petitions, small claim proceedings, and special docket proceedings.

For clarification purposes, § 502.51 would be modified to reflect that rulemaking proceedings may be initiated on the Commission's own motion, as well as by petition. Also, a new paragraph would be added to § 502.62 to point out the requirement in § 502.201(b) that discovery be commenced with the filing of a complaint.

Section 502.63 would be modified for clarification by revising the section heading, as well as deleting references to the 1916 Act. Section 502.64 would be revised to explicitly require answers

to be verified, in conformity with Exhibit 1 to Subpart E.

A new rule, § 502.67, would set forth the exemption procedures under the OSRA, which amended the exemption standard by eliminating inquiries as to whether a proposed exemption would ''substantially impair effective regulation'' or would ''be unjustly discriminatory.'' The new standard looks only at whether the proposed exemption would ''result in substantial reduction in competition'' or would ''be detrimental to commerce.'' If not, then the Commission may determine to grant the exemption. New § 502.67 is substantially similar to old § 572.301, but applies to all exemption applications, rather than solely to agreement exemption applications.

References to the 1916 Act would be deleted from § 502.75 and Exhibit 1 to Subpart E.

The Commission's special docket rules, currently at § 502.92, and Exhibit 1 to Subpart F would be moved to Subpart Q, and modified to reflect changes in the new OSRA.

Sections 502.102, 502.104, 502.105 and 502.112 are being revised for simplification purposes, while § 502.111 is modernized to reflect the use of modern technology, including facsimile transmission of documents.

Proposed changes to § 502.113 would provide a procedure for service of a complaint by complainants when the Commission's Secretary has been unable to obtain service by mail. The presiding officer would also have discretion to dismiss any complaint when service has not been obtained within thirty days after filing the complaint. There have been occasions where the Secretary could not obtain service by mail, and the proposed change would codify the current practice of allowing complainants the option of effecting service in lieu of service by the Secretary.

Section 502.114 would be simplified and modernized by allowing for facsimile service upon agreement between parties, and would also revise a citation to conform with changes made by the OSRA. Correspondingly, § 502.116 would allow for service by facsimile.

A modification to § 502.118 would add notices of appearance to the types of filings requiring submission of an original and four copies, thus codifying existing practice. Section 502.119 would be restructured for simplification.

The provision regarding attendance and mileage fees in § 502.133 would be revised to apply also to witnesses summoned to a deposition, thus bringing the provision into conformity with Rule 45 of the Federal Rules of Civil Procedure. In § 502.143, a citation error would be corrected, while § 502.144 would be modernized to reflect the possibility of notice by facsimile or e-mail and to clarify that filing of motions for postponement of a hearing would be governed by § 502.104.

Section 502.146 would be updated to add service of complaints filed under shortened procedure, § 502.182, and referral of claims under Subpart T as events that trigger commencement of the functions of the Administrative Law Judges. Similarly, Subpart T would be added as to functions under § 502.147. A reference to the 1933 Act is also removed from § 502.147.

In Subpart L, modifications would be made to § 502.201 for clarification and to delete reference to the 1916 Act.

A fifty page limitation on the size of briefs would be imposed for briefs filed under § 502.221, as well as for briefs on exceptions and appeals under § 502.227. This limitation tracks the Federal Rules of Appellate Procedure. The presiding officer or the Commission, as the case may be, would have the discretion to allow parties to exceed these limits.

Sections 502.223 and 502.225 would be amended to prescribe separate content requirements for decisions by the Administrative Law Judges and decisions by the Commission. Initial or recommended decisions by the Administrative Law Judges would include numbered statements of findings and conclusions, and would be limited to issues necessary to resolution of material issues. The content requirements for final decisions by the Commission would remain unchanged.

A new § 502.227(a)(4) would be added to make clear that initial decisions and dismissals by an administrative law judge that have become final are not appealable to a court by a party unless that party has filed exceptions or an appeal with the Commission as provided in § 502.227. The Supreme Court in *Darby* v. *Cisneros*, 509 U.S. 137 (1993), determined that the judicially created doctrine of exhaustion of administrative remedies is restricted by Section 10(c) of the Administrative Procedure Act, 5 U.S.C. 701 et. seq. Under this ruling, a court may hear an appeal of an initial decision even without the plaintiff having first exhausted administrative remedies by filing exceptions, unless the agency has, by rule, required that such an appeal be filed with the agency before a court appeal may be filed. The proposed change would provide such a requirement.

The Commission's rule on interest, § 502.253 would be modified to delete reference to the 1916 Act and the 1933 Act. The rule for obtaining attorney's fees, § 502.254 would be modified to enable the awarding of attorney's fees in small claim proceedings. Currently, § 502.254 excepts small claims proceedings under Subpart S from the award of attorney's fees, but the language of section 11(g) of the 1984 Act requires award of attorney's fees in all cases where reparations are awarded.

Subpart Q would be revised to eliminate the current listing of schedules and forms, as it is duplicative. The Commission's special docket rule would be moved from § 502.92 to Subpart Q, and modified to reflect new provisions in the OSRA allowing refund or waiver of tariff charges for errors in quoting charges. The Commission proposes to expedite its special docket procedures by providing that decisions by deciding officials will become final within ten days, unless exceptions are filed or the Commission determines to review such decision. Currently, decisions are not final for thirty days, and parties may file exceptions within twenty-two days of the decision. Since the filing of exceptions to or review by the Commission of special docket decisions are rare, current procedures inordinately delay the finality of a decision. Also, the revised application form, Exhibit No. 1 to Subpart Q, would require submission of the date a shipment was received. This is important since the date a shipment is received is the date for determining the applicable tariff charges. The application form would also require proof in the form of an affidavit and other available evidence if the application is based on a misquote. Finally, minor changes would also be made to § 502.271 and Exhibit No. 1 to Subpart Q to, among other things, simplify directions, substitute ''tariff materials'' for outdated referrals to ''tariff pages,'' replace tariff ''filing'' references with tariff ''publishing'', and eliminate provisions concerning the 1916 Act.

Regarding small claim proceedings under Subpart S, §§ 502.301 and 502.302 would be revised to delete provisions relating to the 1916 Act and the 1933 Act, while § 502.305 would be revised so that the Commission's rules on awards of interest and attorney's fees apply to small claims proceedings. Moreover, references to the 1916 and 1933 Acts would be removed from the information provisions of Exhibit No. 1 to Subpart S. Similarly, references to the 1916 and 1933 Acts would be removed from § 502.401.

In Subpart V, § 502.501 would be updated to reflect 1996 amendments to the Equal Access to Justice Act.

In Subpart W, references to the 1916 Act and the 1933 Act would be deleted from §§ 502.601 and 502.602. Section 502.604 would be modified to provide for delivery by means other than registered or certified mail of a Notice and Demand Letter affording an opportunity for compromise of a civil penalty. Section 502.605 would be revised to remove provisions for a promissory note as a means of effecting payment of penalties.

The Ocean Shipping Reform Act deleted § 10(b)(13) of the 1984 Act, which had prohibited common carriers from refusing to negotiate with a shippers' association and replaced it with a new section 10(b)(10) to prohibit the unreasonable refusal to deal or negotiate. In Part 571, § 571.1 was based in part upon the now deleted § 10(b)(13). The Commission therefore proposes to redesignate Part 571 as Part 545, and to amend new § 545.1 to delete reference to former § 10(b)(13) and to refer to new § 10(b)(10).

The proposed rule contains no additional information collection or record keeping requirements and need not be submitted to OMB for approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

The Chairman certifies, pursuant to 5 U.S.C. 605, that the proposed rule would not have a significant impact on a substantial number of small entities. The amendments will either have no affect on small entities, or in the case where the amendments are likely to impact small entities, the economic impact will be de minimis.

List of Subjects

46 CFR Part 502

Administrative practice and procedure, Claims, Equal access to justice, Investigations, Lawyers, Maritime carriers, Penalties, Reporting and recordkeeping requirements.

46 CFR Parts 545 and 571

Antitrust, Maritime carriers.

For the reasons stated in the preamble, the Federal Maritime Commission proposes to amend 46 CFR parts 502, 545 and 571 as follows:

PART 502—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for part 502 is revised to read as follows:

Authority: 5 U.S.C. 504, 551, 552, 553, 556(c), 559, 561–569, 571–596; 12 U.S.C. 1141j(a); 18 U.S.C. 207; 26 U.S.C. 501(c)(3); 28 U.S.C. 2112(a); 31 U.S.C. 9701; 46 U.S.C. app. 1114(b), 1705, 1707–1711, 1713–1716; E.O. 11222 of May 8, 1965 (30 FR 6469); 21 U.S.C. 853a; Pub. L. 105–258; and Pub. L. 88–777 (46 U.S.C. app. 817d, 817e).

2. Amend § 502.1 as follows:

a. Revise the first sentence of § 502.1 to read as set forth below;

b. Move ''[Rule 1.]'' to the end of the section.

§ 502.1 Scope of rules in this part.

The rules in this part govern procedure before the Federal Maritime Commission, hereinafter referred to as the ''Commission,'' under the Merchant Marine Act, 1920, Merchant Marine Act, 1936, Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998, Administrative Procedure Act, and related acts, except that subpart R of this part does not apply to proceedings subject to sections 7 and 8 of the Administrative Procedure Act, which are to be governed only by subparts A to Q inclusive, of this part. * * *

3. Amend § 502.2 to read as follows:

a. In the text of paragraph (c) revise ''§ 502.11(b)'' to read ''§ 502.11.''

b. In paragraph (d) remove ''[Rule 2.]'

c. Add paragraph (e) to read as follows:

§ 502.2 Filing of documents; hours; mailing address.

* * * * *

(e) Any pleading, document, writing or other paper submitted for filing which is rejected because it does not conform to the rules in this part shall be returned to the sender. [Rule 2.]

4. Amend § 502.11 as follows:

a. Revise section heading to read as set forth below;

b. Remove paragraph (a).

c. Redesignate paragraphs (b)(1) through (b)(7) as paragraphs (a) through (g).

§ 502.11 Ex parte communications.

* * * * *

§ 502.12 [Amended]

5. In § 502.12, add ''[Rule 12.]'' to the end of the text.

6. In § 502.21, revise the paragraph heading in paragraph (c) to read as follows:

§ 502.21 Appearance.

* * * * *

(c) *Special appearance.* * * *

7. Revise § 502.23 to read as follows:

§ 502.23 Notice of appearance; substitution and withdrawal of representative.

(a) Upon filing of a complaint instituting proceedings or filing of an answer to an order or complaint, the party filing shall notify the Commission of the name(s) and address(es) of the person or persons who will represent them in the pending proceeding. Each person who appears at a hearing shall deliver a written notice of appearance to the reporter, stating for whom the appearance is made. Such notice shall indicate whether the representative wishes to be notified of decisions by telephone, facsimile transmission, or electronic mail. All appearances shall be noted in the record. Petitions for leave to intervene shall indicate the name(s) and address(es) of the person or persons who will represent the intervenor in the pending proceeding if the petition is granted.

(b) A Notice of Appearance should follow the form set forth in Exhibit No. 1 to this subpart.

(c) If an attorney or other representative of record is superseded, there shall be filed a stipulation of substitution signed both by the attorney(s) or representative(s) and by the party, or a written notice from the party to the Commission.

(d) If an attorney wishes to withdraw from representing a party, such attorney shall file an appropriate motion seeking permission to withdraw and provide appropriate reasons for making the motion. Such motion will be decided in consideration of the factors and standards set forth in Rule 1.16 of the American Bar Association's Model Rules of Professional Conduct and by the courts.

8. Revise § 502.24(b) to read as follows:

§ 502.24 Practice before the Commission defined.

* * * * *

(b) The term ''Commission'' as used in this subpart includes any bureau, division, office, branch, section, or unit of the Federal Maritime Commission and any officer or employee of such bureau, division, office, branch, section, or unit. [Rule 24.]

9. Revise § 502.26, to read as follows:

§ 502.26 Attorneys at law.

Attorneys at law who are admitted to practice before the Federal courts or before the courts of any State or Territory of the United States may practice before the Commission. An attorney must represent in writing, filed with the Secretary, that he is admitted to practice and in good standing. An attorney practicing before the Commission is expected to conform to the standards of conduct set forth in the American Bar Association's Model Rules of Professional Conduct in

addition to the specific requirements of this chapter. [Rule 26.]

§ 502.27 [Amended]

10. In § 502.27(a)(1) correct ''§ 503.43(h)'' to read ''§ 503.43(g).''

11. Revise Exhibit No. 1 to Subpart B as follows:

Exhibit No. 1 to Subpart B

Federal Maritime Commission

Notice of Appearance

Docket No. _____:

Please enter my appearance in this proceeding as counsel for _____.

I request to be informed of service of the administrative law judge's initial or recommended decision and of the Commission's decision in this proceeding by:

[ ] telephone (In the event that I am not available when you call, appropriate advice left with my office will suffice.)

[ ] facsimile transmission

[ ] electronic mail

_____

[Name]

_____

[Address]

_____

[Telephone No.]

_____

[Fax No.]

_____

[E-mail address]

_____

[Signature]

12. Revise § 502.42 to read as follows:

§ 502.42 Bureau of Enforcement.

The Director, Bureau of Enforcement, shall be a party to all proceedings governed by the rules in this part except that in complaint proceedings under § 502.62, the Director may become a party only upon leave to intervene granted pursuant to § 502.72, in rulemaking proceedings and in proceedings considering petitions the Director may become a party by designation if the Commission determines that the circumstances of the proceeding warrant such participation, and the Director will not ordinarily be a party to small claims proceedings under § 502.304 and special docket proceedings under § 502.271. The Director or the Director's representative shall be served with copies of all papers, pleadings, and documents in every proceeding in which the Bureau of Enforcement is a party. The Bureau of Enforcement shall actively participate in any proceeding to which the Director is a party, to the extent required in the public interest, subject to the separation of functions required by section 5(c) of the Administrative Procedure Act. (See § 502.224). [Rule 42.]

13. Revise § 502.51 to read as follows:

§ 502.51 Initiation of procedure to issue, amend, or repeal a rule.

(a) *By petition.* Any interested party may file with the Commission a petition for the issuance, amendment, or repeal of a rule designed to implement, interpret, or prescribe law, policy, organization, procedure, or practice requirements of the Commission. The petition shall set forth the interest of petitioner and the nature of the relief desired, shall include any facts, views, arguments, and data deemed relevant by petitioner, and shall be verified. If such petition is for the amendment or repeal of a rule, it shall be accompanied by proof of service on all persons, if any, specifically named in such rule, and shall conform in other aspects to Subpart H of this part. Petitions shall be accompanied by remittance of a $177 filing fee. Replies to such petition shall conform to the requirements of § 502.74.

(b) *By the Commission.* The Commission on its own initiative may initiate the issuance, amendment, or repeal of a rule through notice of proposed rulemaking or advanced notice of proposed rulemaking. [Rule 51.]

§ 502.56 [Amended]

14. In § 502.56, add ''[Rule 56.]'' at the end of the text.

§ 502.61 [Amended]

15. In § 502.61, add ''[Rule 61.]'' to the end of paragraph (d).

16. In § 502.62, redesignate paragraph (g) as paragraph (h), revise redesignated paragraph (h) and add new paragraph (g) to read as follows:

§ 502.62 Complaints and fee.

* * * * *

(g) Complainants desiring to use the discovery provisions of subpart L must commence discovery at the time the complaint is filed, pursuant to § 502.201(b).

(h) For special types of cases, see § 502.271 in subpart Q (Refund or waiver of freight charges); subpart K (Shortened Procedure); and subpart S (Small Claims). [Rule 62.]

17. In § 502.63, remove paragraph (a), redesignate paragraphs (b) through (e) as paragraphs (a) through (d), and revise the section heading to read as follows:

§ 502.63 Statute of limitations for reparations.

* * * * *

18. Amend § 502.64 as follows:

a. Add a sentence to the end of paragraph (a) to read as set forth below;

b. Add ''[Rule 64.]'' to the end of paragraph (d).

§ 502.64 Answer to complaint; countercomplaint.

(a) * * * An answer to the complaint must be verified.

* * * * *

19. Add § 502.67 to read as follows:

§ 502.67 Exemption procedures—General.

(a) *Authority.* The Commission, upon application or on its own motion, may by order or rule exempt for the future any class of agreements between persons subject to the Shipping Act of 1984 or any specified activity of persons subject to the Shipping Act of 1984 from any requirement of the Shipping Act of 1984 if it finds that the exemption will not result in substantial reduction in competition or be detrimental to commerce. The Commission may attach conditions to any exemption and may, by order, revoke any exemption.

(b) *Application for exemption.* Any person may petition the Commission for an exemption or revocation of an exemption of any class of agreements or an individual agreement or any specified activity pursuant to section 16 of the Shipping Act of 1984. A petition for exemption shall state the particular requirement of the Shipping Act of 1984 for which exemption is sought. The petition shall also include a statement of the reasons why an exemption should be granted or revoked, shall provide information relevant to any finding required by the Shipping Act of 1984 and shall comply with § 502.69. Where a petition for exemption of an individual agreement is made, the application shall include a copy of the agreement.

(c) *Participation by interested persons.* No order or rule of exemption or revocation of exemption may be issued unless opportunity for hearing has been afforded interested persons and departments and agencies of the United States.

(d) **Federal Register** notice. Notice of any proposed exemption or revocation of exemption, whether upon petition or upon the Commission's own motion, shall be published in the **Federal Register**. The notice shall include when applicable:

(1) A short title for the proposed exemption or the title of the existing exemption;

(2) The identity of the party proposing the exemption or seeking revocation;

(3) A concise summary of the agreement or class of agreements or specified activity for which exemption is sought, or the exemption which is to be revoked;

(4) A statement that the petition and any accompanying information are available for inspection in the

Commission's offices in Washington, D.C.; and

(5) The final date for filing comments regarding the proposal. [Rule 67.]

§ 502.71 [Amended]

20. In § 502.71, add ''[Rule 71.]'' to the end of the text.

21. In § 502.75, revise paragraph (a) to read as follows:

§ 502.75 Proceedings involving assessment agreements.

(a) In complaint proceedings involving assessment agreements filed under section 5(e) of the Shipping Act of 1984, the Notice of Filing of Complaint and Assignment will specify a date before which the initial decision will be issued, which date will not be more than eight months from the date the complaint was filed.

* * * * *

22. In Exhibit 1 to Subpart E, remove the third paragraph after the heading ''Information to Assist in Filing Formal Complaint,'' beginning with the text ''Under the Shipping Act, 1916 . . . .''

§ 502.91 [Amended]

23. In § 502.91, add ''[Rule 91.]'' to the end of paragraph (d).

Subpart F [Amended]

24. In Subpart F, remove and reserve § 502.92, and remove Exhibit 1.

§ 502.94 [Amended]

25. In § 502.94, add ''[Rule 94.]'' to the end of paragraph (c).

26. Revise § 502.102 to read as follows:

§ 502.102 Enlargement of time to file documents.

(a) Motions for enlargement of time for the filing of any pleading or other document, or in connection with the procedures of subpart L of this part, shall set forth the reasons for the motion and be submitted at least five (5) days before the scheduled date for filing. Except for good cause shown, failure to meet this time requirement may result in summary rejection of the request.

(b) Such motions will be granted only under exceptional circumstances duly demonstrated in the request, and shall conform to the requirements of subpart H of this part, except as to service if they show that the parties have received actual notice of the motion; and in relation to briefs, exceptions, and replies to exceptions, such motions shall conform to the further provisions of §§ 502.222 and 502.227.

(c) Upon motion made after the expiration of the scheduled date, the filing may be permitted where reasonable grounds are found for the failure to file.

(d) Replies to such motions for enlargement of time shall conform to the requirements of § 502.74. [Rule 102.]

27. Add two sentences before the last sentence of § 502.104 to read as follows:

§ 502.104 Postponement of hearing.

* * * Such motions must be received, whether orally or in writing, at least five (5) days before the scheduled date for hearing. Except for good cause shown, failure to meet this requirement may result in summary rejection of the request. * * *

28. Revise § 502.105 to read as follows:

§ 502.105 Waiver of rules governing enlargements of time and postponements of hearings.

The Commission, the presiding officer, or the Chief Administrative Law Judge may waive the requirements of §§ 502.102 and 502.104 as to replies and may rule ex parte on such requests. [Rule 105.]

29. In subpart H, revise § 502.111 to read as follows:

§ 502.111 Form and appearance of documents filed with Commission.

(a) All papers to be filed under the rules in this part must be clear and legible, dated, show the docket description and title of the proceeding, and include the title, if any, and address of the signer. An original signed in ink must be provided. Text shall appear on only one side of the paper and must be double spaced except that quotations must be single spaced and indented. The paper must be strong and durable, not more than 8½ inches wide and 12 inches long, with a left hand margin of 1½ inches. Documents shall be printed in clear type, never smaller than 12 point.

(b) Filings by facsimile for purposes of meeting a deadline will not be accepted unless authorized by the presiding officer or the Secretary.

(c) Facsimile transmissions of signature pages on filings will be tentatively accepted for the purpose of meeting filing deadlines pending receipt of the original signature page within seven working days. [Rule 111.]

30. Amend § 502.112 as follows:

a. Revise the section heading to read as set forth below;

b. Add ''[Rule 112.]'' to the end of paragraph (c)(2).

§ 502.112 Verification of documents.

* * * * *

31. Revise § 502.113 to read as follows:

§ 502.113 Service by the Commission.

(a) Complaints filed pursuant to § 502.62, (including any accompanying discovery requests initiated pursuant to § 502.201(b)), amendments to complaints (unless otherwise authorized by the presiding officer pursuant to § 502.70(b)), and complainant's memoranda filed in shortened procedure cases will be served by the Secretary of the Commission.

(b) Alternatively, should the Secretary be unable to obtain service by mail, proper service of a complaint may be effected by complainant, in which case an affidavit setting forth the method, time and place of service must be filed with the Secretary within five days following service.

(c) In addition to and accompanying the original of every document filed with the Commission for service by the Commission, there shall be a sufficient number of copies for use of the Commission (see § 502.118) and for service on each party to the proceeding.

(d) The presiding officer may dismiss a complaint that has not been served within thirty (30) days after the complaint was filed. [Rule 113.]

32. In § 502.114, revise the section heading and paragraph (a) to read as follows:

§ 502.114 Service by parties of pleadings and other documents.

(a) Except as otherwise specifically provided by the rules in this part, all pleadings, documents, and papers of every kind (except requests for subpoenas, documents served by the Commission under § 502.113, and documents submitted at a hearing or prehearing conference) in proceedings before the Commission under the rules in this part shall, when tendered to the Commission or the presiding officer for filing, show that service has been made upon all parties to the proceeding and upon any other persons required by the rules in this part to be served. Such service shall be made by delivering one copy to each party: by hand delivering in person; by mail, properly addressed with postage prepaid; by courier; or by facsimile transmission if agreed by both parties prior to service.

* * * * *

§ 502.114 [Amended]

33. Amend § 502.114(b) as follows:

a. Revise ''(Rule 53)'' to read ''(Rule 52).''

b. Revise ''(Part 585)'' to read ''(Part 550).''

c. Revise ''13(b)(5) of the Shipping Act of 1984, 46 U.S.C. app. 1712(b)(5) (part 587)'' to read ''13(b)(6) of the Shipping Act of 1984 (part 560).''

34. Revise § 502.116 to read as follows:

§ 502.116 Date of service.

The date of service of documents served by the Commission shall be the date shown in the service stamp theron. The date of service of documents served by parties shall be the date when matter served is deposited in the United States mail, delivered to a courier, delivered in person, or transmitted by facsimile, as the case may be. In computing the time from such dates, the provisions of § 502.101 shall apply. [Rule 116.]

35. In § 502.118, revise paragraph (b)(2) to read as follows:

§ 502.118 Copies of documents for use of the Commission.

* * * * *

(b) * * *

(2) An original and four copies shall be filed with the Secretary of prehearing statements required by § 502.95, stipulations under § 502.162, notices of appearance required by § 502.23, and all other motions, petitions, or other written communications seeking a ruling from the presiding administrative law judge.

* * * * *

36. In § 502.119, revise paragraphs (a) and (b) to read as follows:

§ 502.119 Documents containing confidential materials.

* * * * *

(a) Filings shall be accompanied by a transmittal letter which identifies the filing as ''confidential'' and describes the nature and extent of the authority for requesting confidential treatment. The confidential copies shall consist of the complete filing and shall include a cover page marked ''Confidential-Restricted,'' with the confidential materials clearly marked on each page.

(b) Whenever a confidential filing is submitted, there must also be submitted an original and one copy of a public version of the filing. Such public version shall exclude confidential materials, and shall indicate on the cover page and on each affected page ''confidential materials excluded.''

* * * * *

37. Revise § 502.133 to read as follows:

§ 502.133 Attendance and mileage fees.

Witnesses summoned by subpena to a hearing or deposition are entitled to the same fees and mileage that are paid to witnesses in courts of the United States. Fees and mileage shall be paid, upon request, by the party at whose instance the witness appears. [Rule 133.]

§ 502.143 [Amended]

38. In the text of § 502.143 revise ''§ 502.133, '' to read ''§ 502.113.''

39. In § 502.144:

a. Redesignate the current text as paragraph (a).

b. Revise the section heading as set forth below;

c. Revise the last sentence of redesignated paragraph (a) to read as set forth below;

d. Add new paragraph (b) to read as set forth below.

§ 502.144 Notice of time and place of hearing; postponement of hearing

(a) * * * Notice may be served by mail, facsimile transmission, or electronic mail.

(b) Motions for postponement of any hearing date shall be filed in accordance with § 502.104. [Rule 144.]

40. In § 502.146, revise paragraph (a) and paragraph (c) to read as follows:

§ 502.146 Commencement of functions of Office of Administrative Law Judges.

* * * * *

(a) Upon the service by the Commission of a complaint filed pursuant to § 502.62, or § 502.182, or upon referral under subpart T of this part; or

(b) * * *

(c) Upon forwarding for assignment by the Office of the Secretary of a special docket application pursuant to § 502.271; or

* * * * *

41. In the first sentence of paragraph (a) of § 502.147 remove the phrase ''except with regard to that portion of any order involving the Commission's suspension authority set forth in section 3, Intercoastal Shipping Act, 1933.''

42. In § 502.147, revise paragraph (b) to read as follows:

§ 502.147 Functions and powers.

* * * * *

(b) All of the functions delegated in subparts A to Q and subpart T of this part, inclusive, to the Chief Judge, presiding officer, or administrative law judge include the functions with respect to hearing, determining, ordering, certifying, reporting, or otherwise acting as to any work, business, or matter, pursuant to the provisions of section 105 of Reorganization Plan No. 7 of 1961. [Rule 147.]

43. Amend § 502.201 as follows:

a. Revise paragraph (a) to read as set forth below;

b. Revise the paragraph heading in paragraph (d) to read as set forth below;

c. Revise the paragraph heading in paragraph (f) to read as follows:

§ 502.201 General provisions governing discovery.

(a) Applicability. The procedures described in this subpart are available in all adjudicatory proceedings under the Shipping Act of 1984. Unless otherwise ordered by the presiding officer, the copy requirements of § 502.118(b)(3)(i) shall be observed.

* * * * *

(d) Duty of the parties to meet or confer. * * *

* * * * *

(f) Conferences by order of the presiding officer. * * *

* * * * *

44. In § 502.221, revise paragraph (f) to read as follows:

§ 502.221 Briefs; requests for findings.

* * * * *

(f) All briefs filed pursuant to this section shall ordinarily be limited to fifty (50) pages in length, exclusive of pages containing the table of contents, table of authorities, and certificate of service, unless the presiding officer allows the parties to exceed this limit for good cause shown and upon application filed not later than five (5) days before the time fixed for filing of such a brief or reply. [Rule 221.]

45. Revise § 502.223 to read as follows:

§ 502.223 Decisions—Administrative law judges.

To the administrative law judges is delegated the authority to make and serve initial or recommended decisions. All initial and recommended decisions will include a statement of findings and conclusions, as well as the reasons or basis therefor, upon all the material issues presented on the record, and the appropriate rule, order, sanction, relief, or denial thereof. Where appropriate, the statement of findings and conclusions should be numbered. Initial decisions should address only those issues necessary to a resolution of the material issues presented on the record. A copy of each decision when issued shall be served on the parties to the proceeding. In proceedings involving overcharge claims, the presiding officer may, where appropriate, require that the carrier publish notice in its tariff of the substance of the decision. This provision shall also apply to decisions issued pursuant to subpart T of this part. [Rule 223.]

46. Revise § 502.225 to read as follows:

§ 502.225 Decisions—Commission.

All final decisions will include a statement of findings and conclusions, as well as the reasons or basis therefor,

upon all the material issues presented on the record, and the appropriate rule, order, sanction, relief, or denial thereof. A copy of each decision when issued shall be served on the parties to the proceeding. This provision shall also apply to decisions issued pursuant to subpart T of this part. [Rule 225.]

47. Amend § 502.227 as follows:

a. Revise the section heading to read as set forth below;

b. Redesignate paragraphs (a)(4) through (6) as paragraphs (a)(5) through (7);

c. Add a new paragraph (a)(4) to read as set forth below;

d. Remove ''[Rule 227]'' from paragraph (d);

e. Add new paragraph (e) to read as follows:

§ 502.227 Exceptions to decisions or orders of dismissal of administrative law judge; replies thereto; review of decisions or orders of dismissal by Commission; and judicial review.

(a) * * *

(4) A decision or order of dismissal by an administrative law judge shall only be considered final for purposes of judicial review if the party has first sought review by the Commission pursuant to this section.

* * * * *

(e) All briefs and replies filed pursuant to this section shall ordinarily be limited to fifty (50) pages in length, exclusive of pages containing the table of contents, table of authorities, and certificate of service, unless the Commission allows the parties to exceed this limit for good cause shown and upon application filed not later than five (5) days before the time fixed for filing of such a brief or reply. [Rule 227.]

48. Revise § 502.253 to read as follows:

§ 502.253 Interest in reparation proceedings.

Except as to applications for refund or waiver of freight charges under § 502.271 and claims which are settled by agreement of the parties, and absent fraud or misconduct of a party, interest granted on awards of reparation in complaint proceedings instituted under the Shipping Act of 1984 will accrue from the date of injury to the date specified in the Commission order awarding reparation. Compounding will be daily from the date of injury to the date specified in the Commission order awarding reparation. Normally, the date specified within which payment must be made will be fifteen (15) days subsequent to the date of service of the Commission order. Interest shall be computed on the basis of the average monthly secondary market rate on six-month U.S. Treasury bills commencing with the rate for the month that the injury occurred and concluding with the latest available monthly U.S. Treasury bill rate at the date of the Commission order awarding reparation. The monthly secondary market rates on six-month U.S. Treasury bills for the reparation period will be summed up and divided by the number of months for which interest rates are available in the reparation period to determine the average interest rate applicable during the period. [Rule 253.]

49. Amend § 502.254 as follows:

a. Revise the first sentence of paragraph (a) to read as set forth below;

b. Revise paragraph (c)(1)(i) to read as set forth below:

§ 502.254 Attorney's fees in reparation proceedings.

(a) *Scope.* The Commission shall, upon petition, award the complainant reasonable attorney's fees directly related to obtaining a reparations award in any complaint proceeding under section 11 of the Shipping Act of 1984.

* * *

(c) * * * (1) * * *

(i) With the presiding officer where the presiding officer's decision awarding reparations became administratively final pursuant to § 502.227(a)(3) and § 502.304(g); or

* * * * *

50. Revise Subpart Q to read as follows:

Subpart Q—Refund or Waiver of Freight Charges

502.271 Special docket application for permission to refund or waive freight charges.

(a)(1) A common carrier or a shipper may file a special docket application seeking permission for a common carrier or conference to refund or waive collection of a portion of freight charges if there is:

(i) An error in the tariff;

(ii) An error in failing to publish a new tariff; or

(iii) An error in quoting a tariff.

(2) Such refund or waiver must not result in discrimination among shippers, ports, or carriers.

(b) Such application must be filed within one hundred eighty (180) days from the date of sailing of the vessel from the port at which the cargo was loaded. An application is filed when it is placed in the mail, delivered to a courier, or, if delivered by another method, when it is received by the Commission. Filings by mail or courier must include a certification as to date of mailing or delivery to the courier.

(c) Prior to submission of the application for a refund for an error in a tariff or a failure to publish a new tariff, the carrier or conference must publish a new tariff which sets forth the rate on which refund or waiver would be based.

(d) Such application must be in accordance with Exhibit 1 to this Subpart and must also comply with the following requirements:

(1) Applications must be submitted to the Office of the Secretary, Federal Maritime Commission, Washington, DC 20573–0001.

(2) Applications must be submitted in an original and one (1) copy.

(3) Applications must be sworn to before a notary public or otherwise verified in accordance with § 502.112.

(4) When a rate published in a conference tariff is involved, the carrier or shipper must serve a copy of the application on the conference and so certify in accordance with § 502.117 to that service in the application. A shipper must also make a similar service and certification with respect to the common carrier.

(5) Applications must be accompanied by remittance of an $86 filing fee.

(e) Any application which does not furnish the information required by this subpart may be returned to the applicant by the Secretary without prejudice to resubmission within the 180-day limitation period.

(f)(1) The Secretary in his discretion shall assign all applications to either a Special Dockets Officer or the Office of Administrative Law Judges. Authority to issue decisions under this subpart is delegated to the assigned Special Dockets Officer or Administrative Law Judge.

(2) Applicants will be notified as to the assignment of a deciding official, and the assignment of a special docket number. Formal proceedings as described in other rules of this part need not be conducted. The deciding official may, in his or her discretion, require the submission of additional information.

(g) The deciding official shall issue a decision which, pursuant to § 501.21 of this chapter, shall become final ten (10) days after service of such decision, unless the Commission in its discretion chooses to review such decision within that time, or the applicant chooses to file exceptions to such decision within that time. [Rule 271.]

Exhibit No. 1 to Subpart Q

Application for Refund or Waiver of Freight Charges Due to Tariff or Quoting Error

Federal Maritime Commission Special Docket No. _____ [leave blank].

Amount of Freight Charges to be refunded or waived:

Application of [Name of carrier or shipper] for the benefit of [Name of person who paid or is responsible for payment of freight charges].

1. Shipment(s). Here fully describe:

(a) Commodity [according to tariff description].

(b) Number of shipments.

(c) Weight or measurement, container size, and number of containers of individual shipment, as well as all shipments.

(d)(1) Date(s) of receipt of shipment(s) by the carrier;

(2) Date(s) of sailing(s) [furnish supporting evidence].

(e) Shipper and place of origin.

(f) Consignee, place of destination and routing of shipment(s).

(g) Name of carrier and date shown on bill of lading [furnish legible copies of bill(s) of lading].

(h) Names of participating ocean carrier(s).

(i) Name(s) of vessel(s) involved in carriage.

(j) Amount of freight charges actually collected [furnish legible copies of rated bill(s) of lading or freight bill(s), as appropriate] broken down (i) per shipment, (ii) in the aggregate, (iii) by whom paid, (iv) who is responsible for payment if different, and (v) date(s) of collection.

(k) Rate and tariff commodity description applicable at time of shipment [furnish legible copies of tariff materials].

(l) Rate and commodity description sought to be applied [furnish legible copies of applicable tariff materials].

(m)(1) Amount of applicable freight charges, per shipment and in the aggregate;

(2) Amount of freight charges at rate sought to be applied, per shipment and in the aggregate.

(n) Amount of freight charges sought to be (refunded) (waived), per shipment and in the aggregate.

2. Furnish docket numbers of other special docket applications or decided or pending formal proceedings involving the same rate situations.

3. Fully explain the basis for the application, i.e., the error, failure to publish, or misquote, showing why the application should be granted. Furnish affidavits, if appropriate, and legible copies of all supporting documents. If the error is due to failure to publish a tariff, specify the date when the carrier and/or conference intended or agreed to publish a new tariff. If the application is based on a misquote, the application must include the affidavit of the person who made the misquote describing the circumstances surrounding such misquote along with any other supporting documentary evidence available.

4. Furnish any information or evidence as to whether granting the application may result in discrimination among shippers, ports or carriers. List any shipments of other shippers of the same commodity which (i) moved via the carrier(s) or conference involved in this application during the period of time beginning on the date the intended rate would have become effective and ending on the day before the effective date of the conforming tariff; (ii) moved on the same voyage(s) of the vessel(s) carrying the shipment(s) described in No. 1, above; or (iii), in the case of a misquote, moved between the date of receipt of shipment(s) described in No. 1 above, and the date(s) of sailing(s).

[Here set forth Name of Applicant, Signature of Authorized Person, Typed or Printed Name of Person, Title of Person and Date]

State of , County of . ss:

I, _____, on oath declare that I am _____ of the above-named applicant, that I have read this application and know its contents, and that they are true.

Subscribed and sworn to before me, a notary public in and for the State of _____, County of _____ this _____ day of _____.

(Seal)

_____

Notary Public

My Commission expires _____.

Certificate of Service [if Applicable]

I hereby certify that I have this day served the foregoing document upon the [insert the conference name if a conference tariff is involved; of the name of the carrier if the applicant is a shipper] by delivering a copy [insert means by which copy delivered].

Dated in [insert city, county, state] this _____ day of_____.

[signature]

For:

Certificate of Mailing

I certify that the date shown below is the date of mailing [or date of delivery to courier] of the original and one (1) copy of this application to the Secretary, Federal Maritime Commission, Washington, D.C., 20573.

Dated at _____, this _____ day of _____.

Signature].

For.

§ 502.301 [Amended]

51. In § 502.301, remove paragraph (b) and redesignate paragraphs (c) and (d) as paragraphs (b) and (c).

§ 502.302 [Amended]

52. In § 502.302, remove paragraph (b) and redesignate paragraph (c) as paragraph (b).

53. Revise § 502.305 to read as follows:

§ 502.305 Applicability of other rules of this part.

Except §§ 502.253 and 502.254 or as otherwise specifically provided in this subpart, the rules in subparts A through Q, inclusive, do not apply to situations covered by this subpart. [Rule 305.]

Subpart S—[Amended]

54. In Exhibit 1 to Subpart S, in the section entitled *Information to Assist in Filing Informal Complaints*, remove the third paragraph beginning with the text ''Under the Shipping Act, 1916. . . .''

55. Revise § 502.321 to read as follows:

§ 502.321 Applicability of other rules of this part.

Except as specifically provided in this part, rules in Subparts A through Q, inclusive, of this part do not apply to situations covered by this subpart. [Rule 321.]

§ 502.401 [Amended]

56. Amend § 502.401 as follows:

a. Amend paragraph (b) by removing ''Shipping Act, 1916, 46 U.S.C. app. 801 et seq.;'' and removing ''the Intercoastal Shipping Act 1933, 46 U.S.C. app. 843 et seq.''

b. Remove paragraph (d), and redesignate paragraph (e) as paragraph (d).

57. Amend § 502.501 as follows:

a. Add new paragraph (d)(2)(vi) to read as set forth below;

b. Add new paragraph (e)(3) to read as set forth below;

c. Revise the first sentence of paragraph (f)(2) to read as set forth below;

d. Add ''[Rule 501.]'' to the end of paragraph (g).

§ 502.501 General provisions.

* * * * *

(d) * * *

(2) * * *

(vi) For purposes of paragraph (e)(3) of this section, a small entity as defined in 5 U.S.C. 601.

* * * * *

(e) *Standards for awards.* (1) * * *

(2) * * *

(3) In an adversary adjudication arising from a Commission action to enforce a party's compliance with a statutory or regulatory requirement, if the demand by the Commission is substantially in excess of the decision of the presiding officer and is unreasonable under the facts and circumstances of the case, the presiding officer shall award to the party fees and other expenses related to defending against the excessive demand, unless the party has committed a willful violation of law or otherwise acted in bad faith, or special circumstances make an award unjust.

* * * * *

(f) *Allowable fees and expenses.* (1) * * *

(2) No award for the fee of an attorney or agent under this subpart may exceed $125 per hour. * * *

* * * * *

§ 502.502 [Amended]

58. In § 502.502, add ''[Rule 502.]'' to the end of paragraph (d)(3).

§ 502.503 [Amended]

59. In § 502.503, add ''[Rule 503.]'' to the end of paragraph (j)(2).

60. Revise § 502.601 to read as follows:

§ 502.601 Purpose and scope.

The purpose of this subpart is to implement the statutory provisions of section 19 of the Merchant Marine Act, 1920, section 13 of the Shipping Act of 1984, and sections 2(c) and 3(c) of Public Law 89–777 by establishing rules and regulations governing the compromise, assessment, settlement and collection of civil penalties arising under certain designated provisions of the Merchant Marine Act, 1920, the Shipping Act of 1984, Public Law 89–777, and/or any order, rule, or regulation (except for procedural rules and regulations contained in this part) issued or made by the Commission in the exercise of its powers, duties and functions under those statutes. [Rule 601.]

61. Amend § 502.602 as follows:

a. Revise paragraph (h) to read as set forth below;

b. Add ''[Rule 602.]'' to the end of paragraph (i).

§ 502.602 Definitions.

* * * * *

(h) *''Violation''* includes any violation of sections 19(6)(d), 19(7)(d) and 19(11) of the Merchant Marine Act, 1920; any provision of the Shipping Act of 1984; sections 2 and 3 of Public Law 89–777; and/or any order, rule or regulation (except for procedural rules and regulations contained in this part) issued or made by the Commission in the exercise of its powers, duties and functions under the Merchant Marine Act, 1920, the Shipping Act of 1984, or Public Law 89–777.

* * * * *

§ 502.603 [Amended]

62. In § 502.603, add ''[Rule 603.]'' to the end of paragraph (c).

63. Amend § 502.604 as follows:

a. Revise the first sentence of paragraph (b) to read as set forth below;

b. Add ''[Rule 604.]'' to the end of paragraph (g).

§ 502.604 Compromise of penalties: Relation to assessment proceedings.

* * * * *

(b) *Notice.* When the Commission considers it appropriate to afford an opportunity for the compromise of a civil penalty, it will, except when otherwise authorized by the Commission, or where circumstances render it unnecessary, send a Notice and Demand Letter (''NDL'') to the respondent, by registered or certified mail, or by other means reasonably calculated to give notice. * * *

* * * * *

64. Amend § 502.605 as follows:

a. Revise paragraph (a) to read as set forth below;

b. Add ''[Rule 605.]'' to the end of paragraph (c).

§ 502.605 Payment of penalty; Method; default.

(a) *Method.* Payment of penalties by the respondent is to be made by bank cashier's check or other instrument acceptable to the Commission.

* * * * *

PART 571—INTERPRETATIONS AND STATEMENTS OF POLICY

1. Redesignate part 571 as part 545.

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

Authority: 5 U.S.C. 553, 46 U.S.C. app. 1706, 1707, 1709, and 1716.

3. In redesignated § 545.1, revise paragraph (a) to read as follows:

§ 545.1 Interpretation of Shipping Act of 1984—Refusal to negotiate with shippers' associations.

(a) Section 8(c) of the Shipping Act of 1984 (''1984 Act'') authorizes ocean common carriers and conferences to enter into a service contract with a shippers' association, subject to the requirements of the 1984 Act. Section 10(b)(10) of the 1984 Act prohibits carriers from unreasonably refusing to deal or negotiate. Section 7(a)(2) of the 1984 Act exempts from the antitrust laws any activity within the scope of that Act, undertaken with a reasonable basis to conclude that it is pursuant to a filed and effective agreement.

* * * * *

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 98–31856 Filed 12–1–98; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1312

[STB Ex Parte No. 580]

Regulations for the Publication, Posting and Filing of Tariffs for the Transportation of Property by or with a Water Carrier in the Noncontiguous Domestic Trade

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Surface Transportation Board (Board or STB) proposes to modify its tariff filing regulations to eliminate the option of filing tariffs with the Board electronically through the Federal Maritime Commission (FMC) Automated Tariff Filing and Information System (ATFI), which is being phased out effective May 1, 1999. The Board will, however, entertain special tariff authority requests by individual carriers seeking to file their tariffs electronically.

DATES: Comments are due January 4, 1999.

ADDRESSES: Send comments (an original and 10 copies) referring to STB Ex Parte No. 580 to: Surface Transportation Board, Office of the Secretary, Case Control Branch, 1925 K Street, N.W., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: James W. Greene (202) 565–1578. [TDD for the hearing impaired: (202) 565–1695.]

SUPPLEMENTARY INFORMATION: The ICC Termination Act of 1995, Public Law 104–88, 109 Stat. 803 (1995), transferred from the FMC to the Board the responsibility for regulating port-to-port water carriage in the noncontiguous domestic trade. In connection with the

transfer of jurisdiction, the Board entered into an interagency agreement with the FMC and modified its requirements to allow carriers to continue to utilize the FMC's ATFI system to file their tariffs with the Board. This action permitted the transfer of jurisdiction to occur without requiring the carriers to make any new tariff filings, and comported with Congress' suggestion that the Board continue the FMC's practice of allowing carriers to file their tariffs electronically.[1] The recently-enacted Ocean Shipping Reform Act of 1998, Pub. L. No. 105–258, 112 Stat. 1902 (1998) (OSRA) will, however, eliminate the requirement that ocean carriers file their tariffs with the FMC effective May 1, 1999, and in these circumstances, the FMC will not be accepting new ATFI tariff filings on or after that date.

While ATFI has served well as an electronic filing option for STB tariffs, its feasibility has always been predicated upon the basic system being operated and maintained by the FMC to support its own tariff filing requirements. STB tariff filings constitute less than 5% of total ATFI tariff filings, and absent the 95-plus percent of the filings accounted for by the FMC's requirements, it will not be economically feasible to operate and maintain the ATFI system or any similar system solely for STB tariffs.

Under the interagency agreement between the FMC and the Board, the Board pays an annual fee to FMC to cover the Board's portion of ATFI contract costs and certain in-house services provided by FMC, and FMC remits to the Board the filing and access fees attributable to STB tariffs. However, the Board's share of ATFI costs and fees is minuscule in terms of total system cost and fees. While the drastic reduction in tariff filings would undoubtedly reduce certain variable costs, the fixed costs of ATFI, spread over solely STB tariffs, would require the imposition of prohibitive tariff filing and access fees in order for the Board to recover any reasonable portion of its out-of-pocket costs.[2] In these circumstances, it is clear that ATFI would not be viable solely for STB tariff filings. Similarly, it would not be feasible for the Board to undertake an effort to design, develop and implement a new electronic tariff filing system geared solely to STB requirements, given the limited scope of the Board's remaining tariff filing requirements and the extensive staff and monetary resources that would be required.

Although the Board's regulations will no longer routinely provide for electronic tariff filings if the proposed revisions are adopted, we will not rule out, and indeed will encourage, electronic tariff filing proposals from interested carriers. ATFI filings were initially accepted pursuant to special tariff authority granted by the Board,[3] and we are amenable to special tariff authority requests for individual electronic tariff filing proposals submitted by carriers. By way of illustration in this regard, we would point out that our predecessor organization, the Interstate Commerce Commission (ICC), issued a decision several years ago granting a rail carrier's request to file certain tariffs on computer diskettes.[4] Parties proposing alternative tariff filing systems must, of course, explain how the proposed systems will fulfill all of the various needs for tariff information.[5]

Request for Comments

We invite comments on the proposed regulations. We encourage any commenter that has the necessary technical wherewithal to submit its comments as computer data on a 3.5-inch floppy diskette formatted for WordPerfect 6.1, or formatted so that it can be readily converted into WordPerfect 6.1. Any such diskette submission (one diskette will be sufficient) should be in addition to the written submission (an original and 10 copies).

Small Entities

The Board preliminarily concludes that these rules, if adopted, would not have a significant economic effect on a substantial number of small entities. The proposed regulations will eliminate the existing option to file tariffs electronically through the FMC's ATFI system, but many carriers already opt to file printed tariffs, and any cost differences for alternative tariff filing methodologies that carriers may propose are unlikely to be significant.

Environment

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1312

Motor carriers, Noncontiguous domestic trade, Tariffs, Water carriers.

Decided: November 24, 1998.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

For the reasons set forth in the preamble, the Board proposes to amend part 1312 of title 49, chapter X, of the Code of Federal Regulations as follows:

PART 1312—REGULATIONS FOR THE PUBLICATION, POSTING AND FILING OF TARIFFS FOR THE TRANSPORTATION OF PROPERTY BY OR WITH A WATER CARRIER IN NONCONTIGUOUS DOMESTIC TRADE

1. The authority citation for part 1312 continues to read as follows:

Authority: 49 U.S.C. 721(a), 13702(a), 13702(b) and 13702(d).

§ 1312.1 [Amended]

2. In § 1312.1(c), the definition of ''ATFI'' is removed.

3. Section 1312.6 is amended by revising paragraph (c) to read as follows:

§ 1312.6 Advance notice required.

* * * * *

(c) Receipt of tariffs by the Board. The Board will receive tariff filings between the hours of 8:30 A.M. and 5:00 P.M. Eastern time, on workdays. Tariff filings delivered to the Board on other than a workday, or after 5:00 P.M. on a workday, will be considered as received the next workday.

* * * * *

4. Section 1312.17 is removed.

[FR Doc. 98–32104 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–61–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[I.D. 111998A]

Gulf of Mexico Fishery Management Council; Public Hearings

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

[1] H.R. Rep. No. 422, 104th Cong., 1st Sess. 206 (1995).

[2] We are aware that the FMC's Notice of Inquiry concerning the implementation of OSRA (63 FR 37088) raised the possibility of continuing to operate some portion of ATFI to provide for the electronic filing of service contracts. An electronic filing system geared to the requirements of service contracts, however, would not fulfill the requirements for an electronic tariff filing system

[3] STB Special Tariff Authority No. 4, served October 1, 1996,

[4] Special Tariff Authority No. 93–12, ICC served July 25, 1994.

[5] Our staff is available to consult informally with carriers in this regard.

ACTION: Notice of public hearings; request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene public hearings on a Draft Sustainable Fisheries Act (SFA) Amendment and on a draft regulatory amendment regarding gag and black grouper in Federal waters of the Gulf of Mexico. Some of the hearings in the Gulf region will be joint hearings to receive comments on both draft amendments.

DATES: Written comments on the Draft SFA Amendment and the draft regulatory amendment will be accepted by the Council through January 4, 1999. The public hearings will be held in December 1998. See **SUPPLEMENTARY INFORMATION** for specific dates, times, and locations of the public hearings.

ADDRESSES: Written comments should be sent to, and copies of the Draft SFA Amendment and draft regulatory amendment are available from, the Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301, North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council; Telephone: (813) 228–2815.

SUPPLEMENTARY INFORMATION: In 1996, Congress passed the SFA, which contained new requirements for the management of marine fisheries in Federal waters. To meet these new requirements, the Council developed the Draft SFA Amendment that would amend all fishery management plans (FMPs) prepared by the Council. The Draft SFA Amendment includes alternative management measures for: (1) Reporting bycatch; (2) minimizing bycatch or bycatch mortality; (3) specifying higher standards for overfishing criteria that will restore fishery stocks to maximum sustainable yield (MSY); and (4) establishing rebuilding periods for overfished stocks, such as red snapper, king mackerel, and red drum. The Draft SFA Amendment also identifies communities economically dependent on fishing so that the impacts of fishery management measures on these communities can be assessed.

The section on reporting bycatch discusses five alternatives related to the submission of data by fishermen and vessel observers. The Council recommends that NMFS collect bycatch information by the most appropriate methods, but use mandatory observers only when the Council recommends such an approach.

In the section on measures to minimize bycatch or bycatch mortality, the Council recommends that stone crab traps used in Federal waters be constructed according to Florida law.

In the section on overfishing criteria and stock rebuilding periods for finfish, the Council recommends that MSY, optimum yield (OY), and the overfishing thresholds be set at higher levels than in the existing FMPs. For red snapper, the Council recommends setting MSY and the overfishing threshold at 26–percent spawning potential ratio (SPR), and OY at 36–percent SPR. For red drum, all the coastal migratory species (including mackerels), and all reef fish species (except red snapper, gag, Nassau grouper, and jewfish), the Council recommends setting MSY, OY, and overfishing thresholds at 30–percent SPR. For Nassau grouper and jewfish, the Council recommends setting MSY, OY, and the overfishing threshold at 50–percent SPR. The Council has not selected a proposal for gag. The effect of specifying overfishing criteria at higher levels for the finfish stocks is that additional stocks may be classified as overfished if NMFS approves the final SFA amendment in 1999.

The Council proposes to modify the rebuilding periods for two overfished stocks. It proposes that red snapper be rebuilt by 2033, and king mackerel by 2009. No rebuilding periods are proposed for red drum, Nassau grouper, or jewfish because there was insufficient information to compute the rebuilding periods.

Also, the Draft SFA Amendment does not contain proposed overfished thresholds in terms of biomass (weight) for any of the finfish stocks because there was insufficient information to compute these parameters. The Draft SFA Amendment includes alternatives for overfished thresholds that are expressed in terms of SPR.

In the section on overfishing criteria and stock rebuilding periods for the crustacean fisheries, the Council has proposed setting MSY, OY, and the overfishing thresholds for penaeid shrimp at or above the parent stock numbers (as indexed from current virtual population analysis (VPA) procedures) for the three penaeid species of shrimp in the Gulf of Mexico: (1) Brown shrimp (125 million individuals, age 7+ months during the November through February period); (2) white shrimp (330 million individuals, age 7+ months during the May through August period); and (3) pink shrimp (100 million individuals, age 5+ months during the July through June year). For royal red shrimp, the Council proposes setting MSY, OY, and the overfishing threshold at 650,000 lb (294,840 kg).

For spiny lobster, the Council proposes to set MSY and the overfishing threshold at 20–percent transitional SPR or spawning stock biomass per recruit, but OY would be set at 30–percent SPR. For stone crab, the Council recommends setting MSY, OY, and the overfishing threshold at the harvest level that results from a realized egg production per recruit at or above 70 percent of potential production. This harvest capacity is currently estimated to be between 3.0 and 3.5 million lb (between 1.36 and 1.58 million kg) of claws (minimum 70 mm propodus length). Overfished thresholds are specified as one-half of MSY or slightly higher for the crustacean stocks, none of which is overfished.

Ten public hearings will be held to obtain public comments on the Draft SFA Amendment (see Public Hearing Times and Locations). The public comment period for the Draft SFA Amendment ends on January 4, 1999.

The Council will also hold public hearings on possible regulatory changes to the management of gag and black grouper in Federal waters of the Gulf of Mexico. Issues addressed in the draft regulatory amendment for gag and black grouper include the following: (1) Specification of a total allowable catch (TAC) for gag; (2) discussion of the allocation of the gag TAC between recreational and commercial sectors; (3) a minimum size limit increase for gag and black grouper from 20 to 24 inches (50.8 to 60.9 cm) total length; (4) a 2–fish recreational bag limit for gag as part of the existing 5–fish aggregate grouper bag limit; (5) a zero bag limit for gag for the captain and crew of recreational for-hire vessels; (6) a commercial trip limit for gag; (7) a closed season during peak gag spawning times; and (8) area closures at gag spawning aggregation locations.

The Council currently has no preferred alternatives. However, in its ''1998 Report to Congress on the Status of Fisheries of the United States,'' NMFS identified gag in the Gulf of Mexico as a stock that, while not currently overfished, is approaching an overfished condition. Under the provisions of the Magnuson-Stevens Fishery Conservation and Management Act, the Council is required to take action to prevent overfishing from occurring for stocks identified by NMFS as approaching an overfished condition. The Council will decide which measures to recommend to achieve that goal at its January 11 to 14, 1999, meeting to be held in Biloxi, MS. Comments on the draft regulatory

amendment for gag and black grouper must be received by January 4, 1999.

Public Hearing Times and Addresses

Public hearings will be held from 7:00 p.m. to 10:00 p.m. at all of the following locations, except Panama City, FL, Orange Beach, AL, and Larose, LA; where the hearings on the draft regulatory amendment for gag and black grouper will be from 3:00 p.m. to 5:00 p.m., and the hearings on the Draft SFA Amendment will be from 7:00 p.m. to 10:00 p.m.

Monday, December 7, 1998—Pier House, One Duval Street, Key West, FL—Draft gag and black grouper regulatory amendment;

Monday, December 7, 1998—Holiday Inn-Fort Brown, 1900 E. Elizabeth Street, Brownsville, TX—Draft SFA Amendment;

Tuesday, December 8, 1998—Steinhatchee Elementary School, 1st Avenue South, Steinhatchee, FL—Draft gag and black grouper regulatory amendment;

Tuesday, December 8, 1998—Pier House, One Duval Street, Key West, FL—Draft SFA Amendment;

Tuesday, December 8, 1998—Port Aransas Civic Center Auditorium, 710 West Avenue A, Port Aransas, TX—Draft SFA Amendment;

Wednesday, December 9, 1998—City Hall Auditorium, 3001 Municipal Drive, Madeira Beach, FL—Draft gag and black grouper regulatory amendment;

Wednesday, December 9, 1998—Texas A&M Auditorium, 200 Seawolf Parkway, Galveston, TX—Draft SFA Amendment;

Thursday, December 10, 1998—Courtyard Marriott, 4455 Metro Parkway, Fort Myers, FL—Draft gag and black grouper regulatory amendment;

Thursday, December 10, 1998—New Orleans Airport Hilton & Conference Center, 901 Airline Highway, Kenner, LA—Draft SFA Amendment;

Thursday, December 10, 1998—Ramada Airport Inn & Conference Center, 5303 West Kennedy Boulevard, Tampa, FL—Draft SFA Amendment;

Monday, December 14, 1998—National Marine Fisheries Service Panama City Laboratory, 3500 Delwood Beach Road, Panama City, FL—both the Draft SFA Amendment and the draft gag and black grouper regulatory amendment;

Tuesday, December 15, 1998—Orange Beach Community Center, 27235 Canal Road, Orange Beach, AL—both the Draft SFA Amendment and the draft gag and black grouper regulatory amendment;

Wednesday, December 16, 1998—J. L. Scott Marine Education Center & Aquarium, 115 East Beach Boulevard, US Highway 90, Biloxi, MS—Draft SFA Amendment; and

Thursday, December 17, 1998—Larose Regional Park, 2001 East 5th Street, Larose, LA—both the Draft SFA Amendment and the draft gag and black grouper regulatory amendment.

Copies of the Draft SFA Amendment and the draft regulatory amendment on gag and black grouper may be obtained by calling the Council at 813–228–2815.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by December 7, 1998.

Dated: November 24, 1998.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–32038 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[I.D. 112598B]

RIN 0648–AJ44

Fisheries of the Northeastern United States; Northeast Multispecies and Monkfish Fisheries; Monkfish Fishery Management Plan

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

ACTION: Notice of availability of a fishery management plan; request for comments.

SUMMARY: NMFS announces that the New England and Mid-Atlantic Fishery Management Councils (Councils) have submitted the Monkfish Fishery Management Plan (FMP) for Secretarial review and are requesting comments from the public.

DATES: Comments must be received on or before February 1, 1999.

ADDRESSES: Comments on the Monkfish FMP should be sent to Jon C. Rittgers, Acting Regional Administrator, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on Monkfish FMP.''

Copies of the Monkfish FMP, its regulatory impact review, initial regulatory flexibility analysis, the final environmental impact statement, and the supporting documents are available from Paul J. Howard, Executive Director, New England Fishery Management Council, 5 Broadway, Saugus, MA 01906–1036.

FOR FURTHER INFORMATION CONTACT: E. Martin Jaffe, Fishery Policy Analyst, 978–281–9272.

SUPPLEMENTARY INFORMATION: The FMP proposes an overfishing definition and a 10-year rebuilding schedule to meet the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and implementation of the following measures: Target total allowable catch levels for each of two management areas; limited access; effort limits through days-at-sea allocations; trip limits and incidental harvest allowances; minimum size and mesh limits; gear restrictions; spawning season closures; a framework adjustment process; permitting and reporting requirements, and other measures for administration and enforcement.

A proposed rule that would implement the Monkfish FMP may be published in the **Federal Register** for public comment, following NMFS' evaluation of the proposed rule under the procedures of the Magnuson-Stevens Act. Public comments on the proposed rule must be received by the end of the comment period on the Monkfish FMP to be considered in the approval/disapproval decision on the FMP. All comments received by February 1, 1999, whether specifically directed to the FMP or the proposed rule, will be considered in the approval/disapproval decision on the Monkfish FMP. Comments received after that date will not be considered in the approval/disapproval decision on the Monkfish FMP.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 27, 1998.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–32129 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register

Vol. 63, No. 231

Wednesday, December 2, 1998

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

Foreign Agricultural Service

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Foreign Agricultural Service's (FAS) intention to request an extension for a currently approved information collection procedure. This information is contained in a petition which may be filed with the Department of Agriculture (USDA) requesting emergency relief from increased, injurious imports of certain perishable products entering the United States duty-free from beneficiary countries under the Andean Trade Preference Act.

DATES: Comments on this notice must be received on or before February 1, 1999 to be assured consideration.

ADDRESSES: Mail or deliver comments to Stephen C. Hammond, Director, Import Policies and Programs Division, Foreign Agricultural Service, Stop 1021, 1400 Independence Ave., S.W., Washington, D.C. 20250–1021, (202) 720–2916.

FOR FURTHER INFORMATION CONTACT: Diana Wanamaker, Stop 1021, 1400 Independence Avenue, S.W., Washington, D.C. 20250–1021, (202) 720–1330.

SUPPLEMENTARY INFORMATION:

Title: Emergency Relief from Duty-Free Imports of Perishable Products from Andean Countries.

OMB Number: 0551–0033.

Expiration Date of Approval: April 30, 1999.

Type of Request: Extension for a currently approved information collection.

Abstract: The Andean Trade Preference Act (Pub. L. 102–182, 105 Stat. 1236 (19 U.S.C. 3201 *et. seq.*) (the ''Act''), authorizes the President to proclaim duty-free treatment for imports from Bolivia, Colombia, Ecuador, and Peru, except for certain specifically excluded products. Section 204(e) of the Act provides, in part, that if a petition is filed with the United States International Trade Commission pursuant to the provisions of section 201 of the Trade Act of 1974, as amended (19 U.S.C. 2251), regarding a perishable product and alleging injury from imports from beneficiary countries, then a petition may also be filed with Secretary of Agriculture requesting that emergency relief be granted by the President. Under 7 CFR 1540.43, an entity seeking emergency relief may submit a request to the administrator, FAS, providing appropriate information and data to permit the Secretary of Agriculture to make a determination whether to recommend to the President to take emergency action. The request should contain a description of the imported perishable product concerned and the country of origin; data showing that increased imports of such perishable product are the substantial cause of serious injury, or the threat of serious injury, to the domestic industry producing a perishable product like or directly competitive with the imported product; and provide a statement indicating why emergency action would be warranted. The information collected would be used by FAS to prepare an assessment that would assist the Secretary in making his determination.

Estimate of Burden: Public reporting burden for this collection of information is estimated at $1,106.

Respondents: Non-profit institutions, businesses, or farms.

Estimated Number of Respondents: 2.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 46 hours. Copies of the information collection can be obtained from Kimberly Chisley, the Agency Collection Coordinator, at (202) 720–2568.

REQUESTS FOR COMMENTS: The public is invited to submit comments and suggestions to the above address regarding the accuracy of the burden estimate, ways to minimize the burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information. Comments on issues covered by the Paperwork Reduction Act are most useful to OMB if received within 30 days of publication of the Notice and Request for Comments, but must be submitted no later than 60 days from the date of publication to be assured consideration. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also be a matter of public record.

Signed at Washington, DC, on November 27, 1998.

Lon Hatamiya,

Administrator, Foreign Agricultural Service.

[FR Doc. 98–32128 Filed 12–1–98; 8:45 am]

BILLING CODE 3410–10–M

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers Used for Publication of Legal Notice of Appealable Decisions for the Intermountain Region; Utah, Idaho, Nevada, and Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by all ranger districts, forests, and the Regional Office of the Intermountain Region to publish legal notice of all decisions subject to appeal under 36 CFR 215 and 36 CFR 217. The intended effect of this action is to inform interested members of the public which newspapers will be used to publish legal notices of decisions, thereby allowing them to receive constructive notice of a decision, to provide clear evidence of timely notice, and to achieve consistency in administering the appeals process.

DATES: Publication of legal notices in the listed newspapers will begin with decisions subject to appeal that are made on or after December 15, 1998. The list of newspapers will remain in effect until June 1, 1999 when another notice will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Donald W. Murphy, Regional Appeals Manager, Intermountain Region, 324

25th Street, Ogden, UT 84401, Phone (801) 625-5274.

SUPPLEMENTARY INFORMATION: The administrative appeal procedures, 36 CFR Parts 215 and 217, of the Forest Service require publication of legal notice in a newspaper of general circulation of all decisions subject to appeal. This newspaper publication of notices of decisions is in additions to those who have requested notice in criting and to those known to be interested and affected by a specific decision.

The legal notice is to identify: the decision by title and subject matter; the date of the decision; the name and title of the official making the decision; and how to obtain copies of the decision. In additions, the notice is to state the date the appeal period begins which is the day following publication of the notice.

The timeframe for appeal shall be based on the date of publication of the notice in the first (principal) newspaper listed for each unit.

The newspapers to be used are as follows.

Regional Forester, Intermountain Region

For decisions made by the Regional Forester affecting National Forests in Idaho:
The Idaho Statesman, Boise, Idaho
For decisions made by the Regional Forester affecting National Forests in Nevada:
The Reno Gazette-Journal, Reno, Nevada
For decisions made by the Regional Forester affecting National Forests in Wyoming:
Casper Star-Tribune, Casper, Wyoming
For decisions made by the Regional Forester affecting National Forests in Utah:
Salt Lake Tribune, Salt Lake City, Utah
If the decision made by the Regional Forester affects all National Forests in the Intermountain Region, it will appear in:
Salt Lake Tribune, Salt Lake City, Utah

Ashley National Forest

Ashley Forest Supervisors decisions:
Vernal Express, Vernal, Utah
Vernal District Ranger decisions:
Vernal Express, Vernal, Utah
Flaming Gorge District Ranger for decisions affecting Wyoming:
Casper Star Tribune, Casper, Wyoming
Flaming Gorge District Ranger for decisions affecting Utah:
Vernal Express, Vernal, Utah
Roosevelt and Duchesne District Ranger decisions:
Uintah Basin Standard, Roosevelt, Utah

Boise National Forest

Boise Forest Supervisor decisions:
The Idaho Statesman, Boise, Idaho
Mountain Home District Ranger decisions:
The Idaho Stateman, Boise, Idaho
Idaho City District Ranger decisions:
The Idaho Statesman, Boise, Idaho
Cascade District Ranger decisions:
The Advocate, Cascade, Idaho
Lowman District Ranger decisions:
The Idaho City World, Idaho City, Idaho
Emmett District Ranger decisions:
The Messenger-Index, Emmett, idaho

Bridger-Teton National Forest

Bridger-Teton Forest Supervisor decisions:
Casper Star-Tribune, Casper, Wyoming
Jackson District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Buffalo District Ranger decisions:
Casper Star-Tribune, Jackson, Wyoming
Big Piney District Ranger decisions:
Casper Star-Tribune, Jackson, Wyoming
Pinedale District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Greys River District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Kemmerer District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming

Caribou National Forest

Caribou Forest Supervisor decisions:
Idaho State Journal, Pocatello, Idaho
Soda Springs District Ranger decisions:
Idaho State Journal, Pocatello, Idaho
Montipelier District Ranger decisions:
Idaho State Journal, Pocatello, Idaho
Westside District Ranger decisions:
Idaho State Journal, Pocatello, Idaho

Dixie National Forest

Dixie Forest Supervisor decisions:
The Daily Spectrum, St. George, Utah
Pine Valley District Ranger decisions:
The Daily Spectrum, St. George, Utah
Cedar City District Ranger decisions:
The Daily Spectrum, St. George, Utah
Powell District Ranger decisions:
The Daily Spectrum, St. George, Utah
Escalante District Ranger decisions:
The Daily Spectrum, St. George, Utah
Teasdale District Ranger decisions:
The Daily Spectrum, St. George, Utah

Fishlake National Forest

Fishlake Forest Supervisor decisions:
Richfield Reaper, Richfield, Utah
Loa District Ranger decisions:
Richfield Reaper, Richfield, Utah
Richfield District Ranger decisions:
Richfield Reaper, Richfield, Utah
Beaver District Ranger decisions:
Richfield Reaper, Beaver, Utah
Fillmore District Ranger decisions:
Richfield Reaper, Fillmore, Utah

Humboldt-Toiyabe National Forests

Humboldt Forest Supervisor decisions:
Elko Daily Free Press, Elko, Nevada
Toiyabe Forest Supervisor decisions:
Reno Gazette-Journal, Reno, Nevada
Sierra Ecosystem Coordination Center (SECO):
Carson District Ranger decisions:
Reno Gazette-Journal, Reno, Nevada
Bridgeport District Ranger decisions:
The Review-Herald, Mammoth Lakes, California
Spring Mountains National Recreation Area Ecosystem (SMNRAE):
Spring Mountain National Recreation Area District Ranger decisions:
Las Vegas Review Journal, Las Vegas, Nevada
Central Nevada Ecosystem (CNECO):
Austin District Ranger decisions:
Reno Gazette-Journal, Reno, Nevada
Tonopah District Ranger decisions:
Tonopah Times Bonanza-Goldfield News, Tonopah, Nevada
Ely District Ranger decisions:
Ely Daily Times, Ely, Nevada
Northeast Nevada Ecosystem (NNECO):
Mountain City District Ranger decisions:
Elko Daily Free Press, Elko, Nevada
Ruby Mountains District Ranger decisions:
Elko Daily Free Press, Elko, Nevada
Jarbidge District Ranger decisions:
Elko Daily Free Press, Elko, Nevada
Santa Rosa District Ranger decisions:
Humboldt Sun, Winnemucca, Nevada

Manti-LaSal National Forest

Manti-LaSal Forest Supervisor decisions:
Sun Advocate, Price, Utah
Sanpete District Ranger decisions:
The Pyramid, Mt. Pleasant, Utah
Ferron district Ranger decisions:
Emery County Progress, Castle Dale, Utah
Price District Ranger decisions:
Sun Advocate, Price, Utah
Moab District Ranger decisions:
The Times Independent, Moab, utah
Monticello District Ranger decisions:
The San Juan Record, Monticello, Utah

Payette National Forest

Payette Forest Supervisor decisions:
Idaho Statesman, Boise, Idaho
Weiser District Ranger decisions:
Signal American, Weiser, Idaho

Council District Ranger decisions:
Council Record, Council, Idaho
New Meadows, McCall, and Krassel District Ranger decisions:
Star News, McCall, Idaho

Salmon and Challis National, Forests

Salmon Forest Supervisor decisions:
The Recorder-Herald, Salmon, Idaho
Cobalt District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
North Fork District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Leadore District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Salmon District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Challis Forest Supervisor decisions:
The Challis Messenger, Challis, Idaho
Middle Fork District Ranger decisions:
The Challis Messenger, Challis, Idaho
Challis District Ranger decisions:
The Challis Messenger, Challis, Idaho
Yankee Fork District Ranger decisions:
The Challis Messenger, Challis, Idaho
Lost River District Range decisions:
The Challis Messenger, Challis, Idaho

Sawtooth National Forest

Sawtooth Forest Supervisor decisions:
The Times News, Twin Falls, Idaho
Burley District Ranger decisions:
Ogden Standard Examiner, Ogden, Utah, for those decisions on the Burley District involving the Raft River Unit.
South Idaho Press, Burley, Idaho, for decisions issued on the Idaho portions of the Burley District.
Twin Falls District Ranger decisions:
The Times News, Twin Falls, Idaho
Ketchum District Ranger decisions:
Wood River Journal, Hailey, Idaho
Sawtooth National Recreation Area:
Challis Messenger, Challis, Idaho
Fairfield District Ranger decisions:
The Times News, Twin Falls, Idaho

Targhee National Forest

Targhee Forest Supervisor decisions:
The Post Register, Idaho Falls, Idaho
Dubois District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Island Park District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Ashton District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Palisaded District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Teton Basin District Ranger decisions:
The Post Register, Idaho Falls, Idaho

Uinta National Forest

Uinta Forest Supervisor decisions:
The Daily Herald, Provo, Utah
Pleasant Grove District Ranger decisions:
The Daily Herald, Provo, Utah
Heber District Ranger decisions:
The Daily Herald, Provo, Utah, and
Spanish Fork District Ranger decisions:
The Daily Herald, Provo, Utah

Wasatch-Cache National Forest

Wasatch-Cache Forest Supervisor decisions:
Salt Lake Tribune, Salt Lake City, Utah
Salt Lake District Ranger decisions:
Salt Lake Tribune, Salt Lake City, Utah
Kamas District Ranger decisions:
Salt Lake Tribune, Salt Lake City, Utah
Evanston District Ranger decisions:
Uintah County Herald, Evanston, Wyoming
Mountain View District Ranger decisions:
Uintah County Herald, Evanston, Wyoming
Ogden District Ranger decisions:
Ogden Standard Examiner, Ogden, Utah
Logan District Ranger decisions:
Logan Herald Journal, Logan, Utah

Dated: November 25, 1998.

Jack A. Blackwell,

Regional Forester.

[FR Doc. 98–32053 Filed 12–1–98; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 43–98]

Foreign-Trade Zone 171—Liberty County, Texas; Application for Expansion; Extension of Public Comment Period

The comment period for the above case, submitted by the Liberty County Economic Development Corporation, requesting authority to expand its zone in Liberty County, Texas (63 FR 52241, 9/30/98), is extended to January 29, 1998, to allow interested parties additional time in which to comment on the proposal.

Comments in writing are invited during this period. Submissions should include 3 (three) copies. Material submitted will be available at: Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th & Pennsylvania Avenue, NW, Washington, DC 20230.

Dated: November 25, 1998.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 98–32119 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Initiation of Five-Year (''Sunset'') Reviews.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating five-year (''sunset'') reviews of the antidumping and countervailing duty orders, findings, and/or suspended investigations listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notices of *Institution of Five-Year Reviews* covering these same orders and/or suspended investigations.

FOR FURTHER INFORMATION CONTACT: Melissa G. Skinner, Scott E. Smith, or Martha V. Douthit, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, at (202) 482–1560, (202) 482–6397 or (202) 482–3207, respectively, or Vera Libeau, Office of Investigations, U.S. International Trade Commission, at (202) 205–3176.

SUPPLEMENTARY INFORMATION:

Initiation of Reviews

In accordance with 19 CFR 351.218 (*see Procedures for Conducting Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders*, 63 FR 13516 (March 20, 1998)), we are initiating sunset reviews of the following antidumping and countervailing duty orders, findings, or suspended investigations:

DOC Case No.	ITC Case No.	Country	Product
C–301–401	C-None	Colombia	Textiles & Textile Products.
C–549–401	C-None	Thailand	Certain Textile Mill Products.
C–351–005	C–184	Brazil	Frozen Concentrated Orange Juice.

DOC Case No.	ITC Case No.	Country	Product
A–351–605	A–326	Brazil	Frozen Concentrated Orange Juice.
A–588–401	A–189	Japan	Calcium Hypochlorite.
C–351–029	C4–20	Brazil	Castor Oil.
A–570–825	A–653	China, PR	Sebacic Acid.
A–122–401	A–196	Canada	Raspberries.
C–122–404	C–224	Canada	Live Swine.
C–351–406	C–223	Brazil	Tillage Tools.
A–357–405	A–208	Argentina	Barbed Wire.

Statute and Regulations

Pursuant to sections 751(c) and 752 of the Act, an antidumping (''AD'') or countervailing duty (''CVD'') order will be revoked, or the suspended investigation will be terminated, unless revocation or termination would be likely to lead to continuation or recurrence of (1) dumping or a countervailable subsidy, and (2) material injury to the domestic industry.

The Department's procedures for the conduct of sunset reviews are set forth in *Procedures for Conducting Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders*, 63 FR 13516 (March 20, 1998) (''*Sunset Regulations*''). Guidance on methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's Policy Bulletin 98:3—*Policies Regarding the Conduct of Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin*, 63 FR 18871 (April 16, 1998) (''*Sunset Policy Bulletin*'').

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the *Sunset Regulations* and *Sunset Policy Bulletin*, the Department's schedule of sunset reviews, case history information (*e.g.*, previous margins, duty absorption determinations, scope language, import volumes), and service lists, available to the public on the Department's sunset internet website at the following address: ''http://www.ita.doc.gov/import—admin/records/sunset/''.

All submissions in the sunset review must be filed in accordance with the Department's regulations regarding format, translation, service, and certification of documents. These rules can be found at 19 CFR 351.303 (1998). Also, we suggest that parties check the Department's sunset website for any updates to the service list before filing any submissions. We ask that parties notify the Department in writing of any additions or corrections to the list. We also would appreciate written notification if you no longer represent a party on the service list.

Because deadlines in a sunset review are, in many instances, very short, we urge interested parties to apply for access to proprietary information under administrative protective order (''APO'') immediately following publication in the **Federal Register** of the notice of initiation of the sunset review. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306 (*see Antidumping and Countervailing Duty Proceedings: Administrative Protective Order Procedures; Procedures for Imposing Sanctions for Violation of a Protective Order*, 63 FR 24391 (May 4, 1998)).

Information Required from Interested Parties

Domestic interested parties (defined in 19 CFR 351.102 (1998)) wishing to participate in the sunset review must respond not later than 15 days after the date of publication in the **Federal Register** of the notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth in the *Sunset Regulations* at 19 CFR 351.218(d)(1)(ii). In accordance with the *Sunset Regulations*, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.

If we receive a notice of intent to participate from a domestic interested party, the *Sunset Regulations* provide that *all parties* wishing to participate in the sunset review must file substantive responses not later than 30 days after the date of publication in the **Federal Register** of the notice of initiation. The required contents of a substantive response are set forth in the *Sunset Regulations* at 19 CFR 351.218(d)(3). Note that certain information requirements differ for foreign and domestic parties. Also, note that the Department's information requirements are distinct from the International Trade Commission's information requirements. Please consult the *Sunset Regulations* for information regarding the Department's conduct of sunset reviews.[1] Please consult the Department's regulations at 19 CFR Part 351 (1998) for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: November 20, 1998.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 98–31984 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–331–602]

Certain Fresh Cut Flowers from Ecuador: Notice of Extension of Time Limits for Preliminary Results of Antidumping Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Review.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mark Ross or Davina Hashmi, AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4794 or (202) 482–5760, respectively.

[1] A number of parties commented that these interim-final regulations provided insufficient time for rebuttals to substantive responses to a notice of initiation (*Sunset Regulations*, 19 CFR 351.218(d)(4)). As provided in 19 CFR 351.302(b) (1998), the Department will consider individual requests for extension of that five-day deadline based upon a showing of good cause.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations are references to the provisions codified at 19 CFR part 351 (1998).

Extension of Time Limits for Preliminary Results

The Department has received a request to conduct an administrative review of the antidumping duty order on certain fresh cut flowers from Ecuador. On April 24, 1998, the Department initiated this administrative review covering the period March 1, 1997 through February 28, 1998.

Owing to certain issues surrounding this case, it is not practicable to complete this review within the time limits mandated by section 751(a)(3)(A) of the Act (see Memorandum from Richard Moreland to Robert LaRussa, Re: Extension of Time Limit for Administrative Review of Fresh Cut Flowers from Ecuador, November 24, 1998). Therefore, in accordance with that section, the Department is extending the time limits for the issuance of the preliminary results of review to March 30, 1999. The Department intends to issue the final results of review 120 days after the publication of the preliminary results. This extension of the time limit is in accordance with section 751(a)(3)(A) of the Act.

Dated: November 24, 1998.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 98–32117 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

INTERNATIONAL TRADE ADMINISTRATION

[A–337–804]

Notice of Antidumping Duty Order: Certain Preserved Mushrooms from Chile

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: David J. Goldberger or Katherine Johnson, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–4136 or (202) 482–4929, respectively.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (''the Act''), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department of Commerce (''Department'') regulations are to the regulations at 19 CFR part 351, (1998).

Scope of Order

The products covered by this order are certain preserved mushrooms whether imported whole, sliced, diced, or as stems and pieces. The preserved mushrooms covered by this order are the species *Agaricus bisporus* and *Agaricus bitorquis.* ''Preserved mushrooms'' refer to mushrooms that have been prepared or preserved by cleaning, blanching, and sometimes slicing or cutting. These mushrooms are then packed and heated in containers including but not limited to cans or glass jars in a suitable liquid medium, including but not limited to water, brine, butter or butter sauce. Preserved mushrooms may be imported whole, sliced, diced, or as stems and pieces. Included within the scope of the order are ''brined'' mushrooms, which are presalted and packed in a heavy salt solution to provisionally preserve them for further processing.

Excluded from the scope of the order are the following: (1) All other species of mushroom, including straw mushrooms; (2) all fresh and chilled mushrooms, including ''refrigerated'' or ''quick blanched mushrooms'; (3) dried mushrooms; (4) frozen mushrooms; and (5) ''marinated,'' ''acidified'' or ''pickled'' mushrooms, which are prepared or preserved by means of vinegar or acetic acid, but may contain oil or other additives.

The merchandise subject to this order is classifiable under subheadings 2003.1000.27, 2003.1000.31, 2003.1000.37, 2003.1000.43, 2003.1000.47, 2003.1000.53, and 0711.90.4000 of the Harmonized Tariff Schedule of the United States (''HTS''). Although the HTS subheadings are provided for convenience and Customs purposes, the written description of the merchandise under investigation is dispositive.

Antidumping Duty Order

On November 25, 1998, in accordance with section 735(d) of the Act, the U.S. International Trade Commission (ITC) notified the Department that a U.S. industry is materially injured by reason of imports of certain preserved mushrooms from Chile, pursuant to section 735(b)(1)(A) of the Act. Therefore, in accordance with section 736(a)(1) of the Act, the Department will direct the United States Customs Service to assess, upon further advice by the Department, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price and constructed export price of the merchandise for all relevant entries of certain preserved mushrooms from Chile. These antidumping duties will be assessed on all unliquidated entries of certain preserved mushrooms from Chile entered, or withdrawn from warehouse, for consumption on or after August 5, 1998, the date on which the Department published its preliminary determination notice in the **Federal Register** (63 FR 41786).

On or after the date of publication of this notice in the **Federal Register**, Customs officers must require, at the same time as importers would normally deposit estimated duties, the cash deposits listed below for the subject merchandise. The All Others rate applies to all exporters of subject merchandise not specifically listed below.

The weighted-average dumping margins are as follows:

Exporter/manufacturer	Weighted-average margin percentage
Nature's Farm Products (Chile) S.A.	148.51
All Others	148.51

This notice constitutes the antidumping duty order with respect to certain preserved mushrooms from Chile, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act.

Dated: November 19, 1998.

Holly Kuga,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 98–32118 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 112398B]

Incidental Take of Marine Mammals; Bottlenose Dolphins and Spotted Dolphins

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

ACTION: Notice of issuance of letters of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, and implementing regulations, notification is hereby given that 1-year letters of authorization to take bottlenose and spotted dolphins incidental to oil and gas structure removal activities were issued on October 6, 1998, to Mariner Energy, Inc. of Houston, TX, Forest Oil Corp of Denver, CO., and Pennzoil Exploration and Production, Lafayette, LA; on October 28, 1998, to Vastar Resources, Inc. Houston, Texas; and on November 19, 1998, to CNG Producing Co, New Orleans, LA.

ADDRESSES: The applications and letters are available for review in the following offices: Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910, and the Southeast Region, NMFS, 9721 Executive Center Drive N, St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Hollingshead, Office of Protected Resources, NMFS, (301) 713–2055 or David Bernhart, Southeast Region (727) 570–5312.

SUPPLEMENTARY INFORMATION: Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq*.) directs NMFS to allow, on request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region, if certain findings are made and regulations are issued. Under the MMPA, the term ''taking'' means to harass, hunt, capture, or kill or to attempt to harass, hunt, capture or kill marine mammals.

Permission may be granted for periods up to 5 years if NMFS finds, after notification and opportunity for public comment, that the taking will have a negligible impact on the species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses. In addition, NMFS must prescribe regulations that include permissible methods of taking and other means effecting the least practicable adverse impact on the species and its habitat, and on the availability of the species for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance. The regulations must include requirements pertaining to the monitoring and reporting of such taking. Regulations governing the taking of bottlenose and spotted dolphins incidental to oil and gas structure removal activities in the Gulf of Mexico were published on October 12, 1995 (60 FR 53139), and remain in effect until November 13, 2000.

Issuance of these letters of authorization are based on a finding that the total takings will have a negligible impact on the bottlenose and spotted dolphin stocks of the Gulf of Mexico.

Dated: November 25, 1998.

Patricia A. Montanio,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–32036 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 112398A]

Incidental Take of Marine Mammals; Bottlenose Dolphins and Spotted Dolphins

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

ACTION: Notice of issuance of letters of authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, and implementing regulations, notification is hereby given that 1-year letters of authorization to take bottlenose and spotted dolphins incidental to oil and gas structure removal activities were issued on April 28, 1998, to the Samedan Oil Corp; on May 18, 1998, to Tatham Offshore; on June 5, 1998, to EEX Corp, Newfield Exploration Co, and Mitchell Energy; on July 28, 1998, to The Louisiana Land and Exploration Co. all from Houston, Texas, and on Aug 18, 1998, to Forcenergy of Miami, FL.

ADDRESSES: The applications and letters are available for review in the following offices: Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910, and the Southeast Region, NMFS, 9721 Executive Center Drive N, St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Hollingshead, Office of Protected Resources, NMFS, (301) 713–2055 or David Bernhart, Southeast Region (727) 570–5312.

SUPPLEMENTARY INFORMATION: Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq*.) directs NMFS to allow, on request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region, if certain findings are made and regulations are issued. Under the MMPA, the term ''taking'' means to harass, hunt, capture, or kill or to attempt to harass, hunt, capture or kill marine mammals.

Permission may be granted for periods up to 5 years if NMFS finds, after notification and opportunity for public comment, that the taking will have a negligible impact on the species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses. In addition, NMFS must prescribe regulations that include permissible methods of taking and other means effecting the least practicable adverse impact on the species and its habitat and on the availability of the species for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance. The regulations must include requirements pertaining to the monitoring and reporting of such taking. Regulations governing the taking of bottlenose and spotted dolphins incidental to oil and gas structure removal activities in the Gulf of Mexico were published on October 12, 1995 (60 FR 53139), and remain in effect until November 13, 2000.

Issuance of these letters of authorization are based on a finding that the total takings will have a negligible impact on the bottlenose and spotted dolphin stocks of the Gulf of Mexico.

Dated: November 25, 1998.

Patricia A. Montanio,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 98–32037 Filed 12–1–98; 8:45 am]

BILLING CODE 3510–22–F

DELAWARE RIVER BASIN COMMISSION

Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, December 9, 1998. The hearing will be part of the Commission's regular business meeting which is open to the public and scheduled to begin at 1 p.m. in the Goddard Conference Room of the Commission's offices at 25 State Police Drive, West Trenton, New Jersey.

An informal conference among the Commissioners and staff will be held at 10 a.m. at the same location and will include a Corps of Engineers presentation on section 22 proposals as well as discussions of correspondence concerning upper Basin reservoir releases and proposals for interim reorganization and formation of a Watershed Council.

In addition to the subjects summarized below which are scheduled for public hearing at the business meeting, the Commission will also address the following: Minutes of the October 7, 1998 business meeting; announcements; report on Basin hydrologic conditions; reports by the Executive Director and General Counsel; consideration of resolutions concerning interim DRBC reorganization, establishment of a Water Management Advisory Committee, contract with the Northeast/Midwest Institute, interstate river basin commissions' role in Clean Water Action Plan and public dialogue.

The subjects of the hearing will be as follows:

Current Expense and Capital Budgets. A proposed current expense budget for the fiscal year beginning July 1, 1999, in the aggregate amount of $4,106,600 and a capital budget reflecting revenues of $2,508,748 and expenditures of $2,331,242. Copies of the current expense and capital budgets are available from the Commission on request by contacting Richard C. Gore at (609) 883–9500 ext. 201.

Applications for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact:

1. *Summit Hill Water Authority D–84–3 CP RENEWAL 2.* An application for the renewal of a ground water withdrawal project to supply up to 13.8 million gallons (mg)/30 days of water to the applicant's distribution system from Well Nos. 1, 2, 3 and 4. Commission approval on December 14, 1988 was limited to 10 years and will expire unless renewed. The applicant requests that the total withdrawal from all wells remain limited to 13.8 mg/30 days. The project is located in Summit Hill Borough, Carbon County, Pennsylvania.

2. *New Jersey-American Water Company D–90–108 CP Revised.* An application to revise an existing docket by the addition of Aquifer Storage and Recovery (ASR) Well No. 66 to recharge treated drinking water from the applicant's distribution system into the Middle PRM Aquifer during periods of low water demand. The stored high-quality water will be withdrawn and discharged to the distribution system during periods of high demand with no net withdrawal from the aquifer. The proposed ASR project will not increase monthly or annual allocation of ground water. The project is located in Cherry Hill Township, Camden County, New Jersey.

3. *West Goshen Sewer Authority D–98–20 CP.* A project to upgrade and expand the applicant's existing 4.5 million gallons per day (mgd) sewage treatment plant (STP) to 6.0 mgd to continue serving portions of East Goshen and West Goshen Townships, Chester County, Pennsylvania. The STP is located off South Concord Road in West Goshen Township and will continue to discharge to Chester Creek (locally known as Goose Creek).

4. *Womelsdorf-Robesonia Joint Authority D–98–23 CP.* An application for approval of a ground water withdrawal project to supply up to 8.1 mg/30 days of water to the applicant's distribution system from new Well No. 9, and to retain the existing withdrawal limit from all wells at 23 mg/30 days. The project is located in Millcreek Township, Lebanon County, Pennsylvania.

A Proposal to Adopt the 1999 Water Resources Program. A proposal that the 1998 Water Resources Program and the activities, programs, initiatives, concerns, projections and proposals identified and set forth therein be extended and adopted as the 1999 Water Resources Program and that a staff report of progress during 1998 in completing elements of the program and policies in the 1998 Water Resources program be made a part thereof, in accordance with the requirements of Section 13.2 of the Delaware River Basin Compact.

Documents relating to these items may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact Thomas L. Brand at (609) 883–9500 ext. 221 concerning docket-related questions. Persons wishing to testify at this hearing are requested to register with the Secretary at (609) 883–9500 ext. 203 prior to the hearing.

Dated: November 23, 1998.

Susan M. Weisman,

Secretary.

[FR Doc. 98–32122 Filed 12–1–98; 8:45 am]

BILLING CODE 6360–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6196–4]

State and Tribal Environmental Justice Grants Program Request for Applications Guidance FY 1999; Purpose of Notice

The purpose of this notice is to solicit applications from eligible candidates under the State and Tribal Environmental Justice (STEJ) Grants Program, sponsored by the U.S. Environmental Protection Agency, Office of Environmental Justice.

For FY 1998, EPA awarded five STEJ grants totaling $500,000 to (4) states and (1) tribe. A list of the recipients and their project descriptions are provided in Appendix F.

For FY 1999, EPA expects to once again award a total of $500,000 to states and tribes to demonstrate how to effectively address environmental justice issues and comply with Title VI of the 1964 Civil Rights Act. A maximum of $100,000 will be awarded to each recipient, contingent upon the availability of funds. A total of five grants are expected to be awarded. The standard project and budget periods are for one year. The grantee can request that the project and budget periods be extended up to three years, with the total budget of $100,000 provided during the first year. This guidance outlines the purpose, authorities, eligibility, and general procedures for application and award of the FY 1999 STEJ Grants.

The application must be postmarked no later than Friday, February 26, 1999.

Grants Program Overview

The State and Tribal Environmental Justice (STEJ) Grants Program was created to provide financial assistance to state and tribal environmental departments that are working to address environmental justice issues. With the increased interest in Title VI of the Civil Rights Act of 1964, EPA is seeking, through this assistance program, to support individual state's and tribe's efforts to effectively comply with Title VI in their environmental programs and/

or establish an environmental justice program.

A. Program Goals

The STEJ Grants Program is intended to assist states and tribes in ultimately achieving the following environmental justice goals and objectives:

- Enhance the state or tribal government's effectiveness in complying with Title VI of the Civil Rights Act of 1964.
- Reduce or prevent disproportionately high and adverse human health or environmental effects on low-income communities and/or minority communities.
- Integrate environmental justice goals into a state's or tribe's policies, programs, and activities.
- Provide financial and technical resources to develop an enabling infrastructure at the state/local community level and tribal/tribal community level.
- Set up model programs to address enforcement and compliance issues in affected environmental justice (EJ) communities.
- Integrate measurable EJ goals within the annual Performance Partnership Agreements (PPAs) and Memorandums of Understandings (MOUs) between a state and EPA, or integrate measurable EJ goals within the Tribal Environmental Agreements (TEAs).
- Improve public participation in the decision-making processes (e.g. permitting processes, development of regulations and policies)

B. Background on Environmental Justice

EPA considers Environmental Justice to be the fair treatment and meaningful involvement of all people regardless of race, color, national origin, culture, or income with respect to the development, implementation, enforcement and compliance of environmental laws, regulations, and policies. Fair treatment means that no groups of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local and tribal programs and policies.

On February 11, 1994, President Clinton issued Executive Order (EO) 12898, ''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations'' (Appendix A). Environmental Justice focuses attention on the need to ensure environmental protection for all, and to empower those most often disenfranchised from the decision-making process, the low-income and/or minority communities.

C. Background on Title VI

Title VI states:

> No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

The Presidential memorandum accompanying EO 12898 directs Federal agencies to ensure compliance with the nondiscrimination requirements of Title VI for all Federally-funded programs and activities that affect human health or the environment.

Title VI itself prohibits intentional discrimination. The Supreme Court has ruled, however, that Title VI authorizes Federal agencies, including EPA, to adopt implementing regulations that prohibit discriminatory effects. Frequently, discrimination results from policies and practices that are neutral on their face, but have the effect of discriminating. Facially-neutral policies or practices that result in discriminatory effects violate EPA's Title VI regulations unless it is shown that they are justified and that there is no less discriminatory alternative. (See Appendix B for additional information on Title VI).

Eligible Applicants and Activities

D. Who May Submit An Application?

Any state or tribal agency that manages, or is eligible to manage, an EPA program, which has an expressed interest in working with community-based grassroots organizations and other environmental justice stakeholders to address environmental justice concerns in communities. EPA requests that only one application be submitted from each state or tribe interested in receiving assistance. The project can be a partnership involving more than one state department, or if from a tribe, more than one tribal department. The project may also involve a consortium of state or tribal governments. The degree of support provided by top government officials from either the state or tribe will be an important factor in the selection process.

E. May an Individual or Organization Apply?

No. Only a state or federally-recognized tribal government may apply. However, the applying states or tribes should work with community-based grassroots organizations when developing their proposals. Preference may be given to the states or tribes who involve community-based grassroots organizations in the development of their proposals.

F. What Types of Projects are Eligible for Funding?

Funds are to be used for activities authorized by the appropriate statutory provisions listed in paragraph G below, to accomplish one or both of the following:

1. The development or enhancement of a program to work directly with communities to improve the state's or tribe's compliance with Title VI of the Civil Rights Act of 1964 in the development and implementation of environmental programs.

> Example 1: Create a review team to analyze the state's or tribe's future conduct or action to help ensure its environmental programs have no discriminatory environmental or human health effects based on race, color, or national origin.
>
> Example 2: Demonstrate how to establish an appropriate enforcement program for disproportionately affected communities; and create meaningful community participation opportunities throughout enforcement & compliance activities [e.g. from the time of initial Notice of Violations to final agency enforcement decisions.]

2. The development of a model state or tribal environmental justice executive order, strategic plan, and/or conduct studies, analyses, and training in the development of a state or tribal environmental justice program.

Preferences

Preference may be given to the states or tribes which have not received a STEJ grant in the past and which include the following in their application:

(1) A description of how environmental justice/community-based grassroots organizations were involved in the development of the proposal, and

(2) Identification of the matching or cost sharing funds to be provided by the state or tribe for the project.

G. What are the Statutory Authorities for the Grants?

The State and Tribal Environmental Justice Grants are for multimedia environmental justice activities. For this reason, each project must include activities which are authorized by two or more of the following environmental statutes.

a. Clean Water Act, Section 104(b)(3): conduct and promote the coordination of research, investigations, experiments, training, demonstration, surveys, and studies relating to the causes, extent, prevention, reduction, and elimination of water pollution.

b. Safe Drinking Water Act, Sections 1442(c)(3): develop, expand, or carry out a program (that may combine training,

education, and employment) for occupations relating to the public health aspects of providing safe drinking water.

c. Solid Waste Disposal Act, Section 8001(a): conduct and promote the coordination of research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to solid waste management and hazardous waste management.

d. Clean Air Act, Section 103(b)(3): conduct and promote the coordination and acceleration of research, investigations, experiments, demonstrations, surveys, and studies related to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution.

e. Toxic Substances Control Act, Section 10(a): conduct research, development, and monitoring activities on toxic substances.

f. Federal Insecticide, Fungicide, and Rodenticide Act, Section 20(A): conduct research on pesticides.

g. Comprehensive Environmental Response, Compensation, and Liability Act, Section 311(c): conduct research related to the detection, assessment, and evaluation of the effects on, and risks to, human health from hazardous substances.

h. Marine Protection, Research, and Sanctuaries Act, Section 203: conduct research, investigations, experiments, training, demonstrations, surveys, and studies relating to the minimizing or ending of ocean dumping of hazardous materials and the development of alternatives to ocean dumping.

H. What Regulations Apply to these Grants?

The STEJ Grants will be governed by 40 CFR Part 31, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments, and OMB Circular A–87. Note, in particular, that there are restrictions on the used of grant funds for lobbying and that grant funds may not be used for intervention in federal regulatory or adjudicatory proceedings.

Funding

I. Are Matching Funds Required?

Matching funds are not required, but are encouraged. EPA may give preference to those states or tribes which provide matching funds, since this would demonstrate a greater commitment.

Application Requirements

J. What is Required for Applications?

In order to be considered for funding under this program, proposals must have the following:

1. Application for Federal Assistance (SF 424) the official form required for all federal grants that requests basic information about the grantee and the proposed project. The applicant must submit the original application, and one additional copy, signed by a person duly authorized.

2. Federal Standard Form (SF 424A) and budget detail, which reflects the total budget for the entire duration of the project. Budget figures/projections should support your work plan/narrative. The EPA portion of these grants will not exceed $100,000, therefore your budget should reflect this upper limit on federal funds.

3. Signed ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters'' form, and ''Certification Regarding Lobbying'' form, which can be found in Appendix C.

4. Narrative/work plan of the proposal. A narrative/work plan describes the applicant's proposed project. The pages of the work plan must be letter size 8 ½″ x 11″), with normal type size (12 cpi), and at least 1″ margins. The narrative/work plan should be no more than five pages.

The narrative/work plan must describe:

a. whether one or both of the Eligible Projects, as defined in Section F, are being proposed,

b. how the proposed project will meet the Program goals, as described in Section A,

c. how the project addresses issues related to at least two of the environmental statutes listed in Section G, and

d. discuss how the project will be evaluated, what will be the measures of success, and describe how the project/program will be sustained.

5. A letter of commitment from the department head or government head (e.g., governor, president, chairperson, chief).

6. State and Tribal applicants should establish working relationships with local community-based organizations in developing their proposals.(*) A list of the organizations who participated in the development of the grant proposal, along with contact names and numbers, is required.(*) Many community-based organizations across the nation have already begun implementing environmental justice programs at the local level, which states and tribes may want to use as examples to help build their environmental justice programs. By asking those who are most impacted by environmental injustices to participate in building the state's or tribe's environmental justice program, the states and tribes will be more likely to obtain broad support for the concept and the partnership it reflects.

K. When and Where Must Applications Be Submitted?

The applicant must submit one signed original application with the required attachments and one additional copy to the primary contact of the appropriate EPA regional office (see page 8 and Appendix D). The application must be postmarked no later than Friday, February 26, 1999.

Process for Awarding Grants

Proposals are to be developed by states or tribes (EPA encourages the involvement of community-based/grassroots organizations) and submitted to their respective EPA Regional Offices. The initial review will be conducted by each Region through a Regional panel, which will select the top proposals for submission to EPA Headquarters, for final review and selection. The grants will be processed for award and managed by the Regions. The plan is to fund the five best State and/or Tribal Environmental Justice project proposals.

Note: Among the proposals receiving the highest rating, EPA may take into account the geographic location and diversity of the proposed projects when making final selections.

STEJ Grant Program Schedule

Dec.11—February 26: States and Tribes Develop Proposals and Submit to EPA Regions.

March 1—April 9: EPA Regions Review Proposals and Provide Recommendations to Headquarters.

April 12—May 14: OEJ Headquarters Convenes Review Panel and Receives Recommendations.

May 17—June 4: Headquarters Completes Selections and Submits Final Selections to EPA Regional Offices.

June 7—Aug. 9: EPA Regional Grants Management Offices Process Applications and Award Grants.

September 1: National and Regional Announcements of Awards.

Reporting

State and Tribal agencies that are awarded the State and Tribal Environmental Justice (STEJ) grants will be required to submit semi-annual reports, in accordance with 40 CFR 31.40 and 31.41, to the appropriate Regional Environmental Justice

Coordinator and Project Officer. Reports will include, but not be limited to, information on:

- Funds expended.
- Tasks accomplished.
- Issues/problems encountered and method of resolution.
- Results achieved.

A final summary report is required by 40 CFR section 31.40(b) at the end of the project period. This final report should include a discussion on the continuation and institutionalization of the state's and/or tribe's efforts to comply with Title VI and/or provide for environmental justice.

* * * If you have any questions regarding the interpretation of this guidance, please call your regional contact listed below, or Daniel Gogal, STEJ Grants Manager, Office of Environmental Justice, at (202) 564–2576 or 1–800–962–6215. * * *

EPA Regional STEJ Contact Names and Addresses

Region I: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Primary Contact: Ronnie Harrington (617) 918–1703, USEPA Region 1, One Congress Street, Suite 1100 (SAA), Boston, MA 02114.

Secondary Contact: Pat O'Leary (617) 918–1978.

Region II: New Jersey, New York, Puerto Rico, U.S. Virgin Islands.

Primary Contact: Melva Hayden (212) 637–5027, USEPA Region II, 290 Broadway, 26th Floor, New York, NY 10007.

Secondary Contact: Doug Roberts (212) 637–3408.

Region III: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia.

Primary Contact: Reginald Harris (215) 814–2988, USEPA Region III (3DA00), 841 Chestnut Building, Philadelphia, PA 19107.

Secondary Contact: Mary Zielinski (215) 814–5415.

Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Primary Contact: Gloria Love (404) 562–9672, USEPA Region IV, 61 Forsyth Street, Atlanta, GA 30303.

Secondary Contact: Connie Raines (404) 562–9671.

Region V: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Primary Contact: Ethel Crisp (312) 353–1442, USEPA Region V, 77 West Jackson Boulevard (DM–7J), Chicago, IL 60604–3507.

Secondary Contact: Karla Johnson (312) 886–5993.

Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Primary Contact: Shirley Augurson (214)665–7401, USEPA Region VI (6E–N), 1445 Ross Avenue, 12th Floor, Dallas, TX 75202–2733.

Secondary Contact: Teresa Cooke (214) 665–8145.

Region VII: Iowa, Kansas, Missouri, Nebraska.

Primary Contact: Althea Moses (913) 551–7649 or 1–800–223–0425, USEPA Region VII, 726 Minnesota Avenue, Kansas City, KS 66101.

Secondary Contact: Kim Olson (913) 551–7539.

Region VIII: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Primary Contact: Marcella Devargas (303) 312–6161, USEPA Region VIII (8ENF–EJ), 999 18th Street, Suite 500, Denver, CO 80202–2466.

Secondary Contact: Elisabeth Evans (303) 312–6053.

Region IX: Arizona, California, Hawaii, Nevada, American Samoa, Guam.

Primary Contact: Katy Wilcoxen (415) 744–1117, USEPA Region IX (CMD–6), 75 Hawthorne Street, San Francisco, CA 94105.

Secondary Contact: Willard Chin (415) 744–1204.

Region X: Alaska, Idaho, Oregon, Washington.

Primary Contact: Susan Morales (206) 553–8580, USEPA Region X (OI–085), 1200 Sixth Avenue, Seattle, WA 98101.

Secondary Contact: Joyce Kelly (206) 553–4029.

Note: To obtain copies of the appendices referenced in this document, please contact the individuals identified above for a complete application.

Dated: November 24, 1998.

Robert J. Knox,

Associate Director, Office of Environmental Justice.

[FR Doc. 98–32072 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30464; FRL–6046–6]

American Cyanamid Company; Applications to Register Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by January 4, 1999.

ADDRESSES: By mail, submit written comments identified by the document control number [OPP–30464] and the file symbols to: Public Information and Records Intregrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Ann Sibold, Product Manager (PM-10), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 212, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703 305–6502, e-mail: sibold.ann@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

I. Products Containing Active Ingredients Not Included In Any Previously Registered Products

1. File Symbol: 241-GAA. Applicant: American Cyanamid Company, Agricultural Research Division, P.O. Box 400, Princeton, NJ 08543–0400.

Product Name: AC 303,630 Technical. Technical. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1-pyrrole-3-carbonitrile at 93 percent. Proposed classification/Use: For technical manufacturing.

2. File Symbol: 241-GAI. Applicant: American Cyanamid Company.Product Name: Alert. Insecticide/Miticide. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1-*H*-pyrrole-3-carbonitrile at 21.44 percent. Proposed classification/Use: Restricted. For use on cotton.

3. File Symbol: 241-GAT. Applicant: American Cyanamid Company. Product Name: Pirate. Insecticide/Miticide. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-1*H*-pyrrole-3-carbonitrile at 30.83 percent. Proposed classification/Use: Restricted. For use on cotton.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

II. Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPP–30464] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official notice record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–30464]. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: November 13, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–31682 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–847; FRL–6043–2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–847, must be received on or before January 4, 1999.

ADDRESSES: By mail submit written comments to: Public Information and Records Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Joanne I. Miller (PM 13)	Rm. 237, CM #2, 703–305–6224, e-mail: Miller.joanne@epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA 22202
Cynthia Giles-Parker (PM 22).	Rm. 247, CM #2, 703–305–7740, e-mail: giles-parker.cynthia@epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–847 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES''.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF–847 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

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

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 13, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below petitioner summaries of the pesticide petitions are printed as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. BASF Corporation

PP 7F4870

EPA has received a pesticide petition (PP 7F4870) from BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina 27709–3528 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of quinclorac (3,7-dichloro-8-quinolone carboxylic acid), in or on the raw agricultural commodity wheat and sorghum raw agricultural and food/feed commodities: 0.5 parts per million (ppm) in or on wheat grain, 0.1 ppm in or on wheat straw, 1.0 ppm in or on wheat forage, 0.5 ppm in or on wheat hay, 1.0 ppm in or on wheat bran, 1.5 ppm in or on wheat germ, 0.75 ppm in or on wheat shorts, 0.5 ppm in or on sorghum grain, 0.2 ppm in or on sorghum forage and 0.05 ppm in or on sorghum fodder. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant and animal metabolism*. The metabolism of quinclorac in plants and animals is well understood. Based on a nature of the residue study in wheat and supported by similar studies in rice and sorghum, the residue of concern from quinclorac use in non-oily grains consists only of the parent compound.

2. *Analytical method*. An adequate analytical method for enforcement of the tolerances exists. The analytical method used for quantitative determinations was designed to measure quinclorac residues present as the parent compound.

3. *Magnitude of residues* —(i) *Raw agricultural commodities*. Crop field trials were conducted in wheat and sorghum and treatments were made at the maximum proposed label rate. The maximum amount of quinclorac residue found in wheat and sorghum raw agricultural commodities are: wheat forage 0.88 ppm, wheat hay 032 ppm, wheat grain 0.25 ppm, wheat straw 0.08 ppm, sorghum forage 0.15 ppm, sorghum grain 0.26 ppm, sorghum fodder 0.05 ppm.

(ii) *Processed fractions*. Processing studies were conducted for both wheat and sorghum to determine whether quinclorac residues concentrate during the commercial processing of these commodities. In sorghum, no concentration of residues was found in the production of flour and starch. In wheat, no concentration was found in the production of middlings and flour. Quinclorac residues concentrated 2-fold in the production of bran, 3-fold in the production of germ, and only slightly, 1.3-fold, in shorts. No additional data were needed in support of residues in meat, milk, poultry, and eggs. Maximum residue levels in wheat and sorghum raw agricultural commodities and process fractions were well below levels of current rice tolerances (5 ppm for grain, 12 ppm for straw, and 15 ppm for bran) which originally dictated the animal feeding study dosing levels and subsequent setting of animal product tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data quinclorac does not pose any acute toxicity risks. Several acute toxicology studies place technical-grade quinclorac in Toxicity Category III for acute oral, acute dermal, acute inhalation toxicity, and for eye irritation. Technical 3,7-dichloro-8-quinoline carboxylic acid is in category IV for primary dermal irritation and is a skin sensitizer. The currently registered end use formulations of quinclorac (50% wettable powder and 75% dry flowable formulations) have tested negative for skin sensitization.

2. *Chronic feeding — Nonrodent*. A 1-year feeding study in dogs fed 0, 34, 142, and 513 (males) and 0, 35, 140, and 469 (females) milligrams/kilogram/day (mg/kg/day) resulted in a No Observed Adverse Effect Level (NOAEL) of 140 mg/kg/day based on reduced body weight gains, adverse effect on food efficiency, hematological and clinical chemistry values, increased liver and kidney weights, and microscopic findings in liver and kidneys at 513 mg/kg/day (males) and 469 mg/kg/day (females), the highest dosages tested (HDT).

3. *Chronic feeding/oncogenicity - Rats*. A chronic feeding/carcinogenicity study in rats fed dosages of 1, 56, 186, 385, and 487 mg/kg/day (males) and 0, 60, 235, 478, and 757 mg/kg/day (females) resulted in a NOAEL of 478 mg/kg/day (females) and 385 mg/kg/day (males) based on slight decreases in weight for females at 757 mg/kg/day (HDT) and an equivocal (uncertain) increase in acinar cell hyperplasia of the pancreas in males at 487 mg/kg/day (HDT). There were no carcinogenic effects noted for female rats under the conditions of the study up to 757 mg/kg/day (HDT).

4. *Oncogenicity - Mice*. A carcinogenic study in mice fed dosages of 0, 37.5, 150, 600, and 1,200 mg/kg/day resulted in no carcinogenic effects observed under the conditions of the study up to and including 1,200 mg/kg/day (HDT) and a systemic NOAEL of 37.5 mg/kg/day based on a reduction of body weight at 150 mg/kg/day.

5. *Teratology - Rats*. A developmental study in rats fed dosages of 0, 24.4, 146, and 438 mg/kg/day (HDT) resulted in developmental toxicity NOAEL of 438 mg/kg/day and a maternal toxicity NOAEL of 146 mg/kg/day based on reduced food consumption, increased water intake, and mortality at 438 mg/kg/day (HDT). Under the conditions of this study, quinclorac did not produce any sign of embryo/fetal toxicity and

did not alter fetal morphological development.

6. *Teratology - Rabbits*. A developmental study in rabbits fed dosages of 0, 70, 200, and 600 mg/kg/day resulted in a developmental toxicity NOAEL of 200 mg/kg/day based on an increase in resorptions and postimplantation loss; a decrease in the number of live fetuses and decreased fetal body weights at the 600 mg/kg/day dose level (HDT). At all other treatment levels no embryo/fetal toxicity was observed. The maternal toxicity NOAEL is 70 mg/kg/day based on decreased body weight gain and food consumption at 200 mg/kg/day; and increased water consumption, increased mortality, and discoloration of the kidney at 600 mg/kg/day.

7. *Two-generation reproduction - Rats*. A 2-generation reproduction study with rats fed dosages of 0, 50, 200, and 600 mg/kg/day resulted in a reproductive NOAEL of 200 mg/kg/day based on reduced pup viability and pup weight, and delay in development (pinna unfolding and eye opening) at 600 mg/kg/day with a maternal NOAEL of 200 mg/kg/day based on reduced body weights at 600 mg/kg/day. At treatment levels of 50 and 200 mg/kg/day no substance related finding were noted either in the parent animals or the offspring.

8. *Mutagenicity*. All *Salmonella* Assays testing the appropriate technical 3,7-dichloro-8-quinoline carboxylic acid were negative. The 3,7-dichloro-8-quinoline carboxylic acid was negative in the *in vivo* cytogenetics (Chinese hamster) at dose levels ranging from 2,000 to 8,000 mg/kg and did not induce unscheduled DNA synthesis in the UDS assay at levels ranging from 101 to 1,520 –ug/ml.

9. *Metabolism - Rat*. A metabolism study with rats receiving dosages of 15, 100, 600 and 1,200 mg/kg/day resulted in more than 90% of the administered radioactivity eliminated in the urine within 5 days (most within 24 hours) and 0.7 – 3.7% in the feces. Radioactivity was mainly associated with the unchanged parent compound. The glucuronic acid conjugate of quinclorac was a minor (2 – 5%) metabolite in urine.

10. *Reference dose*. The established Reference Dose (RfD) for quinclorac is based on the 2-year feeding study in mice with a threshold NOAEL of 37.5 mg/kg/day. Using an uncertainty factor of 100, the RfD has been calculated to be 0.38 mg/kg/day.

11. *Cancer classification and risk assessment*. The cancer classification of quinclorac has been reviewed by the FIFRA Scientific Advisory Panel (SAP). The Panel recommended that the compound be classified as a Group D carcinogen (not classifiable as to human carcinogenicity). The EPA Health Effects Peer Review Committee (PRC) evaluated the carcinogenic potential of quinclorac and the conclusions of the SAP and has classified quinclorac as a Group D carcinogen. Since quinclorac is not classified as a carcinogen, a cancer risk assessment was not necessary for approval of the currently established tolerances. Therefore, a cancer risk assessment for the proposed tolerances on wheat and sorghum is also not necessary.

12. In addition to the data described above, BASF is submitting a 21 day dermal study in the rat to supplement the quinclorac toxicology database. Results indicate that the NOAEL for quinclorac in this study is greater than 1,000 mg/kg body weight.

C. Aggregate Exposure / Cumulative Effects

1. *Chronic dietary exposure*. BASF has estimated aggregate dietary exposure based on the Theoretical Maximum Residue Contribution (TMRC) calculation. The TMRC is a ''worst case'' estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are established are treated and that residues are at the tolerances level. Since the proposed label prohibits use in many wheat and sorghum producing states, the TMRC calculation results in a significant overestimate of human dietary exposure.

The quinclorac TMRC for the overall U.S. population from the currently established rice and animal tolerances is 0.001485 mg/kg bwt/day which represents 0.39% of the RfD. A preliminary estimate of dietary exposure to residues of quinclorac from the proposed tolerances in wheat and sorghum increases the TMRC by 0.000836 mg/kg bwt/day and accounts for approximately 0.22% of the RfD for the overall U.S. population.

2. *Acute dietary exposure*. BASF has reviewed the toxicity database for quinclorac and has concluded that there is no acute dietary concern since there is no indication of any significant toxicity from a one day or single event oral exposure. The LD_{50} for technical quinclorac has been determined to be 3,060 mg/kg for males and 2,190 mg/kg for females.

3. *Drinking water exposure*. Other potential sources of exposure for the general population to residues of quinclorac are residues in drinking water and exposure from non-occupational sources. Based on the available studies used in EPA's assessment of environmental risk, BASF does not anticipate exposure to residues of quinclorac in drinking water. There is no established Maximum Concentration Level (MCL) for residues of quinclorac in drinking water under the Safe Drinking Water Act (SDWA).

4. *Non-occupational exposure*. Quinclorac is not currently labeled for any nonagricultural use. An application for use of quinclorac on turfgrass is currently pending. The proposed turf registration restricts use of the product to certified commercial applicators and those under their direct supervision. Use of the product by typical uncertified homeowners will be prohibited. Therefore, potential for non-occupational exposure to the general population is significantly reduced compared to general use turf products. BASF is a member of the industry wide Outdoor Residential Exposure Task Force. The Task Force is currently generating data to assess exposure resulting from the use of turf products.

D. Cumulative Effects

BASF has considered the potential for cumulative effects of quinclorac and other substances that have a common mechanism of toxicity. BASF is not aware of any other EPA registered active ingredient that is structurally similar to quinclorac or has a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that aggregate exposure to quinclorac will utilize approximately 0.22% of the RfD for the U.S. population. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of quinclorac, including anticipated dietary exposure and non-occupational exposures.

2. *Infants and children*. No signs of teratogenicity were observed in either the rat or rabbit Developmental studies. The NOAEL values from the Developmental studies are significantly higher than the NOAEL from the 2-year feeding study in mice (threshold NOAEL of 37.5 mg/kg/day) used to establish the RfD.

In the Reproductive Toxicity study, Quinclorac elicited signs of embryotoxicity only at dose levels where clear maternal toxicity was observed. Fertility and reproduction parameters were not affected even at the highest treatment levels (1,155 mg/kg/

day). The NOAEL values from the Reproduction study are significantly higher than the NOAEL from the 2-year feeding study in mice (threshold NOAEL of 37.5 mg/kg/day) used to establish the RfD.

Based on the demonstrated lack of significant developmental or reproductive toxicity, BASF believes that the RfD used to assess safety to the general population is adequate to assess safety to children. The EPA evaluation of the established rice and animal tolerances concluded that for the subgroup exposed to the highest dietary risk, nonnursing infants less than 1 year old, the TMRC is 0.010065 mg/kg bwt/day or 2.65 % of the RfD. The addition of the wheat and sorghum tolerances increases the TMRC for this subgroup to approximately 0.100726 mg/kg bwt/day or 2.82 % of the RfD. BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of quinclorac, including all anticipated dietary exposure and all other non-occupational exposures.

F. Endocrine Effects

No specific tests have been conducted with quinclorac to determine whether the chemical may have an endocrine like effect in humans. However, there were no significant findings in other relevant tests (developmental and reproductive toxicity tests) which would suggest that quinclorac produces endocrine like effects.

G. International Tolerances

A maximum residue level has not been established under the Codex Alimentarius Commission for quinclorac in wheat and sorghum. (Joanne I. Miller)

2. Novartis Crop Protection, Inc.

PP 2F4107

EPA has received a pesticide petition (PP 2F4107) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 28479-8300. proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of Difenconazole, [(2*S*,4*R*)/(2*R*,4*S*)]/[2*R*,4*R*/2*S*,4*S*)] 1–(2–4–(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan2yl-methyl)-1*H*-1,2,4-triazole in or on the raw agricultural commodity wheat grain, forage, and straw at 0.1 parts per million (ppm); cattle, eggs, goats, hogs, horses, poultry and sheep 0.05; and milk at 0.01 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the residue is adequately understood in plants and animals. The metabolism of difenoconazole has been studied in wheat, tomatoes, potatoes, and grapes. The metabolic pathway was the same in these four separate and distinct crops.

2. *Analytical method*. Novartis has submitted a practical analytical method for detecting and measuring levels of difenoconazole in or on food with the limit of quantitation that allows monitoring of food with residues at or above the levels set in the proposed tolerances. EPA will provide information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from the Field Operations Division, Office of Pesticide Programs.

3. *Magnitude of residues*. Data has been provided from fourteen spring and winter wheat residue trials conducted in major wheat growing states. Application rates were 24 grams a.i. and 48 grams a.i./100 kg seed (10.9 and 21.8 grams a.i./ 100 lb seed, respectively). A processing study was also conducted in which two foliar applications were made in addition to the seed treatment, in an attempt to generate grain samples containing measurable residues. Bran, middlings, shorts and germ, and patent flour were tested for residues.

No residues of difenoconazole (<0.1 ppm) were detected in wheat grain or in any of the processed milled fractions, even when the higher seed treatment rate was coupled with two foliar treatments. The use of difenoconazole as a seed treatment will not result in detectable residues in grain or processed commodities. Similarly, no residues of difenoconazole (0.05 ppm) were detected on wheat forage or straw.

No food additive tolerances are necessary for grain commodities. Tolerances in meat, milk, poultry or eggs were established for enforcement purposes.

B. Toxicological Profile

The following mammalian toxicity studies were conducted and submitted in support of tolerances for difenoconazole.

1. *Acute toxicity*. Difenoconazole has a low order of acute toxicity. The oral rat LD_{50} is 1,453 mg/kg. The rabbit acute dermal LD_{50} is > 2,010 mg/kg and the rat inhalation LC_{50} is > 3.285 mg/L. It is not a skin sensitizer in guinea pig and shows slight eye and dermal irritation in the rabbit.

2. *Genotoxicty*. There was no evidence of the induction of point mutations in an Ames test.

There was no evidence of mutagenic effects in a mouse lymphoma test.

There was no evidence of mutagenic effects in a nucleus anomaly test with Chinese hamsters.

There was no evidence of induction of DNA damage in a rat hepatocyte DNA repair test.

There was no evidence of induction of DNA damage in a human fibroblast DNA repair test.

3. *Reproductive and developmental toxicity*. An oral teratology study in rats had a maternal NOAEL of 16 mg/kg/day based on excess salivation and decreased body weight gain and food consumption. The developmental NOAEL of 85 mg/kg/day was based on effects seen secondary to maternal toxicity including slightly reduced fetal body weight and minor changes in skeletal ossification.

An oral teratology study in rabbits had maternal NOAEL of 25 mg/kg/day based on decreased body weight gain, death, and abortion. The developmental NOAEL of 25 mg/kg/day was based on effects seen secondary to maternal toxicity including slight increase in post-implantation loss and resorptions, and decreased fetal weight.

A 2-generation reproduction study in rats had a parental and reproductive NOAEL of 25 ppm based on significantly reduced female body weight gain, and reductions in male pup weights at 21 days.

4. *Subchronic toxicity*. A 13-week rat feeding study identified liver as a target organ and had a NOAEL of 20 ppm.

A 13-week mouse feeding study identified liver as a target organ and had a NOAEL of 20 ppm.

A 26-week dog feeding study identified liver and eye as target organs and had a NOAEL of 100 ppm.

A 21-day dermal study in rabbits had a NOAEL of 10 mg/mg/day based on decreased body weight gain at 100 and 1,000 mg/kg/day.

5. *Chronic toxicity*. A 24-month feeding study in rats had a NOAEL of 20 ppm based on liver toxicity at 500 and 2,500 ppm. There was no evidence of an oncogenic response.

An 18-month mouse feeding study had an overall NOAEL of 30 ppm based on decreased body weight gain and liver toxicity at 300 ppm. There was an increase in liver tumors only at dose levels that exceeded the maximum

tolerated dose (MTD). The oncogenic NOAEL was 300 ppm.

A 12-month feeding study in dogs had a NOAEL of 100 ppm based on decreased food consumption and increased alkaline phosphatase levels at 500 ppm.

6. *Carcinogenicity*. A 24-month feeding study in rats had a NOAEL of 20 ppm based on liver toxicity at 500 and 2,500 ppm. There was no evidence of an oncogenic response.

An 18-month mouse feeding study had an overall NOAEL of 30 ppm based on decreased body weight gain and liver toxicity at 300 ppm. There was an increase in liver tumors only at dose levels that exceeded the maximum tolerated dose (MTD). The oncogenic NOAEL was 300 ppm.

7. *Animal metabolism*. The metabolism of difenoconazole is well understood. Studies with 14C-difenoconazole in the rat, goat, and hen demonstrate that the majority of the administered dose (76 to > 98%) is eliminated via the excreta as parent and metabolites. Very low concentrations of radioactivity, accounting for <1 to 4% of the applied dose, remain in tissues. The liver and kidney typically show the highest radioactivity, but in the rat, the highest concentration in any tissue was found in the fat.

Concentrations in goat milk reached a plateau on Day 6 of the study at 0.043 ppm for the triazole label and 0.007 ppm for the phenyl label when goats were fed approximately 5 ppm for 10 days. Similarly, very little radioactivity was deposited in eggs; radioactivity reached a plateau of 0.248 to 0.299 ppm in yolks after 7 to 8 days, and 0.007 to 0.153 ppm in whites after 5 days, in hens fed at a rate equivalent to 5 ppm in the diet for 14 consecutive days. CGA–205375, an alcohol resulting from the deskelitalization of the dioxolane ring of difenoconazole, is a major metabolite found in animal tissues, excreta, milk, and eggs. The presence of CGA–71019, containing only the triazole ring, and CGA–189138, containing only the phenyl ring, indicates that bridge cleavage can occur in animals as well as plants. The metabolite patterns in the excreta of hens, goats, and rats were similar.

8. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent compound. Metabolites of difenoconazole are considered to be of equal or lesser toxicity than the parent.

9. *Endocrine disruption*. Developmental toxicity studies in rats and rabbits and a two-generation reproduction study in rats gave no specific indication that difenoconazole may have effects on the endocrine system with regard to development or reproduction. Furthermore, histologic investigations were conducted on endocrine organs (thyroid, adrenal, and pituitary, as well as endocrine sex organs) from long-term studies in dogs, rats, and mice. There was no indication that the endocrine system was targeted by difenoconazole, even when animals were treated with maximally tolerated doses over the majority of their lifetime.

Difenoconazole has not been found in raw agricultural commodities at the limit of quantification. Based on the available toxicity information and the lack of detected residues, it is concluded that difenoconazole has no potential to interfere with the endocrine system, and there is no risk of endocrine disruption in humans.

C. Aggregate Exposure

1. *Dietary exposure — Food*. When the potential dietary exposure to difenoconazole from established and pending tolerances is calculated, the theoretical maximum residue concentration (TMRC) of 0.000473 mg/kg/day utilizes 4.73% of the RfD for the overall U.S. population. For the most exposed population subgroups, children and non-nursing infants, the TMRC is 0.001252 mg/kg/day, utilizing 12.52% of the RfD followed by children (1–6 years) exposed to 11.24% of the RfD.

Novartis has conducted another exposure analysis using additional crops and similar conservative assumptions. In this analysis, oats, barley, cotton and bananas (pending import tolerance) were included in addition to wheat. Tolerances or proposed tolerances were 0.1 ppm each for wheat, oats, and barley, and 0.2 ppm for bananas. Tolerances were 0.01 ppm for milk and 0.05 ppm for all other commodities: beef, goat, horse, rabbit, sheep, pork, turkey, eggs, chicken, and other poultry. Very conservative assumptions were used to estimate residues (i.e. 100% of all wheat, oats, barley and imported bananas used for human consumption or forage was treated and all RACs contained tolerance level residues). These estimates result in a extreme overestimate of human dietary exposure. Calculated TMRC values from these assumptions utilize 4.73% of the RfD for the U.S. population and 12.52% of the RfD for non-nursing infants.

2. *Drinking water*. Other potential sources of exposure of the general population to residues of pesticides are drinking water and non-occupational sources. Difenoconazole is currently used as a seed treatment and residues are, therefore, incorporated into the soil. The likelihood of contamination of surface water from run-off is essentially negligible. In addition, parent and aged leaching, soil adsorption/desorption, and radiolabeled pipe studies indicated that difenoconazole has a low potential to leach in the soil and it would not be expected to reach aquatic environments. For these reasons, and because of the low use rate, exposures to residues in ground water are not anticipated.

3. *Non-dietary exposure*. Non-occupational exposure for difenoconazole has not been estimated since the current registration is limited to seed treatment. Therefore, the potential for non-occupational exposure to the general population is insignificant.

Novartis has considered the potential for cumulative effects of difenoconazole and other substances of common mechanism of toxicity. Novartis has concluded that consideration of a common mechanism of toxicity in aggregate exposure assessment is not appropriate at this time. Novartis has no information to indicate that the toxic effects (generalized liver toxicity) seen at high doses of difenoconazole would be cumulative with those of any other compound. Thus, Novartis is considering only the potential risk of difenoconazole from dietary exposure in its aggregate and cumulative exposure assessment.

D. Safety Determination

1. *U.S. population*. Non-occupational exposure for difenoconazole has not been estimated since the current registration is limited to seed treatment. Therefore, the potential for non-occupational exposure to the general population is insignificant.

Novartis has considered the potential for cumulative effects of difenoconazole and other substances of common mechanism of toxicity. Novartis has concluded that consideration of a common mechanism of toxicity in aggregate exposure assessment is not appropriate at this time. Novartis has no information to indicate that the toxic effects (generalized liver toxicity) seen at high doses of difenoconazole would be cumulative with those of any other compound. Thus, Novartis is considering only the potential risk of difenoconazole from dietary exposure in its aggregate and cumulative exposure assessment.

If more realistic assumptions were used to estimate anticipated residues and appropriate market share, this percentage would be considerably lower, and would be significantly lower than 100%, even for the highest exposed population subgroup. EPA generally has no concern for exposures below 100%

of the RfD. Therefore, Novartis concludes that there is reasonable certainty that no harm will result from daily aggregate exposure to residues of difenoconazole over a lifetime.

2. *Infants and children.* Developmental toxicity and two-generation toxicity studies were evaluated to determine if there is a special concern for the safety of infants and children from exposure to residues of difenoconazole. There was no evidence of embryo toxicity or teratogenicity, and no effects on reproductive parameters, including number of live births, birth weights, and post-natal development, at dose levels that did not cause significant maternal toxicity. In addition, there were no effects in young post-weaning animals that were not seen in adult animals in the 2-generation reproduction study. Therefore, Novartis concludes that it is inappropriate to assume that infants and children are more sensitive than the general population to effects from exposure to residues of difenoconazole.

E. International Tolerances

There are no Codex maximum levels established for residues of difenoconazole. (Cynthia Giles-Parker)

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BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–66260; FRL 6035–9]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn by June 1, 1999, orders will be issued cancelling all of these registrations.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery, telephone number and e-mail: Rm. 216, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provides that a pesticide registrant may, at any time, request that any of its pesticide registrations be cancelled. The Act further provides that EPA must publish a notice of receipt of any such request in the **Federal Register** before acting on the request.

II. Intent to Cancel

This Notice announces receipt by the Agency of requests to cancel some 25 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and 24(c) number) in the following Table 1.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
000070–00055	Kill-Ko Bean Beetle Dust 1% Rotenone	Rotenone
		Cube Resins other than rotenone
000070–00133	Kill Ko Thro Pac Rat Killer	2-(Diphenylacetyl)-1,3-indandione
000070–00170	Kill Ko Rat Killer	2-(Diphenylacetyl)-1,3-indandione
000070–00292	Rigo 3–In–1 Vegetable Dust	Manganese ethylenebis(dithiocarbamate)
		Methoxychlor (2,2-bis(*p*-methoxyphenyl)-1,1,1-trichloroethane)
		Rotenone
		Cube Resins other than rotenone
000491–00265	Bug Blitz	*O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate
		(Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20%
		Pyrethrins
000655–00688	Prentox Cube Flea & Tick Dip	Rotenone
		Cube Resins other than rotenone
000769–00309	Fish-Tox-5 (5% Rotenone)	Rotenone
		Cube Resins other than rotenone
000769–00653	Kills Rats with Para Blox Weather Proof Paraffinized Rat	2-(Diphenylacetyl)-1,3-indandione
000769–00656	SMCP Zinc Phosphide	Zinc phosphide (Zn3P2)
000769–00659	SMCP Singe-Kil	Cacodylic acid
000769–00741	Zinc Phosphide (Rumetan) 90%	Zinc phosphide (Zn3P2)
000769–00743	AFC Zinc Phosphide 80 (Rumetan)	Zinc phosphide (Zn3P2)
000769–00756	Zinc Phosphide Rodenticide for Controlling Orchard Mice	Zinc phosphide (Zn3P2)
000769–00832	Miller V–75 A Dust	Rotenone

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Product Name	Chemical Name
		Cube Resins other than rotenone
000769–00842	Pratt DX Insect Spray	Pine oil
		(Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20%
		Pyrethrins
		Rotenone
		Cube Resins other than rotenone
000769–00854	Tomato & Vegetable Dust or Spray	Basic copper sulfate (Declare copper equivalent)
		Rotenone
		Cube Resins other than rotenone
000769–00855	Pratt 1% Rotenone Dust or Spray	Rotenone
		Cube Resins other than rotenone
000769–00889	Agrisect Rotenone Dust 1%	Rotenone
		Cube Resins other than rotenone
000769–00904	Science 1% Rotenone	Rotenone
		Cube Resins other than rotenone
003342–00004	Tiger Brand 1.0% Rotenone Dust	Rotenone
		Cube Resins other than rotenone
005887–00148	Black Leaf Tomato & Vegetable Insect Killer	Pyrethrins
		Rotenone
		Cube Resins other than rotenone
005887–00149	Rose & Flower Insect Killer	Pyrethrins
		Rotenone
		Cube Resins other than rotenone
007969–00053	Ronilan Fungicide 50W	3-(3,5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione
028293–00198	Unicorn Rotenone Fire Ant Killer	Rotenone
		Cube Resins other than rotenone
042373–00005	Waterbed Conditioner	Poly(oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride)

Unless a request is withdrawn by the registrant within 180 days of publication of this notice, orders will be issued cancelling all of these registrations. Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant directly during this 180–day period. The following Table 2, includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA Company Number.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
000070	Sureco Inc., An Indirect Subsidiary of Verdant Brands, 9555 James Ave., South, Suite 200, Bloomington, MN 55431.
000491	Selig Chemical Industries, 840 Selig Dr., SW., Atlanta, GA 30378.
000655	Prentiss Inc., C.B. 2000, Floral Park, NY 11001.
000769	Sureco Inc., An Indirect Subsidiary of Verdant Brands, 9555 James Ave., South, Suite 200, Bloomington, MN 55431.
003342	Cape Fear Chemicals Inc., Box 695, Elizabeth Town, NC 28337.
005887	Sureco Inc., An Indirect Subsidiary of Verdant Brands, 9555 James Ave., South, Suite 200, Bloomington, MN 55431.
007969	BASF Corp., Agricultural Products, Box 13528, Research Triangle Park, NC 27709.
028293	Unicorn Laboratories, 12385 Automobile Blvd., Clearwater, FL 33762.
042373	Blue Magic Products, Box 4175, Stockton, CA 95204.

III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before June 1, 1999. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** (56 FR 29362) June 26, 1991; (FRL 3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: September 29, 1998.

Linda A. Travers,

Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 98–31808 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–34153; FRL 6044–4]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request for amendment by registrants to delete uses in certain pesticide registrations.

DATES: Unless a request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on June 1, 1999.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery, telephone number and e-mail: Rm. 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of FIFRA, provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

II. Intent to Delete Uses

This notice announces receipt by the Agency of applications from registrants to delete uses in the 11 pesticide registrations listed in the following Table 1. These registrations are listed by registration number, product names, active ingredients and the specific uses deleted. Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before June 1, 1999 to discuss withdrawal of the applications for amendment. This 180–day period will also permit interested members of the public to intercede with registrants prior to the Agency approval of the deletion. *Note: Registration number(s) preceded by ** indicate a 30–day comment period.*

TABLE 1—REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
001001–00011	Spotrete-F	Thiram	Animal repellency (deer, rabbit & rodent)
004816–00708	123 M.A.G.	*N*-Octyl bicyclo heptene dicarboxi mide; Pyrethrins; Piperonyl butoxide	Use on dogs
009779–00256	Riverside 2,4-D LV6	Acetic acid	Drainage ditchbanks
011685–00019	Rhomene MCPA Amine Herbicide	MCPA, dimethylamine salt	Use on rice in California
011685–00020	Weedar Sodium MCPA	MCPA, sodium salt	Use on rice in California
**040083–00001	Lindane Technical	Lindane	Use on treatment of stored timber and lumber; use on dogs
**041014–00009	Marlate 400 Flowable Concentrate	Methoxychlor	Livestock dipping uses

TABLE 1—REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS—Continued

EPA Reg No.	Product Name	Active Ingredient	Delete From Label
**041014–00011	Marlate 300 Methoxy chlor Concentrate	Methoxychlor	Livestock dipping uses
062719–00062	MCPA Amine	MCPA, dimethylamine salt	Use on rice in California
**066951–00001	Lindane Technical Crystals	Lindane	Wood treatment and pet care uses
**066951–00002	Lindane Technical Powder	Lindane	Wood treatment and pet care uses

The following Table 2, includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2—REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Company No.	Company Name and Address
001001	Cleary Chemical Corp., 178 Ridge Road, Dayton, NJ 08810.
004816	AgrEvo Environmental Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
009779	Terra International, Inc., 600 Fourth Street, P.O. Box 6000, Sioux City, IA 51102.
011685	Nufarm Americas, Inc., 1009–D West, St. Maartens Drive, St. Joseph, MO 64506.
040083	INQUINOSA International, S.A., c/o McKenna & Cuneo, L.L.P., 1900 K street, N.W., Washington, DC 20006.
041014	Kincaid Enterprises Inc., P.O. Box 549, Nitro, WV 25143.
062719	Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
066951	Kanoria Chemicals & Industries Ltd., c/o Jellinek, Schwartz & Connolly, Inc., 1525 Wilson Boulevard, Suite 600, Arlington, VA 22209.

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: November 17, 1998.

Linda A. Travers,

Director, Information Resources Services Division, Office of Pesticide Programs.

[FR Doc. 98–31807 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

November 23, 1998.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated information techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 1, 1999. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications, Room 234, 1919 M St., N.W., Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at 202–418–0214 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0669.

Title: Section 76.946, Advertising of rates.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents: 11,365.

Estimated Time Per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 5,683.

Total Annual Costs: None.

Needs and Uses: Section 76.946 states that cable operators that advertise rates for basic service and cable programming service tiers shall be required to advertise rates that include all costs and fees. Cable systems that cover multiple franchise areas having differing franchise fees or other franchise costs, different channel line-ups, or different rate structures may advertise a complete

range of fees without specific identification of the rate for each individual area. In such circumstances, the operator may advertise a ''fee plus'' rate that indicates the core rate plus the range of possible additions, depending on the particular location of the subscriber. The Commission has set forth this disclosure requirement to ensure consumer awareness of all costs and fees associated with basic service and cable programming service tier rates.

OMB Approval Number: 3060–0674.

Title: Section 76.931, Notification of Basic Tier Availability, and Section 76.932, Notification of Proposed Rate Increase.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents: 11,365.

Estimated Time Per Response: 0.5 to 2.0 hours.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 25,572 hours.

Total Annual Costs: None.

Needs and Uses: Section 76.931 states that a cable operator shall provide written notification to subscribers of the availability of basic tier service by November 30, 1993, or three billing cycles from September 1, 1993, and to new subscribers at the time of installation. This notification is to include the following information: (a) That basic tier service is available; (b) The cost per month for basic tier service; and (c) A list of all services included in the basic service tier. Section 76.932 states that a cable operator shall provide written notice to subscribers of any increase in the price to be charged for the basic service tier or associated equipment at least 30 days before any proposed increase is effective. These notice requirements ensure that subscribers are made aware of the price and availability of basic cable service and ensure that subscribers are given due notice of rate increases with basic cable service.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98–32057 Filed 12–1–98; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW, Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 207–011640.

Title: The Amazon Express Joint Service Agreement.

Parties:

Associated Transport Line, L.L.C. (''ATL'')

Consorcio Naviero Peruano S.A. (''CNP'')

Amazon Express (''the Joint Service'')

Synopsis: Under the proposed Agreement, ATL and CNP would operate a joint service to be known as Amazon Express in the trade between United States Atlantic and Gulf ports, and inland points via such ports, and ports on the Amazon River in Brazil, Colombia, Ecuador, and Peru, and inland points via such ports.

Agreement No.: 232–011641.

Title: The COSCON/YMUK Vessel Sharing Agreement.

Parties:

COSCO Container Lines Company (''COSCON'')

Yang Ming (UK) Ltd. (''YMUK'').

Synopsis: The proposed Agreement would permit the parties to charter space to one another and to coordinate their vessel services in the trade between United States Atlantic and Gulf ports, and inland U.S. points via such ports, and ports in Asia and on the Mediterranean, and inland points via such ports. YMUK would also be permitted to charter space aboard its vessels and to subcharter its allocated space aboard COSCON's vessels to Yang Ming Transport Corporation.

Agreement No.: 224–201063.

Title: Alabama-Stevedores of Alabama Terminal Agreement.

Parties:

Alabama State Docks Department

Stevedores (of Alabama) Inc.

Synopsis: The agreement is a permit which provides for cargo and freight handling services; it specifically excludes stevedoring services. The agreement runs through December 31, 2002.

Agreement No.: 224–201064.

Title: Alabama-Strachan Terminal Agreement.

Parties:

Alabama State Docks Department

Strachan Shipping Company d/b/a Alabama Stevedoring and Terminal Operators

Synopsis: The agreement is a permit which provides for cargo and freight handling services; it specifically excludes stevedoring services. The agreement runs through December 31, 2002.

Dated: November 25, 1998.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 98–32027 Filed 12–1–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 98–24]

Go/Dan Industries, Inc. and Atlantic Customs Brokers, Inc. v. Eastern Mediterranean Shipping Corp. dba Atlantic Ocean Lines, ANIL (aka ''ANDY'') K. Sharma, Individually, and Atlantic Ocean Line Corp.; Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by Go/Dan Industries, Inc. and Atlantic Customs Brokers, Inc. (''Complainants'') against Eastern Mediterranean Shipping Corp. dba Atlantic Ocean Lines, Anil (aka ''Andy'') K. Sharma, individually, and Atlantic Ocean Line Corp. (''Respondents'') was served November 27, 1998. Complainants allege that Respondents violated section 10(d)(1) of the Shipping Act of 1984, 46 U.S.C. app. secs. 1709(d)(1), by failing to pay the freight charges to the underlying carrier, resulting in the shipper and its agent having to pay freight charges twice, by failing to provide information about the shipment and causing delay, detention and demurrage charges, and by failing to properly deliver cargo.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record.

Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 29, 1999, and the final decision of the Commission shall be issued by March 28, 2000.

Joseph C. Polking,

Secretary.

[FR Doc. 98–32139 Filed 12–1–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 98–23]

NPR, Inc. v. Board of Commissioners of the Port of New Orleans; Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by NPR, Inc. (''Complainant'') against Board of Commissioners of the Port of New Orleans (''Respondent'') was served November 27, 1998. Complainants allege that Respondents violated section 10(b)(11), (b)(12) and (d)(1) of the Shipping Act of 1984, 46 U.S.C. app. secs. 1709(b)(11), (b)(12) and (d)(1), by forcing Complainant to make a multi-million dollar early termination payment for ceasing direct ocean common carrier service to the Port of New Orleans, while demanding no such early termination payment from other tenants seeking early termination of lease agreements.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 29, 1999, and the final decision of the Commission shall be issued by March 28, 2000.

Joseph C. Polking,

Secretary.

[FR Doc. 98–32140 Filed 12–1–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 98–22]

Trek Bicycle Corporation v. Classic Cargo International, Inc.; Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by Trek Bicycle Corporation (''Complainant'') against Classic Cargo International, Inc. (''Respondent'') was served November 25, 1998. Complainant alleges that Respondent violated sections 10(a)(1), (b)(16)(A) and (d)(1) of the Shipping Act of 1984, 46 U.S.C. app. 1709(a)(1), (b)(16)(A) and (d)(1), by falsely representing transit time and by offering, soliciting, and routing complainant's property without consent of the shipper or consignee, thereby requiring replacement property to be air freighted.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 26, 1999, and the final decision of the Commission shall be issued by March 27, 2000.

Joseph C. Polking,

Secretary.

[FR Doc. 98–32026 Filed 12–1–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL TRADE COMMISSION

Charges for Certain Disclosures

AGENCY: Federal Trade Commission.

ACTION: Notice regarding charges for certain disclosures.

SUMMARY: The Federal Trade Commission announces that the current ceiling on allowable charges under section 612(a) of the Fair Credit Reporting Act (FCRA) will remain unchanged for 1999. Under 1996 amendments to the FCRA, the Federal Trade Commission is required to increase the $8.00 amount referred to in paragraph (1)(A)(i) of section 612(a) on January 1 of each year, based proportionally on changes in the Consumer Price Index, with fractional charges rounded to the nearest fifty cents. The Consumer Price Index increased only 1.49 percent between September 1997, the Date the FCRA amendments took effect, and September 1998. This increase is too small to trigger an increase in the $8.00 figure given the requirement that the figure be rounded to the nearest $0.50. The figure therefore remains at $8.00.

EFFECTIVE DATE: January 1, 1999.

ADDRESSES: Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Keith B. Anderson, Bureau of Economics, Federal Trade Commission, Washington, DC 20580, 202–326–3428.

SUPPLEMENTARY INFORMATION: The Fair Credit Reporting Act, originally enacted in 1970,[1] was extensively amended in 1996. Most of the amendments to the law, including the one discussed in this notice, went into effect on September 30, 1997. Section 612(a)(1)(A) states that, where a consumer reporting agency is permitted to impose a reasonable charge on a consumer for making a disclosure to the consumer pursuant to Section 609, the charge shall not exceed $8 and shall be indicated to the consumer before making the disclosure. Section 612(a)(2) goes on to state that the Federal Trade Commission (''the Commission'') shall increase the $8.00 amount referred to in paragraph (1)(A)(i) of Section 612(a) on January 1 of each year, based proportionally on changes in the Consumer Price Index (CPI), with fractional changes rounded to the nearest fifty cents.

The Commission considers the $8 amount referred to in paragraph (1)(A)(i) of section 612(a) to be the baseline for the effective ceiling on reasonable charges dating from the time the amended FCRA took effect, i.e., September 30, 1997. In November of each year, the Commission calculates the proportional increase in the Consumer Price Index (using the most general CPI, which is for all urban consumers, all items) from September 1997 to September of the current year. The Commission then determines what modification, if any, from the original base of $8 should be made effective on January 1 of each subsequent year, given the requirement that fractional changes be rounded to the nearest fifty cents.

[1] 15 U.S.C. 1681–1681u; Title VI of the Consumer Credit Protection Act.

Between September 1997 and September 1998, the Consumer Price Index for all urban consumers and all items increased by 1.49 percent—from an index value of 161.2 in September 1997 to a value of 163.6 in September 1998. An increase of 1.49 percent in the $8.00 base figure would lead to a new figure of $8.12. However, because the statute directs that the resulting figure be rounded to the nearest $0.50, the increase is too small to result in any change in the allowable charge.

The Commission therefore determines that there will be no modification from the base of $8.00 for 1999.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–32077 Filed 12–1–98; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Premerger Notification: Reporting and Waiting Period Requirements

AGENCY: Federal Trade Commission.

ACTION: Notice of postponement of the effective date of Formal Interpretation 15.

SUMMARY: On October 13, 1998, the Premerger Notification Office (''PNO'') of the Federal Trade Commission (''FTC''), with the concurrence of the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (''DOJ''), published a notice of the adoption of a Formal Interpretation of the Hart-Scott-Rodino Act, which requires certain persons planning certain mergers, consolidations, or other acquisitions to report information about the proposed transactions to the FTC and DOJ. 63 FR 54713 (October 13, 1998). The Interpretation concerns the reportability of certain transactions involving a Limited Liability Company (''LLC''). Under the Interpretation, the formation of an LLC would be reportable if it would unite two or more pre-existing businesses under common control.

This Formal Interpretation was to have become effective on December 14, 1998, after a thirty day comment period. The PNO has postponed the effective date of this Formal Interpretation until February 1, 1999, in order to review and analyze the comments received.

FOR FURTHER INFORMATION CONTACT: Joseph G. Krauss, Assistant Director for the Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326–2713. Thomas F. Hancock, Attorney, Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580. Telephone: (202) 326–2946.

Donald S. Clark,

Secretary.

[FR Doc. 98–32078 Filed 12–1–98; 8:45 am]

BILLING CODE 6750–01–M

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board; Notice of Meeting

AGENCY: General Accounting Office.

ACTION: Notice of meeting on December 21.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will hold a meeting on Monday, December 21, 1998 from *1:00 to 4:00 PM* in room 7C13, the Comptroller General's Briefing Room, of the General Accounting Office building, 441 G St., NW., Washington, DC.

The purpose of the meeting is to discuss the exposure drafts on *Recognition of Contingent Liabilities Arising From Litigation,* and *Deletion of Paragraph 65.2—Material Revenue-Related Transactions Disclosures.*

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2)(1988); 41 CFR 101–6.1015 (1990).

Dated: November 25, 1998.

Wendy M. Comes,

Executive Director.

[FR Doc. 98–32020 Filed 12–1–98; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO–99–04]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

The National Nursing Home Survey (NNHS)—(0920–0353)—Revision—The National Center for Health Statistics—Section 306 of the Public Health Service Act states that the National Center for Health Statistics ''shall collect statistics on health resources * * * [and] utilization of health care, including utilization of * * * services of hospitals, extended care facilities, home health agencies, and other institutions.'' The data system responsible for collecting this data is the National Health Care Survey (NHCS). The National Nursing Home Survey (NNHS) is part of the Long-term Care Component of the NHCS. The NNHS was conducted in 1973–74, 1977, 1985, 1995, and 1997. NNHS data describe this major segment of the long-term care system and are used extensively for health care research, health planning and public policy. The survey provides detailed information on utilization

pattern that is needed in order to make accurate assessments of the effects of health care reform on the elderly. The NNHS also provides detailed information to assess the need for and costs associated with such care. The use of long-term care services will become an increasingly important issue as the population continues to age. Data from earlier NNHS collections have been used by the National Immunization Program at CDC, Office of the U.S. Attorney General, the Bureau of Health Professionals, the National Institute of Dental and Craniofacial Research at NIH, the Agency for Health Care Policy and Research, the American Health Care Association, Johnson and Johnson Pharmaceutical, the Rand Corporation and by several newspapers and journals. NNHS data cover: baseline data on the characteristics of nursing homes in relation to their residents and staff, Medicare and Medicaid certification, costs to residents, sources of payment, residents' functional status and diagnoses. Data collection is planned for the period July–November, 1999. Survey design is in process now. Sample selection and preparation of layout forms will precede the data collection by several months. The total costs to respondents is estimated at $60,000.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Facility Questionnaire	1,500	1	0.333	500
Current Resident Sampling List	1,500	1	0.333	500
Current Resident Questionnaire	1,500	6	0.17	1,530
Discharged Resident Sampling List	1,500	1	0.333	500
Discharged Resident Questionnaire	1,500	6	0.17	1,530
Total				4,560

2. The Development and Implementation of a Theory-Based Health Communications Intervention to Decrease Silica Dust Exposure Among Masonry Workers—New

The National Institute for Occupational Safety and Health—Construction is the most frequently recorded industry on death certificates with mention of silicosis. Overexposure to crystalline silica is well documented in the construction industry, especially in brick laying and masonry. According to 1993 BLS data, there are 136,139 (at 24,362 establishments) masonry and brick laying workers in the U.S. and according to a recent study, approximately 17,400 masonry and plastering workers are exposed to at least five times the NIOSH recommended exposure limit (REL for crystalline silica) and of these workers, an estimated 80 percent of them are exposed to at least 10 times the NIOSH REL.

To effectively prevent silicosis, not only must control measures be improved, but workers must be persuaded to protect themselves and employers must be motivated to provide workers with proper engineering controls and training. Previous research has too often focused on the behaviors and attitudes of workers and not on employers. Since employers have a tremendous influence on the health of workers and since their motivations may differ from workers', it is important to focus on them as well. Well-designed and theory-driven communication interventions have the capacity to promote protective health behaviors. To develop messages that will have the greatest success at motivating workers to protect themselves and employers to protect their workers from silicosis, information on workers' and employers' beliefs, attitudes, and behaviors regarding silicosis must be determined. A recently completed pilot-study indicated a need to motivate employers to provide appropriate engineering controls and respiratory protection and a need to persuade workers to protect themselves.

The goal of this project is to develop a health communication intervention program targeting both masonry contractors and workers that will increase the use of engineering controls (specifically, wet-sawing) and respiratory protection. The aforementioned pilot study will serve as a foundation upon which the intervention will be developed. The effectiveness of the intervention will be evaluated using a pre-post test questionnaire.

The study results will provide a basis for intervention programs that masonry contractors can use to educate their workers regarding risk of exposure to silica dust on masonry work sites. The methodology could be applied to other construction procedures such as jack hammering, sand blasting, and similar dust producing procedures to produce similar intervention programs. Eventually we would hope, silica exposures among construction workers would decrease significantly. The total cost to respondents is $0.00.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Workers	200	2	0.33	132
Contractors	20	2	0.33	13.2
Total				145.2

Dated: November 25, 1998.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–32056 Filed 12–1–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0363]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by January 4, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Investigational Use (21 CFR Part 511) (OMB Control Number 0910–0117)

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is responsible for the approval of new animal drugs for investigational use. Section 512(j) of the act (21 U.S.C. 360b(j)) requires that a sponsor submit to FDA ''Notice of Claimed Investigational Exemption'' (INAD), prior to shipment of the new animal drug for clinical tests in animals. The regulations implementing statutory requirements for INAD approval have been codified under part 511 (21 CFR part 511). The INAD application must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, and (4) name and address of each clinical investigator and the approximate number of animals to be treated or the amount of new animal drugs to be shipped. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to ensure that its use is safe, that distribution is controlled to prevent potential abuse, and that edible products of treated animals will not be distributed for food without proper authorization from FDA. The agency utilizes these required records under its ''Bio-Research Monitoring Program'' to monitor the validity of the studies and to ensure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are sponsored primarily by drug industry firms, academic institutions, and the Government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are both sponsors and investigators.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	190	6	1,147	8	9,176
511.1(b)(5)	190	1.5	287	140	40,180
511.1(b)(6)	190	.005	1	250	250
511.1(b)(8)(ii)	190	.005	1	20	20
511.1(b)(9)	190	.16	30	8	240
Total Burden Hours					49,866

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	7.5	1,434	9	12,906
511.1(b)(3)	190	10	1,912	1	1,912
511.1(b)(7)(ii)	190	2	956	3.5	3,346
511.1(b)(8)(i)	190	4	956	3.5	3,346
Total Burden Hours					21,510

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated time required for reporting requirements, record preparation, and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e., the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: November 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–32021 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0867]

Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of policy interpretation; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice issued jointly by FDA and the Environmental Protection Agency (EPA) that appeared in the **Federal Register** of October 9, 1998 (63 FR 54532). The document set forth legal and policy interpretations of the Federal Food, Drug, and Cosmetic Act (FFDCA) as they relate to the jurisdiction of EPA and FDA over antimicrobial substances used in or on food, including food-contact articles; discussed interpretations of certain terms in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the implementing regulations relevant to the authority of the two agencies; provided a description of how EPA and FDA propose to clarify the post-Food Quality Protection Act (FQPA) regulatory authority over certain antimicrobial substances; and discussed how EPA and FDA plan to handle the review of petitions for antimicrobial substances that will remain under EPA's jurisdiction, and for those that EPA proposes to return to FDA's regulatory authority through EPA rulemaking. The document was published with an incorrect address for FDA's Dockets Management Branch. This document corrects that error. EPA's addresses remain the same.

EFFECTIVE DATE: October 9, 1998.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

In FR Doc. 98–27261, appearing on page 54532 in the **Federal Register** of Friday, October 9, 1998, the following correction is made:

On page 54532, in the first column, under the **ADDRESSES** caption, in the first and second lines from the bottom ''Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.'' is corrected to read ''5630 Fishers Lane, rm. 1061, Rockville, MD 20852.''

Dated: November 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–32025 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1034]

Solvay S.A.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Solvay S.A., has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene polymer films and polyethylene phthalate polymer films intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4634) has been filed by Solvay S.A., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3400 *Emulsifiers and/or surface active agents* (21 CFR 178.3400) to provide for the expanded safe use of naphthalene sulfonic acid-formaldehyde condensate, sodium salt as an emulsifier in vinylidene chloride copolymer or homopolymer coatings applied to polypropylene polymer films and polyethylene phthalate polymer films intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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.

Dated: November 16, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–32023 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1036]

Vale Chemical Co., Inc., et al.; Proposal to Withdraw Approval of 13 New Drug Applications and 1 Abbreviated New Drug Application; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDA's) and 1 abbreviated new drug application (ANDA). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Written requests for a hearing are due by January 4, 1999; data and information in support of the hearing request are due by February 1, 1999.

ADDRESSES: Requests for a hearing, supporting data, and other comments should be identified with Docket No. 98N–1036 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the applications listed in the following table have failed to submit the required

annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 7–112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets.	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11–863	Flavihist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50–042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units.	Pfizer Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 50–067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 50–088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 50–121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50–122	Compocillin-V Chewable Wafers	Do.
NDA 50–129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories.
NDA 50–189	Omnipen Tablets	Do.
NDA 50–197	Unipen Injection	Do.
NDA 50–305	Unipen Capsules	Do.
NDA 50–319	Omnipen Chewable Tablets	Do.
NDA 50–413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87–387	Aminophylline Injection USP,25 mg/milliliter	Pharma-Serve, Inc., 218–20 98th Ave., Queens Village, NY 11429.

Therefore, notice is given to the holders of the applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before January 4, 1999, a written notice of participation and request for a hearing, and (2) on or before February 1, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: November 12, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–32069 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 1998, 10:15 a.m. to 5:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Michael G. Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 140, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12624. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on general issues related to the classification of tracheal gas insufflation (TGI) devices used to provide part or all of the breathing gas for treatment of respiratory failure or respiratory insufficiency. The use of the TGI catheter, tube or lumen only for supply of fresh gas distinguishes TGI from common tracheal tubes and tracheostomy tubes, in which the gas flow alternates between inhalation and exhalation. The draft versions of five questions FDA will ask the committee to address are listed as follows:

1. For the evaluation of effectiveness of specific TGI systems as an adjunct to ventilation of adults, is reduction of minute ventilation (or PCO_2) without appreciable increase in end-expiratory lung volume or pressure a sufficient endpoint? Is this the correct endpoint?

2. For ventilation of adults, is there now sufficient understanding of TGI to be reasonably sure that TGI, with adequate monitoring and other understood safety provisions, will not have worse outcomes? Or does TGI raise concerns that will require that FDA review data on patient outcomes?

3. Are there special considerations about the data FDA should review for TGI submissions in relation to ventilation of children, infants, newborns, or premature infants?

4. What are the minimum system functions that include all the functions needed to provide TGI for clinical use as an adjunct to or replacement for conventional ventilation?

5. What specific safety provisions are important? Is distal pressure monitoring essential?

Procedure: On December 18, 1998, from 12:15 p.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present information or views, orally or in writing, on issues pending before the committee. Written submissions must be made to the contact person by December 11, 1998. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and between approximately 4 p.m. and 4:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 11, 1998, and submit a brief statement of the general nature of the arguments they wish to present, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 18, 1998, from 10:15 a.m. to 12:15 p.m., the meeting will be closed to permit FDA to present trade secret and/or confidential commercial information (5 U.S.C. 522b(c)(4)) regarding pending issues and applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 24, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–32024 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–259]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Evaluation of the EverCare Demonstration; *Form No.:* HCFA–R–259; Use: This survey will capture information on the quality of capitated Medicare coverage to nursing home residents, such as the description of the person, information regarding enrollment/disenrollment, quality of life, satisfaction including issues of access to services, advance medical directives, general health, and functional status. This information will be used to support analyses of enrollment decisions, access to services and providers, and outcomes for both the enrollee and family members. The underlying premise of the EverCare demonstration is that closer attention to primary care needs of high-risk patients through the use of nurse practitioners and/or physicians assistants can reduce the use of hospitals (and emergency rooms). *Frequency:* On occassion; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,150; *Total Annual Responses:* 3,150; *Total Annual Hours:* 1,962.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 16, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–32124 Filed 12–1–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: (Form #HCFA–21, 21B, 21P, 21.11A, 21E, 64, 64.21, 64.21U, 64.21P, 64.21UP, 64EC, 64.21E, 64.9P, 64.10P, 64.11A, 64.9d)]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program.

Form Nos.: HCFA–64, 64.21, 64.21U, 64.21P, 64.21UP, 64EC, 64.21E, 64.9, 64.10, 64.10P, 64.11a, 64.9d.

Use: These new forms are revisions of the currently approved collection report Form HCFA–64. These forms will be used by State Medicaid agencies to report their actual CHIP-related Medicaid expenditures and the numbers of CHIP-related children, and other children being served in the Medicaid program, to the Health Care Financing Administration (HCFA). The forms will be used by the HCFA to ensure that the appropriate level of Federal payments for the State's CHIP-related Medicaid program expenditures are made in accordance with the CHIP and related Medicaid provisions of the BBA of 1997, and to track, monitor, and evaluate the numbers of CHIP-related children and other individuals being served by the Medicaid program.

For a short description of the CHIP-related Medicaid reporting forms, see below:

- HCFA–64 Summary Sheet

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, Summary Sheet. The form HCFA–64 summary sheet is a one-page summary sheet summarizing the total expenditures reported for the quarter. The remaining forms provide additional detail and support the entries made on the summary sheet.

- HCFA–64.9

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, Expenditures in this Quarter. The form HCFA–64.9 is comprised of two pages that are used for detailing, by category, current quarter program expenditures by type of service (e.g., clinical services, dental services). The total figures from the form HCFA–64.9 are transferred to the form HCFA–64 Summary Sheet, Line 6, columns (a) and (b). A separate copy of the form HCFA–64.9 must also be submitted for each waiver granted to the State agency for which expenditures have been incurred. The total waiver figures are already incorporated in the expenditures reported on the ''base'' (one form) form HCFA–64.9.

- HCFA–64.9p

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, Prior Period Adjustment. The form HCFA–64.9p supports claims or adjustments for prior period (years) which are transferred to the form HCFA–64 summary sheet and noted on Lines 7, 8, 10.A., and 10.B., columns (a) and (b). It contains the same service categories as the form HCFA–64.9. This two-page form details the program expenditures, by category, arraying the expenditures by fiscal year. A separate form HCFA–64.9p is prepared to support each fiscal year and each line entry (Lines 7, 8, 10.A., and 10.B.) on the summary sheet. If the prior period adjustment includes waiver-related expenditures, a separate form HCFA–64.9p must be filed for each waiver including HCBS waivers.

- HCFA–64.9d

Allocation of Disproportionate Share Hospital Payment Adjustments to Applicable FFYs. The form HCFA–64.9d has been created to track payments of DSH by Federal Fiscal Year. This one page form details, by Inpatient Hospital Services and Mental Health Facility Services, details the allotment and DSH payments by Federal Fiscal Years. This is authorized under § 1923(f) of the Act.

- HCFA–64.10

Expenditures for State and Local Administration for the Medical Assistance Program, Expenditures in this Quarter. The form HCFA–64.10 supports administrative expenditures reported on the summary sheet. This one page form details, by category, the current quarter expenditures for administering the Medicaid program. The total figures from the ''base'' form HCFA–64.10 summary sheet. The State agency must also file a separate form HCFA–64.10 or each of its waivers granted to the State agency for which expenditures have been incurred. The waiver expenditures reported on a supporting form HCFA–64.10 are already included with the overall expenditures reported on the ''base'' form HCFA–64.10.

- HCFA–64.10p

Expenditures for State and Local Administration for the Medical Assistance Program, Prior Period Adjustments. The form HCFA–64.10p is similar to the form HCFA–64.10 except that it addresses adjustments to prior period expenditures. The totals from the form HCFA–64.10p are transferred to the form HCFA–64 summary sheet, Lines 7, or 8 or 10.A., or 10.B., columns (c) and (d). A separate form HCFA–64.10p must be completed for each line item entry, by fiscal year, on the summary sheet.

- HCFA–64.11

Summary Total of Receipts from form HCFA–64.11A. The form HCFA–64.11 has been created to summarize the information reported on the various HCFA–64.11a forms. This is authorized under § 1903(w) of the Act.

- HCFA–64.11A

Actual Receipts by Plan Name. The form HCFA–64.11a has been created to report the actual receipts by plan names form provider-related donation and health care related taxes, fees and assessments. This is authorized under § 1903(w) of the Act.

- There are no forms numbered 64.1 through 64.8 because of form development and redevelopment over the years. There are also no forms detailing items 9.B. through 9.E. of the summary sheet because there is no need for further breakdown of these figures for reimbursement calculations.

HCFA–64.21

Quarterly Medical Assistance Expenditure By Children's Health Insurance Program Expenditure Categories. States will use this form to

report current quarter expenditures for children who are determined presumptively eligible under section 1920A of the Act.

HCFA–64.21U

Quarterly Medical Assistance Expenditure Categories by Children's Health Insurance Program Expenditure Categories. States will use this form to report current quarter expenditures described under section 1905(u)(2) and 1905(u)(3) of the Act.

HCFA–64.21P

Quarterly Medical Assistance Expenditures By Children's Health Insurance Program expenditure categories. States will use this form to report prior period expenditures for children who are determined presumptively eligible under section 1920A of the Act.

HCFA–64.21UP

Quarterly Medical Assistance Expenditures by Children's Health Insurance Program Expenditure Categories, Prior Period Expenditures. States will use this form to report prior period expenditures described under section 1905(u)(2) and (3) of the Act.

HCFA–64.21E

Number of Children Served Related to Children's Health Insurance Program. States use this form to report the numbers of CHIP-related children, by service delivery system, that are served in the States' Medicaid programs based on age categories.

Note: HCFA is working with States to develop an appropriate format for States to report numbers of CHIP-related children, by service delivery system, that are served in the States' Medicaid programs related to CHIP based on Federal poverty income level categories and under the age categories previously requested. When the format is finalized it will be incorporated into this form.

HCFA–64EC

Number of Children Served Related to Children's Health Insurance Program. States use this form to report the numbers of children (other than CHIP-related children), by service delivery system, that are served in the States' Medicaid programs based on age categories.

Note: HCFA is working with States to develop an appropriate format for States to report numbers of children (other than CHIP-related children), by service delivery system, that are served in the Medicaid program based on Federal poverty income level categories and under the age categories previously requested. When the format is finalized it will be incorporated into this form.

Frequency: Quarterly;

Affected Public: State and Federal government;

Number of Respondents: 56;

Total Annual Responses: 224;

Total Annual Hours: 16,464.

(2) *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Children's Health Insurance Program (CHIP) Budget and Expenditure System State Reporting Forms.

Form Nos.: HCFA–21, 21B, 21P, 21.11A, 21E, 21L;

Use: These forms will be used by State CHIP agencies to report CHIP program budget projections and actual CHIP program benefits and administrative expenditures, and the numbers of children being served in the CHIP program, to the Health Care Financing Administration (HCFA). The information provided by these new forms will be used by HCFA to prepare the grant awards to States for the CHIP, to ensure that the appropriate level of Federal payments for State expenditures under the CHIP are made in accordance with the CHIP-related BBA legislative provisions of 1997, and to track, monitor, and evaluate the numbers of children being served by the CHIP.

For a short description of the CHIP reporting forms, see below:

- Form HCFA–21 Summary Sheet

Quarterly Children's Health Insurance Program Statement of Expenditures for Title XXI Summary Sheet. This form summarizes the total expenditures in the State's CHIP reported by the State for the reporting quarter.

- Form HCFA–21

Children's Health Expenditures by Type of Service for the Title XXI Program, Expenditures in this Quarter. States use this form to report CHIP current quarter expenditures in accordance with services categories authorized under title XXI.

- Form HCFA–21B

Children's Health Insurance Program Budget Report for the Title XXI Program State Expenditure Plan. States use this form to report their budget projections each quarter for their Title XXI CHIPs for the current and budget Federal fiscal years and broken out by quarter.

- Form HCFA–21P

Children's Health Expenditures by Type of Service for the Title XXI Program, Prior Period Adjustments. States use this form to report CHIP prior period adjustment expenditures claimed in the submission quarter in accordance with services categories authorized under title XXI.

- Form HCFA–21.11A

Provider-Related Donations and Health Care Related Taxes, Fees, and Assessments Received Under Section 1903(w) for Title XXI. States use this form to report CHIP-related State receipts of provider related donations, and health care related taxes, fees, and assessments.

- Form HCFA–21E

Children's Health Insurance Program, Number of Children Served. States use this form to report the numbers of children, by service delivery system, that are served in the States' CHIPs based on age categories.

Note: HCFA is working with States to develop an appropriate format for States to report numbers of children, by service delivery system, that are served in the CHIP based on Federal poverty income level categories and under the age categories previously requested. When the format is finalized it will be incorporated into this form.

Frequency: Quarterly;

Affected Public: State and Federal government;

Number of Respondents: 56;

Total Annual Responses: 448;

Total Annual Hours: 7,840.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 16, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–32125 Filed 12–1–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2008–FN]

RIN 0938–AI90

Medicare Program; Recognition of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. for Ambulatory Surgical Centers Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This notice announces the approval of the American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) as an accreditation organization acknowledged by the Medicare program. We have found that AAAASF's standards for ambulatory surgical centers (ASCs) meet or exceed those established by the Medicare program. ASCs accredited by AAAASF will receive deemed status under the Medicare program.

EFFECTIVE DATE: This final notice is effective December 2, 1998, through December 2, 2004.

FOR FURTHER INFORMATION CONTACT: Joan Berry, (410) 786–7233.

SUPPLEMENTARY INFORMATION:

I. Background

A. Determining Compliance of Ambulatory Surgical Centers—Surveys and Deeming

In order to participate in the Medicare program, ambulatory surgical centers (ASCs) must meet conditions for coverage specified in regulations that implement Title XVIII of the Social Security Act (the Act). ASCs enter into a Medicare participation agreement but generally only after they are certified by a State survey agency as complying with the ASC conditions for coverage set forth in the Act and regulations. ASCs are subject to routine surveys by State agencies to determine whether they continue to meet these requirements; an ASC that does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated.

Section 1865 of the Act includes a provision that permits ASCs to be exempt from routine surveys by the State survey agencies to determine compliance with the Medicare conditions of coverage. Specifically, section 1865(b) of the Act provides that if we find that accreditation of a provider entity by a national accrediting body demonstrates that all Medicare conditions or requirements are met or exceeded, we would (for certain providers, including ASCs) ''deem'' these entities as meeting the applicable Medicare conditions. In order to enter the Medicare program under this deeming authority, the entities must meet the regulatory requirements at 42 CFR 489.13 (''Effective date of agreement or approval''). Under our regulations at § 416.40 (''Condition for coverage—Compliance with State licensure law''), an ASC must still meet the State's licensure requirements. However, certification by Medicare is still required to receive payment regardless of whether the certification is by us or the accrediting body.

In making our finding as to whether the standards of an accreditation body demonstrate comparability with all Medicare conditions or requirements, we consider factors such as the body's accreditation requirements, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found to be out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation.

As suppliers, ASCs are included by definition of provider entity in section 1865(b)(4) of the Act. Thus, if we were to recognize an ASC accreditation organization's program as demonstrating that all the Medicare ASC conditions of coverage are met, the ASCs accredited under the approved Medicare program would be considered or ''deemed'' to meet the same conditions for which the accreditation standards have been recognized. The American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) is the third accreditation organization that we have approved for ASCs. The other two accreditation organizations are the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC).

It has been brought to our attention that some ASCs are under the mistaken impression that once deemed authority is granted by HCFA to an accreditation organization, then ASCs must be accredited by such a body to receive Medicare certification. Accreditation by an accreditation organization is voluntary and not required by HCFA for Medicare certification.

B. Deeming Authority Process

On November 23, 1993, we published a final rule (58 FR 61816) that set forth the procedure that we would use to review and approve national accreditation organizations that wish to be recognized as providing reasonable assurance that Medicare conditions of coverage are met (§ 488.4, ''Application and reapplication procedures for accreditation organizations''). A national accreditation organization (Accreditation organization) applying for approval of deeming authority must furnish to us information and materials listed in our regulations at § 488.4. Our regulations at § 488.8 (''Federal review of accreditation organizations'') detail the Federal review and approval process of applications for deeming authority. On April 26, 1996, however, new legislation entitled ''Making Appropriations for Fiscal Year 1996 to Make a Further Down Payment Toward a Balanced Budget and for Other Purposes (Pub. L. 104–134)'' was enacted.

Section 516 of Public Law 104–134 amended section 1865 of the Act in a number of ways. The legislation removed the requirements that accreditation organizations provide reasonable assurance that entities accredited by them would meet Medicare conditions coverage or requirements. In revised section 1865(b)(1) of the Act, organizations are now required to demonstrate that their accredited entities would meet or exceed all of the applicable Medicare conditions. Section 1865(b)(4) includes suppliers (for example, ASCs) under the provider entities that we may consider for deemed status. We are required to publish a proposed notice in the **Federal Register** 60 days after the receipt of a written request for deemed status by a national accreditation body. After review of the national accreditation body's application, the statute requires that we publish a notice of our approval or disapproval within 210 days after we receive a complete package of information and the organization's deeming application.

We received an application from AAAASF on November 18, 1997 and in accordance with the statute, this final notice should have been published by June 16, 1998. However, HCFA was waiting for AAAASF to submit required materials on a quality improvement project for their training program before approving its deeming authority. AAAASF chose to delay the publication date, rather than be denied deemed status and have to reapply for deemed authority. Regulations at § 488.8(c)

specify that the deeming authority for AAAASF will take effect 90 days from the publication of this final notice. Thus, AAAASF cannot award deemed accreditation to a supplier and request HCFA certification before the end of that 90-day period.

C. Ambulatory Surgical Center Conditions for Coverage and Requirements

The regulations specifying the Medicare conditions for coverage for ASCs are located in part 416. These conditions implement section 1832(a)(2)(F)(i) of the Act, which provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by us under section 1833(i)(1) of the Act.

II. Provisions of the Proposed Notice

The proposed notice announced the application of AAAASF for deemed status for its accreditation program only to the extent that it accredits ASCs.

Under section 1865(b)(2) of the Act and our regulations at § 488.8 (''Federal review of accreditation organizations''), our review and evaluation of this national accreditation organization was conducted in accordance with, but was not necessarily limited to, the following factors:

- The equivalency of an accreditation organization's requirements for an entity to be certified compared to our requirements for certification.
- The organization's survey process to determine the following:

* The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

* The comparability of the organization's process to that of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

* The organization's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(b)(2).

* The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

* The ability of the organization to provide us with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization's survey process.

* The adequacy of staff and other resources.

* The organization's ability to provide adequate funding for performing required surveys.

* The organization's policies with respect to whether surveys are announced or unannounced.

- The accreditation organization's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey that we may require (including corrective action plans).

We met with representatives of AAAASF to evaluate its accreditation standards and survey process to determine if the organization demonstrated that its accredited facilities met Medicare conditions. We did a standard by standard comparison of the applicable conditions or requirements to determine which of them met or exceeded Medicare requirements. The representatives responded to our concerns by proposing to change the organization standards for its member ASCs needing Medicare certification. We subsequently received revised survey guidelines and amended standards for their member ASCs requesting Medicare certification.

A. Differences Between the American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. and Medicare Conditions and Survey Requirements

We compared the standards contained in the AAAASF's 1994 Standards Manual for accreditation of ambulatory surgery facilities and its survey process in the 1994 Inspectors Manual to the Medicare ASC conditions and survey procedures. In 18 areas the AAAASF has made the following revisions:

- *Exclusivity Requirement*—AAAASF has included a statement on ASC surgical exclusivity as an integral part of its application package.
- *Unannounced Surveys*—AAAASF has added language to the on-site inspection information to include a declaration that all surveys will be unannounced. In order to accommodate the need to assure that key staff are on hand for surveys without notification of the facility, AAAASF has agreed to request that the facility send staffing schedules on a regular basis once their application is complete.
- *Frequency of Surveys*—AAAASF resurveys an ASC every 3 years. Our original requirement was to survey ASCs every year. In practice, our resurveys have been averaging almost 3 years. Both the JCAHO and AAAHC have 3-year resurvey cycles. Therefore, we accept AAAASF's 3-year resurvey cycle.
- *State and Local Laws*—AAAASF has agreed to assure that out-of-state inspectors receive adequate information on certification, licensure, and scope of practice requirements of that State.
- *Reasonable Assurance*—AAAASF has agreed to modify its process to build in a review of the past history of facilities that already have Medicare certification through the State.
- *Fraud and Abuse*—AAAASF has agreed to require that its inspectors report any suspected instances of fraud and abuse to the appropriate HCFA Regional Office.
- *Hearing Schedules and Appeals*—AAAASF has specified the dates and locations for its Accreditation Committee hearings over the next 4 years.
- *Hospitalization*—AAAASF has inserted the word ''local'' to indicate those hospitals eligible to receive immediate transfers for patients requiring emergency medical care beyond the capabilities of the ASC.
- *Anesthetic Risk and Evaluation*—AAAASF has added language to indicate that a physician must examine each patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed.
- *Recovery Room and Waiting Area*—AAAASF has specified that an ASC must have a separate recovery room and waiting area.
- *Emergency Personnel*—AAAASF has added the requirement that personnel trained in the use of emergency equipment and cardiopulmonary resuscitation must be available whenever a patient is in the facility.
- *Other Practitioners*—AAAASF has added the requirement that if certified operating room technicians are employed that their certification or licensure must be current. Furthermore, if uncertified or unlicensed operating room technicians are used, it must be permissible under State law and the technician must be personally trained by the employing surgeon.
- *Organization and staffing*—AAAASF has added the requirement that a registered nurse must be available for emergency treatment whenever a patient is in the facility.
- *Oral Orders*—AAAASF has added a standard that requires that oral orders for drugs and biologicals must be followed by a written order and signed by the prescribing physician.
- *Laboratory and Radiologic Services*—AAAASF has added the requirement that radiologic services be obtained from a Medicare-approved facility and that ASC laboratories must meet requirements of part 493.

Furthermore, if the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493. Any referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493.

• *Life Safety Code: Surgical Procedures*—AAAASF agreed to require facilities to meet State and local requirements, or the National Fire Prevention Association (NFPA) Standards for Health Care Facilities (NFPA 99), and Life Safety Code (NFPA 101) Chapters 12 and 13 (and appropriate references), whichever is more stringent. Language was added to specify that their regular inspections for installation and maintenance of surgical equipment will be at least annually. In conformity with the NFPA requirements, AAAASF has made standby generator as the mandatory source of emergency power and reduced the time for such generators to reach full power from 30 to 10 seconds.

• *Life Safety Code: Environment*—AAAASF has specified that fire drills must be held once a month for each shift and has made smoke detectors mandatory for all office-based ASCs.

• *Life Safety Code: Standards Addendum*—AAAASF has specified that facilities must be inspected at least annually by the local or State fire control agency if this service is available. If not, AAAASF agrees to contract with a State agency or qualified subcontractor to perform the inspections.

• *Inspector Training Program*—AAAASF has submitted a revised training program that provides for consistent, national training of all inspectors in their processes and integrates instruction in the Medicare requirements based on either the trainer's participation in Medicare training or using Medicare survey experts as instructors.

We have agreed to accept language that requires compliance with the 1985 edition of the Life Safety Code with an encouragement by AAAASF that facilities comply with the 1997 Code. These standards will apply to all facilities regardless of size.

B. Analysis and Responses to Public Comments and Provisions of the Final Notice

We received no comments on our proposed notice. The provisions of the proposed notice are being made final in this notice.

III. Paperwork Reduction Act

The public reporting and record keeping burden reflected in this notice is referenced in the currently approved regulation entitled ''Granting and Withdrawal of Deeming Authority to National Accreditation Organizations (58 FR 61816).'' The paperwork burden referenced in the above mentioned regulation is currently approved by the Office of Management and Budget (OMB), under OMB approval number 0938–0690, with an expiration date of 8/31/99.

IV. Regulatory Impact Statement

In fiscal year 1995, there were 2,105 certified ASCs participating in the Medicare/Medicaid programs. We conducted 211 initial surveys, 288 recertification surveys (both at a cost of $714,069), and 24 complaint surveys. In fiscal year 1996, there were 2,219 certified ASCs. This was an increase of 114 facilities. We conducted 180 initial surveys, 115 recertification surveys (both at a cost of $848,125), and one complaint survey. In fiscal year 1997, there were 2,433 certified ASCs. This was an increase of 214 facilities. We conducted 236 initial surveys, 252 recertification surveys (both at a cost of $1,403,000), and seven complaint surveys. As the data above indicate, the number of ASCs and the cost for conducting ASC surveys by State Agencies are increasing.

As indicated above, there was a 16 percent increase in ASCs within 3 years (fiscal years 1995 through 1997). The fiscal year 1998 appropriation for ASC survey activities to HCFA was decreased as the priority of both initial surveys and resurveys remained in the bottom 10 percent of surveys performed, but without any adjustment for inflation. This does not allow sufficient resources for some regions to meet the survey demand. In an effort to guarantee the continued health, safety, and services of beneficiaries in facilities already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we are approving deeming for ASCs accredited by AAAASF as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 19, 1998.

Nancy-Ann DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–32102 Filed 12–1–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, The History of Medicine Panel.

Date: December 4, 1998.

Time: 8:30 am to 12:00 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Gilbert Meier, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7852, Bethesda, MD 20892, (301) 435–1169.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Ethics/Genome Study Section.

Date: December 7–8, 1998.

Time: 9:00 am to 12:00 pm.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave., N.W., Washington, DC 20007.

Contact Person: Cheryl M. Corsaro, Scientific Review Administrator, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6172, MSC 7890, Bethesda, MD 20892, (301) 435–1045.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 7, 1998.
Time: 10:00 am to 12:00 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Carole L. Jelsema, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7850, Bethesda, MD 20892, (301) 435–1249, jelsemac@drg.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 7, 1998.
Time: 10:00 am to 11:00 am.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Jean Hickman, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4194, MSC 7808, Bethesda, MD 20892, (301) 435–1146.

This noitce is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 7, 1998.
Time: 2:00 pm to 3:00 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Syed M. Quadri, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4144, MSC 7804, Bethesda, MD 20892, (301) 435–1211.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 7, 1998.
Time: 4:00 pm to 5:30 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Garrett V. Keefer, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7808, Bethesda, MD 20892, (301) 435–1152.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 7, 1998.
Time: 12:00 pm to 2:00 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Timothy J. Henry, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4180, MSC 7808, Bethesda, MD 20892, (301) 435–1147.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 8, 1998.
Time: 8:00 am to 5:00 pm.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.
Contact Person: Gertrude K. McFarland, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7816, Bethesda, MD 20892, (301) 435–1784.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 8, 1998.
Time: 10:00 am to 11:00 am.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Carol A. Campbell, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7848, Bethesda, MD 20892, (301) 435–1257.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 8, 1998.
Time: 1:00 pm to 2:00 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Timothy J. Henry, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4180, MSC 7808, Bethesda, MD 20892, (301) 435–1147.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 8, 1998.
Time: 2:00 pm to 4:00 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Houston Baker, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7854, Bethesda, MD 20892, (301) 435–1175, houstonb@drg.NIH.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 8, 1998.
Time: 2:00 pm to 3:30 pm.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge II, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Eugene Zimmerman, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–435–1220.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 9, 1998.
Time: 8:30 am to 5:00 pm.
Agenda To review and evaluate grant applications.
Place: Ramada Inn, 1775 Rockville Pike, Rockville, MD 20852.
Contact Person: Joe Marwah, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5188, MSC 7846, Bethesda, MD 20892, (301) 435–1253.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 9–10, 1998.
Time: 9:00 am to 2:00 pm.
Agenda: To review and evaluate grant applications.
Place: Latham Hotel Georgetown, 3000 M Street, NW, Washington, DC 20007.
Contact Person: John L. Bowers, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1725.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 9, 1998.
Time: 1:00 pm to 2:00 pm.
Agenda To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Sami A. Mayyasi, Scientific Review Administrator, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5112, MSC 7852, Bethesda, MD 20892, (301) 435–1169.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 1:00 pm to 2:00 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: David Monsees, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3199, MSC 7816, Bethesda, MD 20892, (301) 435–0684.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 1:30 pm to 2:00 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge II, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander D. Politis, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, (301) 435–1225, politisa@drg.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 2:00 pm to 4:00 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge II, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Eugene Zimmerman, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–435–1220.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 2:00 pm to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Luigi Giacometti, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7850, Bethesda, MD 20892, (301) 435–1246.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 2:00 pm to 3:30 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anthony C. Chung, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7802, Bethesda, MD 20892, (301) 435–1213.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: December 9, 1998.

Time: 12:30 pm to 1:30 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge II, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander D. Politis, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, (301) 435–1225, politisa@drg.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32063 Filed 12–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. the grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel Science Education Partnership Award.

Date: February 2, 1999.

Time: 8:00 am to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: John D. Harding, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, 301–435–0820.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: November 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32058 Filed 12–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Research Resources Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Research Resources Council, Executive Subcommittee.

Date: January 28, 1999.

Open: 7:30 AM to 8:45 AM.

Agenda: To discuss policy issues.

Place: National Institutes of Health, Conference Room 3B13, Building 31, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PHD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892, 301–496–6023.

Name of Committee: National Advisory Research Resources Council.

Date: January 28–29, 1999.

Open: January 28, 1999, 9:00 AM to Recess.

Agenda: To discuss policy issues.

Place: National Institutes of Health, 9000 Rockville Pike, Conference Room 10, Building 31C, Bethesda, MD 20892.

Closed: January 29, 1999, 8:30 AM to 9:30 AM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Conference Room 10, Building 31C, Bethesda, MD 20892.

Open: January 29, 1999, 10:00 AM to Adjournment.

Agenda: Report of Center Director and other issues related to Council business.

Place: National Institutes of Health, 9000 Rockville Pike, Conference Room 10, Building 31C, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PHD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892, 301–496–6023.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: November 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32059 Filed 12–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group Comparative Medicine Review Committee.

Date: February 17–18, 1999.

Open: February 17, 1999, 8:00 a.m. to 9:30 a.m.

Agenda: To discuss program planning and program accomplishments.

Place: One Washington Circle Hotel, Conference Center, One Washington Circle, Washington, DC 20037.

Closed: February 17, 1999, 9:30 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, Conference Center, One Washington Circle, Washington, DC 20037.

Contact Person: Raymond O'Neill, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive MSC 7905, Room 6018, Bethesda, MD 20892–7965, 301–435–0820.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: November 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32060 Filed 12–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: February 10–11, 1999.

Open: February 10, 1999, 8:00 a.m. to 9:00 a.m.

Agenda: To discuss program planning and program accomplishments.

Place: Holiday Inn Bethesda, Delaware Room, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Closed: February 10, 1999, 9:00 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bethesda, Delaware Room, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: D.G. Patel, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, Bethesda, MD 20892, (301) 435–0822.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32061 Filed 12–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should

notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group General Clinical Research Centers Review Committee.

Date: February 9–11, 1999.

Open: February 9, 1999, 8:00 AM to 9:30 AM.

Agenda: To discuss program planning and program accomplishments.

Place: Bethesda Ramada, Embassy III Room, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Closed: February 9, 1999, 9:30 AM to ADJOURNMENT.

Agenda: To review and evaluate grant applications.

Place: Bethesda Ramada, Embassy III Room, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Charles G. Hollingsworth, DPH, Deputy Director, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda MD 20892–7966, 301–435–0818.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306, 93.333, Clinical Research, 93.333, 93.371, Biomedical Technology, 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: November 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–32062 Filed 12–1–98; 8:45 am]

BILLING 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of Final Revised Sonoran Pronghorn Recovery Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service announces the availability for public review of Final Revised Sonoran Pronghorn (*Antilocapra americana sonoriensis*) Recovery Plan which the Service listed as an endangered species on March 11, 1967 (32 FR 4001). This animal's population is estimated to be less than 300 in the United States and less than 500 in the State of Sonora, Mexico. Distribution is limited primarily to Sonoran desert habitats. Factors that limit population growth are not well understood. However, loss of habitat due to drying of extended reaches of the Gila and Sonoyta Rivers, competition from domestic livestock, and human encroachment are believed to be limiting factors. Illegal hunting and predation on fawns may also be limiting factors. Although the Service considers this document to be in its final form, the Service is interested in comments from interested parties. The Service will consider all comments and may decide to amend this document at a later date based upon input received and upon the results and proceedings of a Sonoran Pronghorn Workshop to be held tentatively during the last week of January 1999.

DATES: The Service will be open to written advice and comment on the Final Revised Recovery Plan through January 29, 1999. Additionally, in cooperation with the U.S. Marine Corps, the Service will co-sponsor a Sonoran Pronghorn Workshop tentatively during the last week in January 1999. Parties interested in attending the Sonoran Pronghorn Workshop tentatively scheduled for the last week of January 1999, should contact Mr. Ron Pearce, Range Management Director, United States Marine Corps Air Station, Yuma, Arizona, at (520) 341–3401.

ADDRESSES: Address requests for copies of the document, comments on the Final Recovery Plan, or requests for more information to Laura Thompson-Olais, Ecologist, Cabeza Prieta National Wildlife Refuge, 1611 North Second Avenue, Ajo, Arizona 85321.

SUPPLEMENTARY INFORMATION: Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for conservation of the species, criteria for recognizing the recovery levels for down-listing or de-listing them, and initial estimates of times and costs to implement the needed recovery measures.

Authority

The Authority for this action is section 4(f) of the Endangered Species Act 16 U.S.C. 1533(f).

The Endangered Species Act of 1973 (Act), as amended, (16 U.S.C. 1531 et seq.) Requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act as amended in 1988 requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will also take these comments into account in the course of implementing approved plans. The Service may also decide to amend the Plan if necessary.

A recovery plan for Sonoran pronghorn was approved in 1982. Subsequent to the development of the original recovery plan, a large group of Sonoran proghorn were documented drinking free-standing water during the summer which verified their use of water. This and additional new information learned about the biology and ecology of the animal have necessitated revision of the original recovery plan.

The availability of the draft revised Sonoran pronghorn recovery plan for review and comment was announced in the **Federal Register** on September 7, 1994. The revised plan, however, was never completed and further changes to the plan have been made since then. This notice gives the public another opportunity for review and comment before the final revised plan is approved.

Recovery will focus on enhancing present populations, addressing expansion of presently used habitat, protecting present range and establishing a new separate herd of self-sustaining animals to guard against catastrophes decimating the core population.

Dated: November 23, 1998.

Renne Lohoefener,

Acting Regional Director.

[FR Doc. 98–32052 Filed 12–1–98; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–0777–58–24–1A; HAG99–0037]

Emergency Closure of Bureau of Land Management Administered Roads—Jackson County, Oregon

AGENCY: Bureau of Land Management, Medford District Office, Ashland Resource Area.

SUMMARY: Notice is hereby given that certain BLM roads in Jackson County, Oregon are hereby closed to all motorized vehicles including off-road vehicles (but excluding tracked snow vehicles) from October 23, 1998 until notice is rescinded. The closure is made under the authority of 43 CFR 9268.3(d)(1)(ii) and 8364.1(a).

The roads and the conditions of this emergency road closure are identified as follows: Roads 41–2E–3, 41–2E–9, 41–2E–10.0, 41–2E–10.1 and connecting spur roads are hereby seasonally closed. These roads are located in Sections 2, 3, 10, 11, and 12 of T.41 S., R. 2 E., and Sections 5, 6, and 7 of T. 41 S., R. 3 E., Willamette Meridian, Jackson County, Oregon. In addition, the road located next to Scotch Creek in Section 1, T. 41 S., R. 2 E. (W. M.) is hereby permanently closed under this order.

Any person who fails to comply with the provisions of this closure order may be subject to the penalties provided in 43 CFR 8360.0–7, which include a fine not to exceed $1,000.00 and/or imprisonment not to exceed 12 months, as well as the penalties provided under Oregon State law.

The roads temporarily closed to motorized use under this order will be posted with signs at barricaded locations.

The purpose of this emergency temporary closure is to prevent excessive erosion, and to protect recent BLM investments in road maintenance work.

This closure is effective from October 23, 1998 until this notice is rescinded.

FOR FURTHER INFORMATION CONTACT: Joe Hoppe, Realty Specialist, at (541) 770–2200.

Dated: November 20, 1998.

Wayne M. Kuhn,

Acting District Manager.

[FR Doc. 98–32123 Filed 12–1–98; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–050–99–1150–00; 8011]

Arizona: Intent to Amend the Yuma District Resource Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the Bureau of Land Management proposes to change the boundaries of the Gran Desierto Dunes Area of Critical Environmental Concern (ACEC).

The Gran Desierto Dunes ACEC is proposed to be expanded north and west to the northern and western boundaries of the Barry M. Goldwater Air Force Range, and east along the International Boundary between the United States and Mexico. The area includes public lands on the Barry M. Goldwater Air Force Range in Townships 9, 10, 11, 12, and 13 South, Ranges. 19, 20, 21, and 22 West, Gila and Salt River Meridian, Yuma County, Arizona.

FOR FURTHER INFORMATION CONTACT: Susanna Henry, Bureau of Land Management, 2555 E. Gila Ridge Road, Yuma, AZ 85365; telephone number: 520–317–3211.

SUPPLEMENTARY INFORMATION: The 25,500-acre Gran Desierto Dunes ACEC was designated in 1990 as part of the Lower Gila South Resource Management Plan (Goldwater Amendment). The Goldwater Amendment also established the 84,500-acre Yuma Desert and Sand Dunes Habitat Management Area (HMA) adjacent to the ACEC. The Goldwater Amendment was later incorporated as part of the Yuma District RMP. The proposed amendment would expand the boundaries of the Gran Desierto Dunes ACEC to absorb the Yuma Desert and Sand Dunes HMA, modify and expand management prescriptions throughout the ACEC, designate a utility corridor between Interstate 8 and the International Boundary, and establish a mitigation and compensation policy within flat-tailed horned lizard habitat on public lands in Arizona.

In 1997, the Flat-tailed Horned Lizard Rangewide Management Strategy (Strategy) and Conservation Agreement was signed by BLM. The purpose of the Strategy is to conserve viable populations of flat-tailed horned lizards. The Strategy outlines Management Areas building on protection supported by existing ACESs in both Arizona and California. The proposed amendment to the Yuma District RMP will be accomplished as a joint document with the Bureau of Land Management, California Desert District as an amendment to the California Desert Conservation Area (CDCA) Plan.

The proposed amendment to the Yuma District and CDCA Plans is being analyzed as part of the proposed action in an environmental assessment. It is anticipated that the Draft EA will be printed and made available to the public for comment in January 1999.

Dated: November 23, 1998.

Maureen A. Merrell,

Assistant Field Manager, Business and Fiscal Services/Acting Field Manager.

[FR Doc. 98–32126 Filed 12–1–98; 8:45 am]

BILLING CODE 4210–32–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 701–TA–223 (Review)]

Agricultural Tillage Tools From Brazil

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the countervailing duty order on agricultural tillage tools from Brazil.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the countervailing duty order on agricultural tillage tools from Brazil would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 F.R. 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera

Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On October 22, 1985, the Department of Commerce issued a countervailing duty order on imports of agricultural tillage tools from Brazil (50 F.R. 42743). The Commission is conducting a review to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is Brazil.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. For purposes of this notice, the Domestic Like Product is discs. In its original determination, the Commission defined two Domestic Like Products (discs and ''other tillage tools''); however, the Commission made an affirmative finding only with respect to discs.

(4) The *Domestic Industry* is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. For purposes of this notice, the Domestic Industry is producers of discs. In its original determination, the Commission defined two Domestic Industries; however, the Commission made an affirmative finding only with respect to producers of discs.

(5) The *Order Date* is the date that the countervailing duty order under review became effective. In this review, the Order Date is October 22, 1985.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the Review and Public Service List

Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability to Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution

As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name,

telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in units and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/ which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in units and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in units and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm's(s') production; and

(b) the quantity and value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country since the Order Date, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(11) (*Optional*) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32089 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–208 (Review)]

Barbed Wire and Barbless Wire Strand From Argentina

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the antidumping duty order on barbed wire and barbless wire strand from Argentina.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the antidumping duty order on barbed wire and barbless wire strand from Argentina would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through

E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 F.R. 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Steet SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On November 13, 1985, the Department of Commerce issued an antidumping duty order on imports of barbed wire and barbless wire strand from Argentina (50 F.R. 46808). The Commission is conducting a review to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is Argentina.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determination, the Commission defined the Domestic Like Product as barbed and barbless wire strand.

(4) The *Domestic Industry* is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the Domestic Industry as producers of barbed wire and barbless wire strand.

(5) The *Order Date* is the date that the antidumping duty order under review became effective. In this review, the Order Date is November 13, 1985.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the Review and Public Service List

Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register.** The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register.** Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submission

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(I)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability To Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution

As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and current operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in short tons and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in short tons and value data in thousands of U.S. dollars). if you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in short tons and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including andidumping or countervailing duties). if you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm's(s') production; and

(b) the quantity and value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country since the Order Date, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(11) *(Optional)* A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32090 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–189 (Review)]

Calcium Hypochlorite From Japan

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the antidumping duty order on calcium hypochlorite from Japan.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. § 1675(c)) (the Act) to determine whether revocation of the antidumping duty order on calcium hypochlorite from Japan would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline

for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On April 18, 1985, the Department of Commerce issued an antidumping duty order on imports of calcium hypochlorite from Japan (50 F.R. 15470). The Commission is conducting a review to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to this review:

(1) Subject Merchandise is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The Subject Country in this review is Japan.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determination, the Commission defined the Domestic Like Product as calcium hypochlorite.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the Domestic Industry as producers of calcium hypochlorite.

(5) The Order Date is the date that the antidumping duty order under review became effective. In this review, the Order Date is April 18, 1985.

(6) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the Review and Public Service List

Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability To Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the

Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution

As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production; and

(b) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date*, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country*, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry*; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32084 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Castor Oil Products From Brazil and Sebacic Acid From China

[Investigation No. 104–TAA–20 (Review) and (Investigation No. 731–TA–653 (Review))

AGENCY: United States International Trade Commission.

ACTION: Institution of five-year reviews concerning the countervailing duty order on castor oil products from Brazil and the antidumping duty order on sebacic acid from China.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the countervailing duty order on castor oil

products from Brazil and/or the antidumping duty order on sebacic acid from China would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205-3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On March 16, 1976, the Department of the Treasury issued a countervailing duty order under section 303 of the Act on imports of castor oil products from Brazil (42 FR 8634). In January 1984, pursuant to section 104 of the Trade Agreements Act of 1979, the Commission determined that industries in the United States would be materially injured by reason of imports of the subject castor oil products (hydrogenated castor oil (HCO) and 12-hydroxystearic acid (HSA)) from Brazil if the countervailing duty order were to be revoked. On July 14, 1994, in an unrelated investigation, the Department of Commerce issued an antidumping duty order on imports of sebacic acid from China (59 FR 35909). The Commission is conducting reviews to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to these reviews:

(1) Subject Merchandise is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The Subject Countries in these reviews are Brazil and China.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determinations concerning castor oil products from Brazil, the Commission defined two separate Domestic Like Products: HCO and HSA. In its original determination concerning sebacic acid from China, the Commission defined the Domestic Like Product as sebacic acid.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the products. In its original determinations concerning castor oil products from Brazil, the Commission defined two separate Domestic Industries, one producing HCO and one producing HSA. In its original determination concerning sebacic acid from China, the Commission defined the Domestic Industry as producers of sebacic acid.

(5) The Order Dates are the dates that the countervailing and antidumping duty orders under review became effective. In the review concerning castor oil products from Brazil, the Order Date is March 16, 1976, and in the review concerning sebacic aid from China, the Order Date is July 14, 1994.

(6) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the Reviews and Public Service List

Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. § 1677(9), who are parties to the reviews. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these reviews must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the

provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the reviews you do not need to serve your response).

Inability to Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determinations in the reviews.

Information to be provided in Response to This Notice of Institution

Please provide the requested information separately for each Domestic Like Product, as defined by the Commission in its original determinations, and for each of the products identified by Commerce as Subject Merchandise. If you are a domestic producer, union/worker group, or trade/business association; import/export Subject Merchandise from more than one Subject Country; or produce Subject Merchandise in more than one Subject Country, you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent Subject Country. As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in these reviews by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing and antidumping duty orders on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. § 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. § 1677(4)(B)).

(6) For certain castor oil products, a list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in Brazil that currently export or have exported Subject Merchandise to the United States or other countries since 1975. For sebacic acid, a list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in China that currently export or have exported Subject Merchandise to the United States or other countries since 1993.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Countries, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Countries accounted for by your firm's(s'') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Countries.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Countries, provide the following information on your firm's(s'') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Countries accounted for by your firm's(s'') production; and

(b) the quantity and value of your firm's(s'') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Countries accounted for by your firm's(s'') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Countries since the Order Dates, and significant changes, if any,

that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Countries, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32086 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Television Receivers From Japan (Inv. No. AA1921–66 (Review)); Color Television Receivers From Korea (Inv. No. 731–TA–134 (Review)); Color Television Receivers From Taiwan (Inv. No. 731–TA–135 (Review)); Small Electric Motors From Japan (Inv. No. 731-TA–7 (Review)); High-Power Microwave Amplifiers From Japan (Inv. No. 731–TA–48 (Review)); and Barium Carbonate From Germany (Inv. No. 731-TA–31 (Review))

AGENCY: International Trade Commission.

ACTION: Termination of five-year reviews.

SUMMARY: The subject five-year reviews were initiated in October 1998 to determine whether revocation of the existing antidumping duty orders/suspension agreement would be likely to lead to continuation or recurrence of dumping and material injury to a domestic industry. On November 23, 1998, the Department of Commerce published notice that it was revoking the orders because no domestic interested party responded to its notice of initiation by the applicable deadline (63 FR 64677, November 23, 1998). Accordingly, pursuant to § 207.69 of the Commission's rules of practice and procedure (19 CFR 207.69), the subject reviews are terminated.

EFFECTIVE DATE: November 23, 1998.

FOR FURTHER INFORMATION CONTACT: Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

Authority: These reviews are being terminated under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.69 of the Commission's rules (19 CFR 207.69).

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32093 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

UNITED STATES INTERNATIONAL TRADE COMMISSION

[Investigation No. 701-TA–224 (Review)]

Live Swine From Canada

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the countervailing duty order on live swine from Canada.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. § 1675(c)) (the Act) to determine whether revocation of the countervailing duty order on live swine from Canada would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205-3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On August 15, 1985, the Department of Commerce issued a countervailing duty order on imports of live swine from Canada (50 FR 32880). Commerce subsequently partially revoked the order, effective April 1, 1991, with respect to slaughter sows and boars and weanlings. (61 FR 45402, August 29, 1996). The Commission is conducting a review to determine whether revocation of the portion of the order that remains effective would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is Canada.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determination when the corresponding Subject Merchandise was defined to be live swine, the Commission made an affirmative determination with respect to one Domestic Like Product, live swine. A Domestic Like Product that corresponds to the current (reduced) scope of the Subject Merchandise would consist of live swine excluding slaughter sows and boars and weanlings.

(4) The *Domestic Industry* is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the Domestic Industry as hog growers, corresponding to the live swine Domestic Like Product. Consequently, for purposes of this notice the Domestic Industry is hog growers. A Domestic Industry that corresponds to a more narrow Domestic Like Product would consist of growers of hogs other than slaughter sows and boars and weanlings.

(5) The *Order Date* is the date that the countervailing duty order under review became effective. In this review, the Order Date is August 15, 1985.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the Review and Public Service List

Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. § 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability to Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution

Where an item below seeks information with respect to the Domestic Like Product, information should be provided for each of the two alternative definitions of the Domestic Like Product described above: Namely, (1) live swine and (2) live swine excluding slaughter sows and boars and weanlings. Where an item below seeks information with respect to the Domestic Industry, information should be provided for each of the two alternative definitions of the Domestic Industry described above: Namely, (1) hog growers and (2) growers of hogs other than slaughter sows and boars and weanlings. As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which

your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. § 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. § 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in thousands of head and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of head and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) The quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of head and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm's(s') production; and

(b) The quantity and value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country since the Order Date, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(11) (*OPTIONAL*) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32088 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–184 (Review) and 731–TA–326 (Review)]

Frozen Concentrated Orange Juice From Brazil

AGENCY: United States International Trade Commission.

ACTION: Institution of five-year reviews concerning the suspended countervailing duty investigation and antidumping duty order on frozen concentrated orange juice from Brazil.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. § 1675(c)) (the Act) to determine whether termination of the suspended investigation and/or revocation of the antidumping duty order on frozen concentrated orange juice from Brazil would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be

downloaded from the Commission's World Wide Web site at *http://www.usitc.gov/rules.htm*.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server *(http://www.usitc.gov)*.

SUPPLEMENTARY INFORMATION:

Background

On March 2, 1983, the Department of Commerce suspended a countervailing duty investigation on imports of frozen concentrated orange juice from Brazil (48 F.R. 8839). On May 5, 1987, the Department of Commerce issued an antidumping duty order on imports of frozen concentrated orange juice from Brazil (52 F.R. 16426). The Commission subsequently affirmed its determination in the antidumping investigation in response to a December 30, 1988, remand order of the United States Court of International Trade. The Commission is conducting reviews to determine whether termination of the suspended investigation and/or revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is Brazil.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise*. In its original determination concerning the suspended countervailing duty investigation and in the subsequent review of that determination, the Commission defined the *Domestic Like Product* as frozen concentrated orange juice. In its remand determination concerning the antidumping duty investigation, three members of the Commission defined the *Domestic Like Product* as frozen concentrated orange juice for manufacturing, a highly concentrated form of frozen concentrated orange juice. One member of the Commission found a broader *Domestic Like Product* consisting of frozen concentrated orange juice (encompassing frozen concentrated orange juice for manufacturing, frozen concentrated orange juice for retail, and single strength orange juice). One other like product combination was also found.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product*, or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination concerning the suspended countervailing duty investigation and in the subsequent review of that determination, the Commission defined the *Domestic Industry* as growers of ''round oranges'' and processors of frozen concentrated orange juice. In its remand determination concerning the antidumping duty investigation, three members of the Commission defined the *Domestic Industry* as growers of round oranges and extractors of orange juice that produce frozen concentrated orange juice for manufacturing; specifically excluded from the *Domestic Industry* were reconstitutors. One member of the Commission defined the *Domestic Industry* as growers and processors, including reconstituting operations of integrated producers. One other domestic industry definition was also used.

(5) The *Order Dates* are the dates that the countervailing duty investigation was suspended and the antidumping duty order under review became effective. In these reviews, the *Order Date* for the suspended countervailing duty investigation is March 2, 1983, and the *Order Date* for the antidumping duty investigation is May 5, 1987.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the Reviews and Public Service List

Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. § 1677(9), who are parties to the reviews. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these reviews must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The

deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the reviews you do not need to serve your response).

Inability to Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determinations in the reviews.

Information To Be Provided in Resonse to This Notice of Institution

Please provide the requested information for each of the products defined by Commerce as *Subject Merchandise*, and provide separate information for each of the two specific definitions of like product, as defined by the Commission in its original determinations: (1) Frozen concentrated orange juice for manufacturing and (2) frozen concentrated orange juice. Information should also be provided separately for the two domestic industries corresponding to each of the like product definitions. As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product*, a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise*, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in these reviews by providing information requested by the Commission.

(4) A statement of the likely effects of the termination of the suspended countervailing duty investigation and revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. § 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry*.

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product*. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. § 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since 1982.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in thousands of gallons and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of gallons and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of gallons and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm's(s') production; and

(b) the quantity and value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country since the Order Dates, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of

production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32085 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–776 (Final)]

Certain Preserved Mushrooms from Chile

Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is materially injured by reason of imports from Chile of certain preserved mushrooms, provided for in subheadings 0711.90.40 and 2003.10.00 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

Background

The Commission instituted this investigation effective January 6, 1998, following receipt of a petition filed with the Commission and the Department of Commerce by the Coalition for Fair Preserved Mushroom Trade and its members: L.K. Bowman, Inc., Nottingham, PA; Modern Mushroom Farms, Inc., Toughkenamon, PA; Monterey Mushrooms, Inc., Watsonville, CA; Mount Laurel Canning Corp., Temple, PA; Mushroom Canning Co., Kennett Square, PA; Sunny Dell Foods, Inc., Oxford, PA; and United Canning Corp., North Lima, OH.[2] The final phase of the investigation was scheduled by the Commission following notification of a preliminary determination by the Department of Commerce that imports of certain preserved mushrooms from Chile were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of August 19, 1998 (63 FR 44470). The hearing was held in Washington, DC, on October 15, 1998, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on November 25, 1998. The views of the Commission are contained in USITC Publication 3144 (November 1998), entitled Certain Preserved Mushrooms from Chile: Investigation No. 731–TA–776 (Final).

Issued: November 27, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32092 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–196 (Review)]

Red Raspberries From Canada

AGENCY: United States International Trade Commission.

ACTION: Institution of a five-year review concerning the antidumping duty order on red raspberries from Canada.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act) to determine whether revocation of the antidumping duty order on red raspberries from Canada would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On June 24, 1985, the Department of Commerce issued an antidumping duty order on imports of red raspberries from Canada (50 FR 26019). The Commission is conducting a review to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to this review:

(1) Subject Merchandise is the class or kind of merchandise that is within the

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] On March 9, 1998, the Commission received notice that Southwood Farms, Hockessin, DE, had joined the petitioning coalition.

scope of the five-year review, as defined by the Department of Commerce.

(2) The Subject Country in this review is Canada.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determination, the Commission defined the Domestic Like Product as red raspberries packed in bulk containers, excluding all other types of berries, fresh-market red raspberries, and retail/institutional packed berries.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the Domestic Industry as growers and packers of red raspberries packed in bulk. One Commissioner defined the Domestic Industry differently.

(5) The Order Date is the date that the antidumping duty order under review became effective. In this review, the Order Date is June 24, 1985.

(6) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the review and public service list

Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service list

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this review available to authorized applicants under the APO issued in the review, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the review. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this review must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the review you do not need to serve your response).

Inability To Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determination in the review.

Information To Be Provided In Response To This Notice o f Institution

As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this review by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s') production; and

(b) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm's(s') imports; and

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report quantity data in thousands of pounds and value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm's(s'') production; and

(b) the quantity and value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country since the Order Date, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32087 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–781–786 (Final)]

Stainless Steel Round Wire From Canada, India, Japan, the Republic of Korea, Spain, and Taiwan

AGENCY: International Trade Commission.

ACTION: Scheduling of the final phase of antidumping investigations.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigations Nos. 731–TA–781–786 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from Canada, India, Japan, the Republic of Korea (Korea), Spain, and Taiwan of stainless steel round wire.[1]

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: November 16, 1998.

FOR FURTHER INFORMATION CONTACT: Diane J. Mazur (202–205–3184), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting

[1] For purposes of these investigations, Commerce has defined the subject stainless steel round wire (SSRW) as ''any cold-formed (*i.e.*, cold-drawn, cold-rolled) stainless steel product of a cylindrical contour, sold in coils or spools, and not over 0.703 inch (18 mm) in maximum solid cross-sectional dimension. SSRW is made of iron-based alloys containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. Metallic coatings, such as nickel and copper coatings, may be applied.'' (See Preliminary Determinations of Sales at Less Than Fair Value and Postponement of Final Determinations—Stainless Steel Round Wire from Canada, India, Japan, Spain, and Taiwan; Preliminary Determination of Sales at Not Less Than Fair Value and Postponement of Final Determination—Stainless Steel Round Wire from Korea; 63 FR 64043, Nov. 18, 1998.)

These products, if imported are currently covered by statistical reporting numbers 7223.00.1015, 7223.00.1030, 7223.00.1045, 7223.00.1060, and 7223.00.1075 of the Harmonized Tariff Schedule of the United States (HTS). Although the HTS statistical reporting numbers are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

The final phase of these investigations is being scheduled as a result of affirmative preliminary determinations by the Department of Commerce that imports of stainless steel round wire from Canada, India, Japan, Spain, and Taiwan are being sold in the United States at less than fair value (LTFV)[2] within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in a petition filed on March 27, 1998, by ACS Industries, Inc., Woonsocket, RI; Al Tech Specialty Steel Corp., Dunkirk, NY; Branford Wire & Manufacturing Co., Mountain Home, NC; Carpenter Technology Corp., Reading, PA; Handy & Harman Specialty Wire Group, Cockeysville, MD; Industrial Alloys, Inc., Pomona, CA; Loos & Co., Inc., Pomfret, CT; Sandvik Steel Co., Clarks Summit, PA; Sumiden Wire Products Corp., Dickson, TN; and Techalloy Co., Inc., Mahwah, NJ.

Participation in the Investigations and Public Service List.

Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

[2]Commerce has made a preliminary determination of sales at not LTFV with respect to the subject imports from Korea. Pending Commerce's final determination of sales at LTFV, the final phase of the Commission's antidumping investigation with respect to Korea is also being scheduled, for purposes of efficiency.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List.

Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.

The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on March 25, 1999, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.

The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on April 6, 1999, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before March 31, 1999. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on April 2, 1999, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written Submissions

Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is April 1, 1999. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is April 13, 1999; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations on or before April 13, 1999. On May 3, 1999, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before May 5, 1999, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

Issued: November 24, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32094 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 701–TA–C (Review) and (Investigation No. 701–TA–D (Review)]

Textiles and Textile Products From Colombia and Certain Textile Mill Products from Thailand

AGENCY: United States International Trade Commission.

ACTION: Institution of five-year reviews concerning the suspended countervailing duty investigations on textiles and textile products from Colombia and certain textile mill products from Thailand.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. § 1675(c)) (the Act) to determine whether termination of the suspended investigations on textiles and textile products from Colombia and certain textile mill products from Thailand would be likely to lead to continuation or recurrence of material injury. Pursuant to section 751(c)(2) of the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; the deadline for responses is January 20, 1999. Comments on the adequacy of responses may be filed with the Commission by February 12, 1999.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193) or Vera Libeau (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

On March 12, 1985, the Department of Commerce suspended countervailing duty investigations on imports of textiles and textile products from Colombia and certain textile mill products from Thailand (50 FR 9832 and 9863). The Commission is conducting reviews to determine whether termination of the suspended investigations would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Definitions

The following definitions apply to these reviews:

(1) Subject Merchandise is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The Subject Countries in these reviews are Colombia and Thailand.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. There were no Commission determinations concerning textiles and textile products from Colombia and certain textile mill products from Thailand. Therefore, for purposes of this notice, you should consider the Domestic Like Product to be co-extensive with the Subject Merchandise described in Commerce's scope of the five-year reviews.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. For purposes of this notice, you should consider the Domestic Industry to be producers of the Domestic Like Product.

(5) The Order Date is the date that the investigations were suspended. In these reviews, the Order Date is March 12, 1985.

(6) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the Reviews and Public Service List

Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and APO Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. § 1677(9), who are parties to the reviews. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification

Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these reviews must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written Submissions

Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is January 20, 1999. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is February 12, 1999. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the

Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the reviews you do not need to serve your response).

Inability to Provide Requested Information

Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act in making its determinations in the reviews.

Information To Be Provided in Response To This Notice of Institution

Please provide the requested information separately for each of the products identified by Commerce as Subject Merchandise. If you are a domestic producer, union/worker group, or trade/business association; import/export Subject Merchandise from more than one Subject Country; or produce Subject Merchandise in more than one Subject Country, you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent Subject Country. As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address if available) and name, telephone number, fax number, and E-mail address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in these reviews by providing information requested by the Commission.

(4) A statement of the likely effects of the termination of the suspended investigations on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. § 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. § 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Countries that currently export or have exported Subject Merchandise to the United States or other countries since 1984.

(7) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm's operations on that product during calendar year 1997 (report value data in thousands of U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm's(s'') production; and (b) the value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s).

(8) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Countries, provide the following information on your firm's(s'') operations on that product during calendar year 1997 (report value data in thousands of U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Countries accounted for by your firm's(s') imports; and

(b) the value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Countries.

(9) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Countries, provide the following information on your firm's(s') operations on that product during calendar year 1997 (report value data in thousands of U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Countries accounted for by your firm's(s') production; and

(b) the value of your firm's(s') exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Countries accounted for by your firm's(s') exports.

(10) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Countries since the Order Date, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise

produced in the Subject Countries, and such merchandise from other countries.

(11) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

AUTHORITY: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32083 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–412]

Certain Video Graphics Display Controllers and Products Containing Same; Notice of Commission Determination Not To Review Initial Determination Granting Motion To Amend Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination granting the complainant's motion to amend the complaint and notice of investigation by adding allegations of infringement of additional patent claims.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205–3107.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in § 210.42 of the Commission's rules of practice and procedure (19 CFR 210.42).

The Commission instituted the above-captioned investigation on July 27, 1998, based on a complaint by Cirrus Logic, Inc. (''Cirrus'') alleging that ATI Technologies Inc. (''ATI'') violated section 337 of the Tariff Act of 1930, as amended, 19 U.S.C.1337, by importing, selling for importation, or selling in the United States after importation certain video graphics display controllers that infringe claims 37 and 43 of Cirrus' U.S. Letters Patent 5,598,525 (''the 525 patent''). On October 14, 1998, Cirrus filed a motion pursuant to Commission rule 210.14(b), 19 CFR 210.14(b), to amend the complaint and notice of investigation to add allegations of infringement of claims 1–10, 12–21, and 23–24 of its ''525 patent.

On October 29, 1998, the presiding administrative law judge (''ALJ'') issued an initial determination (''ID'') (Order No. 14) granting Cirrus'' motion to amend the complaint and notice of investigation. The ALJ found that good cause existed for the amendment, and that such amendment would not prejudice the public interest or the rights of the parties. None of the parties petitioned to review the ALJ's ID.

The Commission determined not to review, and thereby to adopt, the ALJ's initial determination. Copies of the ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov).

Issued: November 25, 1998.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–32095 Filed 12–1–98; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Amendment Pursuant to CERCLA

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on November 5, 1998, a proposed First Amendment to Consent Decree in *United States* v. *Beazer East, Inc.*, (S.D. TX.) (Civil No. H–90–2406), was lodged with the U.S. District Court for the Southern District of Texas, pursuant to Sections 106 and 107 of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. §§ 9606 and 9607. The proposed First Amendment to Consent Decree provides for a change in the remedy selected by the U.S. Environmental Protection Agency, (''EPA'') for the South Calvacade Site (the ''Site''). On March 14, 1991, the Court entered the original Consent Decree in this case under which Beazer East, Inc. (''Beazer'') agreed to reimburse response costs incurred by EPA in connection with the Site, located in northeast Houston, Texas, and to implement the final plan for remedial action selected by EPA, embodied in the Record of Decision (''ROD''). The original ROD called for excavation and ''washing'' of contaminated soils. In June 1997, EPA amended the ROD as it pertains to the soil portion of the remedy, and selected instead a reinforced concrete cap to be constructed over contaminated soils at the Site. The groundwater portion of the remedy, which calls for activated carbon adsorption, remains unchanged. The proposed First Amendment to Consent Decree incorporates by reference EPA's Amended ROD.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments concerning the proposed First Amendment to Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, U.S. Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Beazer East, Inc.*, D.J. ref. 90–11–2–535.

The proposed First Amendment to Consent Decree may be examined at the Office of the United States Attorney for the Southern District of Texas, 515 Rusk Street, 5th Floor, Houston, Texas 77002 and at the Consent Decree Library, 1120 G Street, N.W., 3rd Floor, Washington, D.C. 20005. A copy of the proposed First Amendment to Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., Washington, D.C. 20005. In requesting a copy, please enclose a check in the amount of $20.75 ($0.25 per page for reproduction costs) payable to: Consent Decree Library.

Joel Gross,

Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 98–32031 Filed 12–1–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Extension of Comment Period on Consent Decree Under the Resource Conservation and Recovery Act of 1976 (RCRA) as Amended, 42 U.S.C. § 6928

Under 28 CFR 50.7, notice is hereby given that notice and comment period for the proposed Consent Decree lodged on October 16, 1998 with the United States District Court for the District of Idaho in *United States* v. *FMC Corporation, Inc.,* Civil Action No. 98–0406–I–BLW, is being extended through December 18, 1998. The original notice of this proposed settlement was published in the **Federal Register** on November 2, 1998, Vol. 63, No. 211, Pg. 58769. Informational meetings about the settlement and the Consent Decree will be conducted by the Department of Justice and the Environmental Protection Agency in Pocatello at Cavanaugh's Quality Inn, 1555 Pocatello Creek Rd., from 4:00 to 8:00 p.m., on November 30, 1998, and on the Shoshone-Bannock Fort Hall Reservation, Housing Authority Conference Room, 161 Wardance Circle, from 4:00 to 8:00 p.m. on December 1, 1998.

Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States.* v. *FMC Corporation,* D.J. Ref. 90–7–1–889.

The Consent Decree may be examined at the Office of the United States Attorney, 877 W. Main Street, Suite 201, Boise, Idaho 83702, at U.S. EPA Region 10, 1200 Sixth Avenue, ORC–158, Seattle, Washington 98101, the Idaho State University Library, Government Documents Department, 850 South 9th Avenue, Pocatello, Idaho 83209, and at the Consent Decree Library, 1120 G Street, N.W., 3rd Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 3rd Floor, Washington, D.C. 20005. In requesting a copy, please enclose a check in the amount of $12.50 (25 cents per page reproduction cost), with attachments a check in the amount of $20.75, payable to the Consent Decree Library.

Bruce Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–32033 Filed 12–1–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Two Consent Decrees Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that two proposed consent decrees in *United States, et al.* v. *Montrose Chemical Corporation of California, et al.,* No. CV 90–3122–AAH (C.D. Cal), were lodged on November 16, 1998 with the United States District Court for the Central District of California. The consent decrees resolve claims under Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9607, as amended, brought against defendant CBS Corporation (formerly Westinghouse Electric Corporation) and against Potlatch Corporation and Simpson Paper Company, for natural resource damages associated with contamination of sediments on the Palos Verdes shelf in the vicinity of Los Angeles, California, and for response costs incurred and to be incurred by the United States Environmental Protection Agency in connection with responding to the release and threatened release of hazardous substances at the Montrose Chemical National Priorities List Site in Torrance, CA, and at the aforementioned Palos Verdes shelf.

One proposed consent decree provides that CBS will pay $9.5 million to resolve its liability to the United States and State of California for natural resource damages and response costs as described above. The second proposed consent decree provides that Potlatch and Simpson will pay $12 million to resolve their liability to the United States and State of California for natural resource damages and response costs as described above. Both proposed consent decrees include a covenant not to sue by the United States under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9606 and 9607, and under Section 7003 of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6973.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decrees. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States, et al.* v. *Montrose Chemical Corporation of California, et al.,* No. CV 90–3122–AAH (C.D. Cal), DOJ Ref. #90–11–3–159 and DOJ Ref. #90–11–3–511.

The proposed consent decrees may be examined at the office of the United States Attorney, Central District of California, Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012; the Region IX Office of the Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105; and at the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005, (202) 624–0892. A copy of either proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. In requesting copies please refer to the referenced case and enclose a check in the amount of $67.00 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–32030 Filed 12–1–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Judgment Pursuant to the Clean Water Act

Notice is hereby given that a proposed Consent Judgment in *Reichelt* v. *United States Army Corps of Engineers,* No. 2:93 CV 332 AR (N.D. Ind.), was lodged with the United States District Court for the Northern District of Indiana, Hammond Division, on October 30, 1998. The proposed Consent Judgment concerns alleged violations of sections 301(a) and 404 of the Clean Water Act, 33 U.S.C. 1311(a) & 1344, resulting from the unauthorized filling and ditching of approximately 7 acres of wetlands, with impacts to all wetlands on the entire 18-acre tract, in the Town of Schererville, Lake County, Indiana.

The proposed Consent Judgment would provide for the payment of a $61,360.00 civil penalty within thirty (30) days of entry of judgment; full restoration of the site; and forfeiture of the entire 18-acre tract to the State of Indiana, Department of Natural Resources, within thirty (30) days of completion of the restoration. The required restoration is to consist of, among other things, removal, transport,

and disposal of the fill known as ''black beauty'' in accordance with all applicable federal, state, and local requirements, and regrading, replanting, monitoring, and maintenance of the restored wetlands.

The United States Department of Justice will receive written comments relating to the proposed Consent Judgment for a period of thirty (30) days from the date of publication of this notice. Comments should be addressed to David A. Carson, Environment & Natural Resources Division, U.S. Department of Justice, Suite 945—North Tower, 999 18th Street, Denver, Colorado 80202, and should refer to *Reichelt* v. *United States Army Corps of Engineers,* No. 2:93 CV 332 AR (N.D. Ind.), DJ #90–5–1–6–560.

The proposed Consent Judgment may be examined at the Clerk's Office, United States District Court for the Northern District of Indiana, Hammond Division, 507 State Street, Hammond, Indiana 46320.

Letitia J. Grishaw,

Chief, Environmental Defense Section, Environment and Natural Resources Division, United States Department of Justice.

[FR Doc. 98–32029 Filed 12–1–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to Comprehensive Environmental Response, Compensation, and Liability Act and Resource Conservation and Recovery Act

Notice is hereby given that on November 17, 1998, a proposed Material Modification of Consent Decree and Final Order Between United States of America; State of Missouri; Syntex Corporation; Syntex (U.S.A.) Inc.; Syntex Laboratories, Inc.; and Syntex Agribusiness, Inc. To Address LeMar Drive and McDonnell Park Sites (the Material Modification) was lodged with the United States District Court for the Eastern District of Missouri in *United States* v. *Russell Martin Bliss, et al.* (the *Missouri Dioxin Litigation*), Civil Action No. 84–200C–1 (Consolidated).

The Material Modification amends the Consent Decree, entered by the Court on December 31, 1990, between the United States, the State of Missouri and the Syntex defendants under, *inter alia,* Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606 and 9607, and Section 7003 of the Resource, Conservation and Recovery Act (RCRA), 42 U.S.C. 6973, pursuant to which 28 eastern Missouri dioxin-contaminated sites were remediated and the wastes incinerated at the twenty-eighth site, Times Beach, Missouri. After the satisfactory completion of the work pursuant to that settlement, the incinerator was removed and Times Beach was rededicated as Route 66 State Park. The Material Modification resolves similar potential claims in connection with two subsequently-discovered dioxin sites in St. Louis County, Missouri, the LeMar Drive Site in Ellisville, Missouri and the McDonnell Park Site near St. Ann, Missouri. Pursuant to the proposed settlement, EPA will excavate dioxin-contaminated materials and restore the Sites and the Syntex defendants will contract to incinerate the dioxin-contaminated materials at a commercial facility operated by Safety-Kleen Services, Inc. in Coffeyville, Kansas, which is permitted to incinerate dioxin, and properly dispose of the ash.

For thirty (30) days following this publication, the Department of Justice will receive comments relating to the proposed Material Modification. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Russell Martin Bliss, et al.* (the *Missouri Dioxin Litigation*), Civil Action No. 84–200C–1 (Consolidated), DOJ No. 90–11–2–41H. Also, pursuant to Section 7003(d) of RCRA, 42 U.S.C. 6973(d), opportunity for a public meeting on the proposed settlement in the affected area shall be afforded if requested.

The proposed Material Modification may be examined at the Office of the United States Attorney, Eastern District of Missouri, United States Court and Custom House, 1114 Market Street—Room 401, St. Louis, Missouri 63101. The Material Modification may also be examined at, or a copy obtained in person or by mail from, the United States Department of Justice Consent Decree Library, 1120 G Street, NW—3d Floor, Washington, DC 20005.

In requesting a copy, please enclose a check in the amount of $31.00 (25 cents per page reproduction cost).

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–32032 Filed 12–1–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Administration and Management

Agency Information Collection Activities: Proposed Collection; Comment Request; Applicant Background Questionnaire

AGENCY: Office of the Assistant Secretary for Administration and Management (OASAM), Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Department of Labor is soliciting comments concerning the proposed revision of the ''Applicant Background Questionnaire''.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before February 1, 1999.

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

ADDRESSES: Anderson Glasgow, U.S. Department of Labor, Human Resource Services Center, 200 Constitution Ave. N.W. Room C–5516, Washington, D.C. 20210; Phone: (202) 219–6555 ext. 115; Written comments limited to 10 pages or fewer may also be transmitted by facsimile to: (202) 219–5820; Internet: glasgow-william@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its obligation to provide equal employment opportunities, is charged with ensuring that qualified individuals in groups that are underrepresented in various occupations, are included in applicant pools for the Department's positions. See 5 U.S.C. 7201(c); 29 U.S.c. 791; 29 U.S.C. 2000e–16; 5 C.F.R. 720.204; 29 C.F.R. 1614.101(a). to achieve this goal, DOL employment offices have conducted targeted outreach to a variety of sources, including educational institutions, professional organizations, newspapers and magazines. DOL has also participated in career fairs and conferences that reach high concentrations of Hispanics, African Americans, Native Americans, Asians, and persons with disabilities.

Without the data provided by this collection, DOL does not have the ability to evaluate the effectiveness of any of these targeted recruiting strategies because collection of racial and national origin information only occurs at the point of hiring. DOL needs to collect data on the pools of applicants which result from the various targeted recruitment strategies listed above. After the certification and selection process has been completed, it is necessary to cross-reference the data collected with the outcome of the qualifications review in order to evaluate the quality of applicants from various recruitment sources. With the information from this collection, DOL can adjust and redirect its targeted recruitment to achieve the best result. DOL will also be able to respond to requests for information received from the Office of Personnel management (OPM) in the course of OPM's evaluation and oversight activities.

II. Current Actions

This notice requests an extension of the current Office of Management and Budget approval of the Applicant Background Questionnaire and revision of the Questionnaire form. Extension is necessary to coninue to evaluate the effectiveness of agency recruitment programs in attracting applicants from underrepresented sectors of the population. The revision consists of adding a question concerning whether the respondent has a targeted disabilities, and deleting the request for the respondent to provide his or her Social Security Number.

Type of Review: Revision of a currently approved collection.

Agency: U.S. Department of Labor.

Title: Applicant Background Questionnaire.

OMB Number: 1225-0072.

Affected Public: Applicants for positions recruited in the Department of Labor.

Total Respondents: 3000 per year (estimate).

Frequency: one time per respondent.

Total Responses: 3000 per year (estimate).

Average Time per Response: 5 minutes.

Estimated Total Burden Hours: 250 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Date: November 25, 1998.

Tali R. Stepp,

Director of Human Resources.

[FR Doc. 98–32075 Filed 12–1–98; 8:45 am]

BILLING CODE 6510–23–M

DEPARTMENT OF LABOR

Office of the Secretary

Delegation of Secretary of Labor's Authority and Assignment of Responsibilies Under Certain Sections of the National Defense Authorization Act for Fiscal Years 1993 and 1998 to the Assistance Secretary for Employment and Training

On November 12th, 1998, the Secretary of Labor issued a memorandum to the Assistant Secretary for Employment and Training delegating all authority and assigning all responsibilities of the Secretary of Labor under the National Defense Authorization Act for Fiscal Year 1993, Pub. L. 102-484, § 3161, 42 U.S.C. 7274h, and the National Defense Authorization Act for Fiscal Year 1998, Pub. L. 105-85, § 3153(e), 111 Stat. 1629, 2043 (1997) to the Assistant Secretary for Employment and Training. A copy of that memorandum is annexed hereto as and Appendix.

FOR FURTHER INFORMATION CONTACT: Douglas Holl, U.S. Department of Labor, Employment and Training Administration, at (202) 219-5577, ext. 115.

Signed in Washington, DC this 12th day of November, 1998.

Alexis M. Herman,

Secretary of Labor.

U.S. Department of Labor

Secretary of Labor, Washington, D.C.

November 12, 1998.

Memorandum for: Raymond Bramucci, Assistant Secretary for Employment and Training

From: Alexis M. Herman

Subject: Specific Delegation of Authority to the Assistant Secretary for Employment and Training

Effective immediately, the Assistant Secretary for Employment and Training is hereby delegated all authority and assigned all responsibilities of the Secretary of Labor under the National Defense Authorization Act for Fiscal Year 1993, Pub. L. 102-484, § 3161, 42 U.S.C. 7274h, and the National Defense Authorization Act for Fiscal Year 1998, Pub. L. 105-85, § 3153 (e), 111 Stat. 1629, 2043 (1997). This authority and responsibility may be redelegated.

[FR Doc. 98–32074 Filed 12–1–98; 8:45 am]

BILLING CODE 4510–23–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on the Records of Congress. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives in the Office of Records Services.

DATES: December 17, 1998, from 10:00 a.m. to 11:30 a.m.

ADDRESSES: United States Capitol Building, Room H–130.

FOR FURTHER INFORMATION CONTACT: Michael L. Gillette, Director, Center for Legislative Archives, (202) 501–5350.

SUPPLEMENTARY INFORMATION:

Agenda

Archives I Renovation

Update—Legislative Information Systems
Electronic Access—House Journals, Biographical Directory of Congress
Update—Center for Legislative Archives
Other current issues and new business

The meeting is open to the public.

Dated: November 25, 1998.

John W. Carlin,

Archivist of the United States.

[FR Doc. 98–32068 Filed 12–1–98; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Proposed Information Collection Requests

AGENCY: National Science Foundation.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Reports Clearance Officer invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507(j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by December 30, 1998. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before January 30, 1999.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer: National Science Foundation, Office of Management and Budget; 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or should be electronically mailed to the Internet address splimpto@nsf.gov.

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton, 703–306–1125, x 2017. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Reports Clearance Officer publishes this notice containing proposed information collection requests at the beginning of the Foundation's review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. NSF invites public comment at the address specified above. Copies of the requests are available from Suzanne Plimpton at the address specified above.

Type of Review: New.

Title: Survey of 1996 and 1997 Research and Development Funding and Performance by Nonprofit Organizations; OMB Control Number 3145–0170.

Abstract: OMB clearance for the NSF Survey of Research and Development Funding and Performance by Nonprofit Organizations (NPOs) expired June 30, 1998. The proposed information clearance request is for an extension of the time period for the survey that is now in the field. The survey collects information on the science and engineering (S&E) research and development (R&D) activities of nonprofit organizations in 1996 and 1997. A prior study with similar objectives was conducted in 1973. The purposes of the study are to: (1) develop estimates of the amounts of R&D funding provided by NPOs and the types of organizations supported; (2) develop estimates of the amount of R&D performed by NPOs; and (3) develop estimates of R&D researchers' employment in NPOs.

Expected Respondents: Respondents are nonprofit organizations (NPOs) that funded and/or performed science and engineering research and development in 1996. It will be a mail survey with telephone follow-up as necessary.

NSF is proposing the time extension of one form (Form 1400, the screening survey); the change in format of one form (Form 1402, the Funders survey form); and the reduction in the number of questions in one form (Form 1401, the Performers survey form).

As the table below shows, 2,432 respondents will be asked to complete the qualifying screening survey Form 1400. If they are eligible to participate in the survey, they will also receive either a Form 1401 Performer survey or a Form 1402 Funder survey. Some NPOs have already responded to the Form 1400 (screener) and the 705 eligible organizations will be sent either a Form 1401 or 1402.

Since the answers on the Form 1400 (screener) will determine whether newly contacted organizations will receive the Performer or Funder survey form, we are estimating the number that will be eligible based on the percentage of NPOs that reported themselves eligible in the March 31, 1998 screener mailing. The estimate for the Funders Form 1402 is 245 organizations; the estimate for the Performers Form 1401 is 815 organizations. These figures include both the NPOs that we estimate will be eligible in the next screener mailing and the NPOs that responded after June 30, 1998 to the March 31, 1998 screener (606 Performers 99 Funders).

Additional Information: NSF is requesting emergency clearance for the Survey of Research and Development Funding and Performance by Nonprofit Organizations due to unanticipated poor response to the mailings in March 1998 and June 1998. The universe of possible R&D funders and performers is much larger than we first anticipated. Our initial screening mail-out went to 8,771 organizations; 316 additional funders were selected in the sample but accidentally left off the mailing list. Many of the 5,548 NPOs that we have successfully contacted have either not been involved in R&D or have not met the minimum $250,000 requirement. We used more time than expected locating and contacting small organizations, which often are transient or short-lived. Our plan to use the Employer Identification Number as a unique key to nonprofit organizations was flawed. Many NPOs had more than one EIN and we were unable to determine by EIN codes whether research institutes were independent and in-scope, or part of universities and out-of-scope. We also experienced technical problems. Performers complained about the length of time needed to complete the survey so we have scaled it down substantially. Slowness of the Website also

discouraged some would-be respondents.

Need for data. Failure to continue and complete this survey will result in the U.S. Government continuing to use 1973 data in estimating the nonprofit sector's R&D and the national totals of R&D funding and performance. A complete accurate description of R&D funding and performance is necessary for policymakers for planning, reporting, and tax purposes. Considerable work in drawing the sample has already been completed and $546,000 has been spent. The most efficient and cost effective way for the U.S. Government to obtain the needed data is to complete this survey. Therefore, we are asking that emergency clearance be granted by December 30, 1998 so that we can mail out the survey forms, complete the survey and publish the report in a timely manner.

Burden on the Public. The Foundation estimates that a total annual reporting and recordkeeping burden of 3,441 hours will result from the collection of information. The calculation is:

2,432 NPOs (1,030 Funders+1,402 Performers)×1 screening survey Form 1400× 12.5 minutes=506 hours
815 Performers×1 revised Form 1401×3 hours=2,445 hours
245 Funders×1 reformatted Form 1402×2 hours=490 hours
Total=3,441 hours

Frequency: One-time survey; second form only to eligible Not-for-profit institutions.

Affected Public: Not-for-profit institutions.

Dated: November 25, 1998.

Suzanne Plimpton,

Reports Clearance Officer,

National Science Foundation.

[FR Doc. 98–32028 Filed 12–1–98; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–648]

Umetco Minerals Corp.

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of Receipt of License Amendment Application; Notice of Opportunity for Hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has been asked to amend NRC Source Material License SUA–648 to authorize the licensee, Umetco Minerals Corporation (Umetco), to reclaim the A–9 Repository, located in Natrona County, Wyoming, according to the 1987 Reclamation Plan, as amended by the submittal dated October 27, 1998. This license currently authorizes Umetco to receive, acquire, possess, and transfer uranium at the Umetco East Gas Hills site, which is located approximately 50 miles (80 kilometers) southeast of the town of Riverton, Wyoming.

FOR FURTHER INFORMATION CONTACT: Ms. Elaine Brummett, Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T7-J9, Washington, DC 20555. Telephone (301) 415–6606.

SUPPLEMENTARY INFORMATION:

Background

The Umetco Mineral Corporation (Umetco) site is licensed by the U.S. Nuclear Regulatory Commission (NRC) under Materials License SUA–648 to possess byproduct material in the form of uranium waste tailings, as well as other radioactive wastes generated by past milling operations. The mill has been dismantled and the A–9 Repository contains uranium mills tailings and mill debris. This former mine pit currently has an interim soil cover. The previously approved 1987 reclamation plan for the A–9 Repository calls for the final cover to be composited of 1 foot of clay, 1 foot of filter material, and 7.5 feet of overburden soil, with the top of the cover seeded. Umetco submitted a design enhancement for the A–9 Repository by letter dated October 27, 1998. The changes to the 1987 design are: (1) Replace the vegetated cover surface with rip rap to improve the erosion protection aspects of the cover; (2) reclamation of the adjacent North and South Evaporation Ponds by placing their clay liners into the A–9 Repository; and (3) reclamation of the C–18 Mine Pit with backfill. The design also includes the final site grading plan.

Notice of Opportunity for Hearing

The NRC hereby provides notice that this is a proceeding on an application for a licensing action falling within the scope of Subpart L, ''Informal Hearing Procedures for Adjudications in Materials and Operators Licensing Proceedings,'' of the Commission's Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders in 10 CFR part 2 (54 FR 8269). Pursuant to § 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing. In accordance with § 2.1205(c), a request for a hearing must be filed within thirty (30) days from the date of publication of this **Federal Register** notice. The request for a hearing must be filed with the Office of the Secretary either:

(1) By delivery to the Rulemakings and Adjudications Staff of the Office of the Secretary at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(2) By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff.

Each request for a hearing must also be served, by delivering it personally or by mail to:

(1) The applicant, Umetco Mineral Corporation, PO 1029, Grand Junction, CO 81502;

(2) The NRC staff, by delivery to the Executive Director of Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(3) By mail addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

In addition to meeting other applicable requirements of 10 CFR Part 2 of the Commission's regulations, a request for a hearing filed by a person other than an applicant must describe in detail:

(1) The interest of the requestor in the proceeding;

(2) How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(g);

(3) The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and

(4) The circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(c).

Any hearing that is requested and granted will be held in accordance with the Commission's ''Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings'' in 10 CFR part 2, subpart L.

Dated at Rockville, Maryland, this 24th day of November 1998.

For the Nuclear Regulatory Commission,

Joseph J. Holonich,

Chief Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–32111 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–280 and 50–281]

Virginia Electric and Power Co.; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Virginia Electric and Power Company (the licensee) to withdraw its March 21, 1996, application for proposed amendments to Facility Operating License Nos. DPR–32 and DPR–37 for the Surry Power Station, Unit Nos. 1 and 2, located in Surry County, Virginia.

The proposed changes would have clarified the requirements for testing charcoal adsorbent in the Auxiliary Ventilation and Control Room Air Filtration Systems.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on April 10, 1996 (61 FR 15999). However, by letter dated November 23, 1998, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated March 21, 1996, and the licensee's letter dated November 23, 1998, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at The Swem Library, College of William and Mary, Williamsburg, Virginia 23185.

Dated at Rockville, Maryland, this 25th day of November 1998.

For the Nuclear Regulatory Commission.

Gordon E. Edison,

Senior Project Manager, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 98–32116 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–305]

Wisconsin Public Service Co. (Kewaunee Nuclear Power Plant); Exemption

I

The Wisconsin Public Service Company (WPSC, the licensee) is the holder of Facility Operating License No. DPR–43, which authorizes operation of the Kewaunee Nuclear Power Plant. The operating license states, among other things, that the licensee is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (the Commission) now or hereafter in effect.

The Kewaunee Nuclear Power Plant is a pressurized-water reactor facility located at the licensee's site in Kewaunee County, Wisconsin.

II

By letter dated August 6, 1998, WPSC submitted an exemption request to certain requirements in Title 10 of the Code of Federal Regulations, Part 50, Appendix G, ''Fracture Toughness Requirements,'' which invokes ASME, Section XI, Appendix G pressure-temperature limits for reactor pressure vessels (RPVs).

III

The NRC has established requirements in 10 CFR part 50 to protect the integrity of the reactor coolant system pressure boundary. 10 CFR 50.60(a) and 10 CFR part 50, appendix G.IV.2. require (via reference to 10 CFR 50.55a) that pressure-temperature (P–T) limits be established for RPVs during normal operation and vessel hydrostatic testing based on the methodology provided in the 1989 Edition of ASME Section XI, Appendix G. Pursuant to 10 CFR 50.60(b), alternatives to the requirements of 10 CFR part 50, appendix G.IV.2 may be used when an exemption is granted by the Commission. The underlying purpose of 10 CFR 50.60(a) and 10 CFR Part 50, Appendix G, is to establish fracture toughness requirements for the reactor coolant system pressure boundary to provide adequate margins of safety during normal operation, including anticipated operational occurrences and system hydrostatic tests, to which the pressure boundary may be subjected over its service lifetime.

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security, and (2) when special circumstances are present. Special circumstances are present whenever, according to 10 CFR 50.12(a)(2)(ii), ''Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.''

The NRC staff examined WPSC's rationale to support the exemption request and concluded that the use of Code Case N–588 would also meet the underlying intent of the regulations. The licensee's request for the exemption under the special circumstances of 10 CFR 50.12(a)(2)(ii) was found to be appropriate. Application of the regulation is not necessary to achieve the underlying purpose of the rule because, as stated in the staff Safety Evaluation, dated November 25, 1998, adequate margins of safety on the structural integrity of the reactor coolant pressure boundary are maintained with the application of Code Case N–588. Therefore, the NRC staff has concluded that an exemption to the requirements of 10 CFR 50.60 and 10 CFR part 50, appendix G.IV.2 should be granted to allow WPSC to apply the methodology in ASME Code Case N–588 for the purpose of developing P–T limits for the KNPP RPV.

IV

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), an exemption is authorized by law, will not endanger life or property or common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants an exemption from the requirements of 10 CFR 50.60(a) and 10 CFR part 50, appendix G.IV.2 to allow WPSC to apply the methods in ASME Code Case N–588 for the evaluation of KNPP pressure-temperature limits.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (63 FR 65265).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 25th day of November 1998.

For the Nuclear Regulatory Commission.

Frank J. Miraglia,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 98–32112 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Licenses 37–0826–1 and 37–0826–2—Dockets 30–21230 and 30–30666]

ALARON Corp. Northeast Regional Service Facility—Wampum, Pennsylvania: Renewal of Material Licenses; Finding of No Significant Impact and Notice of Opportunity for a Hearing (NUREG/CR–5549)

The U.S. Nuclear Regulatory Commission is considering the renewal of Material Licenses 37–20826–01 and 37–20826–02 for the continued operation of ALARON Corporation, Northeast Regional Service Facility (NRSF), located in Wampum, Pennsylvania.

Summary of the Environmental Assessment

Identification of the Proposed Action

The proposed action is the renewal of ALARON's Material Licenses 37–20826–01 and 37–20826–02 for at least 10 years. With these renewals, the ALARON facility will continue to conduct ongoing operations involving treatment, decontamination, compaction and repackaging services for generators of radioactively contaminated materials. The proposed action would permit ALARON to possess, manage, and treat, under two NRC Material Licenses, 37–20826–01 and 37–20826–02, limited quantities of byproduct or source materials and sealed sources with atomic numbers less than 97, special nuclear materials in the form of fixed or removable contamination, and depleted uranium.

The Need for the Proposed Action

The action is to determine if the licenses should be renewed or denied. ALARON provides treatment, decontamination, compaction and repackaging services for generators of radioactively contaminated materials. Because these services reduce the quantities or volumes of materials that require disposal as waste, generators choose to have their radioactive waste materials treated at the NRSF to reduce the costs of disposal. Denial of the license renewals for ALARON is an alternative available to NRC, but without the services provided by ALARON, contaminated materials would have to be processed at other facilities providing these services or the amount of low level waste (LLW) disposed of at commercial burial sites would have to increase. While terminating the licenses would eliminate the small impacts of facility operation, eliminating or replacing facility capabilities could lead to environmental impacts elsewhere.

Environmental Impacts of the Proposed Action

Because of the limited scope of activities at the NRSF, this environmental assessment (EA) focuses on impacts to air quality, ecological resources, and human health resulting from normal operations and potential accidents. The proposed action would not (1) cause appreciable changes in employment at the site, (2) affect previously undisturbed areas, (3) generate liquid discharges (except storm water runoff) from the facility, (4) expand the developed area of the site, or (5) require major operations outside existing buildings or the surrounding industrial area. For these reasons, no significant impacts on socioeconomic, historic or archaeological resources, water quality, terrestrial ecology, or noise levels would result from the proposed action.

Air Quality Impacts

The NRSF is located in Lawrence County, which is in attainment of National Ambient Air Quality Standards (NAAQS) for all pollutants except ozone. NAAQS exist for sulfur dioxide (SO_2), nitrogen dioxide (NO_2), carbon monoxide (CO), ozone (O_3), lead, and two sizes of respirable particulate matter: particles less than 10 μm in diameter (designated PM–10) and particles less than 2.5 μm in diameter (designated PM–2.5). The NAAQS are expressed as pollutant concentrations that are not to be exceeded in the ambient air—that is, in the outdoor air to which the general public has access. The U.S. Environmental Protection Agency (EPA) has established emissions levels for conformity analysis below which contributions to air pollution are not considered significant, and for which no further regulatory analysis is required. The proposed action would not be expected to increase emissions to the ambient air from process facilities. Air emitted from process facilities is filtered and recycled through the buildings. The licensee anticipates no changes in operations that would affect air-pollutant emissions.

Ozone is formed from complex chemical reactions involving oxides of nitrogen (NO_X), and volatile organic compounds (VOCs) in the presence of sunlight. Ozone pollution is a cumulative impact of many emissions of NO_X and hydrocarbons and all internal combustion engines emit NO_X and VOCs. Because vehicle movements associated with facility operations emit these pollutants, facility operations contribute to the regional ozone problem. Analysis shows that even under very conservative assumptions, NO_X and VOCs emissions associated with NRSF operations are only a small fraction of the limits below which contributions to air pollution are not considered significant. Because vehicle movements associated with operations contribute much less than the quantities EPA considers worthy of analysis for conformity with air quality plans, the facility makes no significant contribution to the region's ozone pollution problem.

Radioactive Emissions

NRSF does not have liquid discharge paths where licensed (radioactive) material may be released to the environment. There are no floor drains in areas where radioactive material containers are opened. Operations involving radioactive liquids are conducted in areas with spill curbs capable of containing the liquid volume of the largest container holding liquids in the area. Because all areas that might have decontamination chemicals are co-located with radioactive materials, there are no liquid sources for impacts to humans from either hazardous chemicals or radioactive materials.

Airborne contaminants are drawn through HEPA filters, and filtered air is discharged back into the buildings. The exhaust of all HEPA filters is monitored continuously. No atmospheric emissions containing radioactive contaminants are expected to be released.

Accident Evaluation

The EA evaluated one accident as the bounding accident: the potential quantities of licensed and nonradiological materials that might be released to the atmosphere in the unlikely event of a major fire at the NRSF facility. The regulatory analysis documented in NUREG–1140 (McGuire 1988), which assessed the accident potential for doses exceeding EPA protective action guides, was used to evaluate potential impacts. The limiting possession quantities of radionuclides specified in 10 CFR 30.72, are derived from the analyses and conclusions in NUREG–1140. Because they are derived from the analyses in NUREG–1140, these possession limits ensure that accidental releases will not exceed the EPA protective action guide 1-rem exposure to downwind individuals. The quantities of radiological materials ALARON is allowed to possess are limited by license conditions that reference Schedule C in 10 CFR 30.72.

The historical quantities of radionuclides at the NRSF have been far below the limiting quantities.

ALARON's operations with licensed material involve use of fluoroboric acid (HBF_4). In the event of an accident, the primary off-site chemical hazard would be from the gaseous boron trifluoride (BF_3) and hydrogen fluoride (HF) that could result from decomposition of the HBF_4. The evaluation of the potential impacts of this nonradiological material was based on a release to the atmosphere using the same accidental fire scenario as for the radiological materials. The results were compared to the EPA's guidance for chemical hazards under its ''Risk Management Plan Rule.'' Because the total inventory of fluoroboric acid at NRSF is less than EPA's recommended threshold amounts, there is no potential for adverse off-site human health impacts in the event of accidents involving this acid at NRSF.

Conclusion

The NRC staff concludes that the environmental impacts associated with the proposed license renewal for continued operation of ALARON Corporation's Wampum, Pennsylvania, Northeast Regional Service Facility are expected to be insignificant.

Finding of No Significant Impact

The Commission has prepared an EA related to the renewal of Material Licenses 37–20826–01 and 37–20826–02. On the basis of the assessment, the Commission has concluded that environmental impacts that would be created by the proposed action would not be significant and do not warrant the preparation of an Environmental Impact Statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

The EA is being made available as NUREG/CR–5549. Copies of NUREG/CR–5549 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, PO Box 37082, Washington, DC 20402–9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555–0001.

Opportunity for a Hearing

Any person whose interest may be affected by the issuance of this renewal may file a request for a hearing. Any request for hearing must be filed with the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the publication of this notice in the **Federal Register**; be served on the NRC staff (Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852), and on the licensee (ALARON Corporation, RD#2, Box 2140A, Wampum, PA 16157); and must comply with the requirements for requesting a hearing set forth in the Commission's regulations, 10 CFR part 2, subpart L, ''Information Hearing Procedures for Adjudications in Materials Licensing Proceedings.''

These requirements, which the request must address in detail, are:

1. The interest of the requestor in the proceeding;
2. How that interest may be affected by the results of the proceeding (including the reasons why the requestor should be permitted a hearing);
3. The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and
4. The circumstances establishing that the request for hearing is timely—that is, filed within 30 days of the date of this notice.

In addressing how the requestor's interest may be affected by the proceeding, the request should describe the nature of the requestor's right under the Atomic Energy Act of 1954, as amended, to be made a party to the proceeding; the nature and extent of the requestor's property, financial, or other (i.e., health, safety) interest in the proceeding; and the possible effect of any order that may be entered in the proceeding upon the requestor's interest.

Dated at Rockville, Maryland, this 17th day of November, 1998.

For the Nuclear Regulatory Commission.

Larry W. Camper,

Chief, Material Safety Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 98–32114 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–305]

Wisconsin Public Service Corp., Wisconsin Power and Light Co., Madison Gas and Electric Co., Kewaunee Nuclear Power Plant; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Operating License DPR–43, issued to Wisconsin Public Service Corporation, Wisconsin Power and Light Company, and Madison Gas and Electric Company (the licensee), for the Kewaunee Nuclear Power Plant located in Kewaunee County, Wisconsin.

Environmental Assessment

Identification of the Proposed Action

The proposed action would revise the reactor core power distribution peaking factor limits and reactor coolant system operating parameters related to the minimum departure from nucleate boiling ratio safety limit. These proposed changes are the result of analyses performed in support of use of new type fuel assemblies. The new fuel assemblies would be operated within these new thermal-hydraulic and power distribution limits with potential fuel assembly burnups to 59 GWD/MTU and maximum rod average burnup limited to 60 GWD/MTU. Another change included in the proposed amendment is the removal, from the current licensing basis, of the fuel pool turbine missile hazards analysis.

The proposed action is in accordance with the licensee's application for amendment dated April 15, 1998, as supplemented by letters dated July 27 and August 13, 1998, by two different letters dated September 28, 1998, and by a letter dated November 24, 1998.

The Need for the Proposed Action

The proposed action is needed in order for the licensee to have the flexibility to use fuel with increased burnup and to revise the plant safety analyses. The changes in operating parameters and limits will allow longer operating cycles and result in fewer fuel assemblies being needed.

Environmental Impacts of the Proposed Action

The staff has completed its evaluation of the proposed action and made the following findings: (1) The mechanical design of the fuel has been evaluated and found acceptable for use within the analyzed limits, (2) although the extended burnup to 60 GWD/MTU may slightly change the mix of radionuclides that might be released in the event of an accident, analyses of radiological consequences of accidents confirm that there is no significant increase in the probability or consequences of accidents, (3) no significant changes would be made in the amounts or types of any radiological effluents that may be released offsite, (4) there is no significant increase in the allowable

individual or cumulative occupational radiation exposure, and (5) the probability of high trajectory turbine missiles impacting the spent fuel pool target area has been found to be so insignificant that the event need not be further considered as a design basis event.

On February 29, 1988 (53 FR 6041), the staff published ''Extended Burnup Fuel Use in Commercial LWR's; Environmental Assessment and Finding of No Significant Impact.'' This generic environmental assessment of extended fuel burnup in light water reactors found that ''no significant adverse effects will be generated by increasing the present batch-average burnup level of 33 GWD/MTU to 50 GWD/MTU or above as long as the maximum rod average burnup level of any fuel rod is no greater than 60 GWD/MTU.'' In addition, the environmental impacts of transportation resulting from the use of higher enrichment fuel and extended irradiation were published and discussed in the staff assessment entitled, ''NRC Assessment of the Environmental Effects of Transportation Resulting from Extended Fuel Enrichment and Irradiation,'' dated July 7, 1988. That assessement was published in connection with an Environmental Assessment related to the Shearon Harris Nuclear Plant, Unit 1, which was published in the **Federal Register** (53 FR 30355) on August 11, 1988, as corrected on August 24, 1988 (53 FR 32322). In these assessments, collectively, the staff concluded that the environmental impacts summarized in Table S–3 of 10 CFR 51.51 and in Table S–4 of 10 CFR 51.52 for a burnup level of 33 GWD/MTU are conservative and bound the corresponding impacts for burnup levels up to 60 GWD/MTU. These findings are applicable to the proposed action at Kewaunee which will limit burnup to 60 GWD/MTU.

With regard to potential non-environmental impacts, the proposed action involves components located entirely within the restricted area as defined by 10 CFR part 20. It does not affect non-radiological plant effluents and has no other environmental impact. The proposed action does not involve any of the historic sites located in the vicinity of Kewaunee as identified in Section II.C of the Kewaunee Final Environmental Statement. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the Commission concludes that there are no significant environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission concluded that there are no significant environmental effects that would result from the proposed action, any other alternative would have greater environmental impacts and need not be evaluated.

The principal alternative would be to deny the requested amendment. This would not reduce the environmental impact of plant operations and would result in reduced operational flexibility.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement which was issued December 20, 1972.

Agencies and Persons Consulted

In accordance with its stated policy, on November 19, 1998, the staff consulted with Sarah Jenkins, an official of the Public Service Commission of the State of Wisconsin, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the staff has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's application dated April 15, 1998, as supplemented by letters dated July 27, August 13, September 28, and November 24, 1998, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW, Washington, D.C., and at the local public document room located at the University of Wisconsin, Cofrin Library, 2420 Nicolet Drive, Green Bay, Wisconsin 54311–7001.

Dated at Rockville, Maryland, this 25th day of November 1998.

For the Nuclear Regulatory Commission.

William O. Long, Sr.

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NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law 97–415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97–415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from November 6, 1998, through November 19, 1998. The last biweekly notice was published on November 18, 1998 (63 FR 64106).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period.

However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administration Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By January 4, 1999, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Duke Energy Corporation (DEC), et al., Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of amendment request: November 11, 1998.

Description of amendment request: The proposed amendments would revise the Technical Specifications (TS) to correct Surveillance Requirements (SRs) 3.6.11.6 and 3.6.11.7 and the associated Bases. These SRs currently are incorrect and do not reflect the Containment Pressure Control System (CPCS) as designed. Therefore, the proposed amendments would only revise the SRs; no change to the CPCS design is involved.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

First Standard

Implementation of this amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated. Approval of this amendment will have no significant effect on accident probabilities or consequences.

The CPCS is not an accident initiating system; therefore, there will be no impact on any accident probabilities by the approval of this amendment. The design of the CPCS is not being modified by this proposed amendment. The amendment merely aligns [TS] surveillance requirements with the existing design and function of the system. Therefore, there will be no impact on any accident consequences.

Second Standard

Implementation of this amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated. No new accident causal mechanisms are created as a result of NRC approval of this amendment request. No changes are being made to the plant which will introduce any new accident causal mechanisms. This amendment request does not impact any plant systems that are accident initiators, since the CPCS is an accident mitigating system.

Third Standard

Implementation of this amendment would not involve a significant reduction in a margin of safety. Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident situation. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The performance of these fission product barriers will not be impacted by implementation of this proposed amendment. The CPCS is already capable of performing as designed. No safety margins will be impacted.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina.

Attorney for licensee: Mr. Paul R. Newton, Legal Department (PB05E), Duke Energy Corporation, 422 South Church Street, Charlotte, North Carolina.

NRC Project Director: Herbert N. Berkow.

Duke Energy Corporation, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of amendment request: October 15, 1998.

Description of amendment request: The proposed amendments would revise the pressure-temperature limits in the Technical Specifications for Units 1, 2, and 3. The proposed amendments would revise the heatup, cooldown, and inservice test limitations for the reactor coolant system of each unit to a maximum of 26 effective full-power years. The proposed amendments would also revise the Technical Specification for low temperature overpressure protection to reflect the revised pressure-temperature limits of the reactor vessels.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

A. Involve a significant increase in the probability or consequences of an accident previously evaluated?

NO.

Each accident analysis addressed in the Oconee UFSAR [Updated Final Safety Analysis Report] has been examined with respect to the changes to the Reactor Pressure Vessel (RPV) pressure-temperature limit curves and related Low Temperature Overpressure settings. The probability of any design basis accident (DBA) is not affected by this change, nor are the consequences of a DBA affected by this change. The revised pressure-temperature limits, which were developed based on NRC approved methodology or ASME Code [American Society of Mechanical Engineers Boiler and Pressure Vessel Code] Case N–514 as described in the Technical Justification, are not considered to be an initiator or contributor to any accident analysis addressed in the Oconee UFSAR. The added requirement to deactivate one pressurizer heater bank during low temperature operation does not significantly change the probability or consequence of any accident previously analyzed. No existing Technical Specification requirements are being deleted with this revision.

B. Create the possibility of a new or different kind of accident from the accident previously evaluated?

NO.

This license amendment revises Oconee RPV pressure-temperature limits. The revised pressure-temperature limits were developed based on NRC approved methodology or ASME Code Case N–514 as described in the Technical Justification. Operation of Oconee in accordance with these proposed new Technial Specifications will not create any failure modes not bounded by previously evaluated accidents. Consequently, this change will not create the possibility of a new or different accident from any accident previously evaluated.

C. Involve a significant reduction in a margin of safety?

NO.

This license amendment revises Oconee RPV pressure-temperature limits. The revised pressure-temperature limits were developed based on NRC approved methodology or ASME Code Case N–514 as described in the Technical Justification. The purpose of this license amendment is to assure that sufficient operating margin to safety is maintained in the operation of the Oconee reactor pressure vessels by establishing new, more limiting pressure-temperature limit curves and adding the requirement to deactivate one pressurizer heater bank. No plant safety limits, set points, or design parameters are adversely affected. The fuel, fuel cladding, and Reactor Coolant System are not impacted. Therefore, there will be no significant reduction in any margin of safety.

Duke [Duke Energy Corporation] has concluded based on this information that there are no significant hazards considerations involved in this amendment request.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

Attorney for licensee: J. Michael McGarry, III, Winston and Strawn, 1200 17th Street, NW., Washington, DC.

NRC Project Director: Herbert N. Berkow. Duquesne Light Company, et al., Docket No. 50–334, Beaver Valley Power Station, Unit No. 1, Shippingport, Pennsylvania

Date of amendment request: November 11, 1998.

Description of amendment request: The proposed amendment would modify License Condition 2.C(9) to allow, on a one time only basis, an extension to the steam generator inspection interval of technical specification surveillance 4.4.5.3.b. This

would allow the steam generator inspection interval to coincide with the 13th refueling outage or the end of 500 effective full power days, whichever occurs sooner.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change is temporary and allows a one time extension of specific surveillance requirements for Cycle 13 to allow surveillance testing to coincide with the 13th (1R13) refueling outage. The proposed surveillance interval extension will not cause a significant reduction in system reliability nor affect the ability of a system to perform its design function. Current monitoring of plant conditions and the surveillance monitoring required during normal plant operation will be performed as usual to assure conformance with technical specification operability requirements.

The technical specification steam generator tube inspection is intended to prevent the Steam Generator Tube Rupture analyzed in [Updated Final Safety Analysis Report] UFSAR Section 14.2.4 by maintenance of the integrity of the primary to secondary coolant boundary represented by steam generator tubes. The process by which this integrity is maintained is inspection of steam generator tubes at prescribed intervals, and the removal of defective tubes from service. Inspection intervals are based on preventing corrosion growth from exceeding tube structural limits, thereby preventing tube failure. The 1997 steam generator inspection characterized existing steam generator tube degradation, and degraded tubes were removed from service at that time. Degradation growth rates were evaluated for the next operating interval and it was determined that the steam generator tube structural integrity is maintained. Degradation of steam generator tubes was prevented during the extended outage by a carefully controlled, corrosion prevention program.

The proposed change does not affect the UFSAR and is consistent with changes granted for other plants. The surveillance extension does not involve a change to plant equipment and does not affect the performance of plant equipment used to mitigate an accident. This change, therefore, does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Extending the surveillance interval for the performance of specific inspections will not create the possibility of any new or different kind of accidents. No change is required to any system configurations, plant equipment or analyses.

Steam generator tube inspections determine tube integrity and provide reasonable assurance that a tube rupture or primary to secondary leak will not occur. Accidents involving steam generator tube rupture are analyzed in UFSAR Section 14.2.4, ''Steam Generator Tube Rupture.'' The only type of accident that can be postulated from extending the steam generator inspection interval would be a tube leak or rupture which are analyzed in the UFSAR. No new failure modes are created by the surveillance extension. Therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

Surveillance interval extensions will not impact any plant safety analyses since the assumptions used will remain unchanged. The safety limits assumed in the accident analyses and the design function of the equipment required to mitigate the consequences of any postulated accidents will not be changed since only the surveillance interval is being extended. Based on engineering judgement, extending the surveillance interval for the performance of these specific inspections does not involve a significant reduction in the margin of safety derived from the required surveillances.

The margin of safety depends upon maintenance of specific operating parameters within design limits. In the case of steam generators, that margin is maintained through assurance of tube integrity as the primary to secondary boundary. Assurance of tube integrity is provided through periodic in-service inspection of tubes and removal of defective tubes from service. Additional margin is provided through protection from possible consequences of steam generator tube failure by mitigation systems. Radiation monitors provide a detection capability of primary to secondary leakage to enable a prompt response. Maintenance of the steam generator water chemistry in accordance with [Electric Power Research Institute] EPRI guidelines provides additional margin of safety. Therefore, the plant will be maintained within the analyzed limits and the proposed extension will not significantly reduce the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, PA 15001.

Attorney for Licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Robert A. Capra

Entergy Operations, Inc., Docket No. 50–368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas

Date of amendment request: June 30, 1998.

Description of amendment request: The proposed change modifies the Engineered Safety Features Actuation System (ESFAS) portion of the Arkansas Nuclear One, Unit-2 (ANO–2) Plant Protection System (PPS). This modification is designed to defeat the backup power supply for the auctioneered power sources for channel A and D Reactor Protective System (RPS) and ESFAS bistables, and to provide selective logic for Emergency Feedwater Actuation Signals and Main Steam Isolation Signals. This will ensure that ESFAS will have the redundancy and independence sufficient to assure that (1) no single failure results in loss of the protection function with a channel in indefinite bypass, and (2) removal from service of any component or channel does not result in loss of the required minimum redundancy required by the ANO–2 Technical Specifications (TSs). The proposed modification to the ANO–2 PPS has been determined to involve an Unreviewed Safety Question in accordance with 10 CFR 50.59(a)(2).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

An evaluation of the proposed change has been performed in accordance with 10 CFR 50.91(a)(1) regarding no significant hazards considerations using the standards in 10 CFR 50.92(c). A discussion of these standards as they relate to this amendment request follows:

Criterion 1—Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The ANO–2 Plant Protection System (PPS) includes the electrical and mechanical devices and circuitry (from sensors to actuation device input terminals) involved in generating signals associated with the two protective functions, Engineered Safety Feature Actuation System (ESFAS) and Reactor Protective System (RPS). The RPS is that portion of the PPS which generates signals that actuate a reactor trip. The ESFAS is that portion of the PPS which generates signals that actuate Engineered Safety Features (ESF) to mitigate the consequences of an accident.

The ANO–2 Safety Analysis Report (SAR) section 15.1.31 ''Loss Of One DC System'' analyzes failure of a DC bus (FODCB) as initiator and its causes. The causes for the FODCB are DC leg to leg fault in the bus or in the power distribution circuit from the battery. Since the proposed change has no impact on the accident initiator, the frequency of occurrence is not changed. In order for the FODCB as a single failure with an accident to de-energize two [Vital Instrument Buses (]VIBs[)], the FODCB would have to occur prior to the safety bus

energization by offsite bus fast transfer or prior to safety bus energization by the emergency diesel generator (EDG). The potential for de-energization of one pair of VIBs is, therefore, limited to time from initiation of the accident to time for safety bus response to the secondary plant and Reactor Protective System trips.

The effects of the FODCB are being revised to assume a secondary plant trip that results in de-energization of one power division. The existing analysis conclusions remain unchanged. The accident analysis is being revised to include de-energization of a pair of vital AC instrument channels. De-energization of two vital AC sources has not been previously documented as a design bases event.

Auctioneered bistable power supplies for Plant Protection System (PPS) channels A and D are being modified to a single power source for each of these two channels. Single channel trips will result for all PPS functions in channels A or D for loss of its single channel bistable power source. The PPS channels B and C auctioneered power supplies remain unchanged to maintain Recirculation Actuation Signal (RAS) response to a FODCB.

Regarding PPS measurement channels with increasing signal setpoints, de-energization of a single power supply either results in failure of a measurement channel (B or C) to a non-tripped state or in failure of a measurement channel (A or D) to a tripped state. Neither single channel failure scenario impacts accident initiation or mitigation. For PPS measurement channels with decreasing signal setpoints the single channel de-energization events result in failure of a single affected measurement channel to a tripped state. The PPS two out of three logic design with a channel bypassed ensures operability with a single channel failure. Neither condition impacts accident frequency or consequences.

With the exception of Recirculation Actuation Signal (RAS) and Emergency Feedwater Actuation Signal (EFAS), a FODCB results in an automatic ESFAS initiation for those functions with decreasing signal setpoints. For other ESFAS functions with a decreasing signal, channels A and C or channels B and D fail to the tripped state. For those functions with an increasing signal setpoint (including EFAS), a FODCB results in a single channel failing not tripped, one channel tripping, and two channels remaining functional. System level functions remain operable with either a one out of two logic (no channels bypassed) or a one out of one logic (with a channel bypassed).

Interposing relay actuation logic has changed from single trip path to selective trip path logic. This change insures emergency feedwater (EFW) discharge valves will receive an automatic open or close demand based on steam generator level and pressure demands.

Therefore, this change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2—Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

In response to de-energization of a pair of Vital Instrument Buses (VIBs), those ESFAS functions with increasing signal setpoints, as a minimum, remain functional with one out of one logic. One channel trips, one channel does not trip, and two channels remain functional. One of the functional channels may be bypassed without impact on operability. The trip response of those ESFAS functions with decreasing signal to trip setpoints remains unchanged.

EFAS coincidence logic to close the EFW discharge valves requires three out of four channels to be in a non-tripped state. With a FODCB one channel is tripped, one channel is not tripped, and two channels are functional. The close logic becomes two out of two with a FODCB.

By defeating the auctioneered bistable power sources for PPS channel A and D bistables, PPS measurement channel A or D will fail to its tripped state. This change ensures no more than one channel (B or C) fails to a non-tripped state for the FODCB.

With selective logic EFAS pump discharge valves will receive control signals to initiate emergency feedwater and to terminate emergency feedwater flow by open and close demands generated independent of the 120 Volt channel pair de-energization.

The existing ANO–2 Failure Modes and Effects Analysis does not document failure of a pair of vital instrument AC channels. Neither the 120 Volts AC nor the 125 Volt DC system single failure analysis assumes failure of two channels of 120 Volts AC. Even though the failure of either pair of VIBs caused by a FODCB is not a result of the proposed change, the SAR change will address the potential for de-energization of a pair of instrument buses. The ANO–2 SAR will be updated to reflect the documentation and modification of the PPS design to ensure safe plant response.

Even though the plant response to FODCB is being modified, the proposed ANO–2 PPS design resolution does not create the possibility of a new or different kind of accident from any previously evaluated in the SAR. The PPS will have the redundancy and independence sufficient to assure that (1) no single failure results in loss of the protection function, and (2) removal from service of any component or channel does not result in loss of the required minimum redundancy required by the TS. PPS will also meet the single failure criterion of IEEE 279–1971 to the extent that any single failure within the system does not prevent proper protective action at the system level and no single failure will defeat more than one of the four protective channels associated with any one trip function.

Criterion 3—Does Not Involve a Significant Reduction in the Margin of Safety.

Technical Specification Bases 3/4.3.1 & 3/4.3.2 assure sufficient PPS redundancy is maintained to permit a channel to be bypassed. Under the current design, a FODCB will result in reduction of margin by decreasing the number of functional channels to less than two. However, with the proposed modification removal from service of any component or channel for indefinite bypass will not result in loss of the minimum redundancy required by the TS. This activity will restore the margin by ensuring ESFAS required functions remain capable of automatic actuation with a FODCB.

Therefore, this change does *not* involve a significant reduction in the margin of safety.

Based upon the reasoning presented above and the previous discussion of the amendment request, Entergy Operations has determined that even though the proposed PPS design description results in an accident or malfunction of a different type, the requested change does *not* involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801.

Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, DC 20005–3502.

NRC Project Director: John N. Hannon.

Florida Power and Light Company, et al., Docket No. 50–335, St. Lucie Plant, Unit No. 1, St. Lucie County, Florida

Date of amendment request: October 29, 1998.

Description of amendment request: The proposed amendment would revise the terminology used in the St. Lucie Plant Technical Specifications (TS) relative to the implementation and automatic removal of certain reactor protection system trip bypasses to ensure that the meaning of explicit terms used in the TS are consistent with the intent of the stated requirements.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendments are administrative in nature, and do not change the function or the setpoints of the RPS trip bypass features. The revisions simply make corrections to the Notation of TS Tables 2.2–1 and 3.3–1 to ensure that the meaning of explicit terms used in the Notes is consistent with the intent of the stated requirements based on the St. Lucie plant design. The proposed technical specification changes do not involve accident initiators, do not change the configuration or method of operation of any plant equipment that is used to mitigate

the consequences of an accident, and do not alter any conditions assumed in the plant accident analyses. Therefore, operation of either facility in accordance with its proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed amendments are administrative in nature and will not change the physical plant or the modes of plant operation defined in the facility operating licenses. The changes do not involve the addition or modification of equipment nor do they alter the design or operation of plant systems. Therefore, operation of either facility in accordance with its proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Operation of the facility in accordance with the proposed amendment would not involve a significant reduction in a margin of safety.

The proposed amendments are administrative in nature and do not change the function or the setpoints of the RPS trip bypass features. The revisions simply make corrections to the Notation of TS Tables 2.2–1 and 3.3–1 to ensure that the meaning of explicit terms used in the Notes is consistent with the intent of the stated requirements based on the St. Lucie plant design. The proposed changes do not alter the basis for any technical specification that is related to the establishment of, or the maintenance of, a nuclear safety margin. Therefore, operation of either facility in accordance with its proposed amendment would not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration. This notice is intended to replace an exigent notice of consideration of issuance of amendment for St. Lucie Unit 1, previously published as exigent TS amendments for both St. Lucie Units 1 and 2 in the **Federal Register** (63 FR 59809). The amendment request for St. Lucie Unit 2 will continue to be considered as an exigent amendment as noticed in the **Federal Register** (63 FR 59809).

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954–9003.

Attorney for licensee: M.S. Ross, Attorney, Florida Power & Light, P.O. Box 14000, Juno Beach, Florida 33408–0420.

NRC Project Director: Frederick J. Hebdon.

GPU Nuclear, Inc, et al., Docket No. 50–219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Date of amendment request: November 10, 1998.

Description of amendment request: The proposed Technical Specification (TS) change would remove the restriction on the sale or lease of property within the exclusion area and replace the restriction with a requirement to retain complete authority to determine and maintain sufficient control of all activities including the authority to exclude or remove personnel and property within the minimum exclusion distance. A TS Bases page for the proposed change is included. Also included are clarifications and administrative changes which (1) clarify TS definition 1.38 to become ''Site Boundry'' from the current term ''Exclusion Area'' to be consistent with 10 CFR 20.1003 definition for Site Boundry and the 10 CFR 100.3 definition of Exclusion Area, (2) convert the one occurrence of the use of TS definition from Exclusion Area to Site Boundry in TS 6.8.4(a)(9), and (3) revise and update the Table of Contents for Section I Definitions.'

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Would operation of the facility in accordance with the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change is administrative in nature and does not affect the purpose, function, performance, operability or testing of and does not make any physical or procedural changes to plant systems, structures or components. Also, all existing technical specification limiting conditions for operation and surveillance requirements are retained.

[Technical Specification Change Request] TSCR 264 does not change the size or location of the exclusion area. Since the exclusion area size and location are not being changed and no physical or procedural changes are being made to the plant, radiological consequences in the exclusion area are not affected by this TSCR.

This change addresses the existing technical specification restriction on the sale or lease of property within the ''exclusion area'' by ensuring that the licensee will retain at all times the complete authority to determine and maintain sufficient control of all activities through ownership, easement, contract and/or other legal instruments on property within the minimum exclusion distance including the authority to exclude or remove personnel and property within the minimum exclusion distance.

Therefore, since no physical or procedural changes are being made to existing plant systems, structures or components and since the proposed change requires the licensee to retain complete authority and sufficient control of all activities in the exclusion area, operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Would operation of the facility in accordance with the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

The p[ro]posed change is administrative in nature and does not affect the purpose, function, performance, operability or testing of and does not make any physical or procedural changes to plant systems, structures or components. Also, all existing technical specification limiting conditions for operation and surveillance requirements are retained.

This change addresses the existing technical specification restriction on the sale or lease of property within the ''exclusion area'' by ensuring that the licensee will retain at all times the complete authority to determine and maintain sufficient control of all activities through ownership, easement, contract and/or other legal instruments on property within the minimum exclusion distance including the authority to exclude or remove personnel and property within the minimum exclusion distance.

Therefore, since no physical or procedural changes are being made to existing plant systems, structures or components and since the proposed change requires the licensee to retain complete authority and sufficient control of all activities in the exclusion area, operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Would operation of the facility in accordance with the proposed change involve a significant reduction in a margin of safety?

The p[ro]posed change is administrative in nature and does not affect the purpose, function, performance, operability or testing of and does not make any physical or procedural changes to plant systems, structures or components. Also, all existing technical specification limiting conditions for operation and surveillance requirements are retained.

This change addresses the existing technical specification restriction on the sale or lease of property within the ''exclusion area'' by ensuring that the licensee will retain at all times the complete authority to determine and maintain sufficient control of all activities through ownership, easement, contract and/or other legal instruments on property within the minimum exclusion distance including the authority to exclude or remove personnel and property within the minimum exclusion distance.

Therefore, since no physical or procedural changes are being made to existing plant

systems, structures or components and since the proposed change requires the licensee to retain complete authority and sufficient control of all activities in the exclusion area, operation of the facility in accordance with the proposed amendment will not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Ocean County Library, Reference Department, 101 Washington Street, Toms River, NJ 08753.

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Cecil O. Thomas.

Niagara Mohawk Power Corporation, Docket No. 50–410, Nine Mile Point Nuclear Station, Unit 2 (NMP2), Oswego County, New York

Date of amendment request: October 16, 1998.

Description of amendment request: The proposed amendment would make the following revisions to Technical Specifications (TSs) 3/4.7.1.1: (1) Ensure that four service water (SW) pumps are operating with the divisional cross connect valves open during Operational Condition 1, 2 and 3 (current TS requires two SW pumps associated with one loop to be operating); (2) Increase the number of division 1 and 2 heaters required to be operable from 7 per division per intake to 14 per division per intake; (3) The actions necessary for having less than the required equipment is being revised to reflect the new limits for SW equipment; and (4) SW supply header discharge water temperature is being increased from 81 to 82 °F. TS 3.7.1.2, Table 3.3.9–1, and Table 4.3.9.1–1 are revised to add ''when handling irradiated fuel in the secondary containment'' to the applicability section. Table 3.3.9–1 is being revised to decrease the temperature at which the Intake Deicing Heaters are required to be in service from 39 to 38 degrees F. TS 3.7.1.2 proposed change is to specify that the necessary portions of the SW system needed to support equipment required to be operable shall be operable; the Action Section proposed revision reflects this change. TS 4.7.1.2.1 surveillance requirement proposed change is to increase the flow rate of SW pumps from 6500 GPM to 9000 GPM and to change the SW pumps pressure from 80 psi discharge pressure to 70 psi differential pressure; TS 4.7.1.2.2 is being revised to decrease the intake tunnel water temperature from 39 to 38 degrees F. The surveillance for the Intake Deicing Heaters is being changed to reflect the increase in the number of heaters required. The title of ''Plant Service Water System'' is being changed to ''Service Water System.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The SW System is a once-through system which supplies water from Lake Ontario to various essential and non-essential components, as required, during normal plant operation and shutdown conditions. The System is designed with suitable redundancy to provide a reliable source of cooling water for the removal of heat from essential plant components, including the RHR [residual heat removal] heat exchangers, the EDGs [emergency diesel generators], and room coolers for ECCS [emergency core cooling system] equipment, which are required for safe reactor shutdown following a LOCA.

LCO 3.7.1.1 and LCO 3.7.1.2 each currently requires two independent SW System loops to be operable, with one of the loops in operation. The current LCOs do not provide adequate guidance regarding the minimum number of operating pumps. NMPC [Niagara Mohawk Power Corporation] proposes to revise LCO 3.7.1.1 and its associated Actions and SRs to provide assurance that four SW pumps are operable and are operating within acceptable system parameters, with the divisional cross-connect valves open, during Operational Conditions 1, 2, and 3 to meet the limiting LOCA analysis assumptions.

TS Section 3/4.7.1 currently specifies a maximum SW supply header discharge water temperature of 81 degrees F and a limiting temperature for Intake Deicing Heater ystem operability (intake water) temperature of 39 degrees F. In addition, TS Table 3.3.9–1, Action 144, requires the Intake Deicing Heater System heaters to be placed in service when the Lake Ontario water temperature reaches 39 degrees F. NMPC proposes to revise Action 144 of TS Table 3.3.9–1 and TS LCO 3.7.1.1, including its associated Actions and SRs [surveillance requirements], to increase the supply header discharge water temperature to its analytical limit of 82 degrees F and reduce the limiting temperature for the Intake Deicing Heater System Action and operability requirements to 38 degrees F.

Appropriate changes to LCO 3.7.1.2 and its associated Actions and SRs are also proposed in order to assure consistency with the SW System analyses assumptions during shutdown conditions. The current LCO Actions do not account for the varying flows and heat loads that may be required for various plant shutdown conditions. The revision to the Applicability for LCO 3.7.1.2 and TS Tables 3.3.9–1 and 4.3.9.1–1 will assure that the SW System is operable during periods when irradiated fuel is being handled in the secondary containment and essential loads cooled by the SW System are required to be operable (e.g., EDG). A footnote has been added to define Operational Condition * and is consistent with similar footnotes in the TSs. The proposed changes will assure that the necessary ortions of the SW System and the necessary Divisions of the Intake Deicing Heater System heaters are operable that are supporting equipment required to be operable.

It is further proposed to change the system title identified in the Index and in TS Section 3/4.7.1, including the LCOs and SRs, from ''Plant Service Water System'' to ''Service Water System'' to be consistent with the NMP2 [Nine Mile Unit 2] UFSAR [Updated Final Safety Analysis Report].

The changes do not involve any physical alteration of the plant, and the SW System will remain capable of providing sufficient cooling flow for the essential cooling loads during plant operation and also during plant shutdown. The changes will have no impact on the design or function of the SW System and its components, thus assuring that the characteristics and functional performance are maintained consistent with the event precursors and the conditions and assumptions of the current design basis accident and transient analyses. The changes to the LCO AOTs [allowed outage times] are either consistent with or are more conservative than the current AOTs. Based on the above, adequate assurance is provided that the probability of event initiation will remain as previously analyzed. Maintaining four pumps operating within acceptable system parameters, with the divisional cross connect valves open, during Operational Conditions 1, 2, and 3 provides assurance that the essential functions supported by the SW System are maintained. Particularly, adequate SW flow assures that the primary and secondary containments can perform their intended functions of limiting the release of radioactive materials to the environment following a LOCA. The small (1 degree F) change in the SW supply header discharge water (UHS) temperature and Intake Deicing Heater System actuation temperature maintain the current design basis for the UHS and SW Systems such that there will be no impact on the LOCA analyses assumptions or conclusions. The proposed changes to the SW System TSs do not adversely affect the capability of plant systems, structures, and components to respond to any accident in Operational Conditions 4, 5, and *. As a result, there will be no degradation of the primary or secondary containment or any other fission product barriers which could increase the radiological consequences of an accident. In addition, other essential accident mitigation equipment supported by the SW System will not be adversely impacted. It is, therefore,

concluded that operation of NMP2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated. The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The changes do not result in any hardware changes or physical alteration of the plant which could introduce new equipment failure modes, and there will be no impact on the design or function of the SW System or its components. The primary and secondary containment post-LOCA responses remain within previously assessed limits of temperature and pressure. Furthermore, adequate cooling flow is assured during plant operation and also during shutdown conditions such that essential systems and components remain within their applicable design limits. It is, therefore, concluded that no requirements are eliminated or new requirements imposed which could affect equipment or plant operation such that new credible accidents are introduced. Accordingly, operation of NMP2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The changes provide assurance that the SW System will remain capable of providing sufficient cooling flow for the essential cooling loads during plant operation and also during plant shutdown such that essential systems and components remain within their applicable design limits. The changes will have no impact on the design or function of the SW System and its components, thus assuring that the characteristics and functional performance are maintained consistent with the conditions and assumptions of the current design basis accident and transient analyses. Maintaining four pumps operating within acceptable system parameters, with the divisional cross connect valves open, during Operational Conditions 1, 2, and 3 provides assurance that post-LOCA radioactive releases are maintained within 10 CFR 100 limits. The small (1 degree F) change in the SW supply header discharge water (UHS) temperature and the limiting temperature for the Intake Deicing Heater System Action and operability requirements maintains the current design basis for the UHS and SW Systems such that there will be no impact on the LOCA analyses assumptions or conclusions.

These changes will not result in a reduction in margin to the System analytical limits. Furthermore, maintaining the intake bar surface temperature at least 1 degree F above freezing provides an adequate margin to prevent the adherence of ice, and provides assurance that sufficient flow area is always heated such that the SW System will remain capable of providing adequate cooling flow in the event of a LOCA. Similarly, maintaining the required SW System flow and temperature during Operational Conditions 4, 5, and * will assure that the associated equipment is operable such that radioactive releases are maintained within 10 CFR 100 limits. It is, therefore, concluded that the changes do not eliminate any requirements, impose any new requirements, or alter any physical parameters which significantly reduce the margin to an acceptance limit or adversely affect the margins associated with the fission product barriers as established by the design basis accident and transient analyses. Accordingly, operation of NMP2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005–3502.

NRC Project Director: S. Singh Bajwa.

Northeast Nuclear Energy Company (NNECO) et al., Docket No. 50–336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of amendment request: September 28, 1998.

Description of amendment request: The proposed amendment would change Technical Specifications 3.3.2.1, ''Instrumentation—Engineered Safety Features Actuation System''; 3.4.6.2, ''Reactor Coolant System—Reactor Coolant System Leakage''; 3.4.8, ''Reactor Coolant System—Specific Activity''; 3.6.2.1, ''Containment Systems—Depressurization and Cooling Systems Containment Spray and Cooling Systems''; 3.6.5.1, ''Containment Systems—Secondary Containment Enclosure Building Filtration System''; 3.7.6.1, ''Plant Systems—Control Room Emergency Ventilation System''; and 3.9.15, ''Refueling Operations—Storage Pool Area Ventilation System—Fuel Storage.'' Information would also be added to the Bases of the associated Technical Specifications to address the proposed changes.

The proposed amendment would also revise the Operating License DPR–65 by incorporating a change to the Millstone Unit No. 2 Final Safety Analysis Report (FSAR). The change to the FSAR is associated with the revised main steamline break analyses, new determination of the radiological consequences of a main steamline break, and a revised determination of the radiological consequences of the design basis loss-of-coolant accidents (LOCAs).

The proposed changes to the main steamline break analysis, as described in the FSAR, are based on the revised Siemens Power Corporation steamline break methodology. The report describing the revised methodology was submitted by Siemens Power Corporation to the NRC for approval in a letter dated June 30, 1998. The revised methodology was used to perform the Millstone Unit No. 2 plant-specific analysis for post-scram main steamline break. This plant-specific analysis was submitted by NNECO in a letter dated August 12, 1998, which proposed to change the list of documents in the Technical Specifications that describe the analytical methods used to determine the core operating limits. The proposed changes contained in this letter assume approval of the previously submitted revised Siemens Power Corporation steamline break methodology, and the changes to the list of documents in the Millstone Unit No. 2 Technical Specifications that describe the analytical methods used to determine the core operating limits.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

In accordance with 10CFR50.92, NNECO has reviewed the proposed changes and has concluded that they do not involve a significant hazards consideration (SHC). The basis for this conclusion is that the three criteria of 10CFR50.92(c) are not compromised. The proposed changes do not involve an SHC because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

Analyses Changes

The main steam line break analyses and the determinations of the radiological consequences of the main steam line break and loss of coolant accident have been revised. A brief summary of the significant changes to the main steam line break analyses and the radiological consequences of the main steam line break and loss of coolant accident is presented below.

1. The limited fuel failure following a main steam line break outside containment results in an increase in the calculated radiological consequences both off-site and in the control room. To limit the consequences of a main steam line break outside containment, the

Technical Specification allowed steam generator tube leakage will be reduced to 0.035 gpm [gallons per minute] per steam generator.

2. Credit will now be taken for iodine removal from the containment atmosphere by the Containment Spray System (CSS). The use of the CSS for iodine removal has not been previously approved by the NRC.

3. The proposed increase to the allowable control room in-leakage will provide additional operational flexibility to address expected minor system degradation over time. The increase in the allowable control room in-leakage will result in an increase in the calculated dose to the Control Room Operators.

4. The addition of the dose consequences from containment sump backleakage to the Refueling Water Storage Tank (RWST) has been included in the off-site and control room loss of coolant accident (LOCA) analyses increases the consequences of previously evaluated accidents.

The containment sump backleakage into the RWST results in sump water entering the RWST when the RWST is at its minimum level. The RWST will become a radioactive source and contribute a shine dose to the surrounding areas. The increase in dose rates onsite will not prevent operators from remaining in the control room or from accessing equipment needed to mitigate the accident.

All piping and valves associated with RWST backleakage are located in a harsh radiation area. Backflow from the sump might increase dose rates in the area where these components are located. Additional dose contributions, where they occur, do not adversely impact the environmental qualification of the vital equipment located there. All vital equipment would continue to perform its safety function.

5. Credit will be taken in the main steam line break analyses for the recently installed cavitating venturis in the Auxiliary Feedwater System. However, this will not change the amount of fuel failure. Therefore, credit for this equipment will not impact the radiological consequences of a main steam line break.

6. Credit will be taken for the Reactor Coolant System (RCS) low flow reactor trip for the pre-scram inside containment main steam line break analysis. This equipment will be qualified for the expected containment environment following a main steam line break inside containment and will be added to the Environmental Qualification Master List.

7. Millstone Unit No. 1 design basis accidents, loss of coolant and main steam line break, will no longer be evaluated for impact on Millstone Unit No. 2 control room habitability. This credits the decision to decommission Millstone Unit No. 1. [Footnote—B.D. Kenyon letter to the NRC, ''Millstone Nuclear Power Station, Unit No. 1 Certification of Permanent Cessation of Power Operations and that Fuel Has Been Permanently Removed from the Reactor,'' dated July 21, 1998.]

The revised main steam line break analyses and the revised determinations of the radiological consequences of the main steam line break and design basis LOCA analyses take credit for equipment not previously assumed in the analyses, and for plant or equipment operating restrictions not currently contained in the Technical Specifications. The changes to the analyses will not adversely affect the probability of an accident previously evaluated, but the revised analyses results do indicate that the consequences of an accident previously evaluated will increase. Specifically, the following changes cause an increase in the consequences of an accident previously evaluated.

1. The increase in allowable control room in-leakage from 100 SCFM [standard cubic feet per minute] to 130 SCFM when the Control Room Emergency Ventilation System is operating in the recirculation/filtration mode.

The dose to the Control Room Operators from a Millstone Unit No. 2 LOCA increased from 9.25 to 25.8 rem to the thyroid and from 0.205 to 2.29 rem to the skin. The dose to the whole body decreased. (Both low wind speed and high wind speed release conditions were analyzed. The low wind speed condition bounds the high wind speed condition.) The dose to the Control Room Operators from a Millstone Unit No. 3 LOCA increased from 2.67 to 14 rem to the skin and from 0.209 to 1.484 rem to the whole body. The dose to the thyroid decreased. The doses to the Control Room Operators from either a Millstone Unit No. 2 or Unit No. 3 LOCA remain below the GDC [General Design Criterion] 19 criteria of 30 rem thyroid, 5 rem whole body and 30 rem to the skin.

The new calculated doses to the Millstone Unit No. 2 Control Room Operators from a main steam line break outside containment are 29 rem thyroid, 0.03 rem whole body and 0.5 rem skin. The doses to the Millstone Unit No. 2 Control Room Operators are below the GDC 19 criteria of 30 rem thyroid, 5 rem whole body, and 30 rem to the skin. (Note: The dose to the Control Room Operators from a main steam line break was not previously evaluated because fuel failure was not predicted to occur.)

2. The limited fuel failure that is predicted in the revised main steam line break analyses.

Previously, the radiological consequences of a main steam line break were not determined and were not presented in the FSAR because fuel failure was not predicted to occur. Because of the predicted limited fuel failure for the main steam line break outside of containment, the radiological consequences were analyzed. The results to the Exclusion Area Boundary (EAB) are 4.8 rem thyroid and 0.06 rem whole body. The results to the Low Population Zone (LPZ) are 2.3 rem thyroid and 0.02 rem whole body. To meet the dose acceptance criteria to the Millstone Unit No. 2 Control Room Operators, the maximum allowable Technical Specification primary to secondary leak rate is being reduced to 0.035 gpm per steam generator. The results to the Millstone Unit No. 2 Control Room Operators are 29 rem thyroid, 0.03 rem whole body and 0.5 rem skin. The main steam line break outside containment is the limiting accident for the Millstone Unit No. 2 Control Room Operators. However, the dose consequences of a main steam line break are less than the 10CFR100 limits off-site of 300 rem thyroid and 25 rem whole body, and the doses to the Millstone Unit No. 2 Control Room Operators are below the GDC 19 criteria of 30 rem thyroid, 5 rem whole body, and 30 rem to the skin.

3. Taking credit for the low RCS flow reactor trip for the pre-scram inside containment main steam line break analysis.

Previous analyses did not credit the low RCS flow reactor trip in a harsh environment. This credits the low flow trip in a manner not previously reviewed by the NRC for Millstone Unit No. 2. Without credit for this reactor trip, the predicted fuel failure for steam line breaks inside containment would be higher.

4. Taking credit for the removal of radioactive iodine from the containment atmosphere by containment spray.

Previous analyses did not rely on the spray function to reduce iodine concentration in the post-accident atmosphere inside containment. This adds a mitigation function to the CSS that has not been previously reviewed by the NRC for Millstone Unit No. 2. Without credit for the removal of iodine, the predicted dose consequences following a LOCA would be higher.

5. The addition of sump backleakage to the RWST during a LOCA.

The resultant dose contribution to the LPZ from RWST backleakage is 1.487 rem thyroid and 0.11 rem whole body. The total dose to the LPZ from a design basis LOCA is 21.86 rem thyroid and 0.941 rem whole body. The dose is well below the 10CFR100 limits of 300 rem thyroid and 25 rem whole body. The dose to the EAB was not affected because leakage into the RWST does not start until 25.45 hours post-LOCA and the EAB is a 2-hour dose.

The resultant dose contribution to the Millstone Unit No. 2 Control Room Operators from RWST backleakage is 3.75 rem thyroid, 0.017 rem whole body and 0.296 to the skin. The total dose to the Millstone Unit No. 2 Control Room Operators from the LOCA is 25.8 rem thyroid, 0.718 rem whole body and 2.29 rem to the skin. These doses are below the GDC 19 limits of 30 rem thyroid and skin, and 5 rem whole body.

The analyses results meet the guidance contained in SRP [Standard Review Plan] 15.1.5, SRP 15.6.5, and the limits of 10CFR100 and GDC 19. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification Changes

Technical Specification Non-Technical Changes

The minor editorial and non-technical changes to correct spelling (Technical Specification 3.3.2.1), modify the title of a table column (Technical Specification 3.4.8), clarify the type of measurement performed (Technical Specification 3.4.8), and establish consistent terminology (Technical Specification 3.7.6.1) will not result in any technical changes to the Millstone Unit No. 2 Technical Specifications. The proposed changes will have no adverse effect on plant

operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.4.6.2

The reduction in the maximum allowable value of primary to secondary leakage per steam generator is consistent with the new radiological assessment of the potential control room operator exposure following a main steam line break outside of containment. The wording change to SR [Surveillance Requirement] 4.4.6.2.1 will clarify that the water inventory balance is used to verify compliance with the identified and unidentified leakage limits. Pressure boundary leakage would first show up as unidentified leakage during performance of SR 4.4.6.2.1. Further investigation, (plant walkdown) would be necessary to classify the unidentified leakage as pressure boundary leakage. This is consistent with established plant practices to detect pressure boundary leakage.

The addition of the new SR 4.4.6.2.2 will address the primary to secondary leakage limit. The new SR will include an exception to Technical Specification 4.0.4 that will allow the determination of primary to secondary leakage to be deferred until after Mode 4 is entered. Even though verification of compliance with the primary to secondary limit will not be done prior to entering Mode 4, the limit is still expected to be met.

The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.4.8

The addition of the words ''of gross specific activity'' to the Limiting Condition for Operation (LCO), Action Statements, and SR will clarify what the E-Bar limit applies to. This is consistent with the Technical Specification Definition (1.20) for E-Bar.

The addition of a footnote (*) to state the power history requirements for the determination of E-Bar will ensure that the necessary plant conditions are established prior to performing the analysis. This will not affect the E-Bar LCO limit or the requirement to perform the analysis. The proposed change is consistent with NUREG—0212 and NUREG—1432.

The footnote will also specify that the provisions of Specification 4.0.4 are not applicable. This will allow entry into Mode 1, without determining the value of E-Bar, assuming that the power history requirements will not be met until after Mode 1 is entered. This will normally only apply following an extended shutdown.

The Isotopic Analysis for Iodine (including I–131, I–133, and I–135) sample requirement will be expanded to include the LCO requirement for 100/E-Bar. This is consistent with the requirements of Action Statement d. This change will expand the sampling requirement for iodine. Minor wording changes will also be made to be consistent with the proposed changes to the LCO wording.

The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.6.2.1

The revised radiological assessment calculation for the design basis accident credits iodine removal from the containment atmosphere by the CSS. This will require a reduction in the allowed outage time (AOT) of one containment spray train from seven days to seventy two hours. This AOT is consistent with NUREG–0212 and NUREG–1432. This will help ensure that plant equipment assumed in the safety analyses will be available. This is a more restrictive change which will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.6.5.1

The value for the pressure drop across the combined HEPA [high-efficiency particulate air] filters and charcoal adsorber banks specified in SR 4.6.5.1.d.1 will be changed from a generic value [less than or equal to] 6 inches water gauge) to a plant specific value [less than or equal to] 2.6 inches water gauge). This is a more restrictive change which will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.7.6.1

The value for the pressure drop across the combined HEPA filters and charcoal adsorber banks specified in SR 4.7.6.1.e.1 will be changed from a generic value [less than or equal to] 6 inches water gauge) to a plant specific value [less than or equal to] 3.4 inches water gauge). This is a more restrictive change which will have no adverse effect on plant operation.

SR 4.7.6.1.e.2 will be expanded to clarify that the test of the capability of the Control Room Emergency Ventilation Trains to switch to the recirculation mode is performed with the trains initially operating in the normal mode and the smoke purge mode of operation. This will not affect the requirement that the trains be capable of switching to the recirculation mode.

The value of allowable control room air in-leakage specified in SR 4.7.6.1.e.3 will be increased from 100 SCFM to 130 SCFM. This is consistent with the recently revised control room radiological analysis for the design basis accidents.

The proposed increase will provide additional operational flexibility to address expected minor system degradation over time. This increase is supported by the new analysis.

The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

Technical Specification 3.9.15

The value for the pressure drop across the combined HEPA filters and charcoal adsorber banks specified in SR 4.9.15.d.1 will be changed from a generic value [less than or equal to] 6 inches water gauge) to a plant specific value [less than or equal to] 2.6 inches water gauge). This is a more restrictive change which will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes have no adverse effect on how any of the associated systems or components function to prevent or mitigate the consequences of design basis accidents. Also, the proposed changes have no adverse effect on any design basis accident previously evaluated since the changes are consistent with the revised analyses, and the appropriate acceptance criteria are met for the revised analyses. Therefore, the license amendment request does not impact the probability of an accident previously evaluated nor does it involve a significant increase in the consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes will not alter the plant configuration (no new or different type of equipment will be installed) or require any new or unusual operator actions. They do not alter the way any structure, system, or component functions and do not alter the manner in which the plant is operated. The proposed changes do not introduce any new failure modes.

Also, the response of the plant and the operators following these accidents is unaffected by the change. Therefore, the proposed changes will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

Analyses Changes

The acceptance criteria for a main steam line break in the SRP 15.1.5 does not exclude the prediction of fuel failure. Instead, the SRP requires that ''Any fuel damage calculated to occur must be of sufficiently limited extent that the core will remain in place and intact with no loss of core cooling.'' The limited fuel failure that is now predicted in the revised main steam line break analyses meets this acceptance criterion. In addition, the RCS low flow reactor trip that is now being credited to function in a harsh environment to limit fuel failure is already required to be operable by Technical Specifications.

The revised dose consequences for the design basis accidents assumes a control room in-leakage of 130 SCFM. In addition, iodine removal by the CSS, which is already required to be operable by Technical Specifications, is assumed. The acceptance criteria for the dose consequences of the design basis accidents to the EAB, LPZ and the control room personnel is met in the revised analyses. Therefore, the revisions to the dose consequence analyses for the design basis accidents do not involve a significant reduction in the margin of safety.

Technical Specification Changes

The proposed changes will correct spelling and terminology errors, reduce the maximum allowable primary to secondary leakage, add a new surveillance requirement, modify surveillance requirements for RCS specific activity, reduce the allowed outage time for a containment spray train, reduce the allowed pressure drop across the control room and enclosure building HEPA [high-efficiency particulate air] filters, and increase the control room maximum allowed in-leakage. These changes will have no adverse effect on equipment important to safety. The equipment will continue to function as assumed in the design basis accident analysis. Therefore, there will be no significant reduction of the margin of safety as defined in the Bases for the Technical Specifications affected by these proposed changes.

The only adverse impact of the proposed changes is that the dose consequences following an accident may increase. However, the revised analyses show that the acceptance criteria for the accident analyses are met. Therefore, based on the responses above, the proposed changes are deemed safe.

The NRC has provided guidance concerning the application of standards in 10CFR50.92 by providing certain examples (March 6, 1986, 51 FR 7751) of amendments that are considered not likely to involve an SHC. The minor editorial and non-technical changes proposed herein to correct reference, spelling, and terminology errors are enveloped by example (i), a purely administrative change to Technical Specifications. The changes proposed herein to add a new surveillance requirement to verify primary to secondary leakage and to reduce the allowable pressure drop across various ventilation filters are enveloped by example (ii), a change that constitutes an additional limitation, restriction, or control not presently included in the Technical Specifications. All of the other changes proposed herein are not enveloped by any specific example.

As described above, this License Amendment Request does not impact the probability of an accident previously evaluated, does not involve a significant increase in the consequences of an accident previously evaluated, does not create the possibility of a new or different kind of accident from any accident previously evaluated, and does not result in a significant reduction in a margin of safety. Therefore, NNECO has concluded that the proposed changes do not involve an SHC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, Connecticut, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, Connecticut.

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, Connecticut.

NRC Project Director: William M. Dean.

Northeast Nuclear Energy Company, et al., Docket No. 50–336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of amendment request: October 22, 1998.

Description of amendment request: The licensee is proposing to change Technical Specifications 3.3.2.1, ''Instrumentation—Engineered Safety Feature Actuation System Instrumentation''; 3.4.9.3, ''Reactor Coolant System [RCS]—Overpressure Protection Systems''; and 3.5.3, ''Emergency Core Cooling Systems—ECCS Subsystems—Tavg < 300 [degrees] F.'' The proposed changes will allow Millstone Unit No. 2 to prevent an automatic start of any high-pressure safety injection (HPSI) pump when the shutdown cooling system (SDCS) is in operation (Mode 4 and below). An inadvertent start of an HPSI pump could result in overpressurization of the SDCS.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

In accordance with 10CFR50.92, Northeast Nuclear Energy Company (NNECO) has reviewed the proposed changes and has concluded that they do not involve a significant hazards consideration (SHC). The basis for this conclusion is that the three criteria of 10CFR50.92(c) are not compromised. The proposed changes do not involve an SHC because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to Technical Specifications 3.3.2.1 and 3.5.3 will no longer require the HPSI pump, required to be operable in Mode 4, to start automatically on a Safety Injection Actuation Signal (SIAS). (The automatic SIASs on low pressurizer pressure and high containment pressure are not required to be operable in Mode 4. However, the manual safety injection pushbuttons are required in Mode 4). This will allow the operable HPSI pump control switch to be placed in the pull-to-lock position without affecting the operability of that pump. All HPSI pumps will be prevented from automatically starting when the plant is in Mode 4, and the Shutdown Cooling System (SDCS) is aligned to the RCS to prevent an inadvertent start of a[n] HPSI pump which could overpressurize the SDCS. These changes will not reduce the requirement for at least one HPSI pump to be operable in Mode 4. The changes will require an additional operator action to remove the operable HPSI pump breaker control switch from the pull-to-lock position, in addition to initiating safety injection by use of the manual pushbuttons, if Safety Injection System actuation is needed in Mode 4. The requirement to manually initiate a[n] HPSI pump, in addition to manually initiating a[n] SIAS, does not involve complicated equipment manipulations nor require extensive time for performing the required operator actions. The HPSI pump control switches are located in the Control Room on the same panels as the manual SIAS pushbuttons. The additional step required to start a[n] HPSI pump will not add any appreciable time for initiating HPSI flow while in Mode 4. In addition, considering the lower probability of a significant loss of coolant accident in Mode 4, and the slower plant response to a loss of coolant accident in Mode 4, the time required for the additional operator action will have no significant effect on the consequences of the accident. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

The proposed change to Technical Specification 3.4.9.3, Surveillance Requirement (SR) 4.4.9.3.3, will allow the use of the new pull-to-lock feature of the HPSI pump control switches to satisfy low temperature overpressure protection mass input requirements. This will not affect either the LTOP [low-temperature overpressure protection] HPSI pump mass input restrictions or the level of control to ensure the HPSI pumps are not capable of injecting into the RCS. The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

The proposed minor editorial and non-technical changes to add amendment numbers to Page 3/4 3–12 and to revise the wording of SRs 4.4.9.3.2 and 4.4.9.3.3 will not result in any technical changes to the Millstone Unit No. 2 Technical Specifications. The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to the Bases reflect the proposed changes to the applicable Technical Specifications. The proposed changes will have no adverse effect on plant operation. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes will allow the use of the HPSI pump breaker control switch

pull-to-lock feature. Operation of the HPSI pump in Mode 4 will change since the operator will have to start the HPSI pump, in addition to manually initiating safety injection. However, HPSI pump operation is not an accident initiator. Therefore, the proposed changes will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety.

The proposed Technical Specification changes will no longer require the HPSI pump, required to be operable in Mode 4, to start automatically on a[n] SIAS, will allow the use of the new pull-to-lock feature of the HPSI pump control switches to satisfy low temperature overpressure protection mass input requirements, and will make minor editorial and non-technical changes. These changes will have no adverse effect on equipment important to safety. The equipment will continue to function as assumed in the design basis accident analysis. Therefore, there will be no significant reduction in the margin of safety as defined in the Bases for the Technical Specifications affected by these proposed changes.

The only adverse impact of the proposed changes is that an additional operator action will be necessary to initiate HPSI flow in Mode 4, if needed. However, considering the lower probability of a significant loss of coolant accident in Mode 4, and the slower plant response to a loss of coolant accident in Mode 4, the time required for the additional operator action will have no significant effect on the consequences of the accident. Therefore, based on the responses above, the proposed changes are deemed safe.

The NRC has provided guidance concerning the application of standards in 10CFR50.92 by providing certain examples (March 6, 1986, 51 FR 7751) of amendments that are considered not likely to involve an SHC. The minor editorial and non-technical changes proposed herein to add page amendment numbers and clarify wording are enveloped by example (i), a purely administrative change to Technical Specifications. All of the other changes proposed herein are not enveloped by any specific example.

As described above, this License Amendment Request does not impact the probability of an accident previously evaluated, does not involve a significant increase in the consequences of an accident previously evaluated, does not create the possibility of a new or different kind of accident from any accident previously evaluated, and does not result in a significant reduction in a margin of safety. Therefore, NNECO has concluded that the proposed changes do not involve an SHC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, Connecticut, and the Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, Connecticut.

Attorney for licensee: Lillian M. Cuoco, Esq., Senior Nuclear Counsel, Northeast Utilities Service Company, P.O. Box 270, Hartford, Connecticut.

NRC Project Director: William M. Dean.

PECO Energy Company, Docket Nos. 50–352 and 50–353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: October 30, 1998.

Description of amendment request: Limerick Generating Station (LGS), Units 1 and 2, Technical Specifications (TS) Surveillance Requirements 4.8.4.3.b.1, 4.8.4.3.b.2, and 4.8.4.3.b.3 list the Overvoltage (OV), Undervoltage (UV), and Underfrequency (UF) values for the protective instrumentation for the RPS electric power monitoring channels. The proposed changes correct a discrepancy between the General Electric Nuclear Engineering (GENE) Design Specification for Power Supply Monitoring Relays and the existing TS Allowable Values (AVs). The changes will revise the OV, US, and UF values from 132VAC, 109VAC, and 57Hz to 127.6VAC, 110.7VAC, and 57.05Hz respectively.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed Technical Specifications (TS) changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed Tech Spec changes to section 4.8.4.3.b for the Overvoltage (OV), Undervoltage (UV), and Underfrequency (UF) relays are more conservative than the existing TS values. This change provides more protection for the associated RPS components, thus decreasing the probability of a failure in RPS. The associated Non-Conformance Report and calculation provide assurance that the OV/UV/UF settings are acceptable since the calculated values assure that the RPS components will operate within their ratings. There are no physical changes to the associated protective relays by the TS change; thus, original design basis redundancy and separation is maintained. There is no change in the interface of the RPS and its power supplies.

The safety function of the RPS is to initiate a reactor scram in order to protect the primary fission products barrier, the reactor fuel. The proposed TS Change to impose more conservative Allowable Values for the OV, UV, and UF relays will provide additional assurance that the RPS will operate within equipment voltage and frequency ratings, and will not be damaged by power system anomalies. This change will not affect the scram function of RPS; thus, the consequences of any design basis events will not be affected.

Therefore, the proposed TS changes do not involve an increase in the probability or consequences of an accident previously evaluated.

2. The proposed TS changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed TS Allowable Values changes will not result in any physical changes to the RPS Electric Power Monitoring System. Existing setpoints will not be changed, only the TS Allowable Values are being modified to be more conservative.

The system redundancy and independence are not changed, and no new failure modes are introduced.

Therefore, the proposed TS changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed TS changes do not involve a significant reduction in a margin of safety.

Currently, there are no TS bases for the existing RPS Electric Power Monitoring System OV, UV, and UF allowable values. Specific analytical limits for system voltage and frequency are not defined in the Safety Analysis Report, nor discussed in any design basis Allowed Outage Time or accident evaluation.

Investigation into the licensing basis has identified nominal values of +/−10% of 120 VAC and −5% of 60 HZ for the Allowable Values. These values are included in NUREG 0123, from which LGS's TSs were developed. NUREG 0123 also provides no bases for these values.

The proposed changes in the TS Allowable Values is based on a revision to the calculation for RPS Breaker Panel—RPS / UPS [uninterruptible power supply] System Bus Relay Settings. This revision determines the new allowable values based on the design ratings of RPS components, and factors in instrument inaccuracies and margin. These changes will also provide bases for the associated TS section. The proposed changes bring TSs into agreement with plant design specifications.

Therefore, the proposed TS changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, PA 19464.

Attorney for licensee: J.W. Durham, Sr., Esquire, Sr. V.P. and General Counsel, PECO Energy Company, 2301 Market Street, Philadelphia, PA 19101.

NRC Project Director: Robert A. Capra.

Public Service Electric & Gas Company, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: October 22, 1998.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 4.8.2.1.b.3 to increase the minimum battery electrolyte temperature limit from 60°F to 72°F. This change resolves a discrepancy in the electrolyte temperature assumed in the Class 1-E battery sizing calculations versus the limit specified in the TSs.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed TS change does not involve any physical changes to plant structures, systems or components (SSC). The Class-1E batteries will continue to function as designed. The Class-1E battery system is designed to mitigate the consequences of an accident, and therefore, can not contribute to the initiation of any accident. The proposed TS surveillance testing and monitoring requirements will continue to ensure that the Class-1E batteries are capable of performing their required safety functions. In addition, this proposed TS change will not increase the probability of occurrence of a malfunction of any plant equipment important to safety, since the manner i[n] which the Class-1E battery system is operated is not affected by these proposed changes. The proposed changes merely establish TS surveillance acceptance criteria that more appropriately reflect the actual plant design. Therefore, the proposed TS changes would not result in an increase of the consequences of an accident previously evaluated.

Therefore, the proposed TS change does not involve an increase in the probability or consequences of an accident previously evaluated.

(2) The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed TS changes do not involve any physical changes to the design of plant systems, structures or components. The design and operation of the Class-1E battery system is not changed from that currently described in the [Updated Final Safety Analysis Report] UFSAR, only the allocation of battery capacity design margin is affected by the increased TS minimum battery electrolyte temperature limit. The Class-1E battery system will continue to function as designed to mitigate the consequences of an accident. Implementing new TS surveillance acceptance criteria that more appropriately reflect the actual plant design does not permit plant operation in a configuration that would create a different type of malfunction to the Class-1E batteries than any previously evaluated. In addition, the proposed TS changes do not alter the conclusions described in the UFSAR regarding the safety related functions of the Class-1E batteries or their support systems.

Therefore, the proposed TS change does not create the possibility of a new or different kind of accident from any previously evaluated.

(3) The proposed change does not involve a significant reduction in a margin of safety.

The proposed TS change involves the implementation of new TS surveillance acceptance criteria that more appropriately reflect the actual plant design. The new TS minimum battery electrolyte temperature limit enables the Class-1E battery capacity margin to be allocated in a manner which conforms to Hope Creek's current licensing basis. The ability of the Class-1E batteries to independently supply their required loads for four hours without support from battery chargers is not affected by these proposed changes. The safety-related Class-1E support systems will ensure that the proposed TS minimum electrolyte temperature limit is met.

Therefore, the proposed TS change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, NJ 08070.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Project Director: Robert A. Capra.

Southern Nuclear Operating Company, Inc., et al., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: October 15, 1998, as supplemented by letter dated November 11, 1998.

Description of amendment request: The proposed amendments would change the Vogtle Electric Generating Plant, Unit 1 and Unit 2 Facility Operating Licenses to delete or modify certain license conditions, which have become obsolete or inappropriate. In addition, the Technical Specifications would be reconstituted to reflect revised word processing. No change in technical requirements would be involved; however, the font would be changed to Arial 11 point; page numbers would be revised to a limiting condition for operation specific numbering scheme; and intentional blank pages would be deleted.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes either remove or modify provisions in the VEGP [Vogtle Electric Generating Plant] Unit 1 and [Unit] 2 Operating Licenses that have been completed or are otherwise obsolete. Each proposed change is summarized below:

Certain Surveillance Requirements (SRs) that were either added or modified at the time of Improved Technical Specifications (ITS) implementation were listed in the Operating Licenses with a schedule for performance. With the exception of Unit 2 SR 3.8.1.20, all SRs are deleted from the Operating Licenses, because they have since been performed according to schedule, and will henceforth be performed in accordance with the Technical Specifications.

A condition concerning changes to the Unit 1 initial test program is deleted due to the completion of the program.

A condition related to FEMA [Federal Emergency Management Agency] procedures and the emergency plan is deleted from the Unit 1 license due to the obsolescence of the condition.

Conditions requiring the submission of Unit 1 reports concerning the steam generator tube rupture analysis, the reactor vessel level instrumentation system, the safety parameter display system, the detailed control room design review, and the zinc coating of the diesel fuel storage tanks are deleted due to completion of the required activities.

A condition requiring modification of the Unit 1 ventilation exhaust of the alternate radwaste facility is deleted due to completion of the required activity.

An exemption related to the seismic adequacy of the Unit 1 spent fuel racks is deleted because the required actions are completed and the exemption has been determined to be no longer in effect.

A condition in both the Unit 1 and Unit 2 licenses containing reporting requirements for other license conditions is revised due to ambiguities between the requirements in the license condition and those published in NRC regulations.

A schedular exemption for the Unit 2 decommissioning funding report is deleted

because the report was submitted as required and the exemption is no longer in effect.

The Technical Specifications and associated Bases have been converted from WordPerfect® for DOS version 5.1 to Microsoft® Word 97. There were no changes to technical requirements. The only visible changes to the document are as follows: (1) the font was changed to Arial 11 point; [(2)] page numbers were revised to an LCO [limiting condition for operation] specific numbering scheme; and [(3)] intentionally blank pages were deleted.

The proposed changes discussed above are strictly administrative/editorial and do not affect the operation or function of any plant system, component, or structure. Therefore, the proposed changes do not increase the probability of occurrence or the consequences of a previously evaluated accident.

2. The proposed changes do not create the possibility of a new and different type of accident from any previously evaluated.

The proposed administrative/editorial changes do not alter the operation of any plant system or equipment and do not introduce a new mode of operation. Each requirement contained in the license conditions proposed for deletion has either been completed or is obsolete. Since these parts of the license are no longer applicable, deletion of these items does not provide the potential for an accident to be created. The conversion of the Technical Specifications from one word processing format to another did not involve any changes to technical requirements. Thus, the proposed changes cannot create a new accident initiating mechanism, and do not create the possibility of a new and different type of accident from any previously evaluated.

3. The proposed changes do not involve a significant reduction in the margin of safety.

The license conditions proposed for deletion are obsolete and each requirement has been completed. The conversion of the Technical Specifications from one word processing format to another did not involve any changes to technical requirements. Since the proposed changes are strictly administrative/editorial and do not involve any physical or procedural changes to the plant, the margin of safety, as defined in the bases for any Technical Specification is not affected by the proposed changes.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia.

Attorney for licensee: Mr. Arthur H. Domby, Troutman Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia.

NRC Project Director: Herbert N. Berkow.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: November 16, 1996 (TS 98–06).

Brief description of amendments: The proposed amendments would change the Sequoyah Nuclear Plant Technical Specifications (TSs) by revising the emergency diesel generator (EDG) surveillance requirements (SRs) to add a note that allows the SR to be performed in Modes 1, 2, 3 or 4, if the associated components are already out-of-service for testing or maintenance and to remove the SR that verifies certain lockout features prevent EDG starting.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the Tennessee Valley Authority (TVA), the licensee, has provided its analysis of the issue of no significant hazards consideration, which is presented below:

TVA has concluded that operation of SQN Units 1 and 2, in accordance with the proposed change to the TSs, does not involve a significant hazards consideration. TVA's conclusion is based on its evaluation, in accordance with 10 CFR 50.91(a)(1), of the three standards set forth in 10 CFR 50.92(c).

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The probability of occurrence or the consequences for an accident or malfunction of equipment is not increased by this request. The proposal does not alter the way any structure, system or component functions, does not modify the manner in which the plant is operated, and does not alter equipment out-of-service time. This request does not degrade the ability of the D/G [emergency diesel generator] or equipment downstream of the load sequencers to perform their intended function. Deleting the surveillance of a nonsafety-related equipment protection function from TS likewise does not change the probability or consequences of analyzed accident scenarios. Dose consequences remain unchanged by this request.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

A possibility for an accident or malfunction of a different type than any evaluated previously in SQN's FSAR [Final Safety Analysis Report] is not created; nor is the possibility for an accident or malfunction of a different type. The proposal does not alter the way any structure, system or component functions and does not modify the manner in which the plant is operated.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

The margin of safety has not been reduced since the test methodologies are not being changed and LCO [Limiting Condition for Operation] allowed outage times are not being changed. Deleting the surveillance of a nonsafety-related equipment protection function from TS likewise does not reduce the margin of safety. The results of accident analysis remain unchanged by this request.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 10H, Knoxville, Tennessee 37902.

NRC Project Director: Frederick J. Hebdon.

The Cleveland Electric Illuminating Company, Centerior Service Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: October 27, 1998.

Description of amendment request: The proposed amendment would modify the existing Minimum Critical Power Ratio (MCPR) Safety Limit contained in Technical Specification 2.1.1.2. The change would apply additional conservatism by modifying the MCPR Safety Limit values, as calculated by General Electric, by maintaining the limit of 1.09 for two recirculation loop operation and by increasing the limit from 1.10 to 1.11 for single loop operation.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

There is no change to any plant equipment. Per USAR Section 4.2.1, the fuel system design bases are provided in General Electric Standard Application for Reactor Fuel (GESTAR II). The Minimum Critical Power Ratio (MCPR) Safety Limit protects the fuel in accordance with the design basis. The MCPR Safety Limit calculations limit the bundle power to ensure the critical power ratio remains unchanged. Therefore, there is not an increase in the probability of transition boiling. The basis of the MCPR Safety Limit calculation remains the same,

ensuring that greater than 99.9% of all fuel rods in the core avoid transition boiling if the limit is not violated. Therefore, there is no increase in the probability of the occurrence of a previously analyzed accident.

The fundamental sequences of accidents and transients have not been altered. The MCPR Operating Limits are selected such that potentially limiting plant transients and accidents prevent the MCPR from decreasing below the MCPR Safety Limit anytime during the transient. Therefore, there is no impact on any of the limiting USAR Appendix 15B transients. The radiological consequences are the same as previously stated in the USAR, and as approved in the NRC Safety Evaluation for GESTAR II. Therefore, the consequences of an accident do not increase over previous evaluations in the USAR.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The MCPR Safety Limit values are designed to ensure that fuel damage from transition boiling does not occur in at least 99.9% of the fuel rods in the core as a result of the limiting postulated accident. The values are calculated in accordance with GESTAR II and the fuel vendor's interim implementing procedures, which incorporate cycle-specific parameters.

The GESTAR II analysis has been accepted by the NRC as comprehensive for ensuring that fuel designs will perform within acceptable bounds. The MCPR Safety Limit ensures that the fuel is protected in accordance with the design basis. The function, location, operation, and handling of the fuel remain unchanged. In addition, the initiating sequence of events has not changed. Therefore, no new or different kind of accident is created.

3. The proposed change does not involve a significant reduction in a margin of safety.

The MCPR Safety Limit values do not alter the design or function of any plant system, including the fuel. The new MCPR Safety Limit values were calculated using NRC-approved methods described in GESTAR II and the fuel vendor's interim implementing procedures, which incorporate cycle-specific parameters. The MCPR Safety Limit values are consistent with GESTAR II, the NRC Safety Evaluation of GESTAR II, the NRC Safety Evaluation Report for the Perry Nuclear Power Plant and its Supplements for USAR Sections 4.4.1 and 15.0.3.3.1, and the Technical Specification Bases (Section 2.1.1.2) for the MCPR Safety Limit. This change incorporates a cycle-specific MCPR Safety Limit, as opposed to relying on the generic limit. Therefore, the implementation of the proposed change to the MCPR Safety Limit does not involve a reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, OH 44081.

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Stuart A. Richards.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application request: October 27, 1998 (supersedes the April 12, 1996, amendment request). This notice supersedes the staff's proposed no significant hazards consideration determination evaluation for the requested changes that was published on May 8, 1996 (61 FR 20858).

Description of amendment request: The proposed amendment application would change the technical specifications (TS) for the reactor coolant system and associated Bases to allow the installation of electrosleeves in the Callaway steam generators for two fuel cycles.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The electrosleeve configuration has been designed and analyzed in accordance with the requirements of the ASME [American Society of Mechanical Engineers] Code. The applied stresses and fatigue usage for the sleeve are bounded by the limits established in the ASME Code. ASME Code minimum material property values are used for the structural and plugging limit analysis. Mechanical testing has shown that the structural strength of nickel electrosleeves under normal, upset and faulted conditions provides margin to the acceptance limits. These acceptance limits bound the most limiting (3 times normal operating pressure differential) burst margin recommended by RG [Regulatory Guide] 1.121. Leakage testing for 5/8″, 7/8″, 1 1/16″ and 3/4″ tube sleeves has demonstrated that no unacceptable levels of primary to secondary leakage are expected during any plant condition.

The sleeve nominal wall thickness (used for developing the depth-based plugging limit for the sleeve) is determined using the guidance of Regulatory Guide 1.121 and the pressure stress equation of Section III of the ASME Code. The limiting requirement of Regulatory Guide 1.121, which applies to part throughwall degradation, is that the minimum acceptable wall must maintain a factor of safety of three against tube failure under normal operating (design) conditions. A bounding set of design and transient loading input conditions was used for the minimum wall thickness evaluation in the generic evaluation. Evaluation of the minimum acceptable wall thickness for normal, upset and postulated accident condition loading per the ASME Code indicates these conditions are bounded by the design condition requirement minimum wall thickness.

A bounding tube wall degradation growth rate per cycle and a NDE [Non-Destructive Examination] uncertainty has been assumed for determining the sleeve TS plugging limit. The sleeve wall degradation extent is determined by NDE. The degradation which would require plugging sleeved tubes is developed using the guidance of RG 1.121 and is defined in BAW–10219P, to be 20% throughwall for any service induced degradation.

The consequences of failure of the sleeve are bounded by the current steam generator tube rupture analysis included in the Callaway FSAR [Final Safety Analysis Report]. Due to the slight reduction in diameter caused by the sleeve wall thickness, primary coolant release rates would be slightly less than assumed for the steam generator tube rupture analysis (depending on the break location), and therefore, would result in lower total primary fluid mass release to the secondary system.

A risk assessment for installation of Electrosleeves at Callaway Plant was performed for a two-cycle operating period. The results of this evaluation determined that sufficient margins against postulated tube rupture during bounding accident conditions exist for all types of degradation of the Electrosleeve material. The calculated probability of burst for a hypothetical population of 10,000 axial flaws, 100% throughwall of the parent tube and 0.40″ long, is 4.4×10–11 at the end of the second operating cycle. The probability of burst for postulated circumferential flaws and pits is determined to be essentially zero.

The proposed change does not adversely impact any other previously evaluated design basis accident or the results of LOCA [Loss of Coolant Accident] and non-LOCA accident analyses for the current technical specification minimum reactor coolant system flow rate. The results of the analyses and testing demonstrate that the electrosleeve is an acceptable means of maintaining tube integrity. Furthermore, per Regulatory Guide 1.83 recommendations, the sleeved tube can be monitored through periodic inspections with present NDE techniques. These measures demonstrate that installation of sleeves spanning degraded areas of the tube will restore the tube to a condition consistent with its original design basis.

Conformance of the electrosleeve design with the applicable sections of the ASME Code and results of the leakage and mechanical tests, support the conclusion that installation of electrosleeves will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Electrosleeving does not represent a potential to adversely affect any plant component. Stress and fatigue analysis of the repair has shown that the ASME Code and Regulatory Guide 1.121 criteria are not exceeded. Implementation of electrosleeving maintains overall tube bundle structural and leakage integrity at a level consistent to that of the originally supplied tubing during all plant conditions. Leak and mechanical testing of electrosleeves support the conclusions of the calculations that each sleeve retains both structural and leakage integrity during all conditions. Sleeving of tubes does not provide a mechanism resulting in an accident outside of the area affected by the sleeves. Any accident as a result of potential tube or sleeve degradation in the repaired portion of the tube is bounded by the existing tube rupture accident analysis.

Implementation of sleeving will reduce the potential for primary to secondary leakage during a postulated steam line break while not significantly impacting available primary coolant flow area in the event of a LOCA. By effectively isolating degraded areas of the tube through repair, the potential for steam line break leakage is reduced. These degraded intersections now are returned to a condition consistent with the Design Basis. While the installation of a sleeve reduces primary coolant flow, the reduction is far below that caused by plugging. Therefore, far greater primary coolant flow area is maintained through sleeving versus plugging.

3. The proposed change does not involve a significant reduction in a margin of safety.

The electrosleeve repair of degraded steam generator tubes has been shown by analysis to restore the integrity of the tube bundle consistent with its original design basis condition, i.e., tube/sleeve operational and faulted condition stresses are bounded by the ASME Code requirements and the repaired tubes are leaktight. The safety factors used in the design of sleeves for the repair of degraded tubes are consistent with the safety factors in the ASME Code used in steam generator design. The portions of the installed sleeve assembly which represent the reactor coolant pressure boundary can be monitored for the initiation and progression of sleeve/tube wall degradation, thus satisfying the requirements of Regulatory Guide 1.83. The portion of the tube bridged by the sleeve is effectively removed from the pressure boundary, and the sleeve then forms the new pressure boundary. The areas of the sleeved tube assembly which require inspection are defined in BAW–10219P.

In addition, since the installed sleeve represents a portion of the pressure boundary, a baseline inspection of these areas is required prior to operation with sleeves installed. The effect of sleeving on the design transients and accident analyses has been reviewed based on the installation of sleeves up to the level of steam generator tube plugging coincident with the minimum reactor flow rate and the Callaway Safety Analysis.

Provisional requirements cited in other NRC Safety Evaluation Reports addressing the implementation of sleeving have required the reduction of the individual steam generator normal operation primary to secondary leakage limit from 500 to 150 gpd [gallons per day]. Consistent with these evaluations, Union Electric will reduce the per steam generator leak rate of 500 gpd in TS 3.4.6.2.c to 150 gpd. The establishment of this leakage limit at 150 gpd provides additional safety margin. [The staff notes that this leakage limit has been incorporated into the Callaway Technical Specifications via license amendment #119 dated October 1, 1996.]

Finally, Union Electric will reduce the tube plugging limit from 48% through wall to 40% through wall to be consistent with NUREG–1431. The establishment of the plugging limit at 40% through wall provides additional safety margin. [The staff notes that this plugging limit has been incorporated into the Callaway Technical Specifications via license amendment #119 dated October 1, 1996.]

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Missouri-Columbia, Elmer Ellis Library, Columbia, Missouri 65201–5149.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, D.C. 20037.

NRC Project Director: William H. Bateman.

Vermont Yankee Nuclear Power Corporation, Docket No. 50–271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: November 3, 1998.

Description of amendment request: The licensee proposes to make administrative changes to the Technical Specifications to correct errors, add consistency within the Technical Specifications, and make nomenclature changes to support and enhance usability of the Technical Specifications.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated, because:

The proposed changes are purely administrative in nature and have no effect on plant hardware, plant design, safety limit setting, or plant system operation and therefore do not modify or add any initiating parameters that would significantly increase the probability or consequences of an accident previously evaluated.

No new modes of operation are introduced by the proposed changes such that adverse consequences would result. Accordingly, the consequences of previously analyzed accidents are not affected by this proposed license amendment.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated, because:

These changes do not affect the operation of any systems or components, nor do they involve any potential initiating events that would create any new or different kind of accident. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated for the Vermont Yankee Nuclear Power Station.

3. Involve a significant reduction in a margin of safety, because:

These proposed changes do not affect any equipment involved in potential initiating events or safety limits. Therefore, it is concluded that the proposed changes do not involve a significant reduction in a margin of safety.

Administrative changes, as such, do not constitute any significant hazards considerations.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301.

Attorney for licensee: Mr. David R. Lewis, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037–1128.

NRC Project Director: Cecil O. Thomas.

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: November 10, 1998.

Description of amendment request: The proposed changes to North Anna Power Station (NAPS), Units 1 and 2, Technical Specification (TS) 3.4.4 will clarify the operability requirements for the pressurizer heaters and eliminate a potential verbatim compliance issue associated with the pressurizer heaters and emergency power supply. The verbatim compliance issue was created when the Emergency Diesel Generator allowed outage time was changed from 72 hours to 14 days.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the

licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Virginia Electric and Power Company has reviewed the requirements of 10 CFR 50.92 as they relate to the proposed changes for the North Anna Units 1 and 2 and determined that a significant hazards consideration is not involved. The proposed changes will revise the LCO [limiting condition for operation] 3.4.4 to require that the pressurizer have two groups of pressurizer heaters operable with a capacity of greater than or equal to 125 kW and capable of being powered from its associated emergency bus. The Action Statement will also be revised to focus on heater operability. The following is provided to support this conclusion.

(a) Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The pressurizer heaters are not an initiator of any accident previously evaluated. As a result, the probability of any accident previously evaluated is not increased. The pressurizer heaters remain operable as assumed in the accident analysis to mitigate the consequences of any accident. Therefore, the proposed changes to clarify the operability requirements do not significantly increase the probability of occurrence or the consequences of any previously analyzed accident.

(b) Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed Technical Specifications changes do not involve any physical alteration of the plant or changes in methods governing normal plant operation. Operation of and the design of the pressurizer heaters and the associated power supplies are not changed by the proposed changes. The proposed changes do not impose any new or eliminate any existing requirements. Therefore, it is concluded that no new or different kind of accident or malfunction from any previously evaluated has been created.

(c) Does the change involve a significant reduction in a margin of safety?

The proposed Technical Specifications changes will not reduce the margin of safety since the change has no effect on any safety analyses assumptions. The pressurizer heaters remain operable as assumed in the safety analysis to mitigate the consequences of any accident previously analyzed. The proposed changes only clarify the operability requirements for the pressurizer heaters and associated emergency power supplies. Therefore, the proposed changes do not result in a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903–2498.

Attorney for licensee: Donald P. Irwin, Esq., Hunton and Williams, Riverfront Plaza, East Tower, 951 E. Byrd Street, Richmond, Virginia 23219.

NRC Project Director: Herbert N. Berkow.

Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Florida Power and Light Company, et al., Docket Nos. 50–335, and 50–389, St. Lucie Plant, Unit Nos. 1, and 2, St. Lucie County, Florida

Date of amendment request: October 29, 1998.

Description of amendment request: Technical Specification changes (TS) relating to the implementation and automatic removal of certain reactor protection system trip bypasses to ensure that the meaning of explicit terms used in the TSs are consistent with the intent of the stated requirements.

Date of publication of individual notice in the **Federal Register**: November 5, 1998 (63 FR 59809).

Expiration date of individual notice: November 19, 1998.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954–9003.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see: (1) The applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document rooms for the particular facilities involved.

Baltimore Gas and Electric Company, Docket No. 50–318, Calvert Cliffs Nuclear Power Plant, Unit No. 2, Calvert County, Maryland

Date of application for amendment: July 20, 1998.

Brief description of amendment: The amendment implements a modification that constitutes an unreviewed safety question as described in 10 CFR 50.59. The modification involves replacing the service water heat exchangers with new plate and frame heat exchangers having an increased thermal performance capability. The planned modification is similar to the one completed on Unit 1. In addition, by a separate letter dated July 20, 1998, the licensee submitted a request to obtain approval for a temporary one time cooling lineup needed to support emergency diesel generator operability for the installation of the Unit 2 service water heat exchanger replacement, which is currently being reviewed by the NRC

staff. Therefore, since the implementation of the proposed service water heat exchanger modification is dependent on the staff's issuance of the one time Technical Specification (TS) change regarding installation of the modification, this modification should not be implemented prior to the issuance of the one-time TS change for installing the modification.

Date of issuance: November 5, 1998.

Effective date: This license amendment is effective as of the date of its issuance to be implemented after the staff's issuance of the one-time TS change regarding the installation of the service water heat exchanger modification.

Amendment No.: 203.

Facility Operating License No. DPR–69: Amendment revised the Updated Final Safety Analysis Report.

Date of initial notice in **Federal Register**: August 12, 1998 (63 FR 43201).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 5, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Boston Edison Company, Docket No. 50–293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: June 26, 1998.

Brief description of amendment: The amendment modifies various Technical Specification pages to correct typographical errors, remove inadvertent replication of information, and updates various Bases sections.

Date of issuance: November 10, 1998.

Effective date: November 10, 1998.

Amendment No: 178.

Facility Operating License No. DPR–35: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register**: September 23, 1998 (63 FR 50933).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 10, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: March 6, 1998, as supplemented September 11, 1998. The September 11, 1998, supplemental letter contained clarifying information only, and did not change the no significant hazards consideration determination.

Brief description of amendment: The amendment revises Technical Specification 3.9.2 relating to the use of Post-Accident Monitoring Source Range neutron flux detectors as a compensatory measure in the event that one of the two required BF3 neutron flux detectors becomes inoperable during Mode 6 operations (refueling).

Date of issuance: November 12, 1998.

Effective date: November 12, 1998.

Amendment No: 180.

Facility Operating License No. DPR–23: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register**: June 3, 1998 (63 FR 30262).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 12, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Hartsville Memorial Library, 147 West College Avenue, Hartsville, South Carolina 29550.

Duke Energy Corporation, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of application of amendments: September 17, 1998, as supplemented October 15, 1998.

Brief description of amendments: The amendments revised the Updated Final Safety Analysis Report to perform a Keowee Emergency Power Engineered Safeguards Functional Test during the 1998 Unit 3 refueling outage at Oconee.

Date of Issuance: November 12, 1998.

Effective date: As of the date of issuance to be implemented during the 1998 Unit 3 refueling outage.

Amendment Nos.: Unit 1—233; Unit 2—233; Unit 3—232.

Facility Operating License Nos. DPR–38, DPR–47, and DPR–55: Amendments revised the Updated Final Safety Analysis Report.

Date of initial notice in **Federal Register**: September 30, 1998 (63 FR 52304).

The October 15, 1998, letter provided clarifying information that did not change the scope of the September 17, 1998, application and the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 12, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

GPU Nuclear, Inc., Docket No. 50–320, Three Mile Island Nuclear Station, Dauphin County, Pennsylvania

Date of application for amendment: December 2, 1996.

Brief description of amendment: This amendment would revise audit frequency requirements and relocate them from the Technical Specifications to the Quality Assurance Plan.

Date of issuance: November 12, 1998.

Effective date: This amendment is effective immediately to be implemented written 60 days.

Amendment No.: 52.

Facility Operating License No. DPR–73: The amendment revises the Technical Specifications.

Date of initial notice in **Federal Register**: July 30, 1997 (62 FR 40850).

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Unit Nos. 2 and 3, San Diego County, California

Date of application for amendments: May 11, 1998, as supplemented by letter dated October 9, 1998.

Brief description of amendments: The amendments modify the technical specifications (TS) for San Onofre Nuclear Generating Station Unit Nos. 2 and 3 to implement 10 CFR Part 50 Appendix J, Option B for performance-based reactor containment leakage testing.

Date of issuance: November 6, 1998.

Effective date: November 6, 1998, to be implemented within 30 days from the date of issuance.

Amendment Nos.: Unit 2 –144; Unit 3 –135.

Facility Operating License No. NPF–10 and NPF–15: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register**: September 9, 1998 (63 FR 48265).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 6, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Main Library, University of California, P. O. Box 19557, Irvine, California 92713.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: July 6, 1998.

Brief description of amendments: Relocates the description of the reactor coolant system design features in Technical Specification 5.4 to the Updated Final Safety Analysis Report, which already contains the information.

Date of issuance: November 18, 1998.

Effective date: November 18, 1998, to be implemented within 30 days.

Amendment Nos.: Unit 1—Amendment No. 98; Unit 2—Amendment No. 85.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register**: September 9, 1998 (63 FR 48266).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 18, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas.

Date of amendment request: July 6, 1998 , as supplemented on October 28, 1998.

Brief description of amendments: Relocate the Technical Specification 3/4.3.3.3 requirements for Seismic Instrumentation to the Technical Requirements Manual.

Date of issuance: November 18, 1998.

Effective date: November 18, 1998, to be implemented within 30 days.

Amendment Nos.: Unit 1—Amendment No. 99; Unit 2—Amendment No. 86.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register**: September 9, 1998 (63 FR 48267).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 18, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas.

Date of amendment request: July 6, 1998, as supplemented on October 28, 1998.

Brief description of amendments: Relocates the Technical Specification 3/4.7.13 requirements for the Area Temperature Monitoring System to the Technical Requirements Manual.

Date of issuance: November 18, 1998.

Effective date: November 18, 1998, to be implemented within 30 days.

Amendment Nos.: Unit 1—Amendment No. 100; Unit 2—Amendment No. 87.

Facility Operating License Nos. NPF–76 and NPF–80: The amendment revises the Technical Specifications.

Date of initial notice in **Federal Register**: September 9, 1998 (63 FR 48267). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 18, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee.

Date of application for amendments: February 13, 1998 (TS 97–07).

Brief description of amendments: The amendments incorporate new main steam isolation valve (MSIV) requirements that are consistent with NUREG–1431, the Westinghouse Standard Technical Specifications (TS), including testing requirements for the MSIVs that ensure the valves close on an automatic actuation signal.

Date of issuance: November 17, 1998.

Effective date: As of the date of issuance to be implemented no later than 45 days after issuance.

Amendment Nos.: 236 and 226.

Facility Operating License Nos. DPR–77 and DPR–79: Amendments revise the technical specifications.

Date of initial notice in **Federal Register**: April 22, 1998 (63 FR 19980).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 17, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: June 26, 1998 (TS 98–02).

Brief description of amendments: The amendments change the Technical Specifications and their Bases to lower the specific activity limit for the primary coolant system from 1.0 microcurie/gram dose equivalent iodine-131 to 0.35 microcurie/gram, as provided for in NRC Generic Letter 95–05, ''Voltage-Based Repair Criteria for Westinghouse Steam Generator Tubes Affected by Outside Diameter Stress Corrosion Cracking.'' This change allows a proportional increase in main steam line break induced primary-to-secondary leakage when implementing the alternate steam generator tube repair criteria, which the NRC has already approved for Sequoyah Nuclear Plant, Units 1 and 2.

Date of issuance: November 17, 1998.

Effective date: As of the date of issuance to be implemented no later than 45 days after issuance.

Amendment Nos.: 237 and 227.

Facility Operating License Nos. DPR–77 and DPR–79: Amendments revise the technical specifications.

Date of initial notice in **Federal Register**: July 15, 1998 (63 FR 38205).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 17, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, Tennessee 37402.

Tennessee Valley Authority, Docket No. 50–390 Watts Bar Nuclear Plant, Unit 1, (WBN) Rhea County, Tennessee

Date of application for amendment: August 5, 1998 (TS 98–008).

Brief description of amendment: This amendment is in response to your application dated August 5, 1998. The amendment revises the WBN Technical Specifications (TS) and associated TS Bases to allow up to 4 hours to make the residual heat removal suction relief valve available as a cold overpressure mitigation system relief path.

Date of issuance: November 10, 1998.

Effective date: November 10, 1998.

Amendment No.: 14.

Facility Operating License No. NPF–90: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register**: September 23, 1998 (63 FR 50940).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 10, 1998.

No significant hazards consideration comments received: None.

Local Public Document Room location: Chattanooga-Hamilton County Library, 1001 Broad Street, Chattanooga, TN 37402.

TU Electric Company, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: July 10, 1996 (TXX–96405), as supplemented by letters dated October 1, 1996 (TXX–96475), and July 1, 1998 (TXX–98159).

Brief description of amendments: The amendment would take credit for the addition of train oriented Fan Coil Units for each UPS and Distribution Room and would provide redundancy to the existing Air Conditioning (A/C) Units (TS 3/4.7.11 and its associated bases).

Date of Issuance: Date of issuance: November 18, 1998.

Effective date: November 18, 1998, to be implemented within 30 days.

Amendment Nos.: Unit 1—Amendment No. 61; Unit 2—Amendment No. 47.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register**: February 12, 1997 (62 FR 6579).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 18, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, TX 76019.

Wisconsin Public Service Corporation, Docket No. 50–305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin

Date of application for amendment: May 7, 1998.

Brief description of amendment: This amendment revises Technical Specification 5.4, ''Fuel Storage,'' to increase the allowable mass of uranium-235 (U^{235}) per axial centimeter for fuel storage. The requested change will allow the use of new Siemens Power Corporation heavy fuel assembly designs.

Date of Issuance: November 12, 1998.

Effective date: November 12, 1998.

Amendment No.: 141.

Facility Operating License No. DPR–43: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register**: June 17, 1998 (63 FR 33111).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 12, 1998.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin, Cofrin Library, 2420 Nicolet Drive, Green Bay, WI 54311–7001.

Dated at Rockville, Maryland, this 24th day of November 1998.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Acting Director Division of Reactor Projects—III/IV Office of Nuclear Reactor Regulation.

[FR Doc. 98–31931 Filed 12–1–98; 8:45 am]

BILLING CODE 7590–01–P

PRESIDIO TRUST

Management of the Presidio

AGENCY: The Presidio Trust.

ACTION: Notice of availability for public comment.

SUMMARY: This notice announces the availability of and requests comments on the Interim Compendium compiled pursuant to final interim regulations concerning management of the area under the administrative jurisdiction of the Presidio Trust. The final interim regulations were adopted by the Presidio Trust as 36 CFR parts 1001, 1002, 1004, and 1005 and published in the **Federal Register** on June 30, 1998 (63 FR 35694).

DATES: Comments on the Interim Compendium must be received by January 29, 1999.

ADDRESSES: Written comments on the Interim Compendium must be sent to Karen A. Cook, General Counsel, The Presidio Trust, 34 Graham Street, P.O. Box 29052, San Francisco, CA 94129–0052.

FOR FURTHER INFORMATION CONTACT: Karen A. Cook, General Counsel, The Presidio Trust, 34 Graham Street, P.O. Box 29052, San Francisco, CA 94129–0052. Telephone: 415–561–5300.

SUPPLEMENTARY INFORMATION:

Background

The Presidio Trust's final interim regulations at 36 CFR parts 1001, 1002, 1004, and 1005 provide that the Board of Directors of the Presidio Trust ''shall compile in writing all the designations, closures, permit requirements and other restrictions imposed under discretionary authority.'' 36 CFR 1001.7(b). The Board has compiled these in an Interim Compendium. This Interim Compendium was approved by the Board on June 30, 1998 and is currently in effect.

Although public notice and comment on this Interim Compendium is not required by the Trust's regulations or other applicable authority, the Trust's Board has decided to make the Interim Compendium available for public comment for a period of 60 days. Following the public comment period, the Trust will consider any comments received and make any appropriate changes to the Interim Compendium. Because the Trust is currently engaged in a rulemaking concerning management of the Presidio and various administrative matters, the Trust may make other changes to the Interim Compendium both during this comment period and following its close.

How to Obtain Copies

During this comment period, a copy of the Interim Compendium is available for public inspection and copying during normal office hours (9:00 a.m. to 5:00 p.m., excluding Saturdays, Sundays, and Federal holidays) at the offices of the Presidio Trust, 34 Graham Street, The Presidio, San Francisco, CA 94129. Prior to the close of the comment period, upon receipt of a written request and advance payment by check or money order to the Presidio Trust in the amount of $2.40 for photocopying charges, the Trust will mail a copy of the Interim Compendium to any interested member of the public.

Dated: November 23, 1998.

Karen A. Cook,

General Counsel.

[FR Doc. 98–31909 Filed 12–1–98; 8:45 am]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 23572; 813–186]

KECALP Inc., et al.; Notice of Application

November 24, 1998.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under sections 6(b) and 17(b) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to amend a prior order and under sections 6(b) and 17(b) to permit certain transaction otherwise prohibited by section 17(a) of the Act.

SUMMARY OF THE APPLICATION: Applicant request an order to exempt certain limited partnerships registered under the Act as closed-end management investment companies form certain provisions of the Act and permit the partnerships to engage in certain joint transactions. Each partnership is an ''employees' securities company'' as defined in section 2(a)(13) of the Act. The requested order amends several previous orders (collectively, the ''KECALP Order'').[1] In addition, applicant request relief to permit two partnerships to transfer interests in certain investments to an affiliated entity in exchange for limited partnership interests in that entity.

APPLICANTS: KECALP Inc. (''General Partner''); Merrill Lynch KECALP L.P. 1986 (''1986 Partnership''), Merrill Lynch KECALP L.P. 1987 (''1987 Partnership''), Merrill Lynch KECALP L.P. 1989 (''1989 Partnership''), Merrill Lynch KECALP L.P. 1991 (''1991 Partnership''), Merrill Lynch KECALP L.P. 1994 (''1994 Partnership''), Merrill Lynch KECALP L.P. 1997 (''1997 Partnership''), and Merrill Lynch KECALP L.P. 1999 (''1999 Partnership'') (collectively, together with other partnerships that may be organized by the General Partner in the future, the ''Partnerships''); and Merrill Lynch Global Emerging Markets Partners, L.P. (''Global Investment Fund'').

FILING DATES: The application was filed on April 14, 1998, and amended on September 15, 1998. Applicants have agreed to file and amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 16, 1998, and should be accompanied by proof of service on applicants in the form of a affidavit or, for lawyers, a certificate of service. Hearing request should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing tot he Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, South Tower, World Financial Center, 225 Liberty Street, New York, NY 10080–6123.

FOR FURTHER INFORMATION CONTACT: Michael W. Mundt, Staff Attorney, at (202) 942–0578, or Edward P. Macdonald, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549 (tel. (202) 942–8090).

Applicants' Representations

1. Each Partnership is a Delaware limited partnership registered under the Act as a non-diversified, closed-end management investment company. Each Partnership is an ''employees' securities company'' with in the meaning of section 2(a)(13) of the Act and operates according to the terms of the KECALP Order. Limited partnership interests in the Partnerships were offered to certain employees of Merrill Lynch & Co., Inc. (''ML & Co.'') and its subsidiaries and to non-employee directors of ML & Co. The 1997 Partnership also offered limited partnership interests to ML & Co. in connection with certain deferred compensation arrangements. Applicants state that the Partnerships enable directors and certain officers and other employees to pool their investment resources and to receive the benefit of certain investment opportunities that come to the attention of ML & Co. or its subsidiaries. Applicants assert that the Partnerships are primarily for the benefit of the employee/director limited partners and are a significant way for ML & Co. and its subsidiaries to attract and retain qualified personnel.

2. Applicants expect that the General Partner will organize additional partnerships in the future (such partnerships, together with the 1999 Partnership, ''Future Partnerships'').[2] Interests in Future Partnerships will be offered to employees of ML& Co. and its subsidiaries who earn, or whose annualized salary is, at least $100,000 for the calendar year preceding the offering. No employee meting this requirement will be permitted to invest more than 15% of the employee's cash compensation form ML & Co. and its subsidiaries in any partnership unless such employee is an ''accredited investor,'' as defined in rule 501(a) of Regulation D under the Securities Act of 1933 (''1933 Act''). Future Partnerships also may offer limited partnership interests to persons on retainer with ML & Co. or its subsidiaries if the persons qualify as ''accredited investors'' Other than the requirement that they be ''accredited investors,'' persons on retainer will participate in Future Partnerships on the same terms as employees of ML & Co. In addition, ML & Co. and its affiliates may acquire limited partnership interests in Future Partnerships to mirror the election by select employees of ML & Co. and its subsidiaries to participate in compensation or investment programs where the return is linked to the performance of a Partnership. To make such an investment, ML & Co. or its affiliate must (i) determine that the eligibility requirements for employee participation in the compensation or investment program are at least equal to the standards for direct investment by employees of ML & Co. in the Partnership and (ii) agree to vote its interests in Partnership in identical proportions to other limited partners. Persons eligible to invest in the

[1] Merrill Lynch KECALP Ventures Limited Partnership 1982, et al., Investment Company Act Rel. Nos. 12290 (Mar. 11, 1982) (notice) and 12363 (Apr. 8, 1982) (order); Merrill Lynch KECALP Growth Investments Limited Partnership 1983, et al., Investment Company Act Rel. Nos. 18082 (Apr. 8, 1991) (notice) and 18137 (May 7, 1991) (order); Merrill Lynch KECALP Growth Investments L.P. 1983, et al., Investment Company Act Rel. Nos. 20280 (May 5, 1994) (notice) and 20328 (June 1, 1994) (order); Merrill Lynch KECALP L.P. 1994, et al., Investment Company Act Rel. Nos. 21124 (June 8, 1995) (notice) and 21187 (Jul. 5, 1995) (order); and Merrill Lynch KECALP L.P. 1997, et al., Investment Company Act Rel. Nos. 22647 (Apr. 30, 1997) (notice) and 22689 (May 28, 1997) (order).

[2] Any entity that currently intends to rely on the requested order is named as an applicant. Any other existing or future entity that relies on the requested order will comply with the terms and conditions of the application.

Partnerships are referred to as ''Limited Partners.'' Interests in the Partnerships are non-transferable except with the express consent of the General Partner and, in any event, are not transferable to persons who are not Limited Partners, except that interests may be transferred to members of a Limited Partner's immediate family or, by operation of law, to certain other parties under special circumstances.

3. The General Partner is an indirect, wholly-owned subsidiary of ML & Co. that is registered as an investment adviser under the Investment Advisers Act of 1940. The General Partner is responsible for the management of the Partnerships and has the authority to make all decisions regarding the acquisition, management, and disposition of the partnerships' investments. The board of directors of the General Partner (''Board'') will continue to have overall responsibility for a Partnerships' investments.

4. Under the partnership agreements of the Partnerships, the General Partner pays operating expenses in connection with the Partnerships and is entitled to receive annual reimbursements from the Partnerships of up to 1.5% of the Limited Partners' capital contributions. In addition, the General Partner is responsible for any commissions chargeable to the Partnerships with respect to portfolio transactions. Future partnership may pay operating expenses directly and reimburse the General partner for personnel, overhead and other administrative expenses. Amounts paid by the Future Partnership for operating expenses and reimbursements to the General Partner will be subject to an annual aggregate limit of 1.5% of Limited Partners' capital commitments. Appropriate disclosure regarding payments and reimbursements will be set forth in a Future Partnership's offering documents. To the extent provided in their organizational documents, Future Partnerships also may be responsible for payment of commissions and other fees and expenses relating to the acquisition, monitoring and disposition of portfolio investments.

5. The Global Investment Fund is a Delaware limited partnership formed to achieve capital appreciation principally through privately negotiated equity and equity-linked investments in companies operating primarily in emerging markets. ML Global Capital L.L.C., an affiliate of ML & Co., is the general partner of the Global Investment Fund, and ML Global Partners, Inc., a subsidiary of ML & Co., performs the management services. The Global Investment Fund is exempt from regulation under the Act in reliance on section 3(c)(7) of the Act. The Global Investment Fund seeks relief so that the 1994 Partnership and 1997 Partnership may transfer interests in certain investments to the Global Investment Fund in exchange for limited partnership interests in the Global Investment Fund.

6. Under the KECALP Order, ML & Co. or a subsidiary may acquire an investment approved by the General Partner for acquisition by the Partnership and hold the investment (''Warehoused Investment'') until the closing of the Partnership's offering to Limited Partners. Upon completion of its offering, the Partnership would purchase each Warehoused Investment from ML & Co. or the subsidiary at the lesser of each Warehoused Investment's (a) fair value on the date of purchase by the Partnership or (b) purchase cost paid by ML & Co. and its subsidiaries. Applicants assert that the Warehoused Investment procedure facilitates the Partnerships' investment process. The requested order would permit the Partnerships to acquire Warehoused Investments from ML & Co. and its subsidiaries subject to modified conditions that would afford the Partnerships greater flexibility.

7. Under the KECALP Order, the Partnerships also may engage in certain joint transactions and investments with affiliates of the Partnerships. Applicants seek relief to permit certain joint transactions, including transactions involving restructurings and recapitalizations, (collectively, ''Merrill Lynch Investments'') in which the Partnerships are participants with ML & Co. and other affiliated persons of the Partnerships (''Affiliated Co-Investors'') subject to the conditions detailed below.

Applicants' Legal Analysis

A. Warehoused Investments

1. Section 17(a) of the Act generally prohibits sales or purchases of securities between a registered investment company and any affiliated person of that company. ML & Co. and each of its direct and indirect wholly-owned subsidiaries, including the General Partner, are affiliated persons under section 2(a)(3)(C) of the Act. The General Partner is an affiliated person of the Partnerships under section 2(a)(3)(D) of the Act. As a result of these affiliations, sales of securities or other property on a principal basis by the General Partner or an affiliate to the Partnership may be prohibited under section 17(a).

2. Section 6(b) of the Act provides that the Commission shall exempt employees' securities companies from the provisions of the Act to the extent that such exemption is consistent with the protection of investors. Section 17(b) of the Act permits the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned, the proposed transaction is consistent with the policy of each investment company concerned, and the proposed transaction is consistent with the general purposes of the Act.

3. Applicants request relief from section 17(a) pursuant to sections 6(b) and 17(b) of the Act to permit the Partnerships to acquire Warehoused Investments from ML & Co. and direct and indirect wholly-owned subsidiaries of ML & Co. (including the General Partner) subject to conditions modified from the KECALP Order. Under the requested order, (i) the warehouse period during which ML & Co. or a subsidiary may hold a Warehoused Investment would be increased from 12 to 18 months; (ii) the purchase price paid by a Partnership for the Warehoused Investments would be calculated on an aggregate basis, rather than for each Warehoused Investment individually; and (iii) the approval of a Warehoused Investment by the Board for acquisition by a Partnership would be made either prior to or within 30 days of the acquisition of the Warehoused Investment by ML & Co. or its subsidiary.[3]

4. Applicants state that with the proposed changes, the transactions involving Warehoused Investments will continue to meet the standards of sections 6(b) and 17(b). Applicants assert that the revised conditions would allow for a valuation method for Warehoused Investments that is more fair to the public shareholders of ML & Co. and that will not cause a Partnership to pay more than the aggregate fair value of Warehoused Investments acquired on its behalf. In addition, applicants state that the change in the timing of the Board approval will provide the Partnerships with increased investment flexibility by allowing for circumstances where a Partnership has been presented with the opportunity to invest in a transaction, but the Board of Directors of the General Partner has not been able to make all of the required findings prior

[3] Under the KECALP Order, the Board approved the acquisition of a Warehoused Investment prior to its purchase by ML & Co. or a subsidiary and approved the acquisition a second time after the closing of the Partnership's offering to the Limited Partners.

to the purchase by ML & Co. or its subsidiaries.

B. Transaction with the Global Investment Fund

1. Applicants request relief pursuant to sections 6(b) and 17(b) of the Act from section 17(a) of the Act to permit the 1994 Partnership and 1997 Partnership to transfer their interests in certain investments to the Global Investment Fund in exchange for limited partnership interests in the Global Investment Fund. The 1994 Partnership and the 1997 Partnership are invested in certain portfolio companies in which the Global Investment Fund also is invested. Applicants state that the exchange will have no economic effect on the Partnerships because it would be structured so that each Partnership would only change the vehicle through which the Partnerships hold these investments, and the Partnerships' interests in the Global Investment Fund would correspond only to the transferred investments. The transfer of the Partnerships' investments to the Global Investment Fund would not be deemed by the Partnerships to be an event requiring any change in the valuation of the Partnerships' interests in the investments. The Partnerships will not pay any fees to ML & Co. or its affiliates in connection with the transfer. Upon disposition of an investment by the Global Investment Fund, each Partnership would receive the portion of any net proceeds corresponding to its indirect interest in the investments.

C. Joint Investments by the Partnerships and their Affiliates

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit affiliated persons from participating in joint arrangements with a registered investment company unless authorized by the Commission. Rule 17d–1 provides that in passing on applications for such orders, the Commission will consider whether the participation by the investment company is consistent with the provisions, policies, and purpose of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of the other participants.

2. Applicants seek relief pursuant to section 6(b) and rule 17d–1 to permit Merrill Lynch Investments in which the Partnerships are participants with Affiliated Co-Investors. Applicants assert that the proposed conditions that would govern these transactions would assure that the Partnerships participate on a basis no less advantageous than that of Affiliated Co-Investors. Applicants also assert that the community of interest between the Partnerships and ML & Co. would further assure that the transactions would be in the best interests of the Partnerships.

D. Certain Compensation to ML & Co. or Affiliates

1. Section 17(e) of the Act and rule 17e–1 under the Act limit the compensation an affiliated person may receive when acting as agent or broker for a registered investment company. Applicants request an exemption from section 17(e) pursuant to section 6(b) to permit ML & Co. or an affiliated person, acting as an agent or broker, to receive placement fees, financial advisory fees or other compensation in connection with the purchase and sale of securities by a Partnership, provided that the fees or other compensation can be deemed ''usual and customary.'' Applicants state that fees or other compensation will be deemed ''usual and customary'' only if: (i) the Partnership is purchasing or selling securities alongside other unaffiliated third parties who are also similarly purchasing or selling securities; (ii) the fees or other compensation that are being charged to the Partnership are also being charged to the unaffiliated third parties; and (iii) the amount of securities being purchased or sold by a Partnership does not exceed 50% of the total amount of securities being purchased or sold by the Partnership and the unaffiliated third parties. Applicants assert that compliance with section 17(e) could prevent a Partnership from participating in a transaction in which ML & Co. or an affiliate does not, for other business reasons, wish a Partnership to be treated in a more favorable manner than unaffiliated parties also participating in the transaction.

2. Applicants also request an exemption from rule 17e–1 to the extent necessary to permit each Partnership to comply with rule 17e–1 without the necessity of having a majority of the directors of the General Partner who are not ''interested persons'' take the actions and make the approvals specified in the rule. Because all the directors of the General Partner will be affiliated persons, a Partnership could not comply with rule 17e–1 without the requested relief. Applicants state that each Partnership will have a majority of the directors of the General Partner take the actions and make the approvals required in the rule. Each Partnership will otherwise comply with the requirements of rule 17e–1.

F. Custody of Partnership's Assets

1. Section 17(f) of the Act prescribes certain requirements as to the custody of assets of registered investment companies. The KECALP Order permits certain subsidiaries of ML & Co. to act as custodians of the Partnerships' assets without a written contract required by section 17(f). Rule 17f–1(b)(4) under the Act requires that securities held by a custodian that is a member of a national securities exchange be verified periodically by independent public accountants. Applicants request relief from this requirement pursuant to section 6(b) with respect to the Partnerships' assets held by an ML & Co. subsidiary pursuant to the rule. Applicants state that the Partnerships' assets so held are subject to an annual independent audit and that in light of the community of interest between ML & Co. and the Partnerships, compliance with this requirement in the rule would be unduly burdensome.

F. Periodic Reporting

1. Section 30(h) of the Act requires that every officer, director, and member of an advisory board of a closed-end investment company be subject to the same duties and liabilities as those imposed upon similar classes of persons under section 16 of the Securities Exchange Act of 1934. As a result, the General Partner of each Partnership and certain other persons are required to file Forms 3, 4, and 5 with respect to their ownership of interests in a Partnership. Applicants request an exemption pursuant to section 6(b) from the requirements of section 30(h) to the extent necessary to exempt the General Partner, directors and officers of the General Partner, and any other persons who may be deemed members of an advisory board of a Partnership from filing these forms. Applicants assert that the requirement is not necessary for the protection of investors because there is no trading market for the Partnerships' interests and transfers of these interests are severely restricted.

Applicants' Conditions

Applicants agree that the requested order will be subject to the following conditions:

Condition Relating to Warehoused Investments

1. (a) In order for an investment to quality as a Warehoused Investment to be purchased pursuant to the requested relief, (i)(A) the Board must approve such investment for the subsequent Partnership in the manner described in sub-paragraph (b) of condition 1 prior to the time the investment is acquired by

the General Partner or an affiliate thereof and (B) such investment must be acquired by ML & Co. (which term, in these conditions, includes its subsidiaries) with the intention of acquiring the Warehoused Investment for the subsequent Partnership and selling it to such Partnership after the completion of its initial offering or (ii)(A) the Board must approve such investment in the manner described in sub-paragraph (b) of condition 1 within 30 days after the date of the acquisition by ML & Co. and (B) ML & Co. must thereafter hold such investment with the intention of selling it to a Partnership after the completion of the initial offering of the Partnership. The General Partner will maintain at the Partnerships' office written records stating ML & Co.'s intention in acquiring such security, and stating the factors considered by the Board in approving the investment.

(b) Prior to the acquisition of a Warehoused Investment by a Partnership, (i) the Board must make the following fundings: (A) The terms of the Warehoused Investment, including the consideration to be paid, are reasonable and fair and do not involve overreaching of the Partnership or its Limited Partners on the part of any person concerned; (B) the proposed transaction is consistent with the policy of the Partnership as indicated in its filings under the 1933 Act and its reports to Limited Partners; and (C) participation by the Partnership in the proposed transaction is in the best interest of the Limited Partners of the Partnership; and (ii) with respect to any Warehoused Investment that is part of a co-investment with an affiliate, the Board must approve the investment in accordance with the terms of any orders issued by the Commission that are applicable to such co-investment, including the required findings by the Board. The General Partner will maintain at the Partnerships' office written records of the factors considered in any decision regarding a Warehoused Investment.

(c) The purchase price to be paid by a Partnership for Warehoused Investments acquired for the Partnership prior to the closing of its initial offering shall be the lower of (i) the aggregate cost to ML & Co. of purchasing the Warehoused Investments, plus carrying costs as described below in sub-paragraph (d) or (ii) the aggregate fair value of the Warehoused Investments at the time of purchase by the Partnership (as determined by the Board). The General Partner will maintain at the Partnerships' office written records of the factors considered in any determination regarding the value of a Warehoused Investment.

(d) Carrying costs shall be calculated from the date ML & Co. acquired the Warehoused Investment to the date of the acquisition of the proposed investment by the Partnership from ML & Co. and shall consist of interest charges computed at the lower of (i) the prime commercial lending rate charged by Citibank, N.A. (or any successor), during the period for which carrying costs are permitted to be paid until the Partnership acquires the securities or (ii) the effective cost of borrowings by ML & Co. during such period. The effective cost of borrowings by ML & Co. is its actual ''Average Cost of Funds,'' which it calculates on a daily basis by dividing its consolidated financing expenses by the total amount of borrowings during this period.

(e) A Partnership may only acquire a Warehoused Investment from ML & Co. during the lesser of (i) 18 months from the time ML & Co. purchases the Warehoused Investment or (ii) 30 days from the date of closing of the Partnership's initial offering.

Conditions Relating to Joint Transactions

2. (a) To the extent that a Partnership has funds available for investment, the Board will review, among other investments, co-investments with Affiliated Co-investors that may be brought to the attention of the General Partner. The Board will make a determination as to whether each particular investment meets applicable investment criteria and is consistent with the existing composition of the Partnership's portfolio in terms of diversification of investments.

(b) The General Partner will commit to a co-investment with an Affiliated Co-investor only if the Board, by a majority vote at a properly called and held meeting prior to making the investment, concludes, after consideration of all information deemed relevant, that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Limited Partners of the Partnership and do not involve overreaching of the Partnership or Limited Partners on the part of any person concerned;

(ii) The transaction is consistent with the interests of the Limited Partners of the Partnership and is consistent with the Partnership's investment objectives and policies as recited in filings made by the Partnership under the 1933 Act, its registration statement, and reports to its Limited Partners; and

(iii) The investment by an Affiliated Co-investor in such transaction would not disadvantage the Partnership in the making of its investment, maintaining its investment position, or disposing of the investment.

3. The General Partner will not invest the funds of any Partnership in any investments in which ML & Co. or an affiliate has or proposes to acquire the same class of securities of the same issuer, when the investment involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which the Partnership and ML & Co. or an affiliate are participants, unless ML & Co. or any such affiliate agrees that, prior to disposing of all or part of its investment, it will (i) give the General Partner sufficient, but not less than one day, notice of its intention to dispose of such investment and (ii) refrain from disposing of its investment unless the Partnership has the opportunity to dispose of the Partnership's investment prior to or concurrently with, on the same terms as, and pro rata with ML & Co. or such affiliate; provided, however, that the requirements specified in clauses (i) and (ii) will not be deemed to limit or prevent the disposition of an investment by an affiliate to its direct or indirect subsidiary, to any company (a ''Parent'') of which the affiliate is a direct or indirect wholly-owned subsidiary or to a direct or indirect wholly-owned subsidiary of its Parent. For purposes of this condition 3, the term ''affiliate'' of ML & Co. refers to direct and indirect wholly-owned subsidiaries of ML & Co. and to other entities with respect to which ML & Co. or any such subsidiary is authorized to cause such entity to provide the opportunity for a Partnership to participate in the sale of an investment as contemplated by this condition 3.

4. The Board will review quarterly all information concerning co-investment transactions by the Partnerships with Affiliated Co-investors to determine whether all such investments made during the preceding quarter complied with conditions 2 and 3.

5. At least annually, the General Partner will provide to the Partnerships' Limited Partners a written list of co-investment transactions by the Partnerships with Affiliated Co-investors.

6. In any case where co-investments are made with an Affiliated Co-investor, any individual involved in the management of both the Partnerships and the Affiliated Co-investor will not participate in the Partnerships' determination of whether to effect any co-investment transaction.

7. In connection with proposed transactions otherwise prohibited by section 17(d) of the Act and rule 17d–1 under the Act, the General Partner will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any such transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for the Partnership, or any affiliated person of such person, promoter, or principal underwriter.

8. Each Partnership and the General Partner will maintain and preserve, for the life of each such Partnership and at least two years thereafter, such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements that are to be provided to the Limited Partners, and each annual report of such Partnership required by the terms of the applicable partnership agreement, to be sent to the Limited Partners, and agree that all such records will be subject to examination by the Commission and its staff. Each Partnership will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

9. The General Partner will send Partnership financial statements to each Limited Partner who had an interest in a Partnership at any time during the fiscal year then ended. The statements will be audited by the Partnership's independent accountants. At the end of each fiscal year, the General Partner will make a valuation or have a valuation made of all of the assets of the Partnership as of such fiscal year end. In addition, within 90 days after the end of each fiscal year of each of the Partnerships or as soon as practicable thereafter, the General Partner shall send a report to each person who was a Limited Partner at any time during the fiscal year then ended setting forth such tax information as shall be necessary for the preparation by the Limited Partner of his or her federal and state income tax returns, and a report of the investment activities of the Partnership during such year.

Conditions Relating to Certain Other Affiliated Transactions

10. If a Partnership is presented with the opportunity to invest in a transaction where the General Partner has not been able to consider the determinations set forth in sub-paragraph (b) of condition 2, the Partnership may subsequently acquire the investment from ML & Co. or an affiliate to the extent the investment determination of the Board takes place as soon as practicable but no more than 30 days after the date of the acquisition by ML & Co. or its affiliate and payment by the Partnership is made within five business days after approval by the Board. The purchase price paid by a Partnership for any such investment shall be the lower of (i) the fair value of the investment on the date it is acquired by the Partnership (as determined in good faith by the Board) or (ii) the cost of ML & Co. or its affiliate of purchasing the investment.

11. (a) Sales or tenders by the Partnership to an issuer that is an affiliated person of the Partnership may be made only (i) pursuant to a uniform offer by the issuer to purchase its securities on a pro rata basis made to all holders of the class of securities held by the Partnership (provided that the offer need not be made to employees of the issuer) or (ii) pursuant to an offer made to fewer than all holders of the class of securities held by the Partnership, provided that the Partnership will not participate in such transaction unless a securityholder that is an institutional investor with total assets of at least $100 million and is not an affiliated person of the Partnership or ML & Co. participates in such sale or tender on the same terms as the Partnership.

(b) Prior to entering into any transaction specified in paragraph (a) above, the Board must determine, that such action is in the best interests of the particular Partnership and does not involve overreaching of the Partnership on the part of any person. The General Partner shall record in each Partnership's records the basis for such decision. Transactions entered into pursuant to this paragraph must be effected on the same terms applicable to any affiliate participating in the transaction.

12. The Board will adopt procedures pursuant to which it will monitor potential conflicts of interest between the Partnerships and ML & Co. and its affiliates, including other partnerships that may invest in leveraged buyout investments for which Merrill Lynch MBP Inc. (''MBP''), an indirect wholly-owned subsidiary of ML & Co., acts as general partner, in connection with the Partnerships' investments. Such procedures will provide that the officers of the General Partner will annually prepare and present to the Board written information regarding all potential investments made available to the Partnership during the prior year, including Merrill Lynch Investments. The Board's findings regarding potential conflicts of interest, the specific factors considered, and any further actions to be taken based on or in order to implement the directors' findings will be recorded in each Partnership's records.

13. No person will serve as a member of the Board if such person also is a member of the board of directors of MBP.

14. Each of the 1994 Partnership and the 1997 Partnership may transfer its interests in investments it has acquired to the Global Investment Fund in exchange for interests in such fund, provided that prior to such a transfer the General Partner determines that (i) such transfer has no economic effect on the Partnership and (ii) such transfer is consistent with the best interests of such Partnership.

Other Conditions

15. In order for ML & Co. or an affiliate to acquire limited partnership interests in a Partnership in connection with a compensation or investment program offered to select employees of ML & Co. or its subsidiaries, ML & Co. or such affiliate must (i) determine that the eligibility requirements for participation in such compensation program or investment program are at least equal to the standards for direct investment by employees of ML & Co. in the Partnership and (ii) agree to vote its interests in a Partnership in identical proportions as other Limited Partners in respect of any matter submitted for a vote of Limited Partners.

16. Any Partnership created in the future will not be offered to employees of ML & Co. and its subsidiaries who earned, or whose annualized salary was, less than $100,000 with respect to the calendar year preceding the offering of such Partnership. No employee meeting the requirement in the preceding sentence will be permitted to invest more than 15% of his cash compensation from ML & Co. and its subsidiaries in any Partnership unless such employee is an ''accredited investor,'' as defined in rule 501(a) under the 1933 Act.

17. The General Partner will maintain the records required by section 57(f)(3) of the Act and will comply with the provisions of section 57(h) of the Act as if each Partnership were a business development company. All records referred to or required under this order will be available for inspection by the Limited Partners of each Partnership and the Commission.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32043 Filed 12–1–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–23573; 812–11006]

Technology Funding Venture Capital Fund VI, LLC, et al.; Notice of Application

November 25, 1998.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for an order under section 57(i) of the Investment Company Act of 1940 (the ''Act''), and under rule 17d–1 under the Act permitting certain joint transactions otherwise prohibited by section 57(a)(4) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit a business development company (''BDC'') to co-invest with certain affiliates in portfolio companies. The order would supersede several prior orders.[1]

APPLICANTS: Technology Funding Venture Capital Fund VI, LLC (the ''Company''), Technology Funding Medical Partners I, L.P. (''TFMP I''), Technology Funding Venture Partners V, An Aggressive Growth Fund, L.P. (''TFP V''), Technology Funding Venture Partners IV, An Aggressive Growth Fund, L.P. (''TFP IV''), Technology Funding Partners III, L.P. (''TFP III''); Technology Funding Inc. (''TFI'') and Technology Funding Ltd. (''TFL'') (TFI and TFL together are the ''Investment Managers''). Applicants also request that the relief apply to any BDCs currently or in the future advised by the Investment Managers or by entities controlling, controlled by, or under common control with the Investment Managers (''Future Funds'').[2]

FILING DATES: The application was filed on February 13, 1998, and amended on October 13, 1998 and on November 23, 1998.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief 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 December 17, 1998 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, DC 20549. Applicants, 2000 Alameda de las Pulgas, San Mateo, CA 94403.

FOR FURTHER INFORMATION CONTACT: Lisa McCrea, Attorney Adviser, at (202) 942–0562, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 5th Street N.W., Washington, DC 20549 (tel. 202–942–8090).

Applicants' Representations

1. Each of the Company, TFMP I, TFP V, TFP IV, and TFP III (collectively, the ''Funds'') is organized as either a limited liability company or a limited partnership and has elected to be regulated as a BDC under the Act. TFI and TFL are both registered as investment advisers under the Investment Advisers Act of 1940, and serve as investment advisers to the Funds. TFI and TFL also serve as managing general partners (''Managing General Partners'') of the Funds. TFI is a wholly-owned subsidiary of TFL. Each Fund's investment objectives are long-term capital appreciation from venture capital investment in emerging growth companies, and preservation of investor capital through risk management and active involvement with such companies.

2. Each Fund is governed by a board of directors or general partners (''Directors'' or ''General Partners''). At least a majority of the Directors or General Partners of each Fund are natural persons who are not interested persons of the Fund within the meaning of section 2(a)(19) of the Act (''Independent Directors'' and ''Independent General Partners''). No Independent Director or Independent General Partner of a Fund will serve as an Independent Director or Independent General Partner of any other Fund at the same time.

3. Applicants request relief to permit the Funds and any Future Funds (collectively, the ''Co-Investing Funds'') to co-invest in portfolio companies. Applicants state that the Co-Investing Funds will have substantially similar investment objectives.

Applicants' Legal Analysis

1. Section 57(a)(4) of the Act prohibits certain affiliated persons of a BDC from participating in a joint transaction with the BDC in contravention of such rules as the SEC may prescribe. Section 57(i) of the act provides, in part, that, until the SEC prescribes rules under section 57(a)(4), the SEC's rules under section 17(d) of the Act applicable to closed-end investment companies shall be deemed to apply to transactions subject to section 57(d). Because the SEC has not adopted any rules under section 57(a)(4), rule 17d–1 applies.

2. Rule 17d–1 under the Act generally prohibits affiliated persons of a registered investment company from entering into a joint transaction with the company unless the SEC has issued an order permitting the transaction. In passing upon applications under rule 17d–1, the SEC will consider whether the participation by the BDC in such joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

3. Applicants state that, because the Co-Investing Funds may be deemed to be under the common control of the Investment Managers, the Co-Investing Funds may be prohibited by section 57(a)(4) of the Act and rule 17d–1 from participating in the proposed co-investments without exemptive relief.

4. Applicants state that each Co-Investing Fund will participate in the proposed transactions on the same terms as any other Co-Investing Fund. Applicants further state that the proposed conditions would assure, among other things, oversight of the proposed transactions by each Co-Investing Fund's Independent General Partners of Independent Directors.

[1] *Technology Funding Partners III, L.P., et al.,* Investment Company Act Release Nos. 17523 (June 6, 1990) (notice) and 17571 (July 5, 1990) (order); *Technology Funding Partners III, L.P., et al.,* Investment Company Act Release Nos. 17581 (July 11, 1990) (notice) and 17654 (Aug. 7, 1990) (order); *Technology Funding Partners III, L.P., et al.,* Investment Company Act Release Nos. 17600 (July 18, 1990) (notice) and 17685 (Aug. 17, 1990) (order); and *Technology Funding Medical Partners I, L.P., et al.,* Investment Company Act Release Nos. 19615 (Aug. 6, 1993) (notice) and 19672 (Sept. 1, 1993).

[2] All existing BDCs that currently intend to rely on the order have been named as applicants, and any other existing or future entities that subsequently rely on the order will comply with the terms and conditions in the application.

Applicants' Conditions

Applicants agree that the requested order will be subject to the following conditions:

1. The Co-Investing Funds will not have common Independent General Partners or Independent Directors. The Directors or General Partners of each Co-Investing Fund will approve co-investment transactions in advance. The Directors or General Partners of each Co-Investing Fund will be provided with periodic information, compiled by the Investment Mangers, listing all venture capital investments made by the other Co-Investing Funds.

2(a) Before a co-investment transaction will be effected, the Investment Managers will make an initial determination on behalf of each Co-Investing Fund regarding investment suitability. Following this determination, a written investment presentation respecting the proposed co-investment transaction will be made to the Directors or General Partners of each Co-Investing Fund, except that such information need not be distributed to the Directors or General Partners of any Co-Investing Fund that, at that time, does not have funds available for investment. Such information will include the name of each Co-Investing Fund that proposes to make the investment and the amount of each proposed investment. The Investment Managers will maintain at each Co-Investing Fund's office a copy of the written records detailing the factors considered in any such preliminary determination.

2(b) The information regarding the Investment Manager's preliminary determinations will be reviewed by the Independent Directors or Independent General Partners of each Co-Investing Fund. The Directors or General Partners of each Co-Investing Fund, including a majority of the Independent Directors or Independent General Partners, will make an independent decision as to whether and how much to participate in an investment based on what is appropriate under the circumstances. If a majority of Independent Directors or Independent General Partners of any Co-Investing Fund determine that the amount proposed to be invested by the Co-Investing Fund is not sufficient to obtain an investment position they consider appropriate under the circumstances, that Co-Investing Fund will not participate in the joint investment. Similarly, a Co-Investing Fund will not participate in a co-investment transaction if a majority of its Independent Directors or Independent General Partners determine that the amount proposed to be invested is an amount in excess of that which is determined to be appropriate under the circumstances. A Co-Investing Fund will only make a joint investment with another Co-Investing Fund if a majority of the Independent Directors or Independent General Partners of that Co-Investing Fund conclude, after consideration of all information deemed relevant that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the investors in the Co-Investing Fund (the ''Investors'') and do not involve overreaching of the Co-Investing Fund on the part of any person concerned;

(ii) The transaction is consistent with the interests of the Investors of the Co-Investing Fund and is consistent with the Co-Investing Fund's investment objectives and policies as recited in filings made by the Co-Investing Fund under the Securities Act of 1933, its registration statement and reports filed under the Securities Exchange Act of 1934 and its reports to Investors; and

(iii) The investment by one or more of the other Co-Investing Funds would not disadvantage the Co-Investing Fund in the making of such investment, maintaining its investment position or disposing of such investment, and that participation by the Co-Investing Funds would not be on a basis different from or less advantageous than that of another Co-Investing Fund.

2(c) The Independent Directors or Independent General Partners will, for purposes of reviewing each such recommendation of the Investment Managers, request such additional information from the Investment Managers as they deem necessary to the exercise of their reasonable business judgment, and they will also employ such experts, including lawyers and accounts, as they deem appropriate to the reasonable exercise of this oversight function.

3. The Directors or General Partners of each Co-Investing Fund, including a majority of the Independent Directors or Independent General Partners, will make their own decision and have the right to decide not to share a particular investment with another Co-Investing Fund. There will be no consideration paid to the Investment Manager (or affiliated persons of the Investment Managers) directly or indirectly, including without limitation any type of brokerage commission, in connection with a co-investment transaction. The Investment Managers will continue, however, to receive their compensation and expense reimbursement arrangements with respect to each Co-Investing Fund and will participate indirectly in a co-investment transaction only through their existing interests as an Investor in each Co-Investing Fund.

4. Each Co-Investing Fund will be entitled to consider purchasing a portion of each co-investment transaction equal to the ratio of that Co-Investing Fund's net assets to the total net assets of all Co-Investing Funds that have determined to participate in the co-investment transaction, provided that each Co-Investing Fund can determine not to take its full allocation where a majority of the Independent Directors or Independent General Partners and a majority of the Directors or General Partners of the Co-Investing Fund determine that to do so would not be in the best interests of the Co-Investing Fund. When the aggregate amount sought by the Co-Investing Funds exceeds the amount of the co-investment opportunity, the amount invested by each Co-Investing Fund shall be based on the ratio of the net assets of each Co-Investing Fund to the aggregate net assets of all Co-Investing Funds seeking to make an investment. ''Follow-on'' investments, including the exercise of warrants or other rights to purchase securities of the issuer, will be treated in the same manner as the initial co-investment transaction.

5. All co-investment transactions will consist of the same class of securities, including the same registration rights (if any), and other rights related thereto, at the same unit consideration, on the same terms and conditions, and the approvals will be made in the same period. If one Co-Investing Fund elects to sell, exchange or otherwise dispose of an interest in a security that is also held by another Co-Investing Fund, notice will be given to each other Co-Investing Fund at the earliest practical time and each other Co-Investing Fund will be given the opportunity to participate in such disposition at the same time for the same unit consideration and in amounts proportional to its respective holdings of such securities. The Investment Managers will formulate a recommendation as to participation by such Co-Investing Fund in such a disposition, and provide the recommendation to the Independent Directors or Independent General Partners of such Co-Investing Fund. Each Co-Investing Fund will participate in such disposition if a majority of its Independent Directors or Independent General Partners determine that such action is fair and reasonable to the Co-Investing Fund, is in the best interests of the Co-Investing Fund and does not involve overreaching of the Co-Investing Fund or its Investors by any person

concerned. Each Co-Investing Fund will bear its own expenses associated with the disposition of a portfolio security. The Independent Directors or Independent General Partners of each Co-Investing Fund will record in their records the Investment Managers' recommendation and their decision as to whether to participate in such disposition, as well as the basis for their decision that such action is fair and reasonable to, and is in the best interest of, the Co-Investing Fund.

6. A decision by a Co-Investing Fund (i) not to participate in a co-investment transaction, (ii) to take less or more than its full allocation, or (iii) not to sell, exchange, or otherwise dispose of a co-investing Funds electing to participate shall include a finding that such decision is fair and reasonable to the Co-Investing Fund and not the result of overreaching of the Co-Investing Fund or its Investors by any person concerned. The Independent Directors or Independent General Partners of a Co-Investing Fund will be provided quarterly for review all information concerning co-investment transactions made by the Co-Investing Funds, including co-investment transactions in which a Co-Investing Fund has declined to participate, so that they may determine whether all co-investment transactions made during the preceding quarter, including those co-investment transactions that were declined, complied with the conditions set forth above. In addition, the Independent Directors or Independent General Partners of a Co-Investing Fund will consider at least annually the continuing appropriateness of the standards established for co-investment transactions by a Co-Investing Fund, including whether use of the standards continues to be in the best interests of the Co-Investing Fund and its Investors and does not involve overreaching of the Co-Investing Fund or its Investors on the part of any party concerned.

7. The Independent Directors or Independent General Partners of each Co-Investing Fund will maintain the records required by section 57(f)(3) of the Act, and will comply with section 57(h) of the Act, and each Co-Investing Fund will otherwise maintain all records required by the Act. All records referred to or required under these conditions will be available for inspection by the SEC, and will be preserved permanently, the first two years in an easily-accessible place.

8. No Director of affiliated person of any Director or General Partner (other than a BDC sponsored and managed by the Investment Managers) will participate in a transaction with a Co-Investing Fund unless a separate exemptive order with respect to such transaction has been obtained. For this purpose, the term ''participate'' shall not include either the Investment Managers' existing General Partner interests in, or their normal compensation and expense reimbursement arrangements with, each Co-Investing Fund.

9. No co-investment transactions will be made pursuant to the requested order respecting portfolio companies in which any applicant or affiliated person of any applicant has previously acquired an interest, provided that this prohibition shall not be applicable to any previously acquired interest, provided that this prohibition shall not apply to any previous investment specifically permitted by an order of the SEC.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32042 Filed 12–1–98; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40705; File No. SR–EMCC–98–08]

Self-Regulatory Organizations; Emerging Markets Clearing Corporation Order Approving a Proposed Rule Change Relating to the Offering of Shares of Common Stock

November 24, 1998.

On August 17, 1998, Emerging Markets Clearing Corporation (''EMCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–EMCC–98–08) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposal was published in the **Federal Register** on September 21, 1998.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

Pursuant to the rule change EMCC has reclassified 2,000 shares of previously authorized EMCC common stock as Class A common stock (''Class A stock'') and has created a second class of common stock. In addition, the rule change amends EMCC's shareholder agreement to reflect the changes to the common stock.

On March 2, 1998, the Commission authorized EMCC to issue 2,000 shares of common stock (''original stock'').[3] On July 31, 1998, EMCC filed an amendment to its certificate of incorporation to reclassify the original stock as Class A stock and to authorized the issuance of non-voting Class B stock. The creation and offering of the Class B stock is intended to permit EMCC to raise additional capital which EMCC will use in part to fund the development of EMCC projects.

Under the rule change, EMCC will offer the shares of Class B stock to the same entities that were offered the opportunity to purchase the original stock.[4] The purchase price of the Class B stock is $1,000 per share with a minimum purchase requirement of $25,000. EMCC is offering the Class B shares to prospective buyers through an offering letter.[5]

The Class B stock is non-voting and is subject to repurchase upon the determination of EMCC's Board. However, EMCC has no obligation to repurchase Class B shares owned by a member that terminates its EMCC membership prior to the repurchase of all Class B shares. All purchasers of Class A and Class B stock will be required to enter into an amended version of EMCC's shareholders agreement. No dividends will be paid on either the Class A or Class B stock and shareholders may sell or transfer their shares only in compliance with EMCC's amended shareholder agreement.

EMCC's amended shareholder agreement replaces the shareholder agreement written for the original offering.[6] The changes to the shareholder agreement reflect (i) the creation and offering of the Class B stock, (ii) the conditions under which EMCC may repurchase the Class B stock, and (iii) the fact that EMTA has not yet been issued any shares of EMCC stock. In addition, the amended shareholder agreement permits EMCC to issue EMTA 300 Class A shares prior to, concurrent with, or after the closing of

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 40433 (September 11, 1998), 63 FR 50271.

[3] Securities Exchange Act Release No. 39694 (March 2, 1998), 63 FR 10251 [File No. SR–EMCC–98–01].

[4] The original stock was offered to the entities that contributed to the development fund for the organization and initial operation of EMCC.

[5] Each prospective purchaser of the original stock was provided with a copy of EMCC's Form CA–1 (excluding the confidential documents). EMCC will provide the prospective purchasers of the Class B stock with updates to the Form CA–1 as appropriate.

[6] The signatories of the amended shareholder agreement are the National Securities Clearing Corporation (''NSCC''), the International Securities Markets Association (''ISMA''), and the Emerging Markets Traders Association (''EMTA'').

the issuance of Class A stock to all other persons. A further modification reflects that the issuance of the original stock did not occur prior to the previously established deadline of June 30, 1998, and provides that the issuance and sale of Class A stock must be completed by December 31, 1998. Each purchaser of Class A or Class B shares will be obligated to enter into the amended shareholder agreement.

After the Class A stock has been issued, EMCC will amend its articles of incorporation to permit the following actions to be taken upon a two-thirds vote of the shareholders instead of the current requirement of unanimity: (i) any amendment or change to EMCC's certificate of incorporation; (ii) any adoption, amendment or repeal by the shareholders of by-laws of the corporation; (iii) any repurchase of any securities issued by the corporation; and (iv) any issuance of any securities by the corporation.

II. Discussion

Section 17A(b)(3)(A) of the Act [7] requires that a clearing agency be so organized and have the capacity to facilitate the prompt and accurate clearance and settlement of securities transactions. The Commission believes that the rule change is consistent with EMCC's obligations under Section 17A(b)(3)(A) because the additional capital raised by the issuance of the stock should enable EMCC to increase the efficiency of its clearance and settlement of securities transactions. In addition, the amendments to EMCC's articles of incorporation make more efficient EMCC's ability to take corporate actions that may be necessary to facilitate the clearance and settlement of securities transactions.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with Section 17A of the Act [8] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–EMCC–98–08) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[9]

[7] 15 U.S.C. 78q–1(b)(3)(A).

[8] 15 U.S.C. 78q–1.

[9] 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32041 Filed 12–1–98; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40706; File No. SR–NASD–98–87]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Filing Fees Under the Corporate Financing Rule

November 24, 1998.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 23, 1998, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly owned subsidiary, NASD Regulation, Inc. (''NASD Regulation'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD Regulation. 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

NASD Regulation is proposing to amend Section 6 of Schedule A to the NASD By-laws and NASD Conduct Rule 2710, to delete the provisions mandating that Corporate Financing filing fees be paid in the form of a check or money order. Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

Schedule A to the NASD By-Laws

Assessments and fees pursuant to the provisions of Article VI of the By-Laws of the Corporation, shall be determined on the following basis.

Section 1–Section 5 No Change

Section 6—Fees for Filing Documents Pursuant to the Corporate Financing Rule

(a) No change.
(b) No change.
[(c) Filing fees shall be paid only in the form of check or money order payable to the National Association of Securities Dealers, Inc.]
[(d)](*c*) The provisions of Rule 457 adopted under the Securities Act of 1933, as amended, shall govern the computation of filing fees for all offerings filed pursuant to this Section, including intrastate offerings, to the extent the terms of Rule 457 are not inconsistent with this Section.

Section 7–Section 15 No change

* * * * *

2710. Corporate Financing Rule—Underwriting Terms and Arrangements

(a) Definitions No change
(b) Filing Requirements.
(1)–(9) No change.
(1) Filing Fees.
(A) No change.
(B) No change.
[(C) Filing fees shall be paid only in the form of a check or money order payable to the National Association of Securities Dealers, Inc.]
[(D)](*C*) The provisions of SEC Rule 457 adopted under the Securities Act of 1933, as amended, shall govern the computation of filing fees for all offerings filed pursuant to this Rule, including intrastate offerings, to the extent the terms of Rule 457 are not inconsistent with subparagraph (a)[,] *or* (B) [or (C)] above.
(11)–(13) renumbered (10)–(12). (c) No change.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD Regulation 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. NASD Regulation 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

NASD Conduct Rule 2710 (the ''Corporate Financing Rule'') requires that members file most proposed public offerings with the Corporate Financing Department (''Department'') of NASD Regulation. The Corporate Financing Department reviews these filings in order to determine whether the underwriting terms and arranagements are fair and reasonable pursuant to standards set forth in Rules 2710, 2720, and 2810 prior to the commencement of the offering. Section 6 of Schedule A to the NASD By-Laws (''Schedule A'') and Paragraph (b)(10) of Conduct Rule 2710 include identical provisions that impose a fee on each filing, in the amount of $500 plus .01% of the value of securities, with a maximum filing fee

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

limit of $30,500 (the ''Corporate Financing filing fee'').

Section 6(c) of Schedule A and Paragraph (b)(10)(C) of Conduct Rule 2710 currently require that all Corporate Financing filing fees be paid by check or money order. Such a specific provision was originally adopted in order to prevent the payment of filing fees in cash. Since that time, new methodologies have arisen that facilitate the transfer of money. In order to ensure that NASD Regulation has the necessary flexibility to implement newer forms of payment, NASD Regulation proposes to eliminate Section 6(c) of Schedule A and Paragraph (b)(10)(C) of Conduct Rule 2710. Further a conforming change is made to Paragraph (b)(10)(D) of Conduct Rule 2710 to delete the reference to Paragraph (C) of the same section.

Based on this proposal, members may continue to submit Corporate Financing filing fees in the form of a check or money order to the Corporate Financing Department at the same time that the related documents are filed. Cash payment will still not be accepted in accordance with the standard business practice of the Association. The Association will, however, also implement payment of the Corporate Financing filing fee by wire transfer, and intends to inform filers and members generally of this option. In the case where such a wire transfer is used, the payment of the fee on a timely basis will be considered to ''accompany'' the filing of the original offering documents or amended offering documents to which it relates, as required by Sections 6(a) and (b) of Schedule A and by Paragraphs(b)(10)(A) and (B) of Conduct Rule 2710.

2. Purpose

NASD Regulation believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5)[3] of the Act, which requires that the rules of the Association provide for the equitable allocation of reasonable dues, fee, and other charges among members. The Association believes that the proposed rule change provides for the equitable allocation of the fees paid by members in connection with the submission of proposed public offerings with the Corporate Financing Department for review.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD Regulation does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(iii)[4] of the Act and subparagraph (e) of Rule 19b–4[5] thereunder in that it is concerned solely with the administration of a self-regulatory organization.

At any time within 60 days of the filing of a rule change pursuant to Section 19(b)(3)(A) of the Act, the Commission may summarily abrogate the 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 including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file No. SR–NASD–98–87 and should be submitted by December 23, 1998.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32039 Filed 12–1–98; 8:45 am]

BILLING CODE 8010–01–M

[3] 15 U.S.C. 78*o*–3.

[4] 15 U.S.C. 78s(b)(3)(A)(iii).

[5] 17 CFR 240.19b–4(e)(1).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40716; File No. SR–NASD–98–63]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 2 to the Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Fees for Nasdaq's Workstation II Service for Those Subscribers Who Are Not Members of the NASD

November 25, 1998.

I. Introduction

On August 20, 1998, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly-owned subsidiary, The Nasdaq Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify the fees that the NASD charges non-NASD members receiving Nasdaq Workstation II (''NWII'') service. Nasdaq amended the filing on September 10, 1998.[3]

The Commission published notice of the proposed rule change, in the **Federal Register** on October 14, 1998.[4] The Commission received no comments specifically directed toward this proposal.[5] Nasdaq filed a second amendment on November 17, 1998.[6] For the reasons discussed below, the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Robert Aber, Senior Vice President and General Counsel, Nasdaq, to Richard Strasser, Assistant Director, Division of Market Regulation (''Division''), Commission, dated September 10, 1998 (''Amendment No. 1'').

[4] Securities Exchange Act Release No. 40521 (October 5, 1998), 63 FR 55167 (October 14, 1998).

[5] As discussed below, the Commission received comments that were directed toward a parallel proposal, File No. SR–NASD–98–62, which proposed to modify the fees Nasdaq charges NASD members receiving NWII service.

[6] *See* Letter from Robert Aber, Nasdaq, to Richard Strasser, Division, Commission, dated November 17, 1998 (''Amendment No. 2''). Amendment No. 2 deleted language, appearing in the **Federal Register** notice, stating that if non-NASD member subscribers received EWN II technology prior to approval of this proposed rule change, then after approval Nasdaq would bill the non-member subscribers in an amount equal to the differential under the EWN I and the EWN II fee structures.

Commission is approving the proposed rule change as amended.

II. Description of the Proposal

The NASD filed this proposed rule change in conjunction with a parallel proposal to modify the fees charged NASD members, File No. SR–NASD–98–62.[7] The fee schedule set forth in that proposal became effective upon filing in accordance with Section 19(b)(3)(A)(ii) of the Act[8] and Rule 19b–4.

This proposed rule change would increase the monthly fees for NWII service as follows: the monthly Service Charge would increase from $100 per ''server'' to $1500 per ''service delivery platform'' (''SDP''); the monthly Display Charge would increase from $500 to $525 per presentation device (''PD''); and the monthly ''Additional Circuit/SDP Charge'' (formerly the ''Additional Circuit Charge'') would increase from $1150 to $2700. This proposed rule change also clarifies that the fee schedule applies to subscribers who access NWII service through an application programming interface (''API''). Finally, the proposal eliminates the Digital Interface Service fee schedule because Nasdaq no longer provides that service.

Nasdaq proposed this fee change in conjunction with the construction of EWN II, a new network for delivering NWII service. Nasdaq is in the process of converting existing subscribers to the EWN II network. During this process, some NWII subscribers will continue to utilize the existing EWN I network and pay the fees for that service, until they are upgraded to EWN II.

To access NWII service, each subscriber location has at least one SDP, or server, that resides on the network and connects to Nasdaq by a dedicated circuit. Under the EWN II network, each dedicated circuit (''T1 circuit'') will be capable of supporting up to six SDPs. Each SDP can support up to eight PDs, or Nasdaq Workstation IIs, although a firm may elect to have fewer than eight PDs on a single SDP. A subscriber may also obtain NWII service through an API, which allows a firm to obtain NWII Service using the firm's own hardware (*e.g.*, personal computer) and software systems.

Under the new fee structure, a firm with one SDP ($1500) and eight PDs (8 × $525 = $4200) would be charged a monthly fee of $5700 (compared to $4100 under the existing schedule). A firm with one SDP ($1500) and two PDs (2 × $525 = $1050) would be charged a monthly fee of $2550 (compared to $1100 under the existing schedule). If a subscriber chooses to access NWII through an API, the subscriber would be assessed the service charge for each SDP, the display charge for each of the subscriber's linkages (*e.g.*, NWII substitute, quote-update facility), as well as the additional circuit charge. The Additional Circuit/SDP charge will apply if a subscriber obtains additional SDPs and/or T1 circuits without first maximizing the capacity on its SDPs and T1 circuits.

Nasdaq justifies the proposed fee structure on the grounds that it is derived from the fee structure in the contract that Nasdaq and MCI Communications Corporation (''MCI'') entered into in 1997, under which MCI would build and maintain the new network. Nasdaq represents that the proposed fee structure subsidizes its subscribers, in that the proposed Service Charge does not pass on all of the SDP/server costs that Nasdaq incurs under the contract. Nasdaq also represents that the proposed fee schedule's Display Charge in part helps the NASD recoup its subsidy of the SDP/server costs and other expenses associated with the development and the maintenance of NWII.

Although the Commission received no comment letters specifically addressing this filing, Nasdaq's proposal to change the fee schedule applicable to NASD members generated three comment letters.[9] The three letters criticized the proposed fee schedule applicable to NASD members on a number of issues, including: that it disproportionately affects smaller subscribers, that it is unfair to market makers, that it does not adequately place the EWN II network's costs upon the network's beneficiaries, and that Nasdaq has not adequately justified various components of the fee structure and related fees. One letter requested that the Commission review the bidding process and the costs associated with the contract for the new network, to determine a fair cost.[10]

III. Discussion

The Commission finds that the proposed fee schedule for non-NASD members is consistent with the requirements of Section 15A(b)(5) of the Act.[11] Section 15A(b)(5) specifies that the rules of a registered securities association shall provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that the NASD operates or controls.[12]

This proposed rule change provides that NASD members and non-NASD members who subscribe to NWII service will pay the same rates, suggesting that the burden of the new fees was allocated fairly. Moreover, by basing the SDP rates on the costs that Nasdaq pays under the contract to implement the EWN II network, but reducing the impact on smaller users by not passing on all of the SDP costs that Nasdaq incurs, the Commission believes that Nasdaq has sought to minimize the adverse impact of those increased fees on non-NASD members, suggesting that the fees are reasonable under the circumstances.

The Commission is not persuaded by the commenters' criticism (in the parallel rule filing regarding the fees Nasdaq charges NASD members) that the costs were not allocated fairly or that the costs are not justified. None of the commenters disputes the issue that Nasdaq's technical modernization efforts are intended to improve Nasdaq's capacity and to enhance services provided to NASD members and non-members alike. Nor do the commenters dispute Nasdaq's contention that the increased Service Charge is intended to offset the costs associated with the technology modernization efforts. Finally, the commenters do not dispute Nasdaq's representation that Nasdaq has chosen not to pass on the entire cost of each SDP slot to members and non-members. Therefore, the Commission finds that the proposal is consistent with the Act.

The Commission finds good cause for approving Amendment No. 2 prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. Amendment No. 2 merely clarifies that Nasdaq will not attempt to impose the monthly fee changes on non-NASD member subscribers who receive EWN II technology prior to this Order.

[7] Securities Exchange Act Release No. 40434 (September 11, 1998), 63 FR 49937 (September 18, 1998).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] *See* Letter from Douglas Ralston, President, Sherman Ralston, Inc., to Jonathan Katz, Secretary, Commission, dated October 8, 1998; Letter from David Rich, Associate Compliance Director, Jefferies & Company, Inc., to Jonathan Katz, dated October 9, 1998; Letter from Marge Ferguson, President, Wall Street Telecommunications Association, to Jonathan Katz, dated November 4, 1998 (not specifically identifying a file number, but focusing its comments on Nasdaq Level III service, which is available only to NASD members) (''WSTA letter'').

[10] *See WSTA letter.*

[11] 15 U.S.C. 78o–3(b)(5).

[12] In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 2, including whether it is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–98–63 and should be submitted by ?????.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change SR–NASD–98–63, including Amendment No. 2, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32096 Filed 12–1–98; 8:45 am]

BILLING CODE 8010–01–M

[13] *See* 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–40707; File No. SR–PHLX–98–04]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Amending Rule 783, Report of Financial Arrangements and Floor Procedure Advice F–11, Splitting Orders

November 24, 1998.

I. Introduction

On April 27, 1998, the Philadelphia Stock Exchange, Inc. (''PHLX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4[2] thereunder a proposed rule change to amend its financial arrangements rule, Rule 783, and Options Floor Procedure Advice F–11[3] regarding the Splitting of Orders. On October 2, 1998, the PHLX submitted Amendment No. 1 to the proposed rule change.[4] On October 20, 1998, the proposal, as amended, was published for comment in the **Federal Register.**[5] The Commission received no comments on the proposal. This order approves the proposal.

II. Description of the Proposal

The Exchange proposes to amend its financial arrangements rule Rule 783, to require that members, member organizations, foreign currency options participants, participant organizations and general partners or voting stockholders thereof report to the Exchange financial arrangements for amounts greater than $5,000. Currently, PHLX Rule 783 requires that members and member organizations report to the Exchange the obtaining and making of a loan over $2500, including loans to non-members. The proposed definition of financial arrangements includes any consideration over $5000 that constitutes a loan, gift, salary or bonus; the direct financing of a member of or participant organization (except clearing arrangements)[6], any direct equity investment or profit sharing arrangement; and the guarantee of a trading account (except a clearing arrangement). Currently, paragraph (b) of PHLX Rule 783 provides exceptions for certain member-to-member loans. Proposed exceptions to the rule are outlined in proposed paragraph (c) of PHLX Rule 783. The amended rule would not apply to stock loan arrangements[7] or transactions between members affiliated with the same member organization or participants affiliated with the same participant organization or transactions in publicly traded securities of a member organization. All parties involved in the financial arrangement are required to notify the Exchange of eligible financial arrangements without ten (10) business days of the effective date of such arrangements. In the event of termination of the financial arrangement, the parties involved must similarly notify the Exchange of the termination.

In addition, the Exchange proposes to amend Options Floor Procedure Advice F–11 regarding the Splitting of Orders by adding that dually and financially affiliated Registered Option Traders (''ROTs'') will be treated as one interest for the purpose of splitting an order in the trading crowd. Currently, Advice F–11 requires ROTs of the same firm when bidding or offering at the same price and for the same option to be treated as one interest for the purpose of splitting an order in the trading crowd. The proposal would extend the Advice to dually and financially affiliated ROTs further ensuring fairness in the order splitting process. Advice F–11 defines ''dually affiliated'' as those ROTs required to report pursuant to Exchange Rule 793,[8] and ''financially affiliated'' as those ROTs required to report pursuant to Exchange Rule 783. The Exchange also proposes to increase the fine schedule for failing to report dual or financial affiliations from $100.00 to $500.00 for the first offense; $250.00 to $1,000.00 for the second offense; and from $500.00 to a sanction discretionary with the Business Conduct Committee for the third offense and thereafter. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] The PHLX's minor rule violation enforcement and reporting plan (''minor rule plan''), codified in PHLX Rule 970, contains floor procedure advises with accompanying fine schedules. Rule 19d-1(c)(2) under the Act authorizes national securities exchanges to adopt minor rule violation plans for summary discipline and abbreviated reporting; Rule 18d-1(c)(1) under the Act requires prompt filing with the Commission of any final disciplinary action. However, minor rule violation not exceeding $2,500 are deemed not final, thereby permitting periodic, as opposed to immediate, reporting.

[4] Letter from Nandita Yagnik, Esquire, PHLX, to Michael Walinskas, Deputy Associate Director, Division of Market Regulation, SEC dated Sept. 30, 1998. In Amendment No. 1, the PHLX added a requirement that members, member organizations, participants and participant organizations disclose loans and financial arrangements with non-members.

[5] Securities Exchange Act Release No. 40541 (Oct. 9, 1998), 63 FR 56056 (Oct. 20, 1998).

[6] Under the proposal, clearing arrangements are defined as those arrangements in which a company acts as an intermediary in making payments, deliveries or both in connection with transactions in securities, or who provides facilities for comparison of data respecting the terms of settlement of securities.

[7] Under the proposal, a stock loan arrangement shall mean an agreement for the lending and borrowing of securities and shall include a securities contract or other agreement, including related terms, for the transfer of securities against the transfer of funds, securities, or other collateral, with simultaneous agreement by the transferee to transfer to the transferor against the transfer of funds, securities, or other collateral upon notice, at a date certain, upon demand, the same or substituted securities.

[8] PHLX Rule 793 requires persons who are general or limited partners, or an officer, director, stockholder or associated person of more than one member or participant organization or who are affiliated in any manner with a non-member, or non-participant organization which is engaged in the securities business, to disclose this affiliation in writing and to have such affiliation approved in writing by the member or participant organization.

Exchange also proposes a corresponding change to its minor rule plan.

III. Discussion

The Commission believes that the proposed rule change is consistent with Section 6(b)(5) of the Act [9] in that it promotes just and equitable principles of trade and protects investors and the public interest by revising the Exchange's financial arrangement rule and strengthening the order splitting provision of Advice F–11.[10] The Commission believes the increased dollar limit updates the Exchange's financial arrangement rule to take into account inflation without significantly reducing the protections of the rule. The Commission also believes that extending Advice F–11 to dually and financially affiliated ROTs should enhance competition in options traded on the PHLX by preventing one firm from garnering all of the executions in a particular option by splitting orders in the trading crowd among members who are either dually or financially affiliated.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–PHLX–98–04) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–32040 Filed 12–1–98; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3134, Amdt. 1]

Commonwealth of Puerto Rico

In accordance with a notice received from the Federal Emergency Management Agency, the above-numbered Declaration is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to December 31, 1998.

All other information remains the same, i.e., the deadline for filing applications for economic injury is June 24, 1999.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Date: November 24, 1998.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 98–32080 Filed 12–1–98; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Senior Executive Service; Performance Review Board Members

ACTION: Roster of Members of this Agency's Senior Executive Service.

SUMMARY: Section 4314(c) (4) of Title 5, U.S.C. requires Federal agencies publish notification of the appointment of individuals who may serve as members of that Agency's Performance Review Boards (PRB). The following is the FY 1998 Performance Review Board roster:

1. Jadine Nielsen, Chief of Staff;

2. Elizabeth Montoya, Associate Deputy Administrator for Management and Administration;

3. Betsy Myers, Associate Deputy Administrator for Entrepreneurial Development;

4. John Gray, Associate Deputy Administrator for Capital Access;

5. Carolyn J. Smith, Assistant Administrator for Human Resources;

6. Lawrence Barrett, Chief Information Officer;

7. Dave Kohler, Associate General Counsel for General Law;

8. Thomas Dumaresq, Assistant Administrator for Administration;

9. Erline Patrick, Assistant Administrator for Equal Employment Opportunity and Civil Rights Compliance;

10. Calvin Jenkins, Deputy to the Associate Deputy Administrator for Government Contracting and Minority Enterprise Development;

11. Jeanne Sclater, Deputy to the Associate Deputy Administrator for Capital Access;

12. Herbert Mitchell, Deputy Associate Administrator for Disaster Assistance;

13. Francisco Marrero, District Director (Newark);

14. Darryl Hairston, District Director (Washington);

15. Mark Quinn, District Director (San Francisco).

Dated: November 25, 1998.

Aida Alvarez,

Administrator.

[FR Doc. 98–32081 Filed 12–1–98; 8:45 am]

BILLING CODE 8025–01–P

TENNESSEE VALLEY AUTHORITY

Environmental Impact Statement: Union County, Mississippi, Multipurpose Reservoir/Other Water Supply Alternatives

AGENCY: Tennessee Valley Authority.

ACTION: Notice of Intent.

SUMMARY: The Tennessee Valley Authority (TVA) will prepare an environmental impact statement (EIS) on a multipurpose reservoir in Union County, Mississippi, located in northeast Mississippi. The primary purpose of the reservoir is to provide an adequate and reliable water supply for the Union County area. This EIS will also consider other alternative means of meeting the area's water supply needs. Alternatives to be considered will include one or a combination of the following: construction of a surface impoundment on a tributary of the Little Tallahatchie River; installation of one or more water pipelines from existing public water supplies; development of new groundwater sources; and the no action alternative. With this notice, TVA invites comments on the scope of this EIS.

DATES: Comments on the scope of the EIS must be received on or before January 8, 1999. TVA will conduct a public meeting in New Albany, Mississippi to discuss the project and obtain comments on the scope of the EIS. The location and time of this meeting are described below in the Scoping Process section.

ADDRESSES: Comments should be sent to Charles P. Nicholson, National Environmental Policy Act Specialist, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 8C, Knoxville, Tennessee 37902–1499. Comments may also be e-mailed to cpnicholson@tva.gov.

FOR FURTHER INFORMATION CONTACT: Daniel H. Ferry, Tennessee Valley Authority, WT 10D–K, Knoxville, Tennessee 37902–1499, e-mail: dhferry@tva.gov; or Gary D. Hickman, Tennessee Valley Authority, ABL 1A–N, Norris, Tennessee 37828, e-mail: gdhickman@tva.gov.

SUPPLEMENTARY INFORMATION: TVA has been asked by Union County, Mississippi, and the City of New Albany to assist in the evaluation of a proposed reservoir and other means of supplying the area's water supply needs. In addition, TVA has been asked to relocate one of its electrical transmission lines that lies within the proposed reservoir pool if the County and City decide to pursue that alternative.

[9] 15 U.S.C. 78f(b)(5).

[10] In reviewing this proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

Water needs in Union County, Mississippi, are currently supplied by wells operated by municipal water systems, rural water associations, and institutional and industrial users. The average daily water use from the public water systems in 1996 was 2.365 million gallons per day (MGD) and the peak daily use was 4.040 MGD. Two-thirds of the county water needs are supplied by wells in the Eutaw-McShan aquifer, and most of these wells are near the City of New Albany. Pumping from these wells has lowered groundwater levels. New wells drilled in this area have generally been unproductive.

In order to meet projected future water supply needs, Union County and the City of New Albany combined efforts to develop an alternate water supply and have proposed constructing a multipurpose reservoir on a tributary of the Little Tallahatchie River. In order to obtain public input on this proposal and to fully evaluate a range of alternatives, TVA has decided to prepare an EIS.

Alternatives

Alternatives presently under consideration include: (1) No action; (2) construction of a multipurpose reservoir on a tributary to the Little Tallahatchie River; (3) construction of one or more pipelines from an existing water supply system with sufficient capacity to meet the needs of Union County; and (4) construction of new groundwater sources by tapping into additional aquifers. Reasonable alternative actions available to TVA are to relocate the transmission line, and the no action alternative. Some of the water supply alternatives would also involve actions by other federal agencies. TVA has identified two alternative routes for its tramsnission line if it is relocated. TVA invites the public to comment on these alternatives or to suggest other possible alternatives.

Proposed Issues To Be Addressed

The EIS will evaluate the water supply needs of Union County through the year 2050, and potential effects of alternative means of meeting the water supply needs. Potentially important issues for discussion in the EIS include:

1. Effects on stream discharge, water quality, and availability;

2. Impacts on terrestrial and aquatic ecology, including endangered and threatened species;

3. Impacts on floodplains, wetlands, recreation, and existing land uses; and

4. Socioeconomic, historic, archaeological, and cultural effects associated with the alternative actions.

This list is not intended to be all inclusive, nor is it intended to be a predetermination of impacts. As scoping and preparation of the EIS proceed, other issues may be revealed which will necessitate further analyses.

Scoping Process

Scoping, which is integral to the EIS process, is a procedure that solicits public input to the EIS process to ensure that: (1) Issues are identified early and properly studied; (2) issues of little significance do not consume substantial time and effort; (3) the EIS is thorough and balanced; and (4) delays caused by an inadequate EIS are avoided. TVA's procedures implementing the National Environmental Policy Act require that the scoping process commence after a decision has been reached to prepare an EIS in order to provide an early and open process for determining the scope of issues to be addressed and for identifying the significant issues related to a proposed action. The scope of issues to be addressed in an EIS will be determined, in part, from written comments submitted by mail, and comments presented orally or in writing at a public scoping meeting. The preliminary identification of reasonable alternatives and environmental issues provided in this notice is not meant to be exhaustive or final. TVA considers the scoping process to be open and dynamic in the sense that alternatives other than those given above may warrant study and new matters may be identified for potential evaluation.

The scoping process will include both interagency and public scoping. The agencies expected to participate in interagency scoping include the U.S. Army Corps of Engineers, U.S. Fish and Wildlife Service, and various State of Mississippi agencies including the Department of Environmental Quality, Department of Wildlife, Fisheries, and Parks, the Department of Economic and Community Development, State Historic Preservation Office of the Department of Archives and History, and other federal, state and local agencies as appropriate. TVA anticipates that some of these agencies, because of their jurisdiction and/or expertise, will be cooperators in the development of the EIS.

The public is invited to submit written comments or e-mail comments on the scope of this EIS no later than the date given under the **DATES** section of this notice and/or attend the public scoping meeting. TVA will conduct a public meeting on the scope of the EIS in New Albany, Mississippi on Thursday, December 10, 1998. The meeting will be held at the Union County Courthouse, which is located at 116 East Bankhead. Registration for the meeting will be from 5:30 to 6:30 p.m. with the meeting beginning at 6:30 p.m. The meeting will begin with brief presentations by representatives of the Union County Development Association, the City of New Albany, and TVA explaining the proposed project and the EIS process. Following this presentation, attendees will be given the opportunity to express issues and concerns that should be considered in the EIS.

Upon consideration of the scoping comments, TVA will develop alternatives and identify important environmental issues to be addressed in the EIS. Following analysis of the water supply needs and of the environmental consequences of each alternative, TVA will prepare a draft EIS for public review and comment. A notice of availability of the draft EIS will be published in the **Federal Register** and area newspapers. TVA expects to have this draft EIS completed in early 2000.

Dated: November 24, 1998.

Kathryn J. Jackson,

Executive Vice President, Resource Group.

[FR Doc. 98–32055 Filed 12–1–98; 8:45 am]

BILLING CODE 8120–08–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Industry Sector Advisory Committee on Small and Minority Business (ISAC–14)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of meeting.

SUMMARY: The Industry Sector Advisory Committee (ISAC–14) will hold an open meeting on December 7, 1998 from 9:15 a.m. to 3:15 p.m.

DATES: The meeting is scheduled for December 7, 1998, unless otherwise notified.

ADDRESSES: The meeting will be held at the Department of Commerce Room 4830, located at 14th Street and Constitution Avenue, N.W., Washington, D.C., unless otherwise notified.

FOR FURTHER INFORMATION CONTACT: Millie Sjoberg, Department of Commerce, 14th St. and Constitution Ave., N.W., Washington, D.C. 20230, (202) 482–4792 or Bill Daley Jr., Office of the United States Trade Representative, 600 17th St. N.W., Washington, D.C. 20508, (202) 395–6120.

SUPPLEMENTARY INFORMATION: The ISAC–14 will hold a open meeting on

December 7, 1998 from 9:15 a.m. to 3:15 p.m. Agenda topics to be addressed will be:

1. An update by the Assistant Secretary for Trade Development on Trade Development's involvement in the recent APEC Ministerial and JCCT meeting.
2. Advice from the ISAC on small and medium-size enterprise (SME) export issues such as how the government can encourage more SMEs to export, export to multiple markets, use intermediaries (if appropriate), use electronic commerce to increase exports, etc.
3. A focus on electronic commerce including an overview of how electronic commerce can help SMEs export; a discussion of issues such as privacy, security, etc.; electronic commerce with respect to APEC/FTAA/WTO; a discussion of the Y2K issue; a demonstration of AID's Global Technology Network.
4. A briefing on ITA funding.
5. Committee Business.

Pete Felts,

Assistant United States Trade Representative, Intergovernmental Affairs and Public Liaison.

[FR Doc. 98–32049 Filed 12–1–98; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 USC Chapter 35). Section 3507 of Title 44 of the United States Code, requires that agencies prepare a notice for publication in the **Federal Register**, listing information collection request submitted to OMB for approval or renewal under that Act. OMB reviews and approves agency submissions in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms and the reporting and recordkeeping requirements. OMB approval of an information collection requirement must be renewed at least once every three years.

The **Federal Register** Notice with a 60-day comment period soliciting comments on the information collection's described below was published on September 16, 1998 [63 FR 49631].

DATES: Comments on this notice must be received on or before January 4, 1999.

FOR FURTHER INFORMATION CONTACT: For copies of these documents, contact Barbara Davis, Office of Information Management, 202–267–2326.

SUPPLEMENTARY INFORMATION:

U. S. Coast Guard

Title: Safety Approval of Cargo Containers.

OMB Control Number: 2115–0094.

Type of Request: Extension of a currently approved collection.

Forms: N/A.

Affected Public: Container owners; container manufacturers; organizations to which the Coast Guard delegates its approval authority.

Abstract: The information collection requires owners and manufacturers of cargo containers to submit information and keep records to make it possible for the Coast Guard or its appointed agents to conduct the approval process. The reporting requirements are necessary to provide the Coast Guard the information it needs to approve new equipment and designs. The recordkeeping requirements are necessary to assist the Coast Guard in its inspections of containers following approval.

Need: This collection of information addresses the reporting and recordkeeping requirements for containers in 49 CFR Parts 450–453. These rules are necessary because the U.S. is signatory to the International Convention for Safe Containers (CSC). These rules prescribe only the minimum requirements of the CSC.

Burden Estimate: The estimated burden is 71,505 hours annually.

Addresses: Written comments on the DOT information collection request should be forwarded, within 30 days of publication, to Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, Washington, DC 20503, ATTN: USCG Desk Officer. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB official of your intent immediately.

Comments are invited on: whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collections; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

Issued in Washington, DC, on November 20, 1998.

Phillip A. Leach,

Clearance Officer, United States Department of Transportation.

[FR Doc. 98–32065 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed During the Week Ending November 20, 1998

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST–98–4764
Date Filed: November 16, 1998
Parties: Members of the International Air Transport Association
Subject:
PAC/Reso/402 dated October 28, 1998 r–1
Passenger Agency Resolution 850e
CAC/Reso/192 dated November 3, 1998 r–2
Cargo Agency Resolution 851e
Minutes:
PAC/Meet/155 dated October 28, 1998
CAC/Meet/131 dated November 3, 1998
Intended effective date: January 1, 1999.

Docket Number: OST–98–4780
Date Filed: November 18, 1998
Parties: Members of the International Air Transport Association
Subject:
PTC12 Telex Mail Vote 973
South Atlantic-Europe/Mideast Reso 010y
Telex Mail Vote Amendments #1, #2, #3
Intended effective date: December 1, 1998.

Docket Number: OST–98–4781
Date Filed: November 18, 1998
Parties: Members of the International Air Transport Association
Subject:
PTC123 0059 dated November 13, 1998
North Atlantic Passenger Resos r1–18

Minutes—PTC123 0057 dated November 3, 1998
Table—PTC123 Fares 0030 dated November 13, 1998
Intended effective date: March 1, 1999.

Docket Number: OST–98–4782
Date Filed: November 18, 1998
Parties: Members of the International Air Transport Association
Subject:
PTC123 0060 dated November 13, 1998
Mid Atlantic Resos r1–6
PTC123 0061 dated November 13, 1998
South Atlantic Resos r7–19
TABLES:
PTC123 Fares 0031 dated November 13, 1998
PTC123 Fares 0032 dated November 13, 1998
(Minutes, contained in PTC123 0057, are filed this date with the U.S.-related portion of the PTC123 agreement).
Intended effective date : March 1, 1999.

Docket Number: OST–98–4783
Date Filed: November 18, 1998
Parties: Members of the International Air Transport Association
Subject:
PTC23 EUR–SWP 0025 dated November 13, 1998
Europe-Southeast Pacific Expedited Resos r1–002i r2–071kk r3–071rr
Intended effective date: January 1, 1999.

Dorothy W. Walker,

Federal Register Liaision.

[FR Doc. 98–32066 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of The Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending November 20, 1998

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et. seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–98–4531.
Date Filed: November 18, 1998.
Due Date for Answers, Conforming Applications, or Motions to Modify Scope: December 16, 1998.

Application of Cherokee Air, Ltd. pursuant to 49 U.S.C. 41301 and Subpart Q, requests an amendment of its Foreign Air Carrier Permit authorizing it to engage in on-demand charter foreign air transportation between the Commonwealth of the Bahamas (''Bahamas'') and the United States, for more than ten (10) flights per month, subject to the new limitation of operating only passenger aircraft with less than sixty (60) seats.

Docket Number: OST–98–4789.
Date Filed: November 18, 1998.
Due Date for Answers, Conforming Applications, or Motions to Modify Scope: December 16, 1998.
Description: Application of MK Flugfelagid ehf pursuant to 49 U.S.C. 41302 and Subpart Q, applies for a Foreign Air Carrier Permit authorizing it to engage in scheduled foreign air transportation of property and mail between a point or points in Iceland and a point or points in the United States, via intermediate points, and beyond. MK also requests authority to conduct Fifth Freedom cargo charter flights between the United States and points in third countries, to the extent permitted under 14 C.F.R Part 212.

Docket Number: OST–98–4793.
Date Filed: November 19, 1998.
Due Date for Answers, Conforming Applications, or Motions to Modify Scope: December 17, 1998.
Description: Application of Florida West International Airways, Inc. pursuant to 49 U.S.C. 41102 and Subpart Q, request issuance of a new Certificate of Public Convenience and Necessity, or an amendment to its existing international certificate, authorizing FWIA to engage in scheduled foreign air transportation of property and mail between any point or points in the United States and any point in the countries listed in Appendix A to this application. FWIA also requests authority to integrate this certificate authority with all services FWIA is otherwise authorized to conduct pursuant to its exemption and certificate authority consistent with applicable agreements between the U.S. and foreign countries.

Docket Number: OST–98–4798.
Date Filed: November 20, 1998.
Due Date for Answers, Conforming Applications, or Motions to Modify Scope: December 18, 1998.

Application of Air Atlanta-Icelandic pursuant to 49 U.S.C. 41302 and Subpart Q, applies for renewal of its Foreign Air Carrier Permit authorizing it to engage in charter foreign air transportation of persons, property and mail between any point or points in Iceland and any points in the United States. Air Atlanta's Foreign Air Carrier Permit also authorizes it to engage in other charter trips in foreign air transportation, subject to the Department's regulations.

Dorothy W. Walker,

Federal Register Liaison.

[FR Doc. 98–32067 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Receipt of Noise Compatibility Program, Revision and Request for Review, Key West International Airport, Key West, Florida

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the revised current and future noise exposure maps submitted by Monroe County, Florida, for Key West International Airport under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Key West International Airport under part 150 in conjunction with the noise exposure maps, and that this program will be approved or disapproved on or before May 8, 1999.

EFFECTIVE DATE: The effective date of the FAA's determination on the revised noise exposure maps and of the start of its review of the associated noise compatibility program is November 9, 1998. The public comment period ends January 8, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Tommy J. Pickering, P.E., Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, Florida 32822–5024, (407) 812–6331, Extension 29. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the revised noise exposure maps submitted for Key West International Airport are in compliance with applicable requirements of part 150, effective November 9, 1998. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before May 8, 1999. This notice also announces the availability of this program for public review and comment.

Under section 103 of Title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties to the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

Monroe County, Florida, submitted to the FAA on October 26, 1998, revised noise exposure maps, descriptions and other documentation which were produced during the Key West International Airport FAR part 150 noise study conducted between October 1, 1996, and October 25, 1998, was requested that the FAA review this material as the noise exposure maps, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under Section 104(b) of the Act.

The FAA has completed its review of the revised noise exposure maps and related descriptions submitted by Monroe County, Florida. The specific maps under consideration are ''1998 Noise Exposure Map'' and ''2003 Noise Exposure Map'' in the noise compatibility program submission. The FAA has determined that these maps for Key West International Airport are in compliance with applicable requirements. This determination is effective on November 9, 1998. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Key West International Airport, also effective on November 9, 1998. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the revised program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before May 8, 1999.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed revised program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the revised noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, Florida 32822–5024; and

Division Director of Community Services, Public Services Building, 5100 College Road West, Wing 4, Room 405, Key West, Florida 33040.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT:**

Issued in Orlando, Florida, November 9, 1998.

W. Dean Stringer,

Manager, Orlando Airport District Office.

[FR Doc. 98–32133 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (99–04–C–00–BGM) To Impose and Use a Passenger Facility Charge (PFC) at Binghamton Regional Airport in Binghamton New York

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use a PFC at Binghamton Regional Airport in Binghamton New York, under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before January 4, 1999.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Mr. Phil Brito, Manager, New York Airports District Office, 600 Old Country Road, Garden city, New York 11530.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Carl G Olsen, Commissioner of Aviation for the Broome County Department of Aviation, at the following address: Broome County Department of Aviation, Binghamton Regional Airport/Edwin A. Link Field, Box 16, Johnson City, New York 13790.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Broome County Department of Aviation under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Philip Brito, Manager, New York Airports District Office, 600 Old Country Road, Suite 446, Garden City, New York 11530 (Telephone 516–227–3800). The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Binghamton Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On November 23, 1998, the FAA determined that the application to impose and use a PFC submitted by the Broome County Department of Aviation was substantially complete within the requirements of section 158.25 of Part 168. The FAA will approve or disapprove the application, in whole or in part, no later than February 20, 1999.

The following is a brief overview of the application.

Application number: 99–04–C–00–BGM.

Level of the proposed PFC: $3.00.

Proposed charge effective date: January 1, 2002.

Proposed charge expiration date: August 1, 2005.

Total estimated PFC revenue: $1,394,724.

Brief description of proposed projects:

Impose Only Projects

—Maintenance Building, Construction

Impose and Use Projects

—Apron Expansion (West Ramp)

—Maintenance Building, Design

—PFC Administrative Costs-Reimbursement

Use Only Projects

—Terminal Building Rehabilitation

Class or classes of air carriers, which the public agency has requested not be required to collect PFCs: Nonscheduled/On-Demand Air Carriers filing FAA Form 1800–31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Fitzgerald Federal Building, #111, John F. Kennedy International Airport, Jamacia, New York, 11430.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Offices of the Broome County Department of Aviation.

Issued in Jamaica, New York, on November 23, 1998.

Thomas Felix,

Manager, Planning & Programming Branch, AEA–610 Eastern Region.

[FR Doc. 98–32064 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–98–4816]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and Request for Comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD) intentions to request approval for three years of an existing information collection entitled ''Requirements for Establishing U.S. Citizenship (46 CFR 355).''

DATES: Comments should be submitted on or before February 1, 1999.

FOR FURTHER INFORMATION CONTACT: Doris Lansberry, Office of the Chief Counsel, Maritime Administration, 400 Seventh Street, SW., Room 7232, Washington, DC 20590; telephone number 202–366–5712 or fax 202–366–7485. Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Requirements for Establishing U.S. Citizenship (46 CFR 355).

Type of Request: Approval of an existing information collection.

OMB Control Number: 2133–0012.

Form Number: Special Format.

Expiration Date of Approval: Three years from the date of approval

Summary of Collection of Information: In accordance with 46 CFR 355, shipowners, charterers, equity owners, ship managers, etc. seeking benefits provided by statute are required to provide, on an annual basis, an Affidavit of U.S. Citizenship to the Maritime Administration for analysis.

Need and Use of the Information: The Affidavits of U.S. Citizenship filed with the Maritime Administration will be used to determine shipowners, equity owners, ship managers, etc. compliance with the statutory requirements.

Description of Respondents: Shipowners, charterers, equity owners, ship managers.

Annual Responses: 300 responses.

Annual Burden: 1,500 hours.

Comments: Signed written comments should refer to the docket number that appears at the top of this document and must be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Specifically, address whether this information collection is necessary for proper performance of the function of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden and ways to enhance quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., ET., Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at http:/dms.dot.gov.

By Order of the Maritime Administrator.

Dated: November 27, 1998.

Joel C. Richard,

Secretary.

[FR Doc. 98–32121 Filed 12–1–98; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 24, 1998

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before January 4, 1999 to be assured of consideration.

Finacial Management Service (FMS)

OMB Number: 1510–0061.

Form Number: None.

Type of Review: Extension.

Title: Cash Management Improvement Act (CMIA) Annual Report and Direct Cost Claims.

Description: States and territories must report interest owed to and from the Federal Government for major Federal Assistance programs on an annual basis. The data is used by Treasury and other Federal agencies to verify State and Federal interest claims, to assess State and Federal cash management practices and to exchange amounts of interest owed.

Respondents: Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents/ Recordkeepers: 56.

Estimated Burden Hours Per Respondent/Recordkeeper: 500 hours.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 28,000 hours.

Clearance Officer: Jacqueline R. Perry (301) 344–8577, Financial Management Service, 3361–L 75th Avenue, Landover, MD 20785.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860. Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer

[FR Doc. 98–32034 Filed 12–1–98; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 24, 1998.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before January 4, 1999 to be assured of consideration.

Departmental Offices/Office of Foreign Assets Control

OMB Number: 1505–0092.

Form Number: None.

Type of Review: Extension.

Title: Libyan Sanctions Regulations.

Description: Submissions will provide the United States Government with information to be used in enforcing sanctions against the Government of Libya, including prohibitions on travel and financial dealings.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 5.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: Other (initial registration of eligibility).

Estimated Total Reporting Burden: 5 hours.

OMB Number: 1505–0106.

Form Number: None.

Type of Review: Extension.

Title: Reporting on Transactions Engaged in by Oil Affiliates.

Description: This collection implements controls on trade and financial transactions involving Iran and the Government of Iran. It provides the United States Government with information to be used in evaluating activities of affiliates of U.S. persons.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 30.

Estimated Burden Hours Per Respondent: 6 hours, 42 minutes.

Frequency of Response: Quarterly.

Estimated Total Reporting Burden: 201 hours.

OMB Number: 1505–0167.

Form Number: TD F 90–22.52.

Type of Review: Extension.

Title: Cuban Remittance Affidavit.

Descritpion: Pursuant to the Trading with the Enemy Act, 50 U.S.C. App. 1–44, the Cuban Liberty and Democratic Solidarity Act, 22 U.S.C. 6021–91, and the Cuban Assets Control Regulations, 31 C.F.R. Part 515, U.S. persons are prohibited from sending more than $1,000 as a one-time immigration remittance or family remittances of more than $300 per quarter to Cuba. To assure compliance with these statutes and the Regulations, remittance service providers have historically been instructed to require remitters to sign affidavits that authorized ceilings have not been exceeded. Audit experience indicates that the affidavits, which must be retained for five years by service providers, are often haphazardly drafted and executed. To assure uniform and consistent compliance, this form is being standardized and will be distributed in both print and electronic copy to all remittance forwarders. The affidavit requirement is not new, merely the standardized form.

Respondents: Individuals or households.

Estimated Number of Respondents/ Recordkeeping: 1,000,000.

Estimated Burden Hours Per Respondent/Respondent: 45 to 75 seconds.

Frequency of Response: Other (every time a remittance is sent).

Estimated Total Reporting/ Recordkeeping Burden: 66,667 hours.

OMB Number: 1505–0168.

Form Number: None.

Type of Review: Extension.

Title: Travel Service Provider and Carrier Service Provider Submission.

Description: Pursuant to the Trading with Enemy Act, 50 U.S.C. App. 1–44, the Cuban Liberty and Democratic Solidarity Act, 22 U.S.C. 6021–91, and the Cuban Assets Control Regulations, 31 C.F.R. Part 515, the Treasury Department can issue specific licenses to Travel Service Providers (TSPs) and Carrier Service Providers (CSPs) for them to arrange authorized travel for U.S. persons to and from Cuba. To assure compliance with these statutes and Regulations. TSPs and CSPs have historically been required to collect information on the travelers and the travel for their clients. Specifically, the

traveler's full name, mother's maiden name, address, date of birth, passport number (including country of issue), category of travel (licensed, family, official government, official international organization, or journalist fully employed by a new reporting organization), and dates of departure and return must be provided. The Treasury Department's Office of Foreign Assets Control (OFAC) examines this information in performing audits. In accordance with new Regulations, issued May 13, 1998, CSPs must file this information (collected from TSPs) electronically with OFAC between 48 and 72 hours before the flight's departure. Detailed guidance will be provided by OFAC to the CSPs before June 15, 1998, when this new requirements took effect.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 54,600.

Estimated Burden Hours Per Respondent/Recordkeeper: 5 to 10 minutes.

Frequency of Response: Other (prior to each traveler's departure to Cuba).

Estimated Total Reporting/ Recordkeeping Burden: 4,550 hours.

Clearance Officer: Lois K. Holland, (202) 622–1563, Departmental Offices, Room 2110, 1425 New York Avenue, N.W., Washington, DC 20220.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 98–32035 Filed 12–1–98; 8:45 am]

BILLING CODE 4810–25–P

Federal Register

Wednesday
December 2, 1998

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 312, 314 and 601

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 312, 314, and 601

[Docket No. 97N–0165]

RIN 0910–AB20

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing new regulations requiring pediatric studies of certain new and marketed drug and biological products. Most drugs and biologics have not been adequately tested in the pediatric subpopulation. As a result, product labeling frequently fails to provide directions for safe and effective use in pediatric patients. This rule will partially address the lack of pediatric use information by requiring that manufacturers of certain products provide sufficient data and information to support directions for pediatric use for the claimed indications.

DATES: *Effective date.* The regulation is effective April 1, 1999.

Compliance dates. Manufacturers must submit any required assessments of pediatric safety and effectiveness 20 months after the effective date of the rule, unless the assessments are waived or deferred by FDA.

FOR FURTHER INFORMATION CONTACT: Khyati N. Roberts, Center for Drug Evaluation and Research (HFD–103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, or Karen D. Weiss, Center for Biologics Evaluation and Research (HFM–570), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of August 15, 1997 (62 FR 43900) (hereinafter referred to as the proposal), FDA proposed to require that manufacturers of certain new and marketed drugs and biologics conduct studies to provide adequate labeling for the use of these products in children. As described in the proposal, children are subject to many of the same diseases as adults, and are, by necessity, often treated with the same drugs and biological products as adults. However, many drugs and biological products marketed in the United States that are or could be used in children are inadequately labeled for use in pediatric patients or for use in specific pediatric subgroups (Refs. 1 and 2). Indeed, many of the drugs and biological products that are widely used in pediatric patients carry disclaimers stating that safety and effectiveness in pediatric patients have not been established (Refs. 2 and 3). Safety and effectiveness information for some pediatric age groups is particularly difficult to find. For example, there is almost no information on use in patients under 2 years of age for most drug classes (Ref. 1).

As described in more detail in the proposal, the absence of pediatric labeling information poses significant risks for children. Inadequate dosing information exposes pediatric patients to the risk of adverse reactions that could be avoided with an appropriate pediatric dose. The lack of pediatric safety information in product labeling exposes pediatric patients to the risk of age-specific adverse reactions unexpected from adult experience. The proposal cited reports of injuries and deaths in children resulting from use of drugs that had not been adequately tested in the pediatric population. The absence of pediatric testing and labeling may also expose pediatric patients to ineffective treatment through underdosing, or may deny pediatric patients therapeutic advances because physicians choose to prescribe existing, less effective medications in the face of insufficient pediatric information about a new medication. Failure to develop a pediatric formulation of a drug or biological product, where younger pediatric populations cannot take the adult formulation, may also deny pediatric patients access to important new therapies, or may require pediatric patients to take the drug in extemporaneous formulations that may be poorly or inconsistently bioavailable.

The proposed rule described previous steps taken by FDA in recent years to address the problem of inadequate pediatric testing and inadequate pediatric use information in drug and biological product labeling. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research have implemented a ''Pediatric Plan'' designed to focus attention on, and encourage voluntary development of, pediatric data both during the drug development process and after marketing. In addition, in the **Federal Register** of December 13, 1994 (59 FR 64240) (hereinafter referred to as the 1994 rule), FDA issued a regulation requiring manufacturers of marketed drugs to survey existing data and determine whether those data were sufficient to support additional pediatric use information in the drug's labeling. Under the 1994 rule, if a manufacturer determines that existing data permit modification of the label's pediatric use information, the manufacturer must submit a supplemental new drug application (NDA) to FDA seeking approval of the labeling change.

Although the preamble to the 1994 rule recognizes FDA's authority to require drug and biological product manufacturers to conduct pediatric studies on a case-by-case basis, the rule does not impose a general requirement that manufacturers carry out studies when existing information is not sufficient to support pediatric use information. Instead, if there is insufficient information to support a pediatric indication or pediatric use statement, the rule requires the manufacturer to include in the product's labeling the statement: ''Safety and effectiveness in pediatric patients have not been established.''

The response to the 1994 rule has not substantially addressed the lack of adequate pediatric use information for marketed drugs and biological products. Pediatric labeling supplements were submitted for approximately 430 drugs and biologics, a small fraction of the thousands of prescription drug and biological products on the market. Of the supplements submitted, approximately 75 percent did not significantly improve pediatric use information. Over half of the total supplements submitted simply requested the addition of the statement ''Safety and effectiveness in pediatric patients have not been established.'' Others requested minor wording changes or submitted unorganized, unanalyzed collections of possibly relevant data. Approximately 15 percent (approximately 65) of the supplements provided adequate pediatric information for all relevant pediatric age groups, and another 8 percent (approximately 35) provided adequate pediatric information for some but not all relevant age groups.

The absence of adequate pediatric use information remains a problem for new drugs and biologics as well as for marketed products. The proposal presented data from 1988 through the 1990's showing that the percentage of new products entering the marketplace with adequate pediatric safety and effectiveness information has not increased in the last decade.

For example, FDA compared the number of new molecular entities (NME's) approved in 1991 and 1996

with potential usefulness in pediatric patients and looked at the adequacy of pediatric labeling for those drugs. Fifty-six percent (9/17) of the NME's approved in 1991 with potential usefulness in pediatric patients had some pediatric labeling at the time of approval. In 1996, only 37 percent (15/40) of the NME's with potential usefulness in pediatric patients had some pediatric labeling at the time of approval. For both 1991 and 1996, those drugs counted as having pediatric labeling may not have been studied in all age groups in which the drug was potentially useful. The manufacturers of an additional 7 of the 1991 drugs and 17 of the 1996 drugs promised to conduct pediatric studies after approval. Since publication of the proposal, figures for 1997 NME's have become available. In 1997, 39 NME's were approved. Twenty-seven had potential usefulness in pediatric patients, and 33 percent of these (9/27) had some pediatric labeling at the time of approval. Postapproval studies were requested or promised for an additional six. It is uncertain how many of the commitments made for postapproval studies of the 1996 and 1997 drugs will result in pediatric labeling. Of the seven NME's approved in 1991 for which sponsors made commitments to conduct postapproval pediatric studies, pediatric labeling has been added to only one. This figure reflects both studies that resulted in positive labeling, i.e., safety and dosing information, and studies that resulted in warnings against pediatric use. It does not reflect studies that failed to provide any useful information about pediatric use or studies that were completed but the sponsor failed to seek a change in its pediatric use labeling.

These data indicate that voluntary efforts have, thus far, not substantially increased the number of products entering the marketplace with adequate pediatric labeling. FDA has therefore concluded that additional steps are necessary to ensure the safety and effectiveness of drug and biological products for pediatric patients. This rule requires the manufacturers of new and marketed drugs and biological products to evaluate the safety and effectiveness of the products in pediatric patients, if the product is likely to be used in a substantial number of pediatric patients or would provide a meaningful therapeutic benefit to pediatric patients over existing treatments.

In addition to issuing this rule, FDA has initiated other actions that it hopes will encourage the development of adequate pediatric use information. FDA has issued a draft guidance document entitled ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products'' (November 30, 1998). FDA also plans to develop additional guidance on how to develop effectiveness, safety, and dosing information to support pediatric labeling. The agency also supported a provision in the reauthorized Prescription Drug User Fee Act (PDUFA) eliminating user fees for pediatric supplements to encourage the submission of these supplements.

Finally, FDA has issued a guidance document entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products,'' describing the kinds of studies that can support effectiveness in supplemental or original applications. In that document, FDA provides guidance to manufacturers on the circumstances in which FDA may approve an initial or supplemental claim in which substantiation of the results of an adequate and well-controlled trial is provided by information other than a second adequate and well-controlled trial precisely replicating the first trial, or the circumstances in which studies without the extensive documentation ordinarily required could be utilized. This guidance will often be relevant to the data needed to support claims in a pediatric population.

Since the issuance of the proposal, Congress has enacted a bill that has an impact on pediatric studies of certain drugs. The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) contains provisions that establish economic incentives for conducting pediatric studies on drugs for which exclusivity or patent protection is available under the Drug Price Competition and Patent Term Restoration Act (Pub. L. 98–417) and the Orphan Drug Act (Pub. L. 97–414). These provisions extend by 6 months any existing exclusivity or patent protection on a drug for which FDA has requested pediatric studies and the manufacturer has conducted such studies in accordance with the requirements of FDAMA. FDAMA also specifically recognizes FDA's intention to require pediatric studies by regulation and extends by 6 months any existing exclusivity or patent protection on a drug whose manufacturer submits pediatric studies in compliance with this rule, if the studies meet the completeness, timeliness, and other requirements of section 505A. Under FDAMA, a manufacturer who submits pediatric studies required under this rule may receive a 6-month extension of exclusivity or patent protection granted to the manufacturer for that drug.

Although FDA expects the exclusivity offered by FDAMA to provide a substantial incentive for sponsors to conduct some pediatric studies, the agency nonetheless believes that this final rule is necessary to significantly increase the number of drug and biological products that have adequate labeling. Certain limitations on the scope and effect of the exclusivity offered by FDAMA are likely to leave significant gaps in pediatric labeling. For example, because FDAMA exclusivity applies only to products that have exclusivity or patent protection under the Drug Price Competition and Patent Term Restoration Act and the Orphan Drug Act, it provides no incentive to conduct studies on certain categories of products, including most antibiotics, biologics, and off-patent products.

In addition, the voluntary nature of the incentive provided by FDAMA is likely to leave many drugs, age groups, and indications unstudied. Given limited resources to conduct pediatric studies, it is probable that manufacturers will elect to conduct pediatric studies preferentially on those drugs for which the incentives are most valuable, i.e., on drugs with the largest sales. This may leave unstudied drugs that are greatly needed to treat pediatric patients, but that have smaller markets. For similar reasons, manufacturers are less likely to seek FDAMA exclusivity by conducting studies on drugs that require studies in neonates, infants, or young children. The youngest pediatric populations are more difficult to study and may require pediatric formulations, making pediatric studies of these groups more expensive, thereby reducing the value of the incentives provided by FDAMA. Thus, where there is a great medical need for data on drugs with relatively small markets or for studies on neonates, infants, or young children, it may be necessary to require the collection of such data, rather than rely on incentives.

Finally, manufacturers are eligible for FDAMA exclusivity when they submit a study to FDA that is consistent with FDA's written request for such a study. The study results are not required to provide useful information on pediatric use (e.g., the results may be inconclusive), and the sponsor is not required to obtain approval of a supplement adding the information gained in the study to the drug's label. Thus, FDAMA provides no guarantee that the studies conducted under the statute will result in improved pediatric labeling.

For these reasons, FDA believes that there remains an important need for this rule. FDA has concluded, however, that with respect to already marketed drugs eligible for exclusivity under FDAMA, the publication of the list required by section 505A(b) and the availability of pediatric exclusivity may diminish the need to exercise the agency's authority to require studies. Under the rule, FDA has discretion whether to require studies of marketed drugs (see § 201.23 (21 CFR 201.23)). FDA believes that, in exercising its discretion under § 201.23, it is appropriate to determine whether manufacturers will undertake the needed studies voluntarily. FDA will therefore allow an adequate opportunity for manufacturers voluntarily to submit studies for drugs listed by FDA as having a high priority. If, following such an opportunity, there remain marketed drugs for which studies are needed and the compelling circumstances described in the rule are met, the agency will consider exercising its authority to require studies. With respect to marketed drugs and biologics that are not eligible for exclusivity under FDAMA, FDA intends to exercise its authority to require studies as of the effective date of the rule in the circumstances described in the regulation. FDA emphasizes that the appearance of a drug or biologic on the list published under section 505A(b) carries no implication that FDA will require studies on that drug or biologic under this rule. FDA intends to reserve its authority to require studies of marketed drugs and biologics to situations in which the compelling circumstances described in the regulation are present.

FDA intends to issue further regulations and guidance implementing the pediatric exclusivity provisions of FDAMA, which will, among other things, provide guidance on the interaction of this rule and FDAMA exclusivity.

II. Highlights of the Final Rule

This final rule is designed to ensure that new drugs and biological products contain adequate pediatric labeling for the approved indications at the time of, or soon after, approval. The final rule establishes a presumption that all new drugs and biologics will be studied in pediatric patients, but allows manufacturers to obtain a waiver of the requirement if the product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and is not likely to be used in a substantial number of pediatric patients. The rule also authorizes FDA to require pediatric studies of those marketed drugs and biological products that: (1) Are used in a substantial number of pediatric patients for the claimed indications, and where the absence of adequate labeling could pose significant risks; or (2) would provide a meaningful therapeutic benefit over existing treatments for pediatric patients, and the absence of adequate labeling could pose significant risks to pediatric patients.

A. Scope of Rule

The proposed rule would have required an application for a drug classified as a ''new chemical entity'' or a new (never-before-approved) biological product to contain safety and effectiveness information on relevant pediatric age groups for the claimed indications. Based upon comments observing that changes in already marketed chemical entities, such as new indications or dosage forms, can have as much or more therapeutic significance for pediatric patients than the original product, the final rule expands the scope of the rule to include new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration for which an applicant seeks approval. The final rule does not, however, require the submission of pediatric data for a drug for an indication or indications for which orphan designation has been granted under section 526 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bb).

B. Types of Studies Needed

As described in the 1994 final rule, gathering adequate data to establish pediatric safety and effectiveness may not require controlled clinical trials in pediatric patients. Where the course of the disease and the product's effects are similar in adults and pediatric patients, FDA may conclude that pediatric safety and effectiveness can be supported by effectiveness data in adults together with additional data, such as dosing, pharmacokinetic, and safety data in pediatric patients. The rule also does not necessarily require separate studies in pediatric patients. In appropriate cases, adequate data may be gathered by including pediatric patients as well as adults in the original studies conducted on the product.

The specific pediatric information needed in each case will depend on the nature of the application, what is already known about the product in pediatric populations, and the underlying disease or condition being treated. The final rule requires an assessment of safety and effectiveness in pediatric patients only for the indications claimed by the manufacturer. It does not require a manufacturer to study its product for unapproved or unclaimed indications, even if the product is widely used in pediatric patients for those indications. In the proposed rule, the pediatric study requirement for drugs was contained in § 314.50(g) (21 CFR 314.50(g)). In the final rule, the requirement is located in new § 314.55, because § 314.50 does not contain other specific study requirements. The location of the requirement for biological products (§ 601.27 (21 CFR 601.27)) remains unchanged in the final rule.

C. Age Groups

The final rule requires pediatric studies in each age group in which the drug or biological product will provide a meaningful therapeutic benefit or will be used in a substantial number of pediatric patients for the indications claimed by the manufacturer. The relevant age groups will, however, be defined flexibly, depending on the pharmacology of the drug or biological product, rather than following the fixed age categories defined in the 1994 rule and identified in the preamble to the proposed rule. For drugs and biological products that offer a meaningful therapeutic benefit, the rule requires manufacturers to develop pediatric formulations, if needed, for those age groups in which studies are required. Manufacturers may, however, avoid this requirement if they demonstrate that reasonable attempts to develop a pediatric formulation have failed.

D. Not-Yet-Approved Products

1. Deferral of Studies Until After Approval

The final rule permits the submission of pediatric information to be deferred until after approval if there is an adequate justification for deferral, e.g., because pediatric studies should not begin until some safety and/or effectiveness information on adults has been collected, or awaiting the completion of pediatric studies would delay the availability of a product to adults. When trials should begin in particular cases, and whether deferral will be necessary, will depend upon the seriousness of the disease for which the drug or biological product is indicated, the need for the product, the amount of safety and effectiveness data available, and what types of pediatric studies are needed.

In general, FDA expects that studies of drugs or biological products for diseases that are life threatening in pediatric patients and that lack adequate

therapy could begin earlier than studies of drugs that are less urgently needed, ordinarily as early as the availability of preliminary safety data in adults (frequently referred to as phase 1 data), even if data from well-controlled studies are not yet available. For less critical drugs and biologics, pediatric studies could ordinarily begin when additional safety and/or effectiveness data from the initial well-controlled trials in adults (frequently referred to as phase 2 data) became available. Of course, studies of products for exclusively pediatric diseases ordinarily need not await the development of adult data. The timing of individual pediatric studies will, however, necessarily depend on the specific information available about the product in question. For example, a study of a noncritical drug in adolescents might begin after the initial safety studies in adults, if all the parties involved agreed that initiation was appropriate in light of the results of the adult and animal safety studies.

In other cases, studies should not begin in pediatric patients until significantly more adult data are collected. For example, FDA does not believe that early study or use in pediatric patients is appropriate for some so-called ''me-too'' drugs that are expected to be widely used but are members of a drug class that already contains an adequate number of approved products with pediatric labeling. Such drugs may not have been shown to provide any benefit over other products in the same class, and may introduce new risks that are not apparent until the drug has been in wide use after marketing. Studies of such drugs will therefore usually be deferred until the safety profiles of the drugs are well established through marketing experience. To encourage use of properly labeled drugs in pediatric patients, FDA may require the pediatric use section of the approved labeling of such a me-too drug to contain a statement recommending preferential use of other drugs that are adequately labeled for pediatric use.

2. Waiver of the Study Requirement

The pediatric study requirement applies to all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration, unless FDA waives the requirement. Under criteria established in the rule, FDA may waive the study requirement for some or all pediatric age groups. The burden is on the sponsor to justify a waiver. A waiver will be granted if the waiver request demonstrates that the product meets both of the following conditions: (1) The product does not represent a meaningful therapeutic benefit for pediatric patients over existing treatments, and (2) the product is not likely to be used in a substantial number of pediatric patients. There was some confusion in the comments on the proposed rule over these waiver criteria. FDA emphasizes that the study requirement applies to a product that offers a meaningful therapeutic benefit even if it is not used in a substantial number of pediatric patients, and vice versa.

In response to comments, FDA has refined its definitions of ''meaningful therapeutic benefit'' and ''substantial number of pediatric patients.'' To define meaningful therapeutic benefit for both drugs and biologics covered by this rule, FDA has relied, in part, on CDER's current administrative definition of a ''Priority'' drug, applied to pediatric populations. The administrative definition of ''Priority'' products for biologics relies on different criteria (Ref. 2). Use of CDER's Priority drug definition to help define ''meaningful therapeutic benefit'' is not intended to affect the administrative definition of a Priority biologic. The Priority classification for drugs is determined based on CDER's estimate, at the time of NDA submission, of a drug's therapeutic, preventive, or diagnostic value. A Priority drug is defined as one that, if approved, would be a significant improvement in the treatment, diagnosis, or prevention of a disease, compared to marketed products approved for that use. In establishing meaningful therapeutic benefit for pediatric use, the comparison will be to other products adequately labeled for use in the relevant pediatric population. If there are no such products, a new product would usually be considered to have a meaningful therapeutic benefit. Improvement over existing products labeled for pediatric use can be demonstrated by, for example: (1) Evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness in a new subpopulation. Evidence of improvement over existing therapies need not in all cases come from head-to-head trials.

To help ensure that pediatric patients have a sufficient range of treatments available, a product will also be considered to provide a meaningful therapeutic benefit if it is in a class of products or for an indication for which there is a need for additional therapeutic options, notwithstanding the fact that it might not be a priority drug. In contrast to the range of therapies for a given indication often available to adults, there are relatively few instances in which therapeutic alternatives are studied and labeled for pediatric patients. For some diseases, however, it is therapeutically important to have a range of available treatment options, e.g., because there are frequent treatment failures. The Priority definition would cover the first product labeled for pediatric use, but might not cover the second or third product for a given indication or in a given class, if the subsequent product did not offer an advantage over existing therapies. The specific number of products needed will depend upon such factors as the severity of the disease being treated and the adverse reaction profile of existing therapies. FDA will seek further guidance on applying this criterion from a panel of pediatric experts.

Thus, new products will meet the definition of a meaningful therapeutic benefit if: (1) They provide a significant improvement over existing adequately labeled therapies; or (2) if they are indicated for diseases or conditions, or are in product classes, in which there are currently few products labeled for pediatric use and more therapeutic options are needed. FDA expects that over time, as the number of products adequately labeled for pediatric patients grows, the number of new products meeting the second criterion will diminish. FDA emphasizes that the addition of the second criterion for defining meaningful therapeutic benefit under this final rule is not intended to alter the definition of a Priority drug, and that products meeting the second criterion will not thereby be eligible for Priority status. FDA also notes that the rule's definition of meaningful therapeutic benefit is intended to apply only in the pediatric study context.

FDA has also revised the proposed definition of ''a substantial number of pediatric patients.'' Many comments argued that the number chosen by FDA in the proposal (100,000 prescriptions per year or 100,000 pediatric patients with the disease) was arbitrary. Physician mention data from the IMS National Disease and Therapeutic Index (Ref. 38), which tracks the use of drugs by measuring the number of times physicians mention drugs during outpatient visits, shows that pediatric use of drugs is generally grouped in two distinct ranges. Physician mentions of drugs for pediatric use generally fall either below 15,000 per year or above 100,000 per year. Few drugs fall within the two ranges. Thus, selecting a cut-off

for ''substantial number of pediatric patients'' in the middle of the two ranges will provide a reasonable discrimination between products that are widely used and those that are less commonly used, and the specific number chosen will not arbitrarily include or exclude a significant number of drugs. FDA has therefore chosen 50,000 as the cut-off for a substantial number of pediatric patients. Because the number of pediatric patients with the disease or condition is easier to determine than the number of prescriptions per year, a substantial number of pediatric patients will be defined as 50,000 pediatric patients with the disease or condition for which the drug or biological product is indicated. Although physician mentions per year does not correspond exactly to the number of patients with the disease or condition, they provide a rough approximation and the IMS data show that the number of products included or excluded is relatively insensitive to changes in the cut-off chosen. As proposed, a partial waiver for a particular pediatric age group would be available under this method if 15,000 patients in that age group were affected by the disease or condition. This definition of ''a substantial number of pediatric patients'' has not been codified, however, and FDA may modify it, after consulting with a panel of pediatric experts. Any modification will be issued in a guidance document with an opportunity for comment.

FDA will also waive the pediatric study requirement where: (1) The applicant shows that the required studies on the product are impossible or highly impractical because, for example, the population is too small or geographically dispersed; (2) the product is likely to be unsafe or ineffective in pediatric patients; or (3) reasonable efforts to develop a pediatric formulation (if one is needed) have failed.

To reduce the burden on manufacturers in applying for waivers and deferrals, FDA intends to issue a guidance document providing a format for a request for waiver or deferral.

E. Marketed Products

The final rule is also intended to improve pediatric use information for already marketed drugs and biological products. The rule codifies FDA's authority, discussed in the 1994 rule, to require, in the compelling circumstances described in the regulation, that manufacturers of already marketed drugs and biological products conduct studies to support pediatric-use labeling for the claimed indications. The criteria for requiring studies of marketed products have been revised slightly in response to comments.

F. Early Discussions and Pre- and Postmarket Reports

The final rule contains provisions designed to encourage discussions of the need for pediatric studies early in the drug development process, as well as pre- and postmarketing reporting requirements designed to assist FDA in determining whether pediatric studies are needed for particular products and whether required studies are being carried out with due diligence.

G. Pediatric Committee

Many comments on the proposed rule urged FDA to form a committee of outside experts to assist in various aspects of the implementation of the rule. FDA has concluded that such a panel could provide useful advice and experience. FDA will convene a panel of pediatric experts, including at least one industry representative, and seek its advice on a range of issues related to implementation of the rule, including: (1) The agency's implementation of all aspects of the final rule, including its waiver and deferral decisions; (2) which marketed drugs and biological products meet the criteria for requiring studies; (3) when additional therapeutic options are needed for a given disease or condition occurring in pediatric patients; (4) ethical issues raised by clinical trials in pediatric patients; (5) the design of trials and analysis of data for specific products or classes of products; and (6) issues related to the progress of individual studies.

H. Remedies for Violation of the Rule

For violations of this rule, FDA would ordinarily expect to file an enforcement action for an injunction, asking a Federal court to find that the product is misbranded under section 502 of the act (21 U.S.C. 352) or is an unapproved new drug under section 505(a) of the act (21 U.S.C. 355) or an unlicensed biologic under section 351 of the Public Health Service Act, and to require the company to submit an assessment of pediatric safety and effectiveness for the product. Violation of the injunction would result in a contempt proceeding or such other penalties as the court ordered, e.g., fines. FDA does not intend, except possibly in rare circumstances, to disapprove or withdraw approval of a drug or biological product whose manufacturer violates requirements imposed under this rule.

III. Comments on the Proposed Rule

FDA received 54 written comments on the proposed rule from pediatricians, professional societies, parents, members of the pharmaceutical industry, organizations devoted to specific diseases, and patient groups. A significant majority of the comments, primarily those from pediatricians, professional societies, parents, organizations devoted to specific diseases, and patient groups, supported regulations requiring that drugs and biologics be studied in children. Many of these comments described the problems faced by the pediatric community and parents resulting from inadequate pediatric labeling and the absence of pediatric formulations, and argued that a pediatric study requirement was long overdue. Some comments, primarily those from the pharmaceutical industry, opposed a pediatric study requirement, arguing that existing voluntary measures and incentives were sufficient to ensure adequate pediatric labeling. Finally, a number of comments addressed FDA's legal authority to require pediatric testing of drugs and biologics.

FDA also held a day-long public hearing on October 27, 1997, in Washington, DC, at which recognized experts in the field, members of the pharmaceutical industry, and other interested parties were given an opportunity to discuss the issues raised by the proposed rule. There were three panels, each of which comprised representatives from industry, the pediatric community, organizations devoted to specific diseases, patient groups, and a bioethicist. The panels considered the following three issues: (1) When pediatric studies are needed, (2) what types of studies are needed, and (3) special challenges in testing pediatric patients. Those who spoke were nearly unanimous in their support for some kind of regulation requiring pediatric studies of some drugs and biologics. There was, however, a wide range of views on which drugs and biologics should be the subject of required studies and on how the requirement should be implemented.

Many written and oral comments raised specific issues for consideration by the agency. These comments are addressed below.

A. Purpose of Rule

1. FDA received many comments arguing that this rule is needed to ensure adequate medical care for children. Many comments from pediatricians stated that they regularly must prescribe to young children drugs

that are not labeled for children under 6 or even 12, and for which pediatric dosage forms do not exist. One comment stated that, without adequate testing and labeling, physicians must estimate appropriate pediatric doses, and that even at ''appropriate'' doses, it is not known whether use in children is as safe as use in adults. One comment argued that the absence of pediatric labeling puts children at greater risk for adverse drug reactions (ADR's) and therapeutic failures than adults. According to another comment, most common and severe ADR's in pediatric patients would be eliminated by adequate testing, and that perhaps 2 percent of all pediatric hospitalizations are due to ADR's. One comment concluded that the failure to conduct pediatric studies results in a different standard of care for children and adults in this country.

A comment from a pharmaceutical trade association argued, however, that most of the toxicity problems identified by FDA as caused by inadequate pediatric labeling were from the 1950's and that these ''dated'' examples are not relevant to current practice. As an example, the comment cited chloramphenicol, a drug referred to by FDA in the proposed rule because, when it was used in the 1950's in neonates without adequate testing, it was responsible for many infant deaths (Ref. 4). According to the comment, it is now known that chloramphenicol can be used in neonates if the dose is correct. The comment also stated that practicing physicians have access to adequate dosing information from case reports in the medical literature.

FDA agrees that the absence of adequate pediatric labeling puts pediatric patients at risk for adverse drug reactions and ineffective dosing. FDA believes that the reference to new dosing information that permits use of chloramphenicol in infants illustrates the need for this final rule. Had adequate safety and dosing information been available earlier, many babies' lives could have been saved. Instead, adequately supported dosing information was not available until after the drug had been used in a large number of babies, with tragic consequences. FDA also disagrees with the comment that the remaining reports cited in the proposal of unexpected toxicity in pediatric patients from inadequately tested drugs are ''dated.'' Contrary to the assertion in the comment, a majority of these reports are from the 1980's and 1990's (Refs. 5 through 14).

FDA also does not believe that case reports scattered through the medical literature are an adequate substitute for organized and complete pediatric labeling information. To the extent that published experience is informative and credible, it should be used to improve labeling. The comments received from pediatricians reflect their view that there is often no adequately supported dosing and safety information for the drugs they use routinely in their patients. Even where case reports are available, they describe a limited number of pediatric patients and cannot provide sufficient information to establish the safety profile of a drug in pediatric patients.

2. Some comments argued that pediatric studies are needed because differences between children and adults can make extrapolation from adult data treacherous. One comment pointed out that research on antiarrhythmics in pediatric patients has revealed many surprises in dosing and side effects. For example, drugs that bind to milk may cause safety or effectiveness problems in pediatric patients not detected in adults.

FDA agrees that pediatric dosing cannot necessarily be extrapolated from adult dosing information using an equivalence based either on weight milligram/kilogram (mg/kg) or body surface area (mg/m^2). There are potentially significant differences in pharmacokinetics, or unique drug-food interactions, that may alter a drug's blood levels in pediatric patients. Moreover, there can be pharmacodynamic differences between adults and pediatric patients.

3. Several comments argued that voluntary measures have not resulted in a significant increase in pediatric labeling, and that new products continue to enter the market without adequate, or any, pediatric labeling. Pediatricians, professional societies, parents, organizations devoted to specific diseases, and patient groups provided many examples of diseases and drug classes for which pediatric labeling was long-delayed, inadequate, or nonexistent. Acquired immune deficiency syndrome (AIDS) drugs were frequently cited as an example of the industry's failure to obtain adequate pediatric labeling at or near the time of approval. One comment pointed to protease inhibitors, which are theoretically most effective in newborns but have not been tested or approved for use in this group. Even for older children, the comment observed that it has taken over a year after adult approval to obtain pediatric labeling for these life-saving drugs. Another comment stated that the absence of drugs for human immunodeficiency virus (HIV) infection that are appropriately labeled and formulated for pediatric patients causes parents to give children inappropriate doses, sometimes giving up part of their own dose if the child's physician will not prescribe it.

Other comments pointed out that epilepsy is considered a pediatric disease but claimed that many new epilepsy drugs are approved without information for use in pediatric patients. These comments urged that anti-epileptic drugs be added to the list of drug classes with inadequate labeling. A comment from a specialist in pulmonary medicine stated that although asthma is a common disease in pediatric patients, adult formulations are often released first, leaving pediatric patients without effective treatments. Other comments observed that not one of the standard immunosuppressive medications used in pediatric patients has been tested in pediatric patients. One comment contended that poor information about the pharmacokinetics of these drugs in pediatric patients has led to inadequate dosing to achieve effectiveness and possibly unnecessary toxicity.

The American Psychiatric Association commented that significant psychiatric diseases are increasingly diagnosed in pediatric patients, who may be treated with drugs despite the lack of pediatric labeling. According to this comment, most psychoactive medications are underutilized in pediatric patients due to the lack of pediatric labeling and to fear of overdosing. In the case of anti-hyperactivity drugs, however, the comment states that as many children are overtreated as undertreated, especially among pre-school age children. A comment from the National Institute of Mental Health (NIMH) stated that the rule was much needed to provide essential data on the safety and effectiveness of psychiatric medications in pediatric patients. This comment attached seven NIMH reviews of the existing data on psychotropic medications for pediatric patients, identifying many critical knowledge gaps that remain to be addressed by pediatric research.

One comment stated that pediatric nephrologists frequently prescribe drugs to pediatric patients for life-threatening conditions, including antihypertensive medications, diuretics, lipid-lowering agents, and immunosuppressive agents, even for pediatric patients less than 2 years of age, without benefit of formal studies. This comment further stated that drug therapy for chronic conditions like kidney failure is currently based only on experience gained from drug usage in children after approval for the indication in adults, and that

discovering ''inadequate dosing or severe side effects by empiric use of these drugs is not desirable or safe.'' Another comment provided the results of a survey of 4,898 pediatric patients with end-stage renal disease on the medications they receive. Ninety-seven percent received prednisone or prednisolone, 91 percent received cyclosporine, and 84 percent received azathioprine. According to the comment, none of these drugs was studied in pediatric patients and no information on the pharmacokinetics of these drugs in pediatric patients is available.

In contrast, several comments from the pharmaceutical industry argued that voluntary measures, the 1994 rule, and the incentives provided by FDAMA are adequate to assure adequate pediatric labeling and that FDA has not given these steps sufficient time to work. Several comments argued that to obtain pediatric studies, FDA should use encouragement and early discussion with sponsors, together with incentives, rather than imposing new requirements. These comments contended that sponsors should make ''phase 4 commitments'' (commitments to conduct pediatric studies after approval) and FDA should track these commitments. According to one comment, these methods have not been systematically used by FDA. According to another comment, FDA did not describe its present experience in getting manufacturers to conduct pediatric studies. Other comments argued that FDA has not allowed the 1994 rule sufficient time to produce results and that the agency should wait until it has reviewed and acted upon all supplements submitted under that rule before imposing new requirements. One comment contended that if the 1994 rule was successful in producing pediatric labeling for marketed drugs, the new rule should apply only to new drugs. One comment argued that incentives, including exclusivity, waiver of user fees, tax credits, and expedited reviews of pediatric supplements, and liability protection for research physicians, Institutional Review Boards (IRB's), universities, pharmaceutical firms, and parents, are the best means of obtaining pediatric labeling. A few comments argued that excessive litigation will follow imposition of this rule.

Two comments argued that the 53 NME's approved in 1996 demonstrate that pediatric labeling efforts by the industry are adequate, and that new requirements are not needed. Although the figures used in the 2 comments do not agree exactly, these comments stated that 20 or 21 of the 53 have potential for pediatric use. According to these comments, of these, 4 have approved pediatric labeling, 14 have planned or ongoing studies, 1 is switching to over-the-counter (OTC) use, and 1 or 2 have no immediate plans for pediatric labeling activities. One comment contended that, between 1990 and 1997, a 28 percent increase occurred in the number of new drugs in development for pediatric uses, but provided no data to support this claim.

FDA believes that the current state of pediatric labeling for drugs and biologics in the United States, as amply illustrated by comments from the pediatric community, is unsatisfactory. The agency's failure to obtain a significant increase in labeling for either new or marketed drugs or biologics through other measures implemented over the last several years demonstrates the need for a requirement that sponsors conduct pediatric studies of drugs and biologics that represent a meaningful therapeutic benefit to pediatric patients or that will be widely used in pediatric patients. As described in section I of this document, the response to the 1994 rule has not produced a significant improvement in pediatric labeling for marketed drugs. FDA received labeling supplements only for a small fraction of the drugs and biologics on the market. Of those supplements it did receive, over half of the submissions merely sought to add a statement to the product's labeling that ''safety and effectiveness in pediatric patients have not been demonstrated,'' and less than a quarter provided adequate pediatric information for some or all relevant age groups.

The agency's experience in attempting to obtain pediatric labeling for new drugs entering the marketplace through voluntary measures has also been disappointing. As described in the proposal, the percentage of NME's with adequate pediatric labeling has not increased since 1991, when the agency began systematic efforts to obtain better pediatric labeling. Although the number of requests by the agency and commitments by sponsors to conduct phase 4 (postapproval) pediatric studies may have increased, these requests and commitments have so far infrequently resulted in pediatric labeling. Table 1 of this document displays the results of commitments or requests to conduct pediatric studies postapproval between 1991 and 1996. FDA notes that the table does not reflect any labeling supplements under review. There are a total of six pediatric labeling supplements currently under review for NME's approved between 1991 and 1996. These supplements may or may not add significant new labeling information; but, in any case, would not substantially increase the number of successfully conducted postapproval studies.

TABLE 1.—PEDIATRIC LABELING

Status of pediatric labeling	1991	1992	1993	1994	1995	1996	Totals
NME's approved	30	25	25	22	28	53	183
Pediatric studies not needed	14	11	11	7	14	13	70
Label includes some pediatric use information or pediatric studies complete at time of approval	9	4	[1]5	[1]6	5	15	44
Postapproval pediatric studies promised or requested	7	10	[2]10	[2,3]10	[2]10	17	64
Pediatric labeling added after approval	1	0	2	4	2	2	11

[1] In one case, pediatric use information provided for one of two approved indications.
[2] In one case, pediatric data requested for second of two approved indications.
[3] In one case, pediatric data requested for additional age groups.

As Table 1 of this document reflects, FDA's figures disagree with those of the comments for the number of 1996 NME's with potential for pediatric use, the number with some pediatric labeling at the time of approval and the number for which commitments or requests for postapproval studies have been made. The comments did not identify specific drugs, so it is not possible to determine why the two sets of figures conflict. Nevertheless, the historical experience reflected in the table suggests that most of the postapproval pediatric studies for which commitments were made for the

1996 NME's will not result in pediatric labeling. Of the 17 commitments to conduct pediatric studies in 1996, there have thus far been only 2 additions of pediatric labeling. Although some additional studies supporting labeling changes may be submitted in the future, the experience reflected in Table 1 of this document suggests that this will not be a large number. For example, the 27 promised or requested studies for the 1991 through 1993 cohorts have resulted in just 3 additions of pediatric labeling 5 to 7 years after approval. Thus, FDA does not agree that the experience with 1996 NME's demonstrates the adequacy of current efforts to obtain pediatric labeling.

None of the comments claiming that the rule will result in excessive litigation provided any evidence suggesting a relationship between pediatric testing and increased litigation or liability. As shown in the number of NME's with pediatric labeling at the time of approval, a significant minority of drug and biologic manufacturers already conducts pediatric testing. FDA is aware of no evidence that excessive litigation has been associated with this testing.

With respect to the argument that the incentives provided by FDAMA will be sufficient to ensure adequate pediatric labeling, FDA believes that a mixture of incentives and requirements is most likely to result in real improvements in pediatric labeling. FDA is hopeful, e.g., that the FDAMA incentives will make more resources available for pediatric studies. As described earlier, FDA does not believe, however, that incentives alone will result in pediatric studies on some of the drugs and biologics where the need is greatest. The incentives provided by FDAMA are available only for drugs already covered by the exclusivity or patent protection provided by sections 505 and 526 of the act. Thus, the FDAMA incentives are not available for many already marketed drugs, or for many antibiotics or biologics. In addition, limited resources available to conduct pediatric studies and fiduciary obligations to shareholders may cause manufacturers to conduct pediatric studies preferentially on those drugs where the incentives are most valuable, rather than on those drugs or biological products where studies are most needed.

4. Two comments argued that the rule is inconsistent with a 1977 FDA document entitled ''General Considerations for the Clinical Evaluation of Drugs in Infants and Children,'' which recommended, among other things, that ''reasonable evidence of efficacy generally * * * be known before infants and children are exposed to [a drug].''

As described in more detail in section III.D of this document under ''Deferral,'' FDA expects that for drugs and biologics other than those for life-threatening diseases without adequate treatment, clinical trials in pediatric patients will ordinarily begin no earlier than when initial data from well-controlled trials in adults (frequently referred to as phase 2 data) become available to ensure that reasonable preliminary evidence of safety and/or effectiveness is available before pediatric patients are exposed to the drug or biological product. How much evidence of safety or effectiveness is ''reasonable evidence'' that should be available before pediatric trials may begin will be determined on a case-by-case basis. Thus, FDA believes that this rule is substantially consistent with the 1977 document.

FDA notes that the 1977 document was based upon a report prepared for FDA under a contract with the American Academy of Pediatrics (AAP). The AAP is currently developing proposed revisions to this document concerning the types of data needed to support pediatric labeling. The 1977 document, which falls under the general category of guidance documents, does not bind FDA or the public, but represents the agency's current thinking on a particular issue. Alternative approaches may be used if the alternative satisfies the requirements of the applicable statute and regulations (62 FR 8961, February 27, 1997) (Good Guidance Practices document). Until such time as an updated guidance on the clinical evaluation of drugs in infants and children is published, sponsors are encouraged to confer with the agency before initiating pediatric studies.

5. Several comments challenged FDA's use of the 1994 IMS National Disease and Therapeutic Index (NDTI) data on the 10 drugs used most frequently in pediatric patients without adequate labeling, arguing that the data incorrectly imply that physicians have no labeling information, when in fact prescribing information is now, or will be, available for most of the 10 drugs listed.

These comments misunderstand the purpose for which FDA cited the 1994 data. Those data provided a snapshot of the labeling information available to physicians for 10 widely used drugs at a given point in time. Even if additional information had been added to the labels of these drugs in the 4 years since the survey was conducted, there was none available during a year in which the drugs, together, were prescribed to pediatric patients over 5 million times. FDA notes, moreover, that, contrary to the suggestion in the comments, adequate labeling has been added for only 1 of the 10 drugs for the age group described in the proposal.

6. Two comments disputed the estimated number of times their products were prescribed to pediatric patients. One manufacturer argued that the total units sold of Auralgan were less than the listed number of prescriptions. Another manufacturer disputed the estimates of Ritalin usage. This manufacturer also complained that it was not contacted by FDA about use of Ritalin despite the statement in the proposal that FDA had contacted the manufacturers of the top 10 drugs used without adequate labeling in pediatric patients.

Limitations on the data used to estimate number of prescriptions may have resulted in the discrepancy noted by the manufacturers of Auralgan or Ritalin. The number of prescriptions is estimated from data provided by IMS America, Ltd. IMS NDTI surveys a sample of physicians (more than 2,940 physicians representing 27 specialities) to determine the number of times that, during patient contacts, physicians mentioned specific drugs for particular age groups. Physician mentions may not correlate exactly with actual usage. In addition, the NDTI numbers taken from the sample of physicians are extrapolated to the nation as a whole, using a given formula. With respect to the claim that FDA has not contacted the manufacturer of Ritalin, FDA notes that it has scheduled meetings with the manufacturer to discuss use of the drug in children, which have been canceled at the manufacturer's request.

7. One comment challenged FDA's use of quinolones as an example of a class of drug that does not need to be studied in pediatric patients. The comment claimed quinolones do need to be studied in pediatric patients because of their important use in cystic fibrosis patients.

FDA agrees that fluoroquinolones may provide important therapeutic benefits to patients with cystic fibrosis. At present, all approved fluoroquinolones are labeled with the following statement: ''Safety and effectiveness in children and adolescents less than 18 years of age have not been established.'' In addition, the label includes a statement advising that the fluoroquinolones cause arthropathy in juvenile animals. Historically, the agency has recognized a potential therapeutic role for the fluoroquinolones in children with cystic fibrosis and hematology/oncology

disorders. Indeed, FDA recently approved ciprofloxacin labeling containing a discussion of cystic fibrosis experience in the pediatric use subsection. These actions show that the agency recognizes that there may be a need to study fluoroquinolones in some pediatric patients.

8. One comment from a pharmaceutical company argued that serious ethical, legal, medical, and technical difficulties often prevent conducting pediatric studies. The comment cited difficulties in enrolling pediatric patients in sufficient numbers, unwillingness of parents to enroll children, and the absence of pediatric patients with the disease near convenient and qualified study centers. According to the comment, studies have been successfully conducted in pediatric patients in the past where there was a medical need for the drug in pediatric patients, but this rule will require pediatric studies of drugs intended for adults that may or may not be administered to pediatric patients. The comment also contended that the rule will necessitate a massive infusion of resources for industry, FDA, and medical speciality organizations, and that the agency should start with a small list of diseases with similar pathophysiology in adults and children, and a small list of drug classes known to have similar metabolism, and plan a graduated approach.

Contrary to the suggestion in the comment, this rule is designed to require studies only in those settings in which there is a significant medical need or where usage among pediatric patients is likely to be substantial. FDA acknowledges the difficulties encountered in some cases, but agrees that where there is a need for studies these difficulties have been overcome and that pediatric studies have been successfully conducted in many situations. FDA believes that the number of such studies already conducted each year, for example of antibiotics, vaccines, and roughly 25 percent of NME's, support the view that such studies are not medically, ethically, or technically impossible. FDA also emphasizes that this rule will not require studies in settings where ethical or medical concerns militate against studies. As with all studies regulated by FDA, no pediatric study may go forward without the approval of an IRB, which is responsible for ensuring that the study is ethical and adequately protects the safety of the subjects. In addition, the deferral provisions of the rule are specifically designed to ensure that no pediatric study begins until there are sufficient safety and effectiveness data to conclude that the study is ethically and medically appropriate.

B. Scope

The proposal would have covered only original applications for those drugs classified as ''new chemical entities,'' including antibiotics, and new biological products that had never been approved for any indication. A ''new chemical entity,'' defined in 21 CFR 314.108(a), is a drug that contains no previously approved active moiety. Under the proposal, chemical modifications that did not change the active moiety, such as the formation of a different salt or ester of the moiety, would not have required further study. New indications or dosage forms of a previously approved moiety also would not have required further studies. FDA sought comment on whether the requirement should apply more broadly, e.g., to applications for minor chemical variations of approved products, new indications, new dosage forms or new routes of administration.

9. A majority of those who commented on the scope of the rule recommended that the final rule cover all new drugs and biologics, including new dosage forms and indications, because modifications in existing drugs may be as therapeutically significant to pediatric patients as the original drug or biologic. These comments included pediatricians, medical societies, one pharmaceutical company, and one disease-specific organization. Several comments, including two companies, an IRB, the AAP, a disease-specific organization, and a professional society recommended including new indications and dosage forms on a case-by-case basis, generally if their inclusion were recommended by an expert panel. Several comments supported the narrow scope of the proposal, including a pharmaceutical trade association, a professional society, and several companies. The pharmaceutical trade association suggested that the rule might also apply to new formulations uniquely suited to pediatric patients.

FDA has reconsidered the scope of the rule in light of the comments and has concluded that, in some cases, the need for pediatric studies is as great for modifications of existing products and new claims as for the original products. A new indication or dosage form for a previously approved drug, e.g., could be far more relevant to pediatric patients than the originally approved product. From a public health standpoint, FDA cannot justify the distinction in the proposal between new chemical entities and never-before approved biologics, on one hand, and significant modifications of those products, on the other hand. Therefore, FDA has revised proposed §§ 314.55 (proposed 314.50(g)) and 601.27(a) to cover applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration. The final rule exempts from its coverage any drug for an indication or indications for which orphan designation has been granted under the Orphan Drug Act (21 U.S.C. 360bb). FDA believes this exemption is appropriate because the purpose of the Orphan Drug Act is to encourage the development of drugs for patient populations that are so small as to make the manufacture and sale of the drug unprofitable if not for the incentives offered by the Orphan Drug Act. Imposition of a pediatric study requirement on an orphan drug could conflict with the balance struck by the Orphan Drug Act, by further raising the cost of marketing the drug. This exemption does not apply after marketing under § 201.23 of this final rule.

FDA's decision to expand the scope of the rule does not mean, however, that pediatric studies would always be needed for a new product entering the marketplace, or for a new claim. The waiver criteria will apply equally to modifications of existing drugs and biological products. Thus, FDA will require studies only of those new drugs and biologics that offer a meaningful therapeutic benefit to pediatric patients or that are expected to be used in a substantial number of pediatric patients. In many cases, moreover, new dosage forms might need relatively little pediatric data, such as pharmacokinetic data alone.

10. One comment sought clarification of the applicability of the rule to generic drugs. The comment argued that the collection of pediatric data was unwarranted where a generic manufacturer was copying a drug with an adult dose, and that FDA should require a pediatric bioequivalence study only where the innovator submits a supplement for a new dose or regimen in the pediatric population. Another comment from a generic drug trade association argued that bioequivalence studies in children should never be required to support approval of a generic drug.

This rule does not impose any requirements on studies submitted in support of applications for generic copies of approved drugs that meet the requirements of section 505(j) of the act. FDA also does not currently require bioequivalence studies to be conducted

in children for generic drugs. FDA notes that petitions submitted under section 505(j)(2)(C) for a change in active ingredient, dosage form, or route of administration may be denied if ''investigations must be conducted to show the safety and effectiveness of'' the change. Thus, if a petition is submitted for a change that would require a pediatric study under this rule, the petition may be denied.

C. Required Studies

FDA proposed to amend its regulations related to the content of NDA and biologic license applications (BLA's) to include required information on pediatric studies for certain applications. Under the proposal, an application for a new chemical entity or never before approved biologic would have been required to contain data adequate to assess the safety and effectiveness of the product for all pediatric age groups for the claimed indications, unless FDA granted a deferral or full or partial waiver of the requirement. As described in section III.B of this document under ''Scope'', FDA has revised § 314.55(a) (proposed § 314.50(g)(1)) and § 601.27(a)) to cover applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration. Under the final rule, all covered applications will be required to contain data adequate to assess the safety and effectiveness of the product, unless FDA has granted a waiver or deferral of the requirement (see ''Waiver'' and ''Deferred Submission'' in section III.D and E of this document).

Assessments required under this section for a product that represents a meaningful therapeutic benefit over existing treatments must be carried out using appropriate formulations for the age group(s) for which the assessment is required, unless reasonable efforts to produce a pediatric formulation had failed (see ''Waiver'' in section III.E of this document). Comments on issues related to formulation are addressed under ''Pediatric Formulations'' in section III.I of this document.

The proposal did not mandate particular types of studies. The proposal recommended that the sponsor consult with FDA on the types of data that would be considered adequate to assess pediatric safety and effectiveness in particular cases.

FDA received several comments on the design and conduct of clinical trials in pediatric patients.

11. One comment asked for clarification of what is meant by ''adequate evidence'' to demonstrate safety and effectiveness. The comment argued that FDA should not require two adequate and well-controlled trials for pediatric studies, and that the amount of evidence required should depend on the ability of the data to be extrapolated from adult to pediatric patients, the seriousness of the illness to be treated, the ability to assess meaningful measures of efficacy in pediatric patients, and the feasibility of conducting adequate trials in relatively uncommon pediatric disease states. Another comment claimed that the ability to extrapolate from adult efficacy data is limited and argued that well-controlled trials in pediatric patients should be the norm. This comment also stated that safety cannot be extrapolated from adult data and recommended studying 300 pediatric patients for an adequate period to identify frequent ADR's. Other comments questioned the appropriateness of extrapolating from adult effectiveness data in a variety of settings. One comment argued that in the area of blood products, in addition to extrapolating from pharmacokinetic data, it may be appropriate to extrapolate from adult data using relative blood volume replacement. Several comments urged reliance on a variety of other sources of data, including published studies and reports, and actual use information. One comment urged FDA to rely on advanced scientific and statistical methods that optimize safety, convenience, and informativeness, while minimizing unnecessary or uninformative clinical trials.

FDA agrees that ''adequate evidence'' of safety and effectiveness for pediatric patients does not necessarily require two adequate and well-controlled trials. One of two central purposes of the 1994 rule was to make it clear that pediatric effectiveness may, in appropriate circumstances, be based on adequate and well-controlled studies in adults with supporting data in pediatric patients that permit extrapolation from the adult data. FDA agrees, however, that extrapolation from adult effectiveness data would not always be appropriate and that it may not be appropriate to extrapolate pediatric safety from adult safety data. FDA has specifically noted, in the FDA guidance document entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products,'' that if further controlled trial data were needed in a population subset, it would usually be sufficient to conduct a single additional controlled trial. FDA also agrees that useful information can come from data other than adequate and well-controlled trials, and encourages the submission of valid and reliable data from a variety of sources. The type and amount of data required in any particular case will depend upon many factors, including those cited in the comments.

12. One comment urged FDA, in the final rule, to encourage sponsors to use Computer-Assisted Trial Design (CATD), allowing them to reduce number of actual trials in pediatric patients.

FDA encourages the use of any validated scientific method for designing, conducting, or analyzing clinical trials.

13. One comment questioned whether there will be a sufficient pool of pediatric subjects to complete trials, in light of the increase in the number of trials occasioned by the rule.

FDA believes that with appropriate organization, the pool of pediatric patients available for studies should be adequate. The Pediatric Pharmacology Research Units (PPRU's), a network of groups instituted to conduct pediatric research, some of which are located outside of major population centers, have an established record of recruiting pediatric patients and completing valid studies. Even where the number of pediatric patients affected by a disease is small, valid studies have sometimes been successfully conducted. It should also be reemphasized that many of the studies contemplated under the rule are pharmacokinetic studies, dose-response studies with short-term endpoints (pharmacodynamic studies) and safety studies that are likely to impose relatively little burden on individual patients. Where, however, patient recruitment is so difficult as to make the study impossible or highly impractical, the rule permits a waiver of the study requirement (§§ 314.55(c) and 601.27(c)).

14. One comment urged that the final rule include a broader research requirement, and sought to have drug interactions and drug metabolism taken into consideration. Another comment sought to have the final rule codify minimal requirements for studies, such as toxic overdose and pharmacokinetic data. One comment urged FDA not to codify specific requirements for clinical trials, but to establish these requirements in consultation with an expert pediatric committee.

FDA declines to codify specific requirements for pediatric studies. Flexibility is necessary to assure that required studies are appropriate for each product. FDA will, however, consult with a pediatric committee on specific pediatric study issues.

15. One comment from a professional pharmacy organization urged that all protocols for pediatric studies be reviewed by pediatric experts, including a pharmacist knowledgeable about pharmacodynamic factors in each age group.

FDA reviews protocols for pediatric studies submitted in investigational new drug applications (IND's), and its reviewers include experts in pediatrics and pharmacology.

D. Deferred Submission

The proposal recognized that there would be circumstances in which it would be appropriate to permit the submission of pediatric data after approval. Two such circumstances were described in the preamble to the proposal: (1) Where adult safety or effectiveness data need to be collected before the product could be appropriately studied in pediatric patients, and (2) where the product was ready for approval in adults before studies in pediatric patients were completed. Although not included in the text of the proposal, these examples have been added to the final rule. Under the proposal, FDA would have the authority to defer the submission of some or all of the required pediatric data until after approval of the product for adult use, on its own initiative or at the request of the applicant. Under the proposed provisions, if the applicant requested deferral, the request would be required to contain an adequate justification for delaying pediatric studies. If FDA concluded that there were adequate justification for deferring the submission of pediatric use studies, the agency could approve the product for use in adults subject to a requirement that the applicant submit the required pediatric studies within a specified time after approval. It is important to appreciate that deferred submission of pediatric data refers to the date on which the data are submitted, not when the studies are initiated. Thus, deferred studies will generally be initiated before approval, unless it is concluded that the full adult data base or marketing experience are needed before pediatric studies may appropriately begin.

FDA stated in the proposal that it would consult with the sponsor in determining a deadline for the deferred submission, but tentatively concluded that it would require the submission not more than 2 years after the date of the initial approval. To ensure that deferral would not unnecessarily delay the submission of pediatric use information, FDA proposed that a request for deferred submission include a description of the planned or ongoing pediatric studies, and evidence that the studies were being, or would be, conducted: (1) With due diligence, and (2) at the earliest possible time. FDA sought comment on the circumstances in which FDA should permit deferral, and on the factors that should be considered in determining whether a given product was one that should be studied in adults before pediatric patients. FDA received many comments on the deferral provisions in the proposal.

16. A few comments stated that the deferral provisions are an appropriate means of assuring that pediatric patients are not studied before adequate safety data have been gathered. A number of comments from the pharmaceutical industry asserted, however, that the proposal would require concurrent testing in adults and pediatric patients despite medical and ethical reasons for delaying testing pediatric testing. For example, a comment from a pharmaceutical trade association claimed that the rule:

* * * would require testing of new medical compounds in children before safety in adults has been studied adequately, before effectiveness in adults has been established, and in young children and neonates without adequate information about the effects of the drug in older pediatric patients.

These industry comments appear to have misunderstood the explicit deferral provisions of the rule and perceived them as rare exceptions to a usual requirement that adults and children be studied at the same time. Nothing in the rule requires concurrent testing in adults and pediatric patients, nor testing in infants and neonates before testing in older children. As stated previously and in the proposal, the deferral provisions were specifically included to, among other things, ensure that pediatric studies could be delayed when necessary to assure that appropriate safety and/or effectiveness data were available to support pediatric testing.

17. Most of the comments on deferral focused on whether the need for safety and/or effectiveness data in adults before initiating pediatric studies should be a basis for deferral. Comments from disease-specific organizations, medical societies, including the AAP, and pediatricians argued that deferrals should be granted rarely if at all on this basis. One comment argued that delaying availability of life-saving drugs to children cannot be rationalized scientifically, legally, or ethically, and contended that deferral should not be permitted for serious and life-threatening diseases where there is no substantial difference between the disease or the anticipated effect of the drug in children or adults. Another comment argued that deferral should be used sparingly in all age groups, including infants and neonates, and that its use should be evaluated in the context of the seriousness of the condition to be treated, the therapeutic advance the drug represents, and the likelihood that the drug will be given to children as soon as it is approved. According to this comment, the risks of research in pediatric patients may be outweighed by the risks that the drug will be given to them without data.

One comment argued that pediatric studies of important drugs should be conducted in parallel to adult studies, especially in children under 12. Several comments from the pediatric community, however, supported the development of some adult safety and/or effectiveness data before initiation of pediatric studies. One comment from an organization devoted to pediatric AIDS stated that while the general assumption should be that pediatric studies will be submitted at the same time as adult studies, it may be appropriate to have some testing in adults before children. The AAP stated that it is appropriate to begin studies in pediatric patients after phase 1 and phase 2 studies in adults have defined routes of clearance and metabolic pathways. Thus, the comment urged that pediatric studies be conducted during phases 2 and 3, not 4. A comment from a nephrology organization argued that drugs for organ-specific diseases should be studied in phase 3, as soon as phase 1 and 2 trials have shown safety in adults. This and another comment stated that deferring studies until after approval compromises clinical trial enrollment, citing the experience with recombinant erythropoietin. According to these comments, erythropoietin was not studied in pediatric patients until after its approval for adults, and enrollment was so difficult that pediatric studies were not completed for 5 years.

Several comments from the pediatric community also cited limited circumstances in which they believed deferral to be appropriate. A medical society argued that data should be collected after adult studies only for drugs with narrow therapeutic indices, unusual accumulation in the body, where the drug study requires extensive blood sampling, or where the study design places young patients at risk for limited information gain.

Many comments from the pharmaceutical industry argued, in contrast, that deferral should be the

rule, rather than the exception. Most of these comments contended that it was unethical to begin studying drugs in pediatric patients, other than those that are intended primarily for pediatric patients, until the drugs are shown to be reasonably safe and effective in adult patients. All argued that pediatric studies must not be initiated until substantial data in adults are available, but cited different initiation points, e.g., after phase 2, after safety and effectiveness is established in adults and an approvable letter is received, after approval, after 1 year of marketing.

Although many of these industry comments argued that pediatric studies should be conducted exclusively as phase 4 (postapproval) commitments, a significant number of industry comments acknowledged that pediatric studies could begin before approval, generally after phase 2, and that there were circumstances in which deferral was not appropriate. One comment argued that because early pediatric studies often require pediatric formulations and because up to 50 percent of drugs are abandoned before phase 3, it is wasteful to require companies to manufacture a pediatric formulation and begin studies before the end of phase 2. Another comment argued that no pediatric studies should begin before the decision to proceed to phase 3, except where: (1) The disease affects only pediatric patients; (2) the disease mainly affects pediatric patients, or the natural history or severity of the disease is different in pediatric patients and adults; or (3) the disease affects both pediatric patients and adults and lacks adequate treatment options. One comment urged that the final rule state that ''in most cases, pediatric testing should not begin with any drug or biological product until certain adult safety and/or effectiveness information has been collected.'' According to this comment, there could be exceptions where no other therapy was available and there was a potential for the drug to be lifesaving. A pharmaceutical trade association argued for a presumption that pediatric studies not begin until the end of phase 2 or 3, but listed circumstances in which deferral should not occur: (1) Where the disease is life threatening and there is no alternative therapy, (2) where the drug is intended for a pediatric indication, (3) where the drug presents no major safety issues, (4) where the drug class is well studied in pediatric patients, or (5) where a large amount of ''off-label'' use in pediatric patients is anticipated.

In general, FDA expects that some data on adults will be available before pediatric studies begin, but that less data will usually be required to initiate studies of drugs and biologics for life-threatening diseases without adequate treatment than for less serious diseases. Pediatric studies of drugs and biologics for life-threatening diseases may in some cases be appropriately begun as early as the initial safety data in adults become available, because the urgency of the need for such products may justify early trials despite the relative lack of safety and effectiveness information. In such cases, deferral of submission of pediatric studies until after approval will be unnecessary, unless drug development is unusually rapid and the product is ready for approval in adults before completion of the pediatric studies.

Pediatric studies on products for less serious diseases should generally not begin until more adult data have been collected, ordinarily no earlier than the availability of data from the initial well-controlled studies in adults. As noted earlier in this document, there may occasionally be exceptions to this principle where all parties agree that earlier initiation is appropriate. Whether deferral of submission of the data until after approval will be necessary for such products will depend upon when pediatric studies can scientifically and ethically begin in each case and how difficult the studies are to complete.

In some cases, FDA expects that scientific and ethical considerations will dictate that studies not begin until after approval of the drug or biological product. For example, pediatric studies of ''me-too'' drugs that do not offer a meaningful therapeutic benefit and that are members of a drug class that already contains an adequate number of approved products with pediatric labeling may be deferred until well after approval. In cases where a drug has not been shown to have any benefit over other adequately labeled drugs in the class, the therapeutic need is likely to be low and the risks of exposing pediatric patients to the new product may not be justified until its safety profile is well established in adults through marketing experience. Because the basis for the deferral in such cases will be concern that the drug presents risks to pediatric patients that will not be known until there is widespread marketing experience, without offsetting benefit, FDA may require, in appropriate cases, that such drugs carry labeling statements recommending preferential use in pediatric patients of products that are already adequately labeled. Such a statement might read:

> The safety and effectiveness of this product have not been established in children. There are alternative therapies that have been shown to be safe and effective for use in children with [indicated condition]. Ordinarily, products already labeled for use in children should be used in preference to [name of this product].

FDA labeling regulations at 21 CFR 201.57 express the agency's authority to ensure that drugs are safe for use under the conditions prescribed, recommended, or suggested in their labeling, and to require labeling identifying safety considerations that limit the use of drugs to certain situations. Some drugs with no demonstrated advantage over available therapy can nonetheless be expected to have wide use in pediatric patients. Pediatric studies of such drugs should be initiated relatively early, even if they are not completed at the time of approval.

18. A comment from a pharmaceutical company listed several circumstances in which it argued FDA should permit deferral: (1) The pediatric population is so small that enrollment and completion of trials cannot be accomplished in parallel with adult trials, (2) the natural course of the disease is different in adults and children, (3) analytic tools and clinical methodologies cannot be easily adapted to the pediatric population, (4) the drug has complex pharmacokinetic properties in adults making it hard to extrapolate a pediatric dosage range, (5) the scope and nature of nonclinical studies support only adult clinical studies, (6) two or more attempts to develop a pediatric formulation have failed, or (7) unique drug-drug or drug-food interactions in children confound drug development. Another comment added to this list: (1) Where fewer than 200,000 pediatric patients are affected by the disease being treated, and (2) drugs with a low therapeutic index.

FDA agrees that some of these circumstances could make completion of studies prior to approval in adults difficult, but does not agree that they would make studies impossible or impractical in all cases. The need for deferral must be considered case-by-case. A small pediatric population, e.g., might make completion of controlled trials very slow, but might not prevent obtaining pharmacokinetic data. Simply citing a pediatric population under 200,000 will not be sufficient to justify deferral; a small fraction of this number participating in trials may be sufficient to support timely pediatric studies, depending on the nature of the studies. As an example, over 70 percent of the estimated 6,000 pediatric patients with cancer each year are enrolled in clinical trials (Ref. 15). There does not seem to

be any reason to conclude that deferral is warranted solely because the natural course of the disease is different in adults and children. FDA also disagrees that deferral is necessarily warranted where analytic tools and clinical methodologies cannot be easily adapted to pediatric patients. Deferral may be necessary in some cases where the infants and toddlers are unable to provide subjective outcome data, but it may also be possible to utilize alternative endpoints or to extrapolate effectiveness data from older pediatric age groups, obtaining pharmacokinetic data from the younger age groups to determine an appropriate dose. Drugs with a low therapeutic index that do not fulfill an urgent need should, in general, be studied in pediatric patients later in drug development.

With respect to complex pharmacokinetic properties that prevent extrapolation of adult data to pediatric patients, low-therapeutic index drugs, and unique drug-drug or drug-food interactions in pediatric patients, FDA believes that the need for pediatric studies before approval is even greater where these conditions are present; moreover, none of them represents a significant impediment to studies. Recognizing that drugs and biologics approved for adults are regularly prescribed to pediatric patients despite the absence of adequate dosing and safety data, information positively suggesting that dosing and safety cannot be extrapolated from adult data increases the importance of conducting pediatric studies before the product is widely used in pediatric patients. The absence of supporting nonclinical studies (e.g., studies in young animals) should not usually be a basis for deferral. These studies, if needed, are readily conducted. Moreover, a full adult data base provides pertinent safety information that might make further preclinical data unnecessary. Difficulties in developing an adequate pediatric formulation may, in some cases, justify deferral of studies in young pediatric patients. In other cases, however, it may be appropriate to study a less-than-optimal formulation, e.g., an injection, if one is available, in pediatric patients while awaiting the development of a more desirable pediatric formulation.

19. One comment argued that it was ''unacceptable'' to defer pediatric studies to avoid delaying approval for adult use. Instead, the comment urged FDA to provide a ''limited approval'' for adult use until pediatric data are available and impose a monetary penalty for failure to comply. Another comment argued that permitting deferral to avoid delay in adult marketing could be applied to most applications, creating a de facto situation in which pediatric data were understood to be not required until 2 years after approval. One comment stated that while pediatric dosing schedules are essential, pediatric studies should not delay approval of drugs for a major population, adults.

FDA continues to believe that deferral is appropriate where awaiting the completion of pediatric studies would delay the availability of a safe and effective drug or biological product for adults. Granting a deferral does not automatically mean, however, that pediatric studies need not be submitted for 2 years or that initiating them should be long delayed. The proposal suggested 2 years as the maximum period for a deferral. Where pediatric studies are supposed to be nearing completion at the time a product is ready for approval in adults, FDA expects that the period of deferral would be significantly shorter than 2 years. Where some useful pediatric information, e.g., safety information, is available at the time of approval, even if some required studies are not complete, FDA may require that the pediatric use section of the product's labeling include that information, to the extent consistent with 21 CFR 201.57(f)(9). FDA also notes that it has no authority to impose a monetary penalty for failure to submit a required study of a drug or biological product. FDA must ask a court to impose such a penalty in a contempt proceeding.

20. Several comments argued that pediatric trials should be conducted sequentially, beginning with the oldest pediatric age group, and ending with the youngest. One comment stated that IRB's would question testing a drug in younger children before older children. The AAP argued that there is little defense for studying pediatric patients sequentially from oldest to youngest, and that such a policy will result in approvals without data in neonates. This comment argued that the timing of studies should give consideration to safety, but without consideration of sequence. Another comment argued that FDA should not routinely require that drugs for serious and life-threatening diseases be studied sequentially. In HIV, according to this comment, drug testing should be ''as simultaneous as possible'' because safety and dosing may be initiated in each age group in a dose escalating manner regardless of the results in previously tested groups.

FDA agrees that age-dependent sequential studies are not necessarily appropriate. Particularly were there is urgent need for a product, there may be good reason to study older and younger children at the same time.

21. A few comments objected to FDA's tentative decision to require the submission of studies ordinarily no later than 2 years after the initial approval. One comment stated that deferral of up to 2 years was excessive, citing the ''critical'' need to ensure timely performance of pediatric studies in populations where the drug is likely to be used. Another comment stated that 2 years may be adequate for collecting pharmacokinetic data, but not necessarily for collecting safety data. According to this comment, the size of the clinical data base will be the principal determinant of when data should be submitted. A comment from the American Red Cross stated that the extensive IRB review of studies of blood products involving pediatric patients, and the difficulty in enrolling such patients, makes the 2-year deferral deadline unrealistic for this category of product.

FDA agrees with the comments that the 2-year deadline suggested by the proposal may not be appropriate, and that the length of the deferral should be decided on a case-by-case basis. The timing of the deferred submission will depend upon such factors as the need for the drug or biologic in pediatric patients, when sufficient safety data become available to initiate pediatric trials, the nature and extent of pediatric data required to support pediatric labeling, and substantiated difficulties encountered in enrolling patients and in developing pediatric formulations. FDA may also extend the date for submission of studies at the time of approval, e.g., where other drugs in the class have been approved during the pendency of the NDA and the new drug is no longer needed as a therapeutic option.

E. Waivers

FDA does not intend to require pediatric assessments unless the product represents a meaningful therapeutic benefit over existing treatments or is expected to be used in a substantial number of pediatric patients. FDA also does not intend to require pediatric assessments in other situations where the study or studies necessary to carry out the assessment are impossible or highly impractical or would pose undue risks to pediatric patients. Thus, FDA proposed to add § 314.50(g)(3) (now § 314.55(c)) and § 601.27(c) to authorize FDA to grant a waiver of the pediatric study requirement on its own initiative or at the request of the applicant unless the product represented a meaningful therapeutic benefit over existing

treatments, or was likely to be used in a substantial number of pediatric patients. These provisions also require FDA to grant a waiver if necessary studies were impossible or highly impractical, because, e.g., the number of pediatric patients was very small or patients were geographically dispersed, or there was evidence strongly suggesting that the product would be ineffective or unsafe in some or all pediatric populations. If a waiver were granted because there was evidence that the product would be ineffective or unsafe in pediatric patients, this information would be included in the product's labeling.

An applicant could request a full waiver of all pediatric studies if one or more of the grounds for waiver applied to the pediatric population as a whole. A partial waiver permitting the applicant to avoid studies in particular pediatric age groups could be requested if one or more of the grounds for waiver applied to one or more pediatric age groups. In addition to the other grounds for waiver, the proposal would authorize FDA to grant a partial waiver for those age groups for which a pediatric formulation was required (see ''Pediatric Formulations'' in section III.I of this document), if reasonable attempts to produce a pediatric formulation had failed.

The proposal would require the applicant to include in the request for a waiver an adequate justification for not providing pediatric use information for one or more pediatric populations.

FDA would grant the waiver request if the agency found that there was a reasonable basis on which to conclude that any of the grounds for a waiver had been met. If a waiver were granted on the ground that it was not possible to develop a pediatric formulation, the waiver would cover only those pediatric age groups requiring a pediatric formulation.

The agency also proposed two possible methods of determining a ''substantial number of patients.'' The first method would focus on the number of times the drug or biologic was expected to be used in pediatric patients, annually. Under this method, FDA tentatively concluded that 100,000 or more prescriptions or uses per year in all pediatric age groups would be considered a substantial number.

The second proposed method for establishing whether there was a substantial number of pediatric patients would focus on the number of pediatric patients affected by the disease or condition for which the product is intended. Under this method, FDA tentatively concluded that 100,000 pediatric patients affected by the disease or condition for which a product was indicated would be considered a ''substantial number'' of pediatric patients. FDA sought comment on the waiver criteria and on these methods of calculating a substantial number of pediatric patients. FDA also sought comment on whether cost to the manufacturer should justify a waiver.

FDA received many comments on the waiver provisions of the proposal, and has made certain changes in response to the comments, as described below.

22. As proposed, new drugs and biologics are presumptively required to be studied in pediatric patients, unless a waiver is granted. The presumption in the proposal was supported by comments from pediatricians, a pharmacy organization, disease specific organizations, and medical societies, including the AAP. Several industry comments argued, however, that new drugs and biologics should presumptively not be covered by the rule, unless they were specifically identified by FDA as needing to be studied. One of these comments stated that companies should not have to waste the effort of applying for waiver for drugs of no potential benefit to pediatric patients, which the comment estimated as a majority of those developed.

FDA continues to believe that it is appropriate to presume that drugs and biologics should be studied in pediatric patients, and that this presumption should be overcome only if there are clear grounds for concluding that such studies are unnecessary. Pediatric patients are a significant subpopulation, affected by many of the same diseases as adults, and are foreseeable users of new drugs and biologics. The agency has stated, in the context of pediatric studies and other subpopulations, that an application for marketing approval should contain data on a reasonable sample of the patients likely to be given a drug or biological product once it is marketed (59 FR 64240 at 64243; 58 FR 39406 at 39409, July 22, 1993). FDA does not believe that the cost of drafting a waiver request will be great, particularly where the basis for the waiver is that the product has no potential use in pediatric patients. To assist sponsors in preparing such waivers, FDA has included in this document a partial list of diseases that are unlikely to occur in pediatric patients and for which waiver requests need include only reference to this document.

23. FDA received many comments on the proposed criteria for waiving pediatric studies. A few comments supported the proposed criteria. Many comments from pediatricians, medical societies, and disease-specific organizations argued that the proposed grounds for waiver were too broad. Several of these stated that the rule should apply to drugs for all conditions that affect pediatric patients unless there is a special reason not to do so. One comment argued that waivers should be available only for drugs known to be extremely toxic in pediatric patients or to have no anticipated use in pediatric patients.

Other comments from the pharmaceutical industry argued that the waiver provisions were too narrow. One comment from a generic trade association urged that pediatric studies be required only when there is a significant public health concern with respect to the safety of a drug product in pediatric patients or to the availability of adequate pharmacological intervention for pediatric patients for the indication. Another comment stated that the criteria in the proposal ''do not begin to address the complexities associated with moving forward on a clinical development plan'' and argued that additional criteria should include: (1) The lack of correlative safety evidence, (2) liability concerns, and (3) prohibitive cost (but the sponsor, not FDA, should be allowed to determine the importance of cost).

FDA believes that the criteria for waiver in the final rule strike a careful balance. On the one hand, requiring studies for all new products would have potentially severe resource implications for manufacturers and the agency. On the other hand, obtaining studies only where the studies impose no burden on the sponsor would continue to expose millions of pediatric patients to unnecessary risks and ineffective treatment. Requiring pediatric studies only of those drugs or biologics that offer a meaningful therapeutic benefit or that are expected to be used in a substantial number of pediatric patients focuses limited resources on those products that are most critically needed for the care of pediatric patients.

24. Several comments addressed the definition of ''meaningful therapeutic benefit.'' Some comments from the pharmaceutical industry stated that ''meaningful therapeutic benefit'' should be defined as it is used in 21 CFR 314.500. (That regulation applies to drugs ''that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).'') One of these comments

suggested that analogous cases in the pediatric context would be: (1) Where the drug treats a pediatric disease for which no other treatments exist; (2) where the drug treats patients who are unresponsive to or intolerant of other drugs; or (3) where the drug produces a superior response over other treatments. One industry comment argued that the agency should consult with the sponsor, and the pediatric investigators involved to assess whether the drug will provide a ''meaningful therapeutic benefit.'' According to the comment, the assessment should include the likely use of the product in a specific pediatric population, the likely benefit without increased risk to patients versus existing treatments, a ''definitive need'' for a new therapy in very serious or life-threatening illnesses, and the cost and feasibility of developing the necessary formulations and of conducting studies. Another comment from a disease-specific organization argued that ''meaningful therapeutic benefit'' should be a relative term, depending on the severity of the illness, the potential risk posed by the drug, and the availability of alternative treatments. One comment from a medical society devoted to the treatment of psychiatric disorders contended that ''meaningful therapeutic benefit'' should mean that the product enables a child to function better, and participate in age-appropriate activities, such as playing and going to school, without undue pain and suffering from the disease or disorder. Another comment argued that ''meaningful therapeutic benefit'' should mean better response or ability to treat nonresponsive patients. Another comment maintained that the presumption should be that a product represents a meaningful therapeutic benefit in pediatric patients if it is expected to provide a meaningful therapeutic benefit in adults.

Several comments from the pharmaceutical industry contended that it is not possible to define meaningful therapeutic benefit before approval or that FDA should not be responsible for defining it. A pharmaceutical trade association argued that meaningful therapeutic benefit is the decision of the sponsor, not FDA, and that it is not possible to determine meaningful therapeutic benefit until a drug has been used for some period of time. Another comment maintained that FDA must first have adult data to reach the conclusion that a drug offers a meaningful therapeutic benefit. The same comment also argued that a rigorous determination of meaningful therapeutic benefit would require randomized, controlled trials in pediatric patients.

FDA disagrees that it is impossible or beyond FDA's expertise to reach a conclusion before approval about whether a product has the potential to offer a meaningful therapeutic benefit. FDA routinely estimates the therapeutic benefit of new drugs and biologics at the time applications are first submitted, in order to determine whether to assign ''Priority'' (expedited) status to the review of the application. In assigning Priority status to new drug applications, CDER determines whether the product, if approved, ''would be a significant improvement compared to'' marketed (or approved, if such is required) products, including nondrug products or therapies. ''Improvement can be demonstrated by, for example: (1) Evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness in a new subpopulation'' (Ref. 16). These criteria are similar to many of the criteria suggested in the comments. FDA notes that demonstration of an advantage over existing products may come from evidence other than head-to-head comparisons of the new product and existing products. For example, in some cases a new product could be shown to lack an adverse effect associated with an existing product, or to have an effect on a different outcome or on a different stage of disease than an existing product, without a direct comparison of the two products.

FDA has concluded that in determining whether a product offers a meaningful therapeutic benefit, it will use the Priority definition, with some modifications. First, in determining whether a product is expected to be an improvement over other products, the comparison will be made only to other products that are already adequately labeled for use in the relevant pediatric population. Second, it is often therapeutically necessary to have two or more therapeutic options available, because some patients will be unresponsive to a given therapy. Because the Priority definition would not cover more than the first or second product for a given indication or in a given class (unless the product offered an advantage over others for the indication or in the class), a drug or biologic will also be considered to provide a meaningful therapeutic benefit if it is in a class of drugs and for an indication for which there is a need for additional therapeutic options. The specific number of products needed will depend upon such factors as the severity of the disease being treated, and the adverse reaction profile of existing therapies. FDA has added this definition of meaningful therapeutic benefit to §§ 314.55(c)(5) and 601.27(c)(5). This rule's definition of meaningful therapeutic benefit is intended to apply only in the pediatric study context and is not intended to alter the definition of a Priority drug.

25. Several comments addressed the definition of ''a substantial number of pediatric patients.'' A few comments argued that it would be difficult to estimate product use until after marketing. Several comments argued that FDA should not base waivers on the number of patients or prescriptions. Many other comments claimed that the proposed numerical cut-offs are arbitrary. These comments maintained that waivers should be decided on a case-by-case basis. Several comments urged that FDA consult with an expert panel in deciding whether pediatric use was substantial.

Comments from the pediatric community contended that the numerical cut-offs in the proposal were too high, and would preclude studies of many serious diseases affecting fewer than 100,000 pediatric patients. One comment, for example, voiced concern that pediatric patients with less common seizure types may not benefit from the regulations because the use is not sufficiently widespread. Another comment argued that numerical cut-offs should not apply to drugs for serious and life-threatening diseases, unless the number of pediatric patients was so low as to make clinical study impossible. Another comment suggested that studies be required not only for uses greater than 100,000 prescriptions, but for ''drugs used chronically for a defined, though smaller group of pediatric patients, usually for organ-specific diseases, such as kidney failure or hypertension.''

Comments from the pharmaceutical industry argued that the numerical cut-offs proposed by FDA were too low. Some of these comments argued that 100,000 prescriptions per year translates to fewer than 100,000 patients, and that the resulting population could be so small that it would be difficult to study. Several of these comments urged that cut-off for substantial use be 200,000 patients with the disease, the threshold established by the Orphan Drug Act for identifying rare diseases.

FDA has decided to revise its proposed method of defining a substantial number of patients, in light of the comments. Physician mention

data from the IMS National Disease and Therapeutic Index (Ref. 38), which tracks the use of drugs by measuring the number of times physicians mention drugs during outpatient visits, shows that pediatric use of drugs is generally grouped in two distinct ranges. Physician mentions of drugs for pediatric use generally fall either below 15,000 per year or above 100,000 per year. Few drugs fall within the two ranges. Thus, selecting a cut-off for ''substantial number of pediatric patients'' in the middle of the two ranges will provide a reasonable discrimination between products that are widely used and those that are less commonly used, and the specific number chosen will not arbitrarily include or exclude a significant number of drugs. FDA has therefore chosen 50,000 as the cut-off for a substantial number of pediatric patients. Because the number of pediatric patients with the disease is easier to determine than the number of prescriptions per year, a substantial number of pediatric patients will be defined as 50,000 pediatric patients with the disease for which the drug or biological product is indicated. Although physician mentions per year does not correspond exactly to the number of patients with the disease, they provide a rough approximation and the IMS data show that the number of products included or excluded is relatively insensitive to changes in the cut-off chosen. As proposed, a partial waiver for a particular pediatric age group would be available under this method if 15,000 patients in that age group were affected by the disease or condition. This definition of ''a substantial number of pediatric patients'' has not been codified, however, and FDA may modify it, after consulting with the pediatric panel discussed in section III.M of this document (''Pediatric Committee''). Any modification will be issued as a guidance document.

In response to those comments that voiced concern that this definition would exclude a number of serious diseases, FDA emphasizes that the definition of ''meaningful therapeutic benefit'' assures that drugs and biologics will be covered by the rule if they are medically needed as therapeutic options because there are insufficient products adequately labeled for pediatric patients for that indication or in that drug class. Until there are enough adequately labeled products available, many new drugs and biologics for serious and life-threatening diseases will be considered to offer a meaningful therapeutic benefit and thus will be required to be studied, even if the products are not also used in a substantial number of pediatric patients. This will be particularly true during the first few years after implementation of this rule when few drugs and biologics will yet be adequately labeled for use in pediatric patients, and a larger proportion of new entrants into the marketplace will be considered to be medically necessary therapeutic options.

In response to the comments arguing that FDA's proposed numerical cut-off is too low and will result in too many pediatric studies, FDA expects to defer until after approval many of the studies of products that will be used in a substantial number of pediatric patients but that do not offer a meaningful therapeutic benefit. As described previously in response to comments on the deferral provisions, studies of new drugs and biologics that do not offer a meaningful therapeutic benefit and are members of a class that is already adequately labeled for pediatric patients are likely to be deferred until well after approval of the product for adults.

26. A few comments addressed the provisions that would permit waiver if pediatric trials were impossible or impractical. One comment argued that the provision authorizing waiver if the proposed population was ''too small or geographically dispersed'' was too broad. This comment urged that tests should be waived only if ''significant efforts to recruit patients fail.'' The comment also argued that the unsupported suggestion that tests are ''impractical'' should not be accepted, and that evidence of due diligence should be required. Another comment argued that waivers should never be granted because the population is too small or dispersed. According to this comment, many safety and pharmacokinetic studies are already performed in dispersed populations, and the comment maintained that no experimental drug should be administered to a child with a serious or life-threatening disease without requiring that some safety data and pharmacokinetics data be obtained. Another comment observed that although only 600 renal transplants are performed each year in pediatric patients, pediatric academic centers have been creative in forming collaborative efforts to study these small groups. One comment from an organization devoted to children with HIV stated that the ''impossible or highly impractical'' standard must be narrowly interpreted, and that a manufacturer should show that all reasonable efforts to recruit patients have failed. According to this comment HIV/AIDS drugs should be a benchmark of when a waiver should not be granted: Any group as big or bigger than the pediatric AIDS population should be considered big enough to study.

Another comment argued that because of special difficulties encountered in recruiting pediatric patients into studies of blood products, such as parental fear of disease transmission, the inability to obtain a sufficient number of test subjects should be added to the criteria for waiver or to the definition of ''highly impractical.''

FDA agrees with those comments urging that this ground for waiver be interpreted narrowly and that unsupported assertions be rejected as a basis for waiver. Although the number of patients necessary to permit a study must be decided on a case-by-case basis, FDA agrees that there are methods available to conduct adequate studies in very small populations. Moreover, where only safety or pharmacokinetic studies are required to support pediatric labeling, the size of the population or geographic dispersion would only rarely be a sufficient basis to consider trials impossible or highly impractical. Because of the speed and efficiency of modern communications tools, geographic dispersion will justify a waiver only in extraordinary circumstances and will generally have to be coupled with very small population size. FDA is not persuaded that inability to recruit patients because of parental fears associated with administration of the drug is an adequate basis to conclude that studies are impractical where there is also evidence that similar products are regularly prescribed to pediatric patients outside of clinical trials.

27. Several comments responded to the request for comment on whether cost should justify a waiver. Comments from the pediatric community argued that cost to the manufacturer should never or rarely justify a waiver. Two of these comments stated that the cost of failure to study is always higher than the cost of research. Another comment stated that cost may be a factor, but FDA must be careful not to allow studies to be waived automatically because they ''cost too much.'' Two comments from a pharmaceutical company and a pharmaceutical trade association argued that FDA should not have responsibility for assessing the costs of a study.

In light of the comments, FDA has concluded that it does not have an appropriate basis to evaluate and weigh cost in granting or declining to grant a waiver. Therefore, cost will not ordinarily be a factor in determining whether a waiver should be granted.

28. One comment claimed that the proposal lacks adequate regulatory procedures for timely processing of waiver requests and will result in a new layer of bureaucracy.

As described previously in response to comments on the deferral provisions, preliminary decisions on whether to grant waivers will be provided to the sponsor at the end of phase 1 for drugs and biologics for life-threatening diseases and at the end of phase 2 for other products. FDA does not agree that processing of waiver requests will result in a new layer of bureaucracy. The decisions will be made by the division responsible for reviewing the NDA or BLA. FDA intends to ensure that the process is timely and fair. To reduce the burden on manufacturers in applying for waivers and deferrals, FDA intends to issue a guidance document providing a format for a request for waiver or deferral.

29. One comment asked that the rule clarify that the onus is on the manufacturer to justify waivers. Another comment argued that the proposed standard for granting a waiver (''reasonable basis'') places an inadequate burden of proof on manufacturers. According to this comment, manufacturers should be required to present ''persuasive proof,'' and FDA should have to find that the grounds for waiver have ''in fact'' been met.

FDA agrees that the burden is on the manufacturer to justify waivers, but believes that the rule already adequately imposes that burden. The rule requires both a certification from the manufacturer that the grounds for waiver have been met and an adequate justification for the waiver request. FDA believes that it would be inappropriate to require ''proof'' that the grounds for waiver have ''in fact'' been met because each ground requires a degree of speculation about the safety and effectiveness of, or the ability to test, a product, in a population in which it has not yet been tested.

30. Many comments from pediatricians, disease-specific organizations, a pharmacists' organization, a medical society, several companies, a pharmaceutical trade association, and the AAP urged that the decision to require pediatric studies be reviewed by a panel of outside pediatric experts. Some of the comments recommended that the panel include industry representatives. The comments were divided on whether the panel would review only waiver requests or would be responsible for identifying, in the first instance, those drugs that need study. Some of these comments believed that the rule should include no criteria for granting waivers and that the decision should be made on a case-by-case basis in consultation with the expert panel.

As described later in this document, FDA intends to convene a panel of pediatric experts, which will include one or more industry representatives, to assist the agency in implementing this rule. FDA will bring before that panel some issues related to waivers. FDA does not believe, however, that it is reasonable to bring every product undergoing clinical studies before the panel for a decision on whether pediatric studies are required. Because many dozens of drugs and biologics reach the end of phase 1 and phase 2 each year, and the panel could not realistically meet more than once every few months, insisting that each product be brought before the panel would introduce substantial delay into the development and review of drugs and biologics. Moreover, many waiver decisions will be straightforward and noncontroversial.

FDA does, however, agree that it would be beneficial to have the advice of pediatric experts on its administration of the waiver provisions of the rule. FDA will therefore ask the panel, at least on an annual basis for the first several years, to review the agency's waiver decisions and provide advice on whether it believes that the criteria used in making those decisions were appropriate. FDA will use the advice it receives to modify future waiver decisions. FDA also expects to consult with individual members of the panel on difficult waiver decisions in their fields of expertise.

31. One comment suggested that FDA identify diseases that are not likely to occur in pediatric patients, such as prostate cancer, and classes of drugs not likely to be used in pediatric patients, and grant blanket waivers. Another comment listed the following product classes as having no applicability to pediatric patients: Alcohol abuse agents, Alzheimer's agents, Amyotrophic lateral sclerosis agents, antifibrosis therapy, antiparkinsonian agents, fertility agents, gout preparations, multiple sclerosis drugs, oral hypoglycemics, osteoporosis agents, oxytocics, tremor preparations, uterine relaxants, and vasodilators (including cerebral vasodilators).

FDA agrees that there are some disease and drug classes that have extremely limited applicability to pediatric patients and that waiver is appropriate for these. The decision to grant a waiver in such cases would be based on a conclusion that a disease does not have sufficient significance in the pediatric population (either because of frequency or severity) to constitute a meaningful therapeutic benefit for pediatric patients or to be used in a substantial number of pediatric patients. FDA emphasizes that this decision would not be intended to prevent or impede studies of these diseases or drug classes in the pediatric population, should a sponsor wish to conduct them.

The agency has identified the diseases following for which waivers will be likely to be granted. Some of the diseases listed in the comment are included in FDA's list. Others, such as osteoporosis, gout, multiple sclerosis, and tremors can develop in children, and are not included in FDA's list. Waiver decisions on products for the listed diseases are expected to be straightforward and noncontroversial. FDA may add to or revise this list in the future by issuing guidance documents. An applicant who wishes to obtain a waiver because the product is indicated for a disease on the list may refer in the waiver request to this **Federal Register** notice, or to any guidance document modifying this notice. FDA's list follows:

1. Alzheimer's disease.
2. Age-related macular degeneration.
3. Prostate cancer.
4. Breast cancer.
5. Non-germ cell ovarian cancer.
6. Renal cell cancer.
7. Hairy cell Leukemia.
8. Uterine cancer.
9. Lung cancer.
10. Squamous cell cancers of the oropharynx.
11. Pancreatic cancer.
12. Colorectal cancer.
13. Basal cell and squamous cell cancer.
14. Endometrial cancer.
15. Osteoarthritis.
16. Parkinson's disease.
17. Amyotrophic lateral sclerosis.
18. Arteriosclerosis.
19. Infertility.
20. Symptoms of the menopause.

F. Pediatric Use Section of Application

FDA proposed to add § 314.50(d)(7), under which applicants would be required to include in their applications a section summarizing and analyzing the data supporting pediatric use information for the indications being sought. FDA received no comments on this provision. The new pediatric use section will be required to contain only brief summaries of the studies together with a reference to the full description of each provided elsewhere in the application.

G. Planning and Tracking Pediatric Studies

1. Sections 312.23(a)(3)(v), 312.47 (b)(1)(i), (b)(1)(iv) and (b)(2), and 312.82—Early Discussion of Plans for Pediatric Studies

In the proposal, FDA identified several critical points in the drug development process, before submission of an NDA or BLA, during which the sponsor and FDA should focus on the sponsor's plans to assess pediatric safety and effectiveness. These time points include: Any pre-IND meeting or ''end-of-phase 1'' meeting for a drug designated under subpart E of part 312 (21 CFR part 312), the IND submission, the IND annual report, any ''end-of-phase 2'' meeting, the presentation of the IND to an FDA drug advisory committee, and any pre-NDA or pre-BLA meeting. Of these, the pre-IND meeting, the ''end-of-phase 1'' meeting, the IND submission, the IND annual report, the ''end-of-phase 2'' meeting, and the pre-NDA/pre-BLA meeting are codified in part 312, FDA's regulations governing IND's.

In a separate rulemaking, FDA has already amended the IND annual report requirement to include discussion of pediatric patients entered in trials (63 FR 6854, February 11, 1998). In the proposal, FDA proposed to amend §§ 312.23(a)(3)(v), 312.47 (b)(1)(i) and (b)(2), and 312.82 (a) and (b) to specify that these meetings and reports should include discussion of the assessment of pediatric safety and effectiveness. To assist manufacturers in planning for studies that may be required under this proposal, FDA also proposed to inform manufacturers, at the ''end-of-phase 2'' meeting, of the agency's best judgment, at that time, of whether pediatric studies would be required for the product and when any such studies should be submitted. The proposal also stated that, in addition to the discussions of pediatric testing codified in the proposal, FDA would assist manufacturers by providing early consultations on chemistry and formulation issues raised by requirements under this rule.

Because, as described previously, studies of drugs and biologics for life-threatening diseases may begin as early as the end of phase 1, FDA will, at the end-of-phase 1 meeting, provide the sponsor of such a product the agency's best judgment, at that time, whether pediatric studies will be waived or deferred. Section 312.82(b) has been revised to include this requirement. Because studies of other products may begin as early as the end of phase 2, FDA will, at the end-of-phase 2 meeting, provide the agency's best judgment, at that time, whether waiver or deferral is appropriate. Although a formal request for deferral or waiver is not required until submission of the NDA or BLA, FDA has revised § 312.47(b)(1)(iv) to state that a manufacturer who plans to seek a waiver or deferral should provide information related to the waiver or deferral in the advance submission required before the end-of-phase 1 or end-of-phase 2 meeting, as appropriate.

As described earlier, a pediatric study required under this rule may be eligible for exclusivity under FDAMA, if such study ''meets the completeness, timeliness, and other requirements of [section 505A].'' (See 21 U.S.C. 355A(i).) Among other requirements, a pediatric study must, to be eligible for exclusivity, be responsive to a written request for the study from FDA. To obtain a written request, a manufacturer may submit a proposed written request to FDA that contains the information described in a guidance document issued by FDA entitled, ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act.'' A manufacturer who has been told in the end-of-phase 1 or end-of-phase 2 meeting that it is FDA's best judgment at that time that it does not intend to waive the study requirement may submit a proposed written request at any time thereafter. FDA will issue a written request for a study required under this rule promptly after an adequate proposed written request is submitted.

FDA also sought comment on the types of evidence that FDA should examine to ensure that deferred pediatric studies are carried out in a timely fashion. In response to comments, FDA has revised §§ 312.47 (b)(1)(iv) and (b)(2) to require submission of information about planned and ongoing pediatric studies.

32. One comment supported the proposed provisions and the need for early consultation with sponsors, stating that discussions should take place as early as possible in drug development. The comment urged that proposed § 312.47(b)(1) be revised to acknowledge the possibility that studies could already be underway.

FDA agrees with this comment and has revised § 312.47(b)(1) as suggested in the comment.

33. Several comments provided suggestions on how to assure that deferred studies are carried out expeditiously. One comment urged that the criteria to ensure deferred studies are carried out in a timely fashion be modeled on the AIDS Clinical Trials Group (ACTG) system of National Institute of Allergy and Infectious Diseases (NIAID). Another comment recommended that evidence demonstrating that the required studies were underway be submitted to FDA within 6 months of approval. This comment suggested that the evidence should include: (1) A finalized protocol, (2) evidence of sufficient entry of patients to address the objective of the protocol, and (3) a time line for data analysis and submission to FDA. Another comment argued that the burden should be on manufacturers to provide evidence that studies are being conducted with due diligence through submission of protocols, progress reports and certifications by researchers. To hold manufacturers accountable, this comment suggested that nonproprietary information related to deferrals be made available to the public, including deferral requests, FDA action, postmarketing status reports, and the time line for deferred studies. One comment argued that FDA's current procedures are adequate to track the timeliness of pediatric studies. A pharmaceutical trade association argued that FDA should institute an adequate tracking system and meet periodically with the sponsor to discuss the progress of the studies, but that no new rules are needed.

FDA agrees that an adequate system for ensuring that studies, both deferred and nondeferred, are carried out in a timely manner requires the submission of plans and progress reports from the sponsor at defined intervals. As described previously, FDA will provide sponsors with a preliminary decision on whether pediatric studies will be required and their timing at the end-of-phase 1 meeting, for drugs and biologics for life-threatening diseases, and at the end-of-phase 2 meeting, for other products. FDA has revised § 312.47(b)(1)(iv) to state that sponsors should submit, in the advance submission for the end-of-Phase 2 meeting, a proposed time line for protocol finalization, enrollment, completion, data analysis, and submission of pediatric studies, or, in the alternative, information to support a planned request for waiver or deferral. For drugs and biologics for life-threatening diseases, the submission should be made in advance of the end-of-Phase 1 meeting. FDA has also revised § 312.47(b)(2)(iii) to state that sponsors should submit, in the submission in advance of the pre-NDA or pre-BLA meeting, information on the status of needed and ongoing pediatric studies. The proposed language of § 312.47 has been slightly modified to

seek information on ''needed'' and ongoing studies rather than ''planned'' and ongoing studies. This change has been made because not every sponsor elects to have an end-of-phase 1 or end-of-phase 2 meeting. In those cases, the need for a pediatric study may be discussed for the first time at the pre-NDA or pre-BLA meeting. FDA has also revised the title of § 312.47(b)(2) from ''`Pre-NDA' meetings'' to ''`Pre-NDA' and `pre-BLA' meetings.'' This is merely a clarification, because part 312 is expressly applicable to products subject to the licensing provisions of the Public Health Service Act, as well to products subject to section 505 of the act and 21 CFR 312.2(a).

2. Sections 314.81(b)(2) and 601.37—Postmarketing Reports

To permit FDA to monitor the conduct of postapproval studies to ensure that they are carried out with due diligence, FDA proposed to amend § 314.81(b)(2) of the postmarketing report requirements to require applicants to include in their annual reports: (1) A summary briefly stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated; (2) where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population; (3) an analysis of available safety and efficacy data in the pediatric population and changes proposed in the label based on this information; (4) an assessment of data needed to ensure appropriate labeling for the pediatric population; and (5) whether the sponsor has been required to conduct postmarket pediatric studies and, if so, a report on the status of those studies. (Additional postmarketing reporting requirements are described under ''Remedies'' in section III.L of this document.) Although the proposal was intended to cover both drugs and biological products, the proposal inadvertently omitted a postmarketing reports requirement specifically applicable to biological products. In the final rule, FDA has corrected this oversight and included an identical postmarketing reports requirement in § 601.37.

FDA notes that FDAMA includes a provision requiring reports of postmarketing studies in a form prescribed by the Secretary of Health and Human Services (the Secretary) in regulations. (Section 506 of the act (21 U.S.C. 356B).) At such time as regulations implementing this provision are issued, FDA may modify or withdraw §§ 314.81(b)(2) and 601.37 for consistency with the implementing regulations.

34. Three comments from the pharmaceutical industry agreed that it was appropriate to require postmarketing reports on the progress of postapproval pediatric studies. One comment argued, however, that collection of this information along with an adequate system to track pediatric studies could preclude the need to finalize the rule. Another comment argued that the required analyses of pediatric data ''may lead to exposure of a larger number of children to an unapproved product.'' This comment also contended that estimates of patient exposure are difficult to obtain and unreliable.

FDA disagrees that postmarket reports and a tracking system are an adequate means of assuring that drugs and biologics are appropriately labeled for pediatric use. As shown above, even postmarket commitments to conduct pediatric studies have infrequently resulted in pediatric labeling submissions. FDA also disagrees that the analyses required under § 314.81(b)(2) require exposure of any new patients. The analyses referred to in the provision are of already collected data. Finally, the rule requires estimates of patient exposure ''where possible.'' If there are no data on which to make such estimates, the estimates are not required. FDA notes, however, that there are commercial data bases designed to estimate use of marketed drugs.

35. One comment argued that FDA should require postmarket surveillance of approved drugs that do not have pediatric labeling, to generate helpful comparative information and provide additional information useful for analysis of adverse event profiles.

The provisions of the final rule require manufacturers of approved drugs without pediatric labeling to conduct postmarket surveillance on their products and provide an analysis of available safety and efficacy data in the pediatric population.

H. Studies in Different Pediatric Age Groups

Because the pharmacokinetics and pharmacodynamics of a drug or biological product may be different in different pediatric age groups or stages of development, FDA proposed to require an assessment of safety and effectiveness in each pediatric age group for which a waiver was not granted. The following age categories for the pediatric population were distinguished in the proposal: (1) Neonates (birth to 1 month); (2) infants (1 month to 2 years); (3) children (2 years to 12 years), and (4) adolescents (12 years to 16 years). The proposal stated that the need for studies in more than one age group would depend on whether the drug or biological product was likely to be used or offered meaningful therapeutic benefit in each age group (see ''Waivers'' section III.E of this document), the metabolism and elimination of the drug, and whether safety and effectiveness in one age group could be extrapolated to other age groups. The proposal further stated that it would not ordinarily be necessary to establish effectiveness in each age group, but there would generally need to be pharmacokinetic data in each group to allow dosing adjustments. The proposal recognized that studies in neonates and young infants present special problems, and sought comment on whether it is appropriate to require the assessment of safety and effectiveness in this age group.

36. Several comments addressed the requirement that all relevant age groups be studied. Some comments opposed studies in more than one age group. One comment contended that requiring safety data in each pediatric group may place an unnecessary burden on the sponsor, and that FDA should require safety data only in one group, presumably that with the highest potential use. Another comment claimed that requiring studies in all four age groups would almost never be justified. In most cases, according to this comment, it should be possible to study a single subgroup and extrapolate. Other comments argued that studies in more than one age group could be necessary depending on the pharmacokinetics of the drug, the disease, and expected use of the drug. Most of these comments stated that the type and extent of studies in different age groups must be decided on a case-by-case basis. Several comments contended that drugs should be studied in each age group in which they are expected to be used. One comment stated that studies in toddlers are especially needed. A comment from an organization devoted to pediatric AIDS argued that all age groups should be studied unless the manufacturer provides compelling evidence that it would be impossible or virtually impossible to study that group.

FDA continues to believe that studies in more than one age group may be necessary, depending on expected therapeutic benefit and use in each age group, and on whether data from one age group can be extrapolated to other age groups.

37. Many comments argued that the pediatric subgroups identified in the proposal were arbitrary and that FDA should be flexible in determining which age ranges or stages of development need to be studied. A comment from a pharmaceutical trade association contended that rigid age divisions for required studies were inappropriate, and that the method by which the compound is cleared from the body must be considered in light of what is known about physical development. The AAP stated that the groups identified in the proposal provide acceptable guidelines, but should not be adhered to rigidly. One comment argued that the definition of pediatric patients should include all subgroups of growth and development from 0 to 21 years.

FDA agrees that the age ranges identified in the proposal may be inappropriate in some instances and that it will be reasonable in some cases to define subgroups for study using other methods, such as stage of development. FDA has deleted the references in the rule to specific age ranges.

38. Several comments addressed inclusion of neonates in studies. One comment maintained that because neonates are a special challenge, they should not ordinarily be included in studies under this rule. Another comment described the difficulties in conducting studies in infants and neonates and recommended that before studies in this group there be an assessment of ''the expected extent of use and potential benefit in this patient population'' and an evaluation of safety data in adults and older pediatric patients. One comment contended that there are not many instances in which the benefit will outweigh the risk of exposing neonates and young infants to drugs. This and another comment also argued that it is not always possible to extrapolate from data in older pediatric patients. A pharmaceutical trade association maintained that validated end-points and ability to assess these by age should determine which age groups to include, and that it may not be possible to study certain end-points in very young pediatric patients. One comment argued that early research on neonates raises special ethical issues. Citing the 1977 FDA guideline, this comment asserted that testing in neonates should occur only when substantial evidence of benefit or superiority over accepted agents has been demonstrated in older pediatric patients and adults.

Other comments argued that neonates should not be excluded from studies. According to one comment, study designs will be appropriate and necessary ethical issues will be addressed if neonatologists are included in the review of studies. Another comment stated that neonates represent the greatest disparity in drug disposition compared to adults, and that, on a scientific and ethical basis, they must therefore be included in drug studies. The AAP stated that premature infants, newborns, and infants are more difficult to study, but that the difficulties do not outweigh the importance of studying them. According to this comment, inadequate study of neonates has led to frequent and severe toxicity. This comment agreed that it is inappropriate to extrapolate from older pediatric patients to the youngest age group.

FDA agrees that the benefits and risks to premature infants, neonates, and infants must be carefully weighed before these pediatric patients are included in pediatric studies. Although the agency believes that studies in these groups may be frequently waived or deferred until adequate safety data have been collected, there will be cases in which the drug or biologic is important and expected to be used in these groups. In such cases, it will be appropriate to require studies in these groups. To exclude them from study would be to subject the most vulnerable patients to the risks of the drugs in clinical use without adequate information about safety or dosing. FDA agrees that studies in neonates and young infants raise special ethical issues, but once these issues are addressed in each case, the studies should proceed.

I. Pediatric Formulations

As described in the proposal, testing of a product in pediatric patients could require the development of a pediatric formulation. Many young children are unable to swallow pills and may require a liquid, chewable or injectable form of the product. A standardized pediatric formulation also ensures bioavailability and consistency of dosing, compared to alternatives such as mixing ground-up tablets with food, and permits meaningful testing of safety and effectiveness. FDA proposed in §§ 201.23, 314.50(g)(1) (now 314.55(a)) and 601.27(a) to require a manufacturer to produce a pediatric formulation, if one were necessary, only in those cases where a new drug or new biological product provided a meaningful therapeutic benefit over existing treatments, and where the study requirement had not been waived in the age group requiring the pediatric formulation. The proposal recognized that the difficulty and cost of producing a pediatric formulation may vary greatly depending upon such factors as solubility of the compound and taste. FDA proposed to waive the requirement for pediatric studies (see ''Waivers'' in section III.E of this document) in age groups requiring a pediatric formulation, if the manufacturer provided evidence that reasonable attempts to produce a pediatric formulation had failed.

FDA sought comment on whether it is appropriate to require a manufacturer to develop a pediatric formulation, on whether the cost of developing a pediatric formulation should ever justify a waiver of the pediatric study requirement, and on how to define ''reasonable attempts'' to develop a pediatric formulation.

39. Many comments from the pediatric community argued that it is appropriate to require manufacturers to produce pediatric formulations. Several comments from pediatricians and parents described the difficulties and uncertainties in attempting to administer adult formulations to pediatric patients, and argued that pediatric formulations are essential to assure bioavailability, accurate dosing, and patient compliance, and to avoid wasting medications. The AAP argued that FDA should require development of an appropriate formulation for each age group for which the drug will be used, taking into account ease of administration and ability to dose accurately.

Comments from the pharmaceutical industry described technical problems in producing pediatric formulations, including stability, taste and palatability, and claimed that FDA underestimated these difficulties. Some of these comments maintained that requiring development of pediatric formulations during the investigational phase will necessitate diversion of resources, increase the cost of the adult formulation, and create a disincentive to produce drugs with pediatric uses. One comment argued that it would be wasteful to require development of a pediatric formulation before some evidence of effectiveness has been collected and dose selection has been achieved, because before that time the drug could be abandoned because of lack of safety or effectiveness. A pharmaceutical trade association opposed a pediatric formulation requirement, arguing that the government has no right to tell manufacturers what products to market. This comment stated that only if FDA successfully demonstrated that ''all attempts to develop a voluntary solution have failed'' might the industry consider other options. One comment stated that

a single drug could require more than one pediatric formulation for different pediatric age group, such as a chewable tablet, a nonalcohol containing liquid, and sprinkles. Counting failed attempts, this comment claimed that producing a pediatric formulations may cost millions of dollars.

FDA believes that for drugs and biologics that offer a meaningful therapeutic benefit to pediatric patients, it is essential to provide pediatric formulations that ensure bioavailability and accurate dosing. FDA disagrees that it is inappropriate for the government to require manufacturers to produce pediatric formulations. As many comments demonstrated, adult formulations of these drugs are frequently used in pediatric patients because there is no other choice. Drug manufacturers profit from these uses, but do not take responsibility for them. Where a product is commonly being used in a subpopulation for an indication recommended by the manufacturer, it is appropriate to require the manufacturer to take steps to ensure that the use is safe and effective.

FDA agrees that producing a pediatric formulation can be difficult or, rarely, impossible and has attempted to account for this problem by permitting waiver of the pediatric study requirement where reasonable attempts to produce a pediatric formulation have failed. FDA notes that the pharmaceutical industry did not respond to FDA's request to help define what should constitute such ''reasonable attempts.''

To permit pediatric studies that may begin, for products for life-threatening diseases, at the end of phase 1, or, for other products, at the end of phase 2, it may be necessary to begin development of a pediatric formulation before initiation of clinical trials. FDA does not agree that it is wasteful to begin development of a pediatric formulation at this stage. This rule is premised on the view that for drugs and biologics that will have important use in pediatric patients, it is the responsibility of the manufacturer to ensure that use is safe and effective. Although some such products may ultimately prove to be unsafe or ineffective, work on pediatric formulations of such products is not necessarily more wasteful than work on adult formulations. FDA does not agree that manufacturers will be required to develop several pediatric formulations for different age groups. Even for a drug that was to be used in all pediatric age groups, a liquid formulation, e.g., might be usable in all age groups.

FDA has no basis to conclude that producing pediatric formulations will increase the cost of adult formulations or create disincentives for producing drugs and biologics with pediatric uses. No evidence was submitted to support either of these assertions.

40. Several comments discussed how to define ''reasonable attempts'' to produce a pediatric formulation. The AAP argued that difficulty in producing a pediatric formulation should be a basis for waiver only if the sponsor provides data showing that formulation experts encountered insurmountable problems of solubility, stability, compatibility, or palatability using accepted methods, and that cost be given only limited consideration. The AAP urged that such an assertion be corroborated by a panel of pediatric experts and FDA as well as formulation experts. Another comment agreed that formulations appropriate for younger age groups should be developed unless the manufacturer shows it would be virtually impossible. This comment argued that if a manufacturer wants to show that the cost is prohibitive, it should provide information allowing the financial and other costs of development to be seen in terms of the entire drug development process. Another comment argued that waivers should not be based on whether reasonable efforts to develop a pediatric formulation have failed because this ground for a waiver would permit small companies to avoid producing pediatric formulations on cost grounds. This comment urged that waivers be allowed only if a pediatric formulation cannot be produced for scientific or technological reasons. One comment argued that even if producing a pediatric formulation is impossible, the manufacturer should be required to study the adult formulation in pediatric patients, because it will be used in pediatric patients.

One industry comment urged that the decision to require a pediatric formulation be made on a case-by-case basis. Another comment argued that pediatric formulations should be required only if a panel of pediatric experts concludes that there is a genuine pediatric need and substantial benefit.

FDA agrees that the burden should be on the manufacturer to provide evidence that experts in formulation chemistry had encountered unusually difficult technological problems in the development of a pediatric formulation. In determining whether those problems were sufficiently severe to warrant a waiver of pediatric studies, FDA will consider the potential importance of the product for pediatric patients. The more important the product, the more efforts should be made to develop a pediatric formulation. FDA will also, at its discretion, take to the Advisory Committee for Pharmaceutical Sciences questions about whether ''reasonable attempts'' have been made to produce pediatric formulations in particular cases. Although FDA believes that it is appropriate to consider the cost to the manufacturer in determining whether attempts to produce a pediatric formulation have been reasonable, the agency received no helpful guidance on how to assess whether the costs of producing a pediatric formulation were unreasonable. In addition to any informative cost information provided by the manufacturer, FDA will take into account whether a product is still under patent or exclusivity protection. FDA will assume that manufacturers can incur greater costs for products that have significant patent life or exclusivity remaining.

41. One comment contended that FDA chemistry requirements have increased over the last 10 years. Another comment urged that FDA be more flexible in its review of formulations, e.g., by permitting generally recognized as safe (GRAS) substances in pediatric formulations.

FDA recently held a conference on pediatric formulations at which the agency sought input from industry on identifying the regulatory issues that affect the development of pediatric formulations for both new and approved marketed drugs. At this meeting, FDA also requested proposals for solutions to facilitate the development and approval of pediatric formulations. FDA is committed to removing unnecessary burdens on the review and approval of pediatric formulations.

42. Two comments urged manufacturers to provide formulas in product labeling for extemporaneous pediatric formulations made by pharmacists. These comments stated that the current practice among hospital pharmacies is to use unvalidated formulas, resulting in a lack of consistency from one hospital to another, no stability testing, and, in some cases, reluctance to produce pediatric formulations at all because of the lack of guidance. One comment stated that information on extemporaneous formulations should be provided only where: (1) A commercial formulation is not possible or (2) the drug has extremely limited use in pediatric patients.

FDA is concerned that the availability of this approach may undermine efforts to produce standardized pediatric formulations. There are, however, one or two examples in which approved labeling carries directions for producing

extemporaneous pediatric formulations. FDA will consider, on a case-by-case basis whether such an approach is appropriate, e.g., where it has not been possible to develop a stable commercial formulation.

J. Marketed Drug and Biological Products

FDA proposed in § 201.23 to codify its authority to require, in certain circumstances, a manufacturer of a marketed drug or biological product to submit an application containing data evaluating the safety and effectiveness of the product in pediatric populations. FDA proposed to impose such a requirement only where the agency made one of two findings: (1) That the product was widely used in pediatric populations and the absence of adequate labeling could pose significant risks to pediatric patients; or (2) the product was indicated for a very significant or life-threatening illness, but additional dosing or safety information was needed to permit its safe and effective use in pediatric patients.

Before requiring a study under this section, FDA proposed to consult with the manufacturer on the type of studies needed and on the length of time necessary to complete them, and would notify the manufacturer, by letter, of the agency's tentative conclusion that such a study was needed and provide the manufacturer an opportunity to provide a written response and to have a meeting with the agency. At the agency's discretion, such a meeting could be an advisory committee meeting. If, after reviewing any written response and conducting any requested meeting, FDA determined that additional pediatric use information was necessary, FDA proposed to issue an order requiring the manufacturer to submit a supplemental application containing pediatric safety and effectiveness data within a specified time. The proposal referred to the order in one place as a letter. FDA has clarified the final rule by stating that the manufacturer will receive ''an order, in the form of a letter.'' A few other minor clarifying revisions have also been made in this section.

FDA sought comment on whether it should codify its authority to require the manufacturers of marketed drugs and biologics to conduct pediatric studies, and, if so, on the circumstances in which the agency should exercise that authority.

43. Many comments from the pediatric community agreed that FDA should codify its authority to require pediatric studies on marketed drugs. Several comments from the pharmaceutical industry argued that FDA lacked authority to require studies of marketed drugs and that the 1994 rule sufficiently addressed pediatric labeling for marketed drugs. Some comments argued that adding pediatric labeling for indications applicable to pediatric patients should be at the sponsor's discretion. Others claimed that incentives are better than requirements. One comment contended that the proposed requirement forces manufacturers ''to take on unwanted liabilities in order to maintain an asset which was created and earned under a different set of rules.'' Other comments maintained that companies should not be required to conduct new studies, and that pediatric labeling should be based on existing data, such as marketing experience and dosing regimens generally accepted by experts. A comment from a pharmaceutical trade association argued that studies should not be required but that FDA should work with industry and others to ''develop creative ways to obtain the needed labeling information'' for marketed drugs.

FDA believes that it has ample authority to require pediatric studies of marketed drugs and biologics, as described in the preamble to the 1994 rule (59 FR 64240 at 64243) and in ''Legal Authority'' section IV of this document. FDA has also concluded, as described previously, that the response to the 1994 rule and other voluntary measures have not produced a significant improvement in pediatric labeling for many marketed drugs and biologics. In addition, as one pharmaceutical company conceded, manufacturers are unlikely to initiate clinical research on marketed drugs whose patents have expired, or are about to expire. FDA has therefore concluded that where pediatric information is critical to patient care, it is necessary to require that pediatric studies be carried out. FDA notes that new requirements are sometimes imposed on already marketed consumer products when such requirements are necessary to protect the public health. FDA emphasizes, however, that it will require studies of marketed products only in the compelling circumstances described in the regulation.

44. FDA received many comments on the grounds for requiring studies of marketed products. Comments from medical societies, pediatricians, and disease-specific organizations argued that the proposed grounds were too narrow. One comment stated that pediatric studies should be required of any marketed drug that is likely to be used in pediatric patients. Several comments argued that the phrase ''very significant illness'' was ill-defined. One comment stated that it was ''so open-ended and subjective as to be impossible for use as a regulatory standard.'' Another comment suggested that any definition of ''very significant illness'' would be arbitrary and overbroad. Several comments urged that the same criteria that are applied to not-yet-approved drugs be applied to marketed drugs. One of these comments argued that even if the criteria remain as proposed, ''widely used'' and ''significant risk'' should be defined in terms of the severity of the illness. According to this comment, if the consequences of no treatment are serious, the absence of labeling should be more readily found to present a significant risk. One industry comment maintained that the requirement should apply to marketed drugs only where there is a ''compelling need'' for pediatric data. One comment argued that the requirement should apply to all marketed drugs unless an expert panel concluded that studies were not required, while other comments urged that FDA utilize an expert panel to affirmatively identify and prioritize marketed drugs that should be studied in pediatric patients. Some of these comments suggested that there be no criteria and that the panel should determine which drugs should be studied on a case-by-case basis. One comment suggested that the list should be prioritized using the number of pediatric prescriptions.

FDA believes that criteria are necessary to assure consistency and fairness in deciding which marketed drugs and biologics are studied. FDA has reviewed the grounds for requiring pediatric studies of marketed drugs and biologics and has revised them in light of the comments. FDA has concluded that the phrase ''very significant illness'' is not sufficiently defined and agrees that it would be less confusing to use the same concepts that are used in defining which new products will be subject to the pediatric study requirement. FDA has therefore replaced the concept of ''very significant illness'' and replaced it with ''meaningful therapeutic benefit.'' However, to ensure that this authority is reserved for cases in which there is a compelling need for studies, FDA has added the requirement (already present in the first criterion) that FDA also find that the absence of adequate labeling could pose significant risks for pediatric patients. The second criterion will now read:

* * * there is reason to believe that the drug product would represent a meaningful therapeutic benefit over existing treatments for pediatric patients for one or more of the claimed indications, and the absence of adequate labeling could pose significant risks to pediatric patients.

FDA has also revised the first criterion to conform more closely to the criteria for requiring studies in not-yet-approved drugs and biologics, replacing ''widely used'' with ''used in a substantial number of pediatric patients.'' FDA will use the same definition of ''substantial number'' for both marketed and not-yet-approved drugs and biologics. The first criterion will, however, continue to include the requirement that ''the absence of adequate labeling could pose significant risks to patients.'' FDA believes that the pediatric study requirement may impose greater burdens on the manufacturers of marketed drugs and biologics than the manufacturers of not-yet-approved products, and that it is appropriate to require such studies only in the compelling circumstances described in the regulation. In determining which marketed products ''could pose significant risks to patients,'' FDA will consider such factors as the severity of the illness and the consequences of inadequate treatment, the number of pediatric prescriptions, and any available information on adverse events associated with use of the product.

FDA emphasizes that it intends to exercise its authority under § 201.23 only in compelling circumstances. FDA has estimated that it will require studies of approximately two marketed drugs per year.

FDA agrees that an expert panel can provide useful experience and guidance in developing a prioritized list of marketed drugs and biologics that meet the criteria for required studies. FDA intends to seek advice on developing such a list from a pediatric panel, as described in section III.M of this document (''Pediatric Committee'').

FDA also notes that FDAMA requires the agency to publish a list of marketed drugs for which ''additional pediatric information may produce health benefits in the pediatric population.'' FDA published this list within 180 days of the enactment of FDAMA, as required by that statute. Although the products on the list designated as high priority may be appropriate candidates for required studies under this rule, the list of high priority products is not necessarily exhaustive. Other products that might be subject to a requirement under this rule might not appear on the list. FDA also emphasizes that there is no implication that the agency will require studies of any particular product on the list. As noted in the Introduction to this preamble, before imposing any requirements under § 201.23, FDA intends to allow manufacturers eligible for FDAMA incentives an adequate opportunity to voluntarily conduct studies of marketed drugs in response to those incentives. If, following such an opportunity, there remain marketed drugs for which studies are needed and the compelling circumstances described in the rule are met, the agency will consider exercising its authority to require studies.

45. One comment claimed that the proposal requires studies only from manufacturers of innovator drugs (sponsors of the original application for the drug), while the major market share for many of these drugs is now held by generic manufacturers. This comment argued that a waiver should be granted if ANDA holders fail to share the costs of required studies. Another comment argued that the pediatric study requirement should apply only to the sponsor of the original application.

Where the agency requires pediatric studies on a multi-source marketed drug, each manufacturer of that drug, whether innovator or generic, will be responsible for satisfying the study requirement. To avoid duplication of research, FDA will encourage all the manufacturers to jointly fund an appropriate study. If, however, a joint study is not agreed to, each manufacturer will be responsible for submitting adequate studies.

K. Ethical Issues

In the proposal, FDA noted that because pediatric patients represent a vulnerable population, special protections are needed to protect their rights and to shield them from undue risk. To address ethical concerns in research on pediatric patients, both the AAP (Ref. 17) and the Department of Health and Human Services (DHHS), 45 CFR part 46, subpart D, have developed guidelines for the ethical conduct of clinical studies in pediatric patients. FDA advised in the proposal that sponsors should adhere to these guidelines for pediatric studies conducted under this rule. The agency also sought comment on ethical issues raised by the proposal.

46. A few comments addressed appropriate ethical guidelines for pediatric studies. Several comments said that existing ethical guidelines provide an adequate framework for pediatric studies. A comment from the AAP stated that ethical conduct should be guided by the DHHS and AAP guidelines, and that IRB approval that explicitly ensures protection of vulnerable subjects should be obtained. This comment also stated that the AAP guidelines provide a means to ensure ethical conduct of studies without impeding pediatric research. One comment said that DHHS ethics regulations may not provide sufficient protection for pediatric patients and suggested incorporating AAP guidelines for ethical conduct of pediatric studies into FDA's human subjects protections regulations. Another comment contended that pediatric studies should strictly adhere to regulations currently in effect for studies of human subjects who are unable to give consent, and urged FDA to further define requirements for investigation in vulnerable populations.

FDA believes that adherence to the DHHS and AAP guidelines will provide sufficient protection to pediatric patients from the risks of research. FDA will, however, seek advice from a panel of pediatric experts on whether additional protections are necessary.

47. Several comments addressed the ethics of requiring pediatric studies as described in the proposal. Two comments asserted that children are overmedicated and that administering drugs to children is unacceptable and ''ungodly.'' Comments from the pharmaceutical industry claimed that the rule as drafted would result in unethical testing of pediatric patients. One comment maintained that the regulations do not adequately protect pediatric patients from the risks of research because they impose a ''general rule that a deferral of testing in pediatrics will only be granted in narrow and limited circumstances.''

In contrast, comments from the pediatric community maintained that far more serious ethical concerns are raised by using untested drugs in pediatric patients than by conducting pediatric research. A comment from the AAP stated that there is no greater ethical dilemma than whether to give a drug with insufficient safety and effectiveness data to a child, or to withhold treatment and let the disease progress unabated.

Some comments suggested specific points in drug development at which pediatric testing becomes ethical. One comment argued that testing in pediatric patients before efficacy is demonstrated in adults may unnecessarily expose pediatric patients to a product's risks before its benefits are established. Another comment contended that it is unethical to begin studying drugs in pediatric patients that are not intended primarily for pediatric patients until the drug is adequately characterized in

adult patients, including choice of appropriate adult dose and establishment of reasonable evidence of safety and efficacy with an acceptable therapeutic margin. A pharmaceutical trade association argued that it is unethical to begin trials in pediatric patients until enough adult safety and effectiveness data have been gathered to conclude that the drug ''is likely to be approved for use in adults.''

FDA believes that some of the comments from the pharmaceutical industry misstate the application of the rule. As described fully previously, deferral of pediatric studies is specifically permitted in those cases where data should be collected in adults before exposing pediatric patients to the agent. There is no suggestion in either the proposed or final rule that deferral will be granted only in ''narrow and limited circumstances.'' FDA believes that, as drafted, the deferral provisions of the rule permit ethical pediatric testing that does not expose pediatric patients to inappropriate risks.

48. A few comments urged that placebo-controlled trials in pediatric patients be used rarely if at all. The AAP stated that placebo controls should not be used where that design would impose a substantial increase in risk to the child or would impede the ability to perform useful clinical trials. This comment urged that alternatives to placebo controls be used wherever possible and that where placebo controls are used, the study design should incorporate safeguards to avoid undue risk.

The question of appropriate control group arises only when there is a need for controlled trials to establish efficacy in the pediatric population. FDA agrees that alternatives to placebo-controlled trials should be used wherever they can provide sufficient information to establish effectiveness. FDA often accepts data from active control studies for certain therapeutic classes, such as anti-infectives and oncologic drugs. (See 21 CFR 314.126.) In some cases, new treatments can also be studied against a placebo together with a background of existing therapy, i.e., studied in ''add-on'' trials.

49. One comment argued that parents should not be given money or equivalent compensation for participation in drug studies. This comment suggested that any compensation could be put in the child's IRA.

The IRB overseeing a research study, rather than FDA, is responsible for determining whether compensation offered to the subjects of the study is ethically appropriate.

L. Remedies

If a manufacturer failed, in the time allowed, to submit adequate studies to evaluate pediatric safety and effectiveness required under proposed § 201.23(c) or § 314.55 (proposed § 314.50(g)), FDA proposed to consider the product misbranded under section 502 of the act or an unapproved new drug under section 505(a) of the act (see ''Legal Authority,'' in section IV of this document). Although proposed § 201.23 expressly covered both drugs and biologics, FDA inadvertently omitted in that section a reference to actions against biologics that have not obtained a license under section 351 of the Public Health Service Act. Such a reference has been added in the final rule. When a product is misbranded or an unapproved new drug, sections 302, 303, and 304 of the act (21 U.S.C. 332, 333, 334) authorize injunction, prosecution or seizure. FDA may also seek an injunction or bring a prosecution under the Public Health Service Act. In the proposal, FDA advised that it would bring an enforcement action for injunctive relief for failure to submit a required assessment of pediatric safety or effectiveness. Violation of the injunction would result in a contempt proceeding or such other penalties as the court ordered, e.g., fines. As noted in the proposal, FDA does not intend to deny or withdraw approval of a product for failure to conduct pediatric studies, except possibly in rare circumstances, because removal of a product from the marketplace could deprive other patients of the benefits of a useful medical product. Such circumstances might arise where the predominant use of the product was in pediatric patients rather than adults, and there were life-threatening risks associated with use of the product in pediatric patients when used without proper dosing and safety information in the labeling.

To assist FDA in determining whether pediatric assessments are needed or are being carried out with due diligence, FDA proposed to amend § 314.81(b)(2) (21 CFR 314.81(b)(2)) (annual postmarketing reports) to require that annual reports filed by the manufacturer contain information on labeling changes that have been initiated in response to new pediatric data, analysis of clinical data that have been gathered on pediatric use, assessment of data needed to ensure appropriate labeling for the pediatric population, and information on the status of ongoing pediatric studies. FDA also proposed to require that, where possible, the annual report contain an estimate of patient exposure to the drug product, with special reference to the pediatric population.

50. Several comments agreed with the agency that withdrawal or denial of approval is infeasible and supported the use of injunctive remedies. One comment argued that if FDA provides no incentives, disincentives to avoid pediatric trials must be strong, and that withdrawal and denial of approval must therefore be used as a remedy.

FDA continues to believe that refusal to approve or removal from the market is generally an unsatisfactory remedy from a public health perspective because it denies adequately studied populations access to safe and effective medicines.

51. Several comments supported the imposition of monetary fines. One comment urged that fines be imposed in the amount of a percentage of the profits to ensure that large and small companies had an equal disincentive. Several comments argued that fines should be used by FDA to fund pediatric studies carried out by government or private agencies. One comment contended that monetary penalties, such as fines or shortening of exclusivity, are the only practical remedy because industry and government are economically driven, but that injunctions are too costly.

Although FDA continues to believe that court-imposed fines are an appropriate remedy for failure to submit pediatric assessments, the agency has no authority itself to impose fines for violation of this rule, to set the amount of such fines, or to take the fines and direct them to specific activities.

52. Two comments opposed treating violative products as ''misbranded'' because this could limit access to the drugs or could delay availability of the products for adult use. According to one comment, FDA should consider a misbranding charge only if the sponsor failed to meet a phase 4 commitment. Another comment argued that injunction or prosecution are appropriate only as a final response, and that other, unspecified means are more efficient to elicit compliance. This comment also argued that seizure would serve only to deprive patients of safe and effective drugs.

The comments arguing that a misbranding charge could limit access or delay approval provided no basis for concluding that these results would occur, and FDA is aware of none. FDA agrees that injunction and prosecution are appropriate remedies only after the sponsor has been given an adequate opportunity to meet its obligations under the rule. FDA emphasizes, however, that providing adequate

pediatric labeling cannot be long-delayed without putting the health of pediatric patients at risk and that the agency will not accept unwarranted delays in submitting required studies. FDA also notes that it does not intend ordinarily to use seizure as a remedy for failure to conduct required studies.

53. Some comments offered additional or alternative remedies for failure to conduct required studies. One comment urged that failure to provide information to support pediatric labeling result in highly visible warnings on prescription and OTC labels that the drug has not been approved by FDA for pediatric use. Two comments argued that the label should disclose the status of pediatric studies, whether waivers or deferrals had been requested or granted, and the timetable for full compliance. Another comment contended that incentives are more effective than penalties, and that FDA discussions with sponsors during drug development will achieve the results sought in the proposal.

FDA agrees that publicity can sometimes be a useful tool for encouraging compliance. FDA does not believe, however, that it is feasible to include in labeling detailed information on the status of pediatric trials, because that information could change frequently. As described in section III.M of this document, FDA will, in appropriate cases, bring issues related to the progress of pediatric studies before a panel of pediatric experts, and may utilize other forms of publicity to provide the public with information about the status of required pediatric studies. FDA notes, e.g., that FDAMA contains provisions concerning disclosure of information on the status of postmarketing studies. FDA may also consider the use of prominent warnings about the absence of data on pediatric use, if necessary in particular cases.

M. Pediatric Committee

A large number of comments recommended that FDA form a panel of pediatric experts to provide advice on a range of topics related to implementation of this rule. Two comments recommended that an expert panel give advice on all facets of the rule. Several comments suggested more specific roles for the panel. For example, the AAP recommended that the panel provide advice on waiver requests, which marketed drugs require study, whether a drug is ''widely used,'' whether to accept a manufacturer's failure to develop a pediatric formulation, relevant age groups for study, the appropriateness of deferral, and appropriate timetables for completion of deferred studies. A disease-specific organization urged that a pediatric committee assist in establishing ''pediatric guidelines and practice,'' including a list of drugs for which studies would be required, protocol design, formulations, and age ranges. Two industry comments recommended that the panel review which drugs require testing and labeling, at what phase of drug development pediatric patients should be exposed, when waivers should be granted, what methods should be used to evaluate safety and effectiveness, the economic burdens on industry, and liability issues. Several comments, including comments from a pharmaceutical trade association, a disease-specific organization, a medical society, and pediatricians, recommended that the panel give advice on which drugs should be studied in pediatric patients. One comment suggested that FDA appoint a pediatric pharmacology expert to each of the existing drug advisory committees, except possibly the Fertility and Maternal Health Advisory Committee.

FDA has concluded that a panel of pediatric experts could provide useful advice and experience on several aspects of the implementation of the rule. FDA will therefore convene a panel of pediatric experts, including at least one industry representative, and seek its advice on a range of issues. Such a panel may be composed of pediatric experts appointed to each of FDA's existing drug advisory committees. As described in section III.E of this document under ''Waivers,'' FDA does not believe that it would be practical to ask such a committee to review every waiver or deferral request. However, the agency will ask the panel to provide annual oversight of the agency's implementation of the final rule, including the agency's record of granting or refusing waivers and deferrals. FDA will also seek the advice of the panel in identifying specific marketed drugs and biological products that should be studied in pediatric patients, and the age groups in which they should be studied. FDA will also ask for advice on assessing when additional therapeutic options are needed in treating specific diseases and conditions occurring in pediatric patients. As described previously, FDA will seek the panel's advice on ethical issues raised by clinical trials in pediatric patients, and whether additional rules should be implemented in this area. Where a manufacturer is not carrying out required studies according to the agreed upon timetable, FDA may seek the advice of the panel on whether the manufacturer is acting with due diligence. In addition, FDA may bring before the panel other issues that arise in the implementation of the rule, including the design of trials and analysis of data for specific products and classes of products.

N. Other Comments

54. Several comments suggested various forms of oversight for the implementation of the rule. One comment suggested that FDA establish a plan to prospectively evaluate these regulations, including their effect on the cost of drug development and on the time to new drug approval, and the number and success of pediatric studies actually performed. Another comment urged FDA to appoint a ''Children's Studies Ombudsman.'' One comment asked that the rule include an appeals mechanism to resolve disputes between sponsors and agency reviewers.

As described previously, FDA intends to convene a panel of pediatric experts, including at least one representative of the pharmaceutical industry, to, among other things, review the agency's implementation of the rule. FDA notes that it already has procedures for resolution of disputes between sponsors and FDA reviewing divisions, 21 CFR 312.48 and 314.103, and that these procedures will be available for disputes that arise under this rule.

55. Several comments contended that the rule is inconsistent with requirements in Canada, Europe, and Japan for pediatric studies. These comments argued that the rule was at odds with harmonization efforts and urged FDA to harmonize its requirements with those of other countries. One comment recommended that the United States, the European Union (EU), and Japan adopt pediatric drug development as a topic for global discussion and harmonization.

Although FDA is not required to harmonize its labeling regulations and enforcement with those of our International Conference on Harmonization (ICH) partners, harmonization is a goal that the agency strives to achieve. FDA intends to work through the ICH process to harmonize methods for conducting pediatric studies.

56. A few comments sought additional incentives for pediatric studies. One industry comment suggested that FDA should provide: (1) Priority reviews for applications containing pediatric data or ongoing studies; (2) waiver of user fees for pediatric effectiveness supplements; and (3) application of the subpart E

regulations (21 CFR part 312, subpart E) to pediatric development of new drugs and biological products, to address the issues associated with small sample size and therapeutic need.

Since the publication of the proposal, two significant new incentives have become available for pediatric research. First, as described elsewhere in this document, FDAMA provides 6 months of exclusive marketing to certain applicants who conduct pediatric studies. Second, as a result of changes made during the reauthorization of the PDUFA, user fees are no longer required for supplements that are solely for the purpose of adding a new indication for use in pediatric populations.

IV. Legal Authority

In the proposal, FDA cited as authority for the requirements in the rule sections 502(a), 502(f), 505(d)(7) of the act, and § 201.5 (21 CFR 201.5), which require adequate directions for use and prohibit false or misleading labeling; section 201(n) of the act, which defines as misleading labeling that fails to reveal material facts related to consequences of the customary or usual use of a drug; sections 201(p), 301(a) and (d) (21 U.S.C. 331(a) and (d)), and 505(a) of the act, which subject a drug to enforcement action if it is not recognized as safe and effective or approved for the conditions prescribed, recommended, or suggested in the labeling; section 502(j) of the act, which prohibits drugs that are dangerous to health when used in the manner suggested in their labeling; sections 505(i) and 505(k) of the act, which authorize FDA to impose conditions on the investigation of new drugs, including conditions related to the ethics of an investigation, and to require postmarketing reports; section 701(a) of the act, which authorizes FDA to issue regulations for the efficient enforcement of the act; and section 351 of the Public Health Service Act, which formerly required biological products to meet standards designed to insure their ''continued safety, purity, and potency.'' FDA notes that section 351 was amended by FDAMA, and now requires biological products to be ''safe, pure, and potent.''

FDA has authority under section 302 of the act and under the Public Health Service Act to seek an injunction requiring studies of certain marketed drugs on the grounds that the absence of pediatric safety and effectiveness information in the labeling renders the product misbranded or an unapproved new drug. The act also authorizes seizures of misbranded or unapproved drugs under section 304 of the act. Misbranding drugs and introducing unapproved new drugs into interstate commerce are prohibited acts under sections 301(a), (d), and (k) of the act. The statutory definition of ''drug'' is set out at section 201(g) of the act.

57. Several comments agreed that FDA has authority to require pediatric testing of drugs and biological products. One comment argued that the act already gives FDA the authority to require that all drugs be tested in pediatric patients, and that the rule, which permits waivers and deferred testing in some cases, weakens the agency's existing statutory authority. One comment contended a provision of FDAMA granting exclusivity to ''any pediatric study [that] is required pursuant to regulations promulgated by the Secretary [and that meets certain other requirements]'' shows that Congress agrees that FDA has authority to require pediatric studies. This comment also argued that, to the extent that FDA's position on its authority to require pediatric studies has changed, the change in position is justified because the proposal articulates a reasoned basis for the change.

FDA agrees that it has the authority to require pediatric testing of drugs and biologics. For the reasons cited in the preamble to the proposed and final rules, FDA has concluded that the requirements in the rule appropriately balance the need for adequate pediatric labeling and the limitations on resources available for pediatric testing and agency review. FDA also agrees that the reference in FDAMA, which was enacted after the proposal was issued, to pediatric studies required by FDA, demonstrate that Congress is aware of FDA's position that it has the authority to issue this rule and agrees that the agency has such authority. Finally, FDA agrees that it has articulated a reasoned basis for its position that the agency has authority to require pediatric studies, but notes that FDA previously stated its position that it has the authority to require pediatric studies in 1994 (59 FR 64240 at 64243).

58. Several comments argued that FDA lacks authority to require pediatric studies of drugs. A few comments cited remarks by former Commissioner David Kessler during a 1992 speech. In that speech, David Kessler stated his opinion that FDA does not have ''the authority to require manufacturers to seek approval for indications which they have not studied.'' Other comments argued that FDA has no authority to require the study of any indications or populations other than those proposed by the manufacturer. One comment challenged FDA's reliance on section 201(n) of the act for not-yet-approved drugs, claiming that the agency cannot know what will be the ''customary or usual uses'' of an unmarketed drug. A few comments argued that the agency's legal theory would authorize the agency to require studies of all off-label indications.

FDA disagrees that any of these arguments show that FDA lacks authority to issue this rule. Under FDA's longstanding policy, statements made in speeches, even by Commissioners, are informal expressions of opinion and do not constitute a formal agency position on a matter. As such they are not binding on the agency. (See, e.g., 21 CFR 10.85(k).)

FDA also disagrees that it has no authority to require a drug or biologic to be studied in a population that is expected to use the product for the claimed indication, or that this is a new position. The agency has repeatedly stated that an application for marketing approval should contain data on a reasonable sample of the patients likely to be given the product once it is marketed (59 FR 64240 at 64243; 58 FR 39406 at 39409). The agency has also previously asserted its authority to require studies in pediatric patients and in other subpopulations for both not-yet-approved products and marketed products. In the preamble to the 1994 rule, FDA made the following statement:

> If FDA concludes that a particular drug is widely used, represents a safety hazard, or is therapeutically important in the pediatric populations, and the drug sponsor has not submitted any pediatric use information, then the agency may require that the sponsor develop and/or submit pediatric use information.
>
> If FDA has made a specific request for the submission of pediatric use information because of expected or identified pediatric use, and the sponsor fails to provide such information, the agency may consider the product to be a misbranded drug under section 502 of the act, or a falsely labeled biological product under section 351 of the PHS Act, as an unapproved new drug or unlicensed biological product. (See 21 U.S.C. 355 and 42 U.S.C. 262.)
>
> (59 FR 64240 at 64248; see also 58 FR 39406 at 39409)

The act and implementing regulations require drugs to be adequately labeled for their intended uses. See sections 502(f) of the act and § 201.5. ''Intended uses'' encompass more than the uses explicitly included in the manufacturer's proposed labeling. *Id.*, 21 CFR 201.128. In determining the intended uses of a drug for which it must be adequately labeled, FDA may consider both the uses for which it is expressly labeled and those for which the drug is commonly used, § 201.5.

FDA may also consider the actual uses of the drug of which the manufacturer has, or should have, notice, even if those uses are not promoted by the manufacturer, 21 CFR 201.128. Section 201(n) of the act defines labeling as misleading if it fails to include material facts about the consequences of ''use of the [drug] * * * under such conditions of use as are customary or usual.'' Sections 201(p) and 505(d) of the act authorize FDA to require evidence establishing the safety and effectiveness of uses ''suggested'' by the manufacturer's labeling as well as those expressly recommended in the labeling. Thus, the agency has authority to require a manufacturer to establish the safety and effectiveness of, and adequately label its product for, use of the product in a subpopulation for which the product is not labeled if that use is common or suggested in the labeling.

As described in the proposal, there is extensive evidence that drugs and biologics indicated for diseases that affect both adults and pediatric patients are routinely used in pediatric patients despite the absence of pediatric labeling, and even in the face of disclaimers stating that safety and effectiveness have not been established in pediatric patients. FDA may therefore consider pediatric use to be ''customary or usual'' or ''commonly used'' where the drug is indicated for a disease or condition that affects both adults and children, and the drug is not contraindicated in pediatric patients. FDA may also consider pediatric use to be ''suggested'' in a drug's labeling even where such use is not expressly recommended or is even disclaimed. The medical community generally expects that drugs and biological products will behave similarly in demographic subgroups, including age and gender subgroups, even though there may be variations among the subgroups, based on, e.g., differences in pharmacokinetics. Thus, where a drug or biological product is indicated for a disease suffered equally by men, women, and children, and is not contraindicated in women or pediatric patients, the product will be widely prescribed for all three subgroups even if it were studied only in, or labeled only for, men.

FDA disagrees that it can know nothing, in advance of marketing, about whether a drug or biological product will be used in pediatric patients. The evidence cited in the proposal and confirmed by comments from the pediatric community is overwhelming that products indicated for diseases that affect both adults and children are and will be commonly used in pediatric patients. Indeed, pediatricians often have no choice but to use these products in pediatric patients. A drug product that provides a meaningful therapeutic benefit either because it represents a significant improvement in therapy or because it is a necessary therapeutic option can be expected to be routinely used in the treatment of pediatric patients. Under the rule, the decision that a product will provide a meaningful therapeutic benefit or will be used in a substantial number of pediatric patients is made on a case-by-case basis, depending upon such factors as the number of pediatric patients affected by the disease for which the product is indicated, the availability and adequacy of other therapeutic options to treat pediatric patients for the disease, and whether similar products, e.g., products in the same drug class, have been widely used in pediatric patients.

Finally, FDA emphasizes that this rule applies only where a product is expected to have clinically significant use in pediatric populations for the indications already claimed by the manufacturer. The record before the agency documents widespread evidence of actual use of products in the pediatric population for indications labeled for adults. This record supports FDA's conclusion that it has authority to require pediatric studies of drugs and biologics that have or are expected to have clinically significant use among pediatric patients for the claimed indications. The agency has not examined evidence concerning the use of approved products for diseases or conditions not in the label, and the rule does not apply in those situations.

59. Two comments addressed the agency's reliance on section 701(a) of the act. One comment argued that 701(a) of the act, in combination with the substantive statutory provisions cited by FDA, authorizes this rule because the agency has demonstrated that the rule is reasonably related to the purposes of the act. Another comment argued that 701(a) of the act does not authorize the agency to enforce requirements beyond those imposed by the act.

Section 701(a) of the act gives the Secretary authority to issue regulations for the efficient enforcement of the act. Consonant with the Supreme Court's determination that the language of the act should not be read restrictively, but in a manner consistent with the act's purpose of protecting the public health, a regulation issued under section 701(a) of the act will be sustained so long as it is reasonably related to the purposes of the act. *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240, 246 (2nd Cir. 1977). FDA believes that it has demonstrated that this regulation is reasonably related to the purposes of the act.

V. Implementation Plan

FDA proposed that the rule would become effective 90 days after the date of its publication in the **Federal Register**. For new drug and biologic product applications submitted before the effective date of the final rule, the agency proposed a compliance date of 21 months after the effective date of the final rule (for a total of 2 years after issuance of the final rule). For new drug and biologic product applications submitted on or after the effective date of the final rule, the agency proposed a compliance date of 15 months after the effective date of the final rule (for a total of 18 months after issuance of the final rule). FDA has revised the final rule to become effective 120 days after publication in the **Federal Register**, to allow additional time for comment on the revised information collection requirements. FDA has also revised the compliance dates. All applications will have a compliance date of 20 months after the effective date of the rule (for a total of 2 years after publication of the final rule).

60. Two industry comments argued that the proposed effective dates were too short. One of these suggested that 15 and 21 months were too short to develop a pediatric program and formulation, conduct trials, analyze data, and submit an application. Two comments asked that FDA clarify what ''compliance'' means. According to one of these comments, 15 months would be adequate for initiation of discussions with a sponsor about plans, but inadequate for completion of studies. This comment also argued that it is not in children's interest to rush through pediatric studies to meet an arbitrary deadline. Another comment offered the example of Ritonavir, a drug to treat HIV infection, for which pediatric studies reportedly took 21 months even after development of a pediatric formulation. According to the comment, it took 15 months to agree on a protocol, 3 months to recruit patients, and 3 months to the first interim analysis of data. One disease-specific organization argued that the effective dates were too long. This comment proposed 12 months from the effective date of final rule, which could be extended by 6 months if genuine difficulties occurred. This comment also urged that compliance with the early discussion requirements be immediate. One comment argued that pending applications should be granted a full

waiver and treated as marketed products.

''Compliance,'' as referred to in the proposal, means the submission of an assessment of pediatric safety and effectiveness under § 314.55(a) (proposed § 314.50(g)(1) or 601.27(a)), unless a waiver or deferral for all relevant age groups has been granted. FDA has reconsidered the compliance dates and has concluded that applications submitted on or after the effective date of the final rule should be given 20 months from the effective date of the final rule to achieve compliance. Although FDA does not believe that development of, and agreement on, a protocol should take 15 months, protocol development, recruitment, enrollment, and data analysis may together take up to 2 years. There is no reasonable basis on which to distinguish between an application submitted 1 day before the effective date of the final rule, and one submitted a day later.

All other provisions of the rule will become effective on the effective date of the rule. One hundred twenty days from the date of publication in the **Federal Register** is sufficient time to meet these new requirements.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

With respect to the following collection of information, FDA invited comment on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

OMB filed a Notice of Action, not approving the proposed collection of information. OMB requested that, as part of the final rule, FDA address all comments received on the information collection requirements contained in the rule, particularly with respect to the reporting burden imposed by the rule. FDA received one comment concerning the proposed burden estimates of this rulemaking under the PRA. The comment contended that FDA underestimated the time required to comply with the annual reporting requirements of the proposed rulemaking.

The agency received several comments that questioned the accuracy of FDA's estimate of the burden of the proposed collection of information as being too low and requested changes. For example, one comment requested changes in the burden estimate for manufacturers requesting deferrals of submission of pediatric data as well as the estimate for manufacturers to submit pediatric information in their annual report. In addition, the estimate for manufacturers to submit in their annual reports the analysis of available safety and efficacy data conducted or obtained in the pediatric population as well as proposed labeling was questioned. Based on these comments the agency increased the proposed burden estimates. These issues are discussed in more detail in the preamble to the final rule.

Concerning § 314.50(d)(7), the comment stated that in order to comply with this requirement, ''one company'' estimated that, for one pediatric reporting project, medical staff had spent at least 118 hours, rather than the 8 hours that FDA had estimated, reviewing the medical literature and summarizing the findings. FDA does not believe that this comparison is fully appropriate because § 314.50(d)(7) does not require an applicant to review the medical literature, or other studies, *de novo*. It simply requires an applicant to provide a brief summary of data that have already been fully reported and analyzed elsewhere in the same application. However, because the data to be summarized may be more extensive than originally estimated, FDA has, in response to the comment, increased its estimate of the reporting burden for this requirement from 8 hours to 50 hours.

Concerning § 314.55(a), the comment contended that FDA's estimate of 10 companies submitting NDA's annually for NME's is too low. The comment implied that, based on data for 1996, 50 companies would be a more realistic estimate. The comment also contended that FDA's estimate of 16 hours for a manufacturer to prepare the report of the data supporting the safety and effectiveness of the drug for the indication for the pediatric population is too low. In response to this comment, FDA has revised its burden estimate from 16 to 48 hours. FDA has also made a corresponding change in the estimate for § 601.27(a). FDA has revised the estimate of the number of companies affected from 10 to 51 to reflect the broader scope of the rule.

Concerning § 314.55(b), the comment stated that FDA's estimate of 9 manufacturers requesting deferrals of the submission of pediatric study data and the estimate that this would take 8 hours to complete are too low. In response to this comment, FDA has revised its burden estimate from 8 hours to 24 hours. FDA has also made a corresponding change in the estimate for § 601.27(b). FDA has revised the estimate of the number of companies affected from 8 to 51 to respond to the comment and to reflect the broader scope of the rule.

Concerning § 314.81(b)(2)(i), the comment contended that FDA's estimate of 1.5 hours for manufacturers to submit pediatric information in their annual reports is too low. In response to this comment, FDA has revised its burden estimate from 1.5 hours to 8 hours and has made a corresponding change in its estimate for § 601.27(c).

Concerning § 314.81(b)(2)(vi)(*c*), the comment contended that FDA's estimate of 1.5 hours for manufacturers to submit in their annual reports the analysis of available safety and efficacy data conducted or obtained in the pediatric population as well as proposed labeling changes is too low. The comment stated that even an estimate of 15 hours would be too low. Although the comment did not provide an estimate of the hours required to satisfy § 314.81(b)(2)(i) and (b)(2)(vi)(*c*), FDA has increased its estimates to 8 and 24 hours, respectively.

Based upon these comments, FDA has decided to increase the agency's proposed burden estimates. These revisions are reflected in the Table 2 of this document. In addition, the burden estimates for §§ 314.55(a), (b), and (c), and 601.27(a), (b), and (c), have increased because of the new requirements in the final rule to include, in addition to applications for new chemical entities and never-before-approved biologics, applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration. These estimates are based upon FDA's analysis of all marketing applications and efficacy

supplements approved over the 5-year period of 1993 to 1997 and those that would likely have needed additional pediatric data had this rule been in effect by 1993 (see ''Analysis of Impacts,'' in section VIII of this document). In addition, burden estimates have been added in Table 2 of this document for the new requirements in the final rule concerning submissions for end-of-phase 1 and end-of-phase 2 meetings under § 312.47(b)(1)(iv) and submissions for pre-NDA meetings under § 312.47(b)(2). These estimates are based on FDA's records of the number of these meetings held during 1997. Finally, burden estimates have been added for new postmarket report requirements added for biological products under § 601.37 (a), (b), and (c), corresponding to § 314.81 (b)(2)(i), (b)(2)(vi)(*c*), and (b)(2)(vii). These estimates are based upon FDA's records of the number of licensed biological products.

Title: Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients.

Description: This final rule includes the following reporting requirements: (1) Reports on planned pediatric studies in IND's (§ 312.23(a)(10)(iii)); (2) Reports for end-of-phase 1 and end-of-phase 2 meetings (§ 312.47(b)(1)(iv)) and reports for pre-NDA meetings (§ 312.47(b)(2)); (3) Summaries of data on pediatric safety and effectiveness in NDA's (§ 314.50(d)(7)); (4) Reports assessing the safety and effectiveness of certain drugs and biological products for pediatric use in NDA's and BLA's or in supplemental applications (§§ 314.55(a) and 601.27(a)); (5) Requests seeking deferral of required pediatric studies (§§ 314.55(b) and 601.27(b)); (6) Requests seeking waiver of required pediatric studies (§§ 314.55(c) and 601.27(c)); (7) Postmarketing reports of analyses of data on pediatric safety and effectiveness (§§ 314.81(b)(2)(vi)(*c*) and 601.37(a)(1)); (8) Postmarketing reports on patient exposure to certain marketed drug products (§§ 314.81(b)(2)(i) and 601.37(a)(2)); (9) Postmarketing reports on labeling changes initiated in response to new pediatric data (§§ 314.81(b)(2)(vi)(*c*) and 601.37(a)(3)); and (10) Postmarketing reports on the status of required postapproval studies in pediatric patients (§§ 314.81(b)(2)(vii) and 601.37). The purpose of these reporting requirements is to address the lack of adequate pediatric labeling of drugs and biological products by requiring the submission of evidence on pediatric safety and effectiveness for products with clinically significant use in children.

Description of Respondents: Sponsors and manufacturers of drugs and biological products.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
201.23	2	1	2	48	96
312.47(b)(1)(iv)	27	1.2	32	16	512
312.47(b)(2)	36	1.3	46	16	736
314.50(d)(7)	213	1	213	50	10,650
314.55(a)	51	1	51	48	2,448
314.55(b)	51	1	51	24	1,224
314.55(c)	176	1	176	8	1,408
314.81(b)(2)(i)	625	1	625	8	5,000
314.81(b)(2)(vi)(*c*)	625	1	625	24	15,000
314.81(b)(2)(vii)	625	1	625	1.5	937.5
601.27(a)	2	1	3	48	144
601.27(b)	2	1	3	24	72
601.27(c)	3	1	4	8	32
601.37(a)	69	1	69	8	552
601.37(b)	69	1	69	24	1,656
601.37(c)	69	1	69	1.5	103.5
Total	.....	.....	.....	.....	40,571

[1]There are no capital or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VIII. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (Pub. L. 104–4). 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). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact of the rule on small entities. The Unfunded Mandates Reform Act (Pub. L. 104–4) (in section 202) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments,

in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation).

The agency has reviewed this final rule and has determined that the rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, and in these two statutes. This rule is an economically significant regulatory action, because of its substantial benefits. It is also a significant regulatory action as defined by the Executive Order due to the novel policy issues it raises. With respect to the Regulatory Flexibility Act, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Since the rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of $100 million or more in any one year, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

FDA is requiring that a limited class of important new drugs and biologicals that are likely to be used in pediatric patients contain sufficient data and information to support directions for this use. As the approved labeling for many of these new products lacks adequate pediatric information, their use in children greatly increases the risk of inappropriate dosing, unexpected adverse effects, and suboptimal therapeutic outcomes. This rule is designed to ensure that new drugs, including biological drugs, that are therapeutically important and/or likely to be used in a substantial number of children contain adequate pediatric labeling at the time of, or soon after, approval.

The agency estimated the costs to industry of the required new pediatric studies by first determining what the annual costs would have been in 1993 to 1997, had the rule become effective in 1993. The methodology included: (1) Constructing a data base of all 583 NDA's and efficacy supplements approved by the agency over that 5-year period for drugs and biologicals likely to produce health benefits in the pediatric population, (2) determining which of those applications would have been required to conduct additional pediatric studies, (3) calculating how many unapproved and already marketed drugs and biologicals would have needed additional pediatric studies, and (4) estimating the size and cost of the additional studies. The analysis indicated that, on average, this regulation would have required an estimated 378 additional pediatric studies on about 82 drugs and biologicals per year. These studies would have involved a total of 10,860 pediatric patients, 7,408 in efficacy studies, and 3,452 in PK studies. In addition, an estimated 33 of the 82 drugs and biologicals needing new pediatric data each year may have needed new pediatric dosage forms. FDA judges that the additional studies would have cost about $45 million and the new dosage formulations about $33 million annually, for a total annual cost of almost $80 million. The agency found, however, that roughly 42 percent of the costs of the studies would have been spent voluntarily had the extended pediatric exclusivity provisions of the recent FDAMA statute been in place. Adjusting for this effect lowers the agency's final cost estimate for this rule to about $46.7 million per year.

FDA could not develop a quantifiable estimate of the benefits of this regulation, although numerous anecdotal examples illustrate the current health problem. To consider some of the potential benefits, the agency examined hospitalization rates for five serious illness (asthma, HIV/AIDS, cancer, pneumonia, and kidney infections) and found significantly higher rates for children than for middle-aged adults. Although FDA can not estimate the extent to which these differentials reflect the relative lack of pharmaceutical safety and efficacy information for pediatric compared to adult use, the agency calculated that a 25 percent reduction in these differentials would lead to direct medical cost savings of $228 million per year. FDA also estimates that about two-thirds of the approved applications needing pediatric studies will be addressed by the incentives established by FDAMA. If the estimated medical cost savings were adjusted by a similar ratio, the analysis suggests that a 25 percent reduction in the pediatric/adult hospitalization rate differentials would yield annual savings of $76 million for these five illnesses.

B. Number of Affected Products and Required Studies

In the preamble to its proposal, FDA explained that neither the precise number of drugs that would require additional pediatric studies nor the cost of these studies could be predicted with certainty. To develop plausible estimates of the number of new drugs and biologicals that would be affected, the agency had examined the pediatric labeling status at time of approval for each NME and important biological approved from 1991 to 1995, and used these estimates to project the number of drugs that would have required additional pediatric data had the proposal been in place over that period.

Several industry comments declared that FDA's analysis of the proposal substantially underestimated the economic impact by understating both the number and size of the studies that would be required. Only two of the comments, however, included alternative estimates. One suggested that each new drug could require the testing of 300 or more pediatric patients for safety data alone. The other comment estimated that, ''each new drug studied would probably require a minimum of six clinical trials (two each in Phases I, II, and III), for one indication and one formulation.'' This comment explained that Phase I trials would include 20 patients, Phase II trials 50 patients, and Phase III trials 100 patients. Assuming two trials for each phase, the comment projected that 34,000 pediatric patients would need to be studied each year (170 patients x 2 trials x 100 drugs).

FDA agrees that some applications will require data from a substantial number of pediatric patients. The agency believes, however, that most studies will not include large numbers of pediatric patients. For example, FDA does not necessarily require two pediatric studies for each trial phase. Moreover, FDA's 1994 final rule (59 FR 64240) explains that extrapolations from adult effectiveness data based on PK studies and other safety data can be sufficient to provide the necessary pediatric dosing information for those drugs and biologicals that work by similar mechanisms in adults and children. The agency expects that the majority of the studies will rely, to some extent, on such extrapolations.

On the other hand, the proposal primarily addressed drugs and biologicals that contained no previously approved active moiety. The final rule requires pediatric data for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration that represent a meaningful clinical benefit over existing treatments for children, or that are likely to be widely used in children. The rule also requires pediatric studies for marketed drugs and biologicals that are already widely used among children for the claimed indications, if the absence of adequate labeling could pose significant risks; or if the drug would provide a meaningful clinical benefit over existing treatments for pediatric patients, but additional dosing or safety information is needed to permit their safe and effective use in children.

To develop a revised estimate of the number of drugs and biologicals that

would require additional pediatric data, FDA constructed a data base of all 583 applications and efficacy supplements approved over the 5-year period from 1993 to 1997 for drugs and biologicals for which pediatric labeling would be likely to provide a significant health benefit. The selected drugs and biologicals included all those for which the active moiety was listed in the priority section in the **Federal Register** of May 20, 1998 (63 FR 27733), document entitled ''List of Drugs For Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population'' (''List''). Mandated by FDAMA, this publication includes the agency's priority list of drugs and biologicals that would likely provide a significant benefit to the pediatric population. The selection criteria used to prepare this priority list were almost identical to those set forth in this final rule, i.e.,

- The drug product, if approved for use in the pediatric population, would be a significant improvement compared to marketed products labeled for use in the treatment, diagnosis, or prevention of a disease in the relevant pediatric population (i.e., a pediatric priority drug); or,
- The drug is widely used in the pediatric population, as measured by at least 50,000 prescription mentions per year; or,
- The drug is in a class or for an indication for which additional therapeutic options for the pediatric population are needed.

FDA then identified each of the 583 applications that would likely have needed additional pediatric studies had this rule been in effect. The number and type of studies needed were projected based on specific decision rules derived from agency experience in reviewing drug applications and developed strictly for the purpose of estimating the regulatory costs of this rule. Although in practice, these rules would have been subject to numerous exceptions, in the aggregate, FDA believes that they provide plausible estimates of the total number and type of pediatric studies that would have been required. The decision rules were as follows:

1. All New Chemical Entities (NCE's) and biologicals were assumed to need both an efficacy study and a PK study for each age group identified in the priority section of the ''List'' as needing pediatric information, although FDA believes that this assumption overstates the true number of efficacy studies that will be needed.

2. For the following categories of applications, both an efficacy and a PK study were assumed for each designated age group. Again, FDA believes that this assumption may overstate the true number of efficacy studies that will be needed:

Neurological drugs;
Oncology drugs;
Nausea agents;
Pulmonary agents;
NSAIDs—arthritis/pain;
AIDS/HIV agents;
Asthma drugs;
Anesthesia drugs;
Hormones;
Dermatological agents;
Acne agents

3. A PK study alone was assumed sufficient for each relevant age group for the following types of non-NCE applications:

Allergies;
Infectious diseases;
Cardiovascular diseases;
Imaging agents;
Hematology agents;
GI disorders;
Urologic drugs

4. If pediatric labeling was already adequate as the result of an approved application, additional applications for new dosage forms were assumed to be exempt.

5. If a second applicant sought approval for the same indication of the same drug as a previous applicant that had already satisfied the pediatric labeling requirements, the second applicant was considered exempt from the pediatric labeling requirement.

6. Because the regulation imposes requirements only on new NDA's or efficacy supplements that specifically address an indication needing pediatric data, no pediatric requirements were assumed for an NDA supplement submitted for a new indication not identified as needing pediatric data.

7. Orphan drugs were excluded from additional research requirements.

The results of this analysis (see Table 3 of this document) show that about 44 percent, or an estimated 255, of the total 583 drug and biological applications for the products on the priority section of the ''List'' drugs approved over the 5-year period would have required additional pediatric studies, had the rule been in effect starting in 1993. Assuming separate studies for each pediatric age group specified in the ''List,'' indicates that an estimated 459 efficacy studies and 713 PK studies would have been required for these applications.

These estimates understate the required research effort, however, because they omit pediatric studies for drugs that fail to gain approval. It is difficult to judge how much additional pediatric research would be directed towards nonapprovable products. The agency notes, however, that because only about 63.5 percent of all NME's that enter phase III trials are eventually approved (Ref. 18), the number of drugs entering phase III trials is about 58 percent greater than the number of actual approvals (100/63.5 = 1.58). Moreover, there are two additional complications. First, under the rule, FDA expects to defer for several years the conduct of pediatric studies of ''me-too'' drugs that do not offer a meaningful therapeutic benefit and that are members of a drug class that already contains an adequate number of approved products with pediatric labeling. No additional pediatric studies would be expected for this group of never approved drugs. On the other hand, applications for ''lifesaving'' drugs may need to begin pediatric trials by the start of Phase II. On the assumption that these two factors would roughly offset, FDA has retained the 58 percent figure as a reasonable adjustment factor to account for the number of studies conducted for drugs that fail to gain approval. Finally, each year, the agency expects to identify about two ''already marketed'' drugs that require additional pediatric efficacy data.

As shown in Table 4 of this document, adjusting for the ''never approved'' and the ''already marketed'' applications implies that, had this rule become effective in 1993, about 1,892 new pediatric studies would have been required over the 1993 to 1997 period. About 740 of the studies would have been efficacy studies and 1,151 PK studies. Thus, on average, each year, the rule would have required about 378 new pediatric studies for about 82 NDA's and or NDA supplements—148 efficacy studies and 230 PK studies.

TABLE 3.—APPROVED NEW DRUG APPLICATIONS AND THEIR SUPPLEMENTS FROM 1993 TO 1997

Approval year	Applications for "List" Drugs	Applications needing pediatric studies	Efficacy studies required	PK studies required	Total studies required	New dosage forms
1993	77	43	63	122	185	12
1994	76	42	74	118	192	17
1995	107	38	69	107	176	13
1996	177	74	147	213	360	29
1997	146	58	106	153	259	19
Total	583	255	459	713	1,172	90
Average	117	51	92	143	234	18

TABLE 4.—ALL NEW DRUG APPLICATIONS AND THEIR SUPPLEMENTS FROM 1993 TO 1997 [1]

Approval year	Applications for "List" Drugs [2]	Applications needing pediatric studies	Efficacy studies required	PK studies required	Total studies required	New dosage forms
1993	124	69	102	197	299	22
1994	123	68	119	190	310	32
1995	173	61	111	173	284	24
1996	286	119	237	344	581	54
1997	236	94	171	247	418	35
Total	942	411	740	1,151	1,892	167
Average	188	82	148	230	378	33

[1] Includes estimates for "unapproved" and "already marketed" drugs.
[2] Adjusted for "unapproved" and "already marketed" drugs.

C. Number of Pediatric Patients

The number of pediatric patients needed varies with the particular type of drug studied. However, based on agency experience, FDA estimates that, for each pediatric age group studied, typical pediatric PK studies may involve about 15 patients and typical efficacy studies about 50 patients. For example, if 2 of the 4 age groups lack PK studies, FDA assumed that a total of 30 subjects would be needed for the studies. If 3 of the 4 age groups lack efficacy studies, a total of 150 subjects were assumed to be needed in all 3 age groups. These assumptions indicate that, had this rule become effective in 1993, each year, about 82 NDA's would have required additional pediatric studies; 7,408 pediatric patients in efficacy studies and 3,452 pediatric patients in PK studies, for an annual total of about 10,860 pediatric patients.

D. Costs of Compliance

1. Cost of Pediatric Studies

FDA's analysis of the proposal assumed that new studies would cost pharmaceutical firms from $5,000 to $9,000 per pediatric patient. Only one comment, that of a large U.S. pharmaceutical company, submitted actual estimates of the cost of conducting pediatric trials. This comment stated that a PK or bioavailability/bioeqivalency study of 20 patients would cost at least $100,000, a Phase II trial of 50 patients would cost a minimum of $150,000, and a Phase III trial of 100 patients would cost $200,000. For its revised analysis, therefore, FDA assumes that a PK study of 15 patients will cost $100,000 per affected age group and that an efficacy study of 50 patients will cost $150,000 per affected age group. Although a few trials may need to be larger and, thus more expensive; others will require substantially fewer pediatric patients. Thus, FDA believes these figures reasonably project the average added costs.

As FDA estimates that the regulation would have required pharmaceutical companies to annually conduct an estimated 378 additional pediatric studies for 82 NDA's, 148 efficacy studies, and 230 PK studies; the above unit cost estimates imply total industry costs of $45 million annually. Although the industry comment that included the cost data projected clinical trial costs totaling over $100 million per year, this estimate assumed the need for 34,000 additional pediatric patients. FDA found that had this rule been in place over the 1993 to 1997 period, it would have required additional data from about 10,860 patients per year.

2. Cost of New Formulations

In its earlier analysis of the proposal, FDA calculated that about 30 percent of all NME's were available only in tablets or hard capsules at the time of approval. Acknowledging the potential difficulties of developing new formulations for certain drugs, FDA estimated that the overall costs could average $1 million for each new formulation developed. Several comments questioned the agency's estimates. Based on an informal survey of its members, a major industry trade association reported that the development of a pediatric formulation could take from 5 months to 4 years and cost from $500,000 to $3.5 million. It also objected to the agency's estimate of the number of drugs that would require reformulation. The association, however, apparently misunderstood FDA's methodology. The agency had found that 10 of 14 drugs per year would not need reformulation because a potentially adequate dosage form (liquid, an injectable, a solution, a dermatological, etc.) was already available. The association believed that FDA has assumed that only tablets and/or capsules were available for the ten drugs. None of these comments,

however, offered an alternative methodology for projecting the aggregate value of these costs.

To develop reasonable estimates of the number of new dosage forms that would be needed, FDA again reviewed all of the 255 approved drug applications that would likely have required new pediatric studies during the 1993 to 1997 period, had this rule been in place. The agency generally assumed that those drugs identified as having a meaningful clinical pediatric benefit for the youngest three age groups, but available only in tablets or hard capsules at the time of approval, would have needed to develop an alternative dosage form. The agency also assumed that a new pediatric formulation would not be counted if a more appropriate pediatric dosage form was subsequently approved for the same drug. FDA is aware that these estimates can not be considered precise. For example, not all liquids are adequate for pediatric populations. On the other hand, new formulations may not be needed if a drug is used primarily for children between the ages of 8 and 12 years. Nevertheless, as shown in Table 3 of this document, the results of this methodology show that about 35 percent of the approved applications needing studies, or about 18 per year, would have needed new dosage forms. Table 4 of this document raises this estimate by 83 percent, or to 33 per year, to account for the number of new dosage forms developed for drugs not subsequently approved. While FDA cannot confidently predict a typical initiation time for this effort, the 83 percent adjustment calculation assumes that work on about 25 percent of all new formulations would be initiated at the start of Phase 2 trials and 75 percent by the start of Phase 3 trials. (The probability of approval was assumed to be .635 for a drug entering phase 3 trials and .31 for a drug entering phase 2 trials (Ref. 18).)

The development of some pediatric formulations will be difficult, the development of others relatively straightforward and achieved without substantial problem. The rule requires only that sponsors take all reasonable steps to develop needed new formulations. Thus, while acknowledging that the cost for particularly difficult formulations may be higher, FDA has retained its average cost estimate of $1 million to develop each new dosage form and projects this total industry cost at nearly $33 million per year.

3. Cost of Added Paperwork Requirements

The rule also requires additional industry effort for new or expanded paperwork reporting. Section VI of this document describes these reporting tasks, discusses the industry comment that questioned the agency's estimate of the paperwork burden for the proposal, and presents the agencies revised estimate for this final rule. As shown in that section, FDA projects an annual burden of about 40,000 hours per year. On the assumption that 25 percent of these hours will be for upper management staff, 50 percent for middle management staff, and 25 percent for administrative and clerical support, at respective labor costs of $52, $34, and $17 per hour, FDA estimates these total paperwork costs at about $1.4 million per year.

4. Total Costs

Table 5 of this document summarizes the agency's estimates of costs for efficacy studies, PK studies, new dosage forms, and paperwork. Because the expense of pediatric trials and dosage form development will be spread over 2 or 3 years for any given drug, the total costs to industry in any given year are unlikely to vary as much as shown in Table 5. Most importantly, however, the average $80.1 million annual cost figure reflects only what the rule would have cost had the rule been in effect from 1993 to 1997. The incentives generated by the additional 6-month marketing exclusivity offered by FDAMA will reduce the future costs of the regulation.

TABLE 5.—ESTIMATED INDUSTRY COSTS—COMPLIANCE WITH PEDIATRIC LABELING

[in millions]

Year	Efficacy studies	PK studies	New dosage form developed	Paperwork	Total
1993	$15.3	19.7	22.3	1.4	58.6
1994	17.9	19.0	31.6	1.4	69.9
1995	16.7	17.3	24.1	1.4	59.5
1996	35.6	34.4	53.9	1.4	125.2
1997	25.7	24.7	35.3	1.4	87.0
Average Per Year	$22.2	$23.0	$33.4	$1.4	$80.0

FDA cannot develop precise adjustments for the forthcoming effects of FDAMA, due to the complexity of the economic forecasting that would be needed. Nevertheless, the agency developed rough projections of the potential impact of this statute by comparing the estimated present value of the 6-month exclusivity gain with the estimated cost of the new pediatric studies, for each of the 85 drugs with applications approved in 1993 and 1994 that would have needed new pediatric labeling. (More recent years were not used, because the revenues of newer drugs are far below their peak values.) Where the estimated exclusivity gain exceeded the cost of all required studies, including the development of new dosage forms, FDA concluded that the studies for that drug would have been initiated voluntarily and their cost attributable to FDAMA rather than to this regulation.

The methodology assumed that a 6-month gain of marketing exclusivity would be worth about 25 percent of a drug's annual sales revenue during the year the exclusivity is needed, less 60 percent for production, administrative, and marketing costs (Ref. 19). Costs of conducting the required studies for each of the 85 drugs were based on the cost estimates described previously ($150,000 for each efficacy study, $100,000 for each PK study, and $1 million for each new dosage form. The present value of the additional revenues (at a 7 percent discount rate) were calculated from 1997 sales data published by IMS America (Ref. 20). Because 1997 sales revenues probably underestimate the sales revenues that will be realized at the time that the added exclusivity is used, this methodology likely underestimates the effects of FDAMA, hence overestimating the costs of the rule. In general,

however, this analysis was insensitive to the precise assumptions used. For example, using an 11 percent rather than 7 percent discount rate raises the cost totals by only $1.2 million per year.

The analysis found that the necessary studies would have been conducted voluntarily for 56 out of the 85 affected applications (66 percent). Adjusting estimates of only the approved applications by this percentage (FDAMA was not assumed to affect studies for applications not obtaining approval), FDA projects that the annual costs attributable to this rule will be approximately $46.7 million, or about 42 percent below the non-FDAMA adjusted figure of $80 million.

Further, although the agency has not yet evaluated the full economic impact of the FDAMA legislation, it believes that the present value of the net revenues expected from the 6 months of added exclusivity granted under the new FDAMA legislation will greatly exceed the additional costs imposed by this regulation. One industry publication (MedAdNews, June 1998, p. 10) for example, reports that products currently valued at $41 billion in annual sales will come off patent between 1998 and 2008, or an average of $11 billion per year. Alternatively, FDA estimates that the annual revenues for NCE's coming off patent may average between $200 and $300 million each. If 25 NCE's lose exclusivity each year, these annual revenues would range from $5 billion to $7.5 billion. If only 60 percent of these NCE's become eligible for extended exclusivity, the methodology described above implies that industry net incomes will increase from $300 to $450 million per year. Thus, FDAMA and this rule, taken together, will provide critical pediatric information without diverting current resources from pharmaceutical innovation.

COM041COM041*E. Benefits*

The rule addresses two major problems associated with the lack of adequate information on the effects of drugs on pediatric patients: (1) Adverse drug reactions in children due to inadvertent drug overdoses or other drug administration problems that could be avoided with better information on appropriate pediatric use; and (2) under use of safe and effective drugs for children due to the prescribing of an inadequate dosage or regimen, a less effective drug, or no drug at all because of uncertainty over the drug's effect on children or the unavailability of a pediatric formulation. By developing improved information on whether, and in what dosage, a drug is safe and effective for use in children, FDA believes that the regulation will result in fewer adverse drug reactions and fewer instances of less-than-optimal treatment of pediatric patients.

Despite numerous reports of children endangered by the absence of adequate drug labeling, FDA has found no systematic studies in the literature that evaluate the overall magnitude of the harm that results from the incomplete labeling of drugs for use in children. In the preamble to the proposal, the agency specifically requested, ''information on any available studies or data related to the incidence and costs of either undertreatment or avoidable ADE's in pediatric age groups due to the lack of information on the effects of pharmaceuticals.'' The comments received cited case after case of children who have died or suffered because of the inadequate testing of drugs in children, but the information was largely anecdotal and related to particular instances of drug misuse or underuse.

For example, physicians who care for HIV-infected patients expressed frustration at their inability to treat children with drugs known to be effective in adults. Pulmonary specialists described the dearth of information on risks versus benefits of new antimicrobials for pediatric patients, citing the example of ciprofloxacin, a quinolone that may be valuable in treating cystic fibrosis, although the safety and effectiveness of the drug in children has not been established. Comments received from asthma specialists reaffirmed the difficulties of administering medications, treating drug side effects, or withholding treatment for children with asthma, due to the lack of research on drug safety and effectiveness.

In both written comments and in commentary at the public hearing in October 1997, concerns were raised about the costs of not implementing a requirement for pediatric labeling. Avoidable adverse outcomes, cited in relation to pediatric dosage problems, included opportunistic infections from too much immunosuppression, and loss of grafts in pediatric renal transplant patients with too little immunosuppression. Comments also cited added health care, including increased hospitalizations, required as a result of less effective treatment for pediatric patients. One comment estimated the cost of delayed access in terms of infant deaths, attributing an additional 2,000 unnecessary infant deaths over a 2-year period to the delay in access to AZT for HIV-exposed infants. Another suggested using the Vaccine Injury Compensation program figure of $250,000 per child as the value of an avoided death resulting from an ADR. Other comments confirmed that many adverse outcomes develop quickly and would be detected in early clinical studies (e.g., ''gray syndrome'' in babies treated with chloramphenicol).

While clearly demonstrating the critical need for improved pediatric information, these comments do not suggest a practical methodology for quantifying the aggregate benefits of this rule. FDA, also, has been unable to develop a precise assessment of the probable regulatory benefits. The agency's approach to estimating regulatory benefits therefore is framed in terms of the following two questions: (1) Are data available to assess current differences in the *safety* of drug therapy for adults versus children with the same condition? and (2) Are data available to assess current differences in the *effectiveness* of drug therapy for adults versus children with the same condition?

FDA first attempted to assess the *safety* of drug therapy by looking for differences in the frequency and severity of ADR's for adults versus children treated for the same condition. The available clinical and health survey data, however, did not provide a reliable estimate of the contribution of ADR's to pediatric as compared to adult rates of mortality and morbidity. ADR-related data are limited by the lack of a general requirement and a ready mechanism for the comprehensive reporting of incidents directly attributable to ADR's (Ref. 21). Moreover, most available studies have not addressed ADR rates and associated death rates by age group within a treated condition (Refs. 22, 23, and 24). For example, one study of pediatric patients shows an ADR-related admission rate in the range of only 2.0 to 3.2 percent, well below the average for adult and pediatric studies combined. Pediatric cancer patients, however, experienced a 22 percent ADR-admission rate (Ref. 25), suggesting that pediatric risks may be significantly greater within condition-defined subpopulations. In addition, potential concerns about negative public attention (Ref. 26) or liability inhibit reporting of ADR's. Finally, for many seriously ill patients, it is very difficult to attribute a specific medical outcome to a particular medication, as opposed to some other complication in the patient's condition, or misadventure in the patient's care. The agency found therefore that it could not rely on available ADR studies to derive an assessment of the potential benefits of this rule.

Data to assess the *effectiveness* of drug therapy would indicate differences in clinical outcomes, or in other health care utilization concomitant with drug therapy. If drug therapies for children were less effective than that for adults with the same condition, one might see longer recovery times, or lower recovery rates, together with increased health services use, assuming a similar prognosis and course of illness. A limitation to this approach is that the prognosis and course of illness may not be the same in children and adults with the same serious health condition, even if the same drugs were included in best-practice treatment. Moreover, differential patterns of health care utilization may reflect variations in physician practice patterns, insurance benefits, or patient and family behavior and preferences, rather than measures of drug effectiveness. Notwithstanding such limitations, comparisons of health care resource use for one therapeutic approach compared to another are commonly used in evaluations of therapy effectiveness in the field of pharmacoeconomics. In this instance, FDA finds that health care utilization data may provide at least an indirect indication of potential benefits. Hospitalization rates, in particular, are the most extensively studied measure of morbidity related to adverse drug reactions and of quality of care for a number of chronic (e.g., asthma) and acute conditions (e.g., pneumonia) (Refs. 27 and 28). While hospitalizations due to adverse drug reactions or drug therapy undertreatment are not always recognized, these admissions are routinely classified with a primary diagnosis of the underlying disease. FDA therefore has relied on diagnosis-related hospitalization rates to develop an order-of-magnitude assessment of the potential benefits of this rule.

For this assessment, the agency compared rates of hospitalization of pediatric patients to rates of hospitalization of adult patients for several important disease conditions. Next, the agency examined the potential direct and indirect cost savings that would be realized by diminishing any age-related disparities. The pediatric population was defined to be all persons under the age of 15 and the comparison group to be those adults between the ages of 15 and 44. (The exclusion of older adult patients minimizes the confounding effect of the age-related increased morbidity and mortality.) Comparisons were limited to asthma, HIV/AIDS, cancer, pneumonia, and kidney infection, as these conditions are life threatening, occur in both adults and children, and comparable data are available for adult and pediatric patients. Moreover, reports received in the FDA Spontaneous Reporting System (SRS) in 1993 indicated that the therapeutic areas for which the highest number of ADR's were reported for patients under age 15, relative to the number reported for patients 15 to 44, included those for anti-infectives, pulmonary drugs and oncology drugs.

Direct costs were based on the estimated number of cases, hospitalization rates, and length of stay for each of the selected conditions. The number of cases reported were based on national health survey (Ref. 29) and public surveillance data (Refs. 30, 31, and 32). In 1994, the total number of cases for these 5 conditions, in patients under age 15, was approximately 6.65 million. The total number of cases for patients ages 15 to 44 was approximately 8.3 million. The number of hospitalizations per year for which the selected condition was the primary diagnosis was obtained from the National Hospital Discharge Survey (Ref. 33). As shown in Table 6 of this document, the pediatric hospitalization rate exceeded the adult rate for all five conditions.

TABLE 6.—HOSPITALIZATION RATES PER PATIENT PER YEAR

Primary diagnosis	Rate under age 15	Rate for ages 15–44
Asthma	.045	.024
HIV/AIDS	.533	.233
Cancer	4.247	3.903
Pneumonia	.147	.129
Kidney Infection	.191	.073

The average length of hospital stay (ALOS) for patients with the selected condition as the primary diagnosis (based on ICD–9 code) was obtained from recent hospital survey data (Ref. 34), the average cost per day of inpatient hospital care for each of the selected conditions was based on hospital charge data reported in the survey (Ref. 35), and the cost of physician services associated with each episode of hospitalization was based on physician charge data (Ref. 36). Each episode of care was assumed to include physician charges for emergency room service, daily inpatient visits, and a postdischarge office visit. For cancer hospitalizations, daily inpatient visits and a followup office visit were included. The calculation of indirect costs assumed 8 hours of parental time away from work for each episode of hospitalization and income and productivity losses based on average employee compensation, as reported in the 1997 U.S. Statistical Abstract. A detailed description of all assumptions, calculations, and data sources is included in the full agency report (Ref. 37).

The assumed hypothesis is that a substantial fraction of the difference between pediatric and adult hospitalization rates for like disease conditions are attributable to the greater range of drug therapies and better information on drug dosages for adults. FDA cannot estimate the precise magnitude of the relevant fraction. Nevertheless, if the differentials between pediatric and adult hospitalization rates were reduced by 25 percent, the resulting direct cost savings would be $228 million, with indirect cost savings of $5.3 million per year. If the differentials were reduced by as much as 50 percent, the direct cost savings would be $456 million per year, with indirect savings of $10.6 million. Even if the differentials were as low as 10 percent, the resulting reductions in hospitalization would lead to direct cost savings of $91.2 million, with indirect savings of $2.1 million per year.

The timing of the benefit after the rule's implementation is uncertain. The previous values represent the potential benefit over time as the safety and effectiveness of drugs are more extensively tested, new and already marketed drugs become labeled for use in children, and new formulations and dosage forms are developed to facilitate therapy for children. The figures may overestimate the impact for the selected conditions over the next few years, but may underestimate the potential benefits for these patients in the longer term if there is an increasing prevalence of asthma, cancer, and respiratory and other infectious diseases in the pediatric population. Thus, the lower reduction estimate may be more realistic in the near-term, with the higher reduction estimates offering a better indication of longer-term benefit.

As discussed previously, FDA believes that the new FDAMA statute will cause some of these pediatric studies to be conducted voluntarily. In its assessment of costs, the agency found that about two-thirds of the applications for approved drugs needing pediatric studies may be undertaken voluntarily due to the incentives established by FDAMA. Adjusting the previous medical cost savings by a similar ratio suggests that if all of the new pediatric studies achieved a 25 percent reduction in the pediatric/adult hospitalization differentials, the additional studies prompted by this rule would yield

annual savings of $76 million for just those five diseases. This estimate may represent a lower bound on the benefits to pediatric patients, however, because a number of other disease conditions are also common to children and adults, including such life-threatening conditions as hypertensive disease and renal disease. These pediatric populations also would experience significant benefits from increased safety and access to drug treatments currently available only to adult patients. Moreover, the analysis omits any quantification of benefits for reduced pain and suffering and reduced pediatric mortality. Thus, the full benefits of the rule could easily exceed $100 million per year. Therefore, in accordance with the SBREFA, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (the Administrator) has determined that this rule is likely to result in an annual effect on the economy of $100 million or more and thus is a major rule for the purpose of congressional review.

F. Small Entities

The rule will impose a burden on relatively few small entities, because new drug development is typically an activity completed by large multinational firms. Only one industry comment questioned the agency's determination that the rule would not have a significant effect on a substantial number of small entities. That comment indicated that about 1,500 small entities are conducting diagnostic and therapeutic R&D in the United States and that ''[c]ontributions to new drug approvals by the 'biotech' and 'small pharma' sector are increasing year by year, and the pace of change will—almost certainly—continue.''

FDA agrees that small firms contribute substantially to the early development of many new drugs and biologicals. Nevertheless, because of the considerable resources needed for clinical testing and marketing, the agency finds that very few of these small firms retain ownership and control through the large-scale clinical testing and approval stages. Moreover, many of the products that are sponsored by small companies are eligible for orphan designation and therefore exempted from this rule. To approximate the number of small firms that might be significantly affected, FDA determined the sponsor company size for all of the approved applications that may have required additional pediatric studies had this rule been in place over the years from 1993 to 1997. The agency found that, on average, based on the Small Business Administration's definition of a small firm, only three approved applications per year were submitted by small companies. Multiplying by the previously described 1.58 factor to account for unapproved applications increases this estimate of the number of small entities that may have been significantly affected by this rule to just five small firms per year. Because the agency has certified that the rule will not impose a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act does not require the agency to prepare a Regulatory Flexibility Analysis. Moreover, the agency further points out that the required new studies will comprise a very small part of the total cost of developing new drugs or biologics, which is generally estimated in the hundreds of millions of dollars for each new drug.

G. Regulatory Alternatives

The agency carefully examined two major alternatives to the final rule. The first alternative considered was the initial proposal, which covered only NCE's. The estimated cost of this alternative, excluding the FDAMA adjustment, would be about $40 million, or roughly 50 percent of the cost of the final rule. The agency rejected this alternative because of the predominant view of the medical community that additional pediatric data were needed for all of the drugs and biologicals that may be therapeutically significantly in pediatric populations, not just for the new chemical entities.

The other major alternative considered was to delay implementation of the rule until the effects of the new FDAMA statute were reviewed. FDA fully expects the FDAMA exclusivity provisions to provide a substantial incentive to conduct large numbers of pediatric studies. Nevertheless, the agency finds that relying on these incentives, alone, would leave numerous gaps in many important areas of pediatric labeling. For example, as described earlier in this preamble, voluntary research may overlook studies for many important drugs, especially where such studies require the development of new pediatric dosage forms. Thus, notwithstanding FDAMA incentives, FDA has determined that this regulation is necessary to protect the pediatric population and that further delay is not warranted.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Pina, L.M., Drugs Widely Used off Label in Pediatrics, Report of the Pediatric Use Survey Working Group of the Pediatric Subcommittee, in News Along the Pike, January 1997.

2. Food and Drug Administration, Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements, May 1998.

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List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 201, 312, 314, and 601 are amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.23 is added to subpart A to read as follows:

§ 201.23 Required pediatric studies.

(a) A manufacturer of a marketed drug product, including a biological drug product, that is used in a substantial number of pediatric patients, or that provides a meaningful therapeutic benefit over existing treatments for pediatric patients, as defined in §§ 314.55(c)(5) and 601.27(c)(5) of this chapter, but whose label does not provide adequate information to support its safe and effective use in pediatric populations for the approved indications may be required to submit an application containing data adequate to assess whether the drug product is safe and effective in pediatric populations. The application may be required to contain adequate evidence to support dosage and administration in some or all pediatric subpopulations, including neonates, infants, children, and adolescents, depending upon the known or appropriate use of the drug product in such subpopulations. The applicant may also be required to develop a pediatric formulation for a drug product that represents a meaningful therapeutic benefit over existing therapies for pediatric populations for whom a pediatric formulation is necessary, unless the manufacturer demonstrates that reasonable attempts to produce a pediatric formulation have failed.

(b) The Food and Drug Administration (FDA) may by order, in the form of a letter, after notifying the manufacturer of its intent to require an assessment of pediatric safety and effectiveness of a pediatric formulation, and after offering an opportunity for a written response and a meeting, which may include an advisory committee meeting, require a manufacturer to submit an application containing the information or request for approval of a pediatric formulation described in paragraph (a) of this section within a time specified in the order, if FDA finds that:

(1) The drug product is used in a substantial number of pediatric patients for the labeled indications and the absence of adequate labeling could pose significant risks to pediatric patients; or

(2) There is reason to believe that the drug product would represent a meaningful therapeutic benefit over

existing treatments for pediatric patients for one or more of the claimed indications, and the absence of adequate labeling could pose significant risks to pediatric patients.

(c)(1) An applicant may request a full waiver of the requirements of paragraph (a) of this section if the applicant certifies that:

(i) Necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed, or

(ii) There is evidence strongly suggesting that the product would be ineffective or unsafe in all pediatric age groups.

(2) An applicant may request a partial waiver of the requirements of paragraph (a) of this section with respect to a specified pediatric age group, if the applicant certifies that:

(i) The product:

(A) Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group, *and*

(B) Is not likely to be used in a substantial number of patients in that age group, *and*

(C) The absence of adequate labeling could not pose significant risks to pediatric patients; *or*

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of patients in that age group is so small or geographically dispersed, or

(iii) There is evidence strongly suggesting that the product would be ineffective or unsafe in that age group, or

(iv) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(3) FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraphs (c)(2) or (c)(3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

(d) If a manufacturer fails to submit a supplemental application containing the information or request for approval of a pediatric formulation described in paragraph (a) of this section within the time specified by FDA, the drug product may be considered misbranded or an unapproved new drug or unlicensed biologic.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

3. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 371; 42 U.S.C. 262.

4. Section 312.23 is amended by redesignating paragraph (a)(10)(iii) as paragraph (a)(10)(iv) and adding new paragraph (a)(10)(iii) to read as follows:

§ 312.23 IND content and format.

(a) * * *

(10) * * *

(iii) *Pediatric studies.* Plans for assessing pediatric safety and effectiveness.

* * * * *

5. Section 312.47 is amended by revising paragraph (b)(1)(i) and the first sentence of paragraph (b)(1)(iv), by removing the fifth sentence of paragraph (b)(1)(v) and adding two sentences in its place, by revising the heading of paragraph (b)(2) and the second and last sentences of the introductory text of paragraph (b)(2), and by redesignating paragraph (b)(2)(iii) as paragraph (b)(2)(iv) and by adding new paragraph (b)(2)(iii) to read as follows:

§ 312.47 Meetings.

* * * * *

(b) * * *

(1) *End-of-Phase 2 meetings*—(i) *Purpose.* The purpose of an end-of-phase 2 meeting is to determine the safety of proceeding to Phase 3, to evaluate the Phase 3 plan and protocols and the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

* * * * *

(iv) *Advance information.* At least 1 month in advance of an end-of-Phase 2 meeting, the sponsor should submit background information on the sponsor's plan for Phase 3, including summaries of the Phase 1 and 2 investigations, the specific protocols for Phase 3 clinical studies, plans for any additional nonclinical studies, plans for pediatric studies, including a time line for protocol finalization, enrollment, completion, and data analysis, or information to support any planned request for waiver or deferral of pediatric studies, and, if available, tentative labeling for the drug. * * *

(v) *Conduct of meeting.* * * * The adequacy of the technical information to support Phase 3 studies and/or a marketing application may also be discussed. FDA will also provide its best judgment, at that time, of the pediatric studies that will be required for the drug product and whether their submission will be deferred until after approval. * * *

(2) *''Pre-NDA'' and ''pre-BLA'' meetings.* * * * The primary purpose of this kind of exchange is to uncover any major unresolved problems, to identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness, to identify the status of ongoing or needed studies adequate to assess pediatric safety and effectiveness, to acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information), to discuss appropriate methods for statistical analysis of the data, and to discuss the best approach to the presentation and formatting of data in the marketing application. * * * To permit FDA to provide the sponsor with the most useful advice on preparing a marketing application, the sponsor should submit to FDA's reviewing division at least 1 month in advance of the meeting the following information:

* * * * *

(iii) Information on the status of needed or ongoing pediatric studies.

* * * * *

6. Section 312.82 is amended by revising the last sentence of paragraph (a) and by removing the second sentence of paragraph (b) and adding two sentences in its place to read as follows:

§ 312.82 Early consultation.

* * * * *

(a) *Pre-investigational new drug (IND) meetings.* * * * The meeting may also provide an opportunity for discussing the scope and design of phase 1 testing, plans for studying the drug product in pediatric populations, and the best approach for presentation and formatting of data in the IND.

(b) *End-of-phase 1 meetings.* * * * The primary purpose of this meeting is to review and reach agreement on the design of phase 2 controlled clinical trials, with the goal that such testing will be adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, and to discuss the need for, as well as the design and timing of, studies of the drug in pediatric patients. For drugs for life-threatening diseases, FDA will provide its best judgment, at that time, whether pediatric studies will be required and whether their submission will be deferred until after approval. * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

7. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 371, 374, 379e.

8. Section 314.50 is amended by adding paragraph (d)(7) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(d) * * *

(7) *Pediatric use section.* A section describing the investigation of the drug for use in pediatric populations, including an integrated summary of the information (the clinical pharmacology studies, controlled clinical studies, or uncontrolled clinical studies, or other data or information) that is relevant to the safety and effectiveness and benefits and risks of the drug in pediatric populations for the claimed indications, a reference to the full descriptions of such studies provided under paragraphs (d)(3) and (d)(5) of this section, and information required to be submitted under § 314.55.

* * * * *

9. Section 314.55 is added to subpart B to read as follows:

§ 314.55 Pediatric use information.

(a) *Required assessment.* Except as provided in paragraphs (b), (c), and (d) of this section, each application for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Where the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, FDA may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies. Studies may not be needed in each pediatric age group, if data from one age group can be extrapolated to another. Assessments of safety and effectiveness required under this section for a drug product that represents a meaningful therapeutic benefit over existing treatments for pediatric patients must be carried out using appropriate formulations for each age group(s) for which the assessment is required.

(b) *Deferred submission.* (1) FDA may, on its own initiative or at the request of an applicant, defer submission of some or all assessments of safety and effectiveness described in paragraph (a) of this section until after approval of the drug product for use in adults. Deferral may be granted if, among other reasons, the drug is ready for approval in adults before studies in pediatric patients are complete, or pediatric studies should be delayed until additional safety or effectiveness data have been collected. If an applicant requests deferred submission, the request must provide a certification from the applicant of the grounds for delaying pediatric studies, a description of the planned or ongoing studies, and evidence that the studies are being or will be conducted with due diligence and at the earliest possible time.

(2) If FDA determines that there is an adequate justification for temporarily delaying the submission of assessments of pediatric safety and effectiveness, the drug product may be approved for use in adults subject to the requirement that the applicant submit the required assessments within a specified time.

(c) *Waivers*—(1) *General.* FDA may grant a full or partial waiver of the requirements of paragraph (a) of this section on its own initiative or at the request of an applicant. A request for a waiver must provide an adequate justification.

(2) *Full waiver.* An applicant may request a waiver of the requirements of paragraph (a) of this section if the applicant certifies that:

(i) The drug product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and is not likely to be used in a substantial number of pediatric patients;

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed; or

(iii) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in all pediatric age groups.

(3) *Partial waiver.* An applicant may request a waiver of the requirements of paragraph (a) of this section with respect to a specified pediatric age group, if the applicant certifies that:

(i) The drug product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients in that age group, and is not likely to be used in a substantial number of patients in that age group;

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of patients in that age group is so small or geographically dispersed;

(iii) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in that age group; or

(iv) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(4) *FDA action on waiver.* FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraphs (c)(2) or (c)(3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

(5) *Definition of ''meaningful therapeutic benefit''.* For purposes of this section and § 201.23 of this chapter, a drug will be considered to offer a meaningful therapeutic benefit over existing therapies if FDA estimates that:

(i) If approved, the drug would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared to marketed products adequately labeled for that use in the relevant pediatric population. Examples of how improvement might be demonstrated include, for example, evidence of increased effectiveness in treatment, prevention, or diagnosis of disease, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of compliance, or evidence of safety and effectiveness in a new subpopulation; or

(ii) The drug is in a class of drugs or for an indication for which there is a need for additional therapeutic options.

(d) *Exemption for orphan drugs.* This section does not apply to any drug for an indication or indications for which orphan designation has been granted under part 316, subpart C, of this chapter.

10. Section 314.81 is amended by revising paragraph (b)(2)(i) and (b)(2)(vii), and by adding paragraph (b)(2)(vi)(*c*) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(i) *Summary.* A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study. The summary shall briefly state whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

* * * * *

(vi) * * *

(*c*) Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(vii) *Status reports.* A statement on the current status of any postmarketing studies performed by, or on behalf of, the applicant. The statement shall include whether postmarketing clinical studies in pediatric populations were required or agreed to, and if so, the status of these studies, e.g., to be initiated, ongoing (with projected completion date), completed (including date), completed and results submitted to the NDA (including date). To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application.

* * * * *

PART 601—LICENSING

11. The authority citation for 21 CFR part 601 is revised to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263.

12. Section 601.27 is added to subpart C to read as follows:

§ 601.27 Pediatric studies.

(a) *Required assessment.* Except as provided in paragraphs (b), (c), and (d) of this section, each application for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Where the course of the disease and the effects of the product are similar in adults and pediatric patients, FDA may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled effectiveness studies in adults, usually supplemented with other information in pediatric patients, such as pharmacokinetic studies. In addition, studies may not be needed in each pediatric age group, if data from one age group can be extrapolated to another. Assessments required under this section for a product that represents a meaningful therapeutic benefit over existing treatments must be carried out using appropriate formulations for the age group(s) for which the assessment is required.

(b) *Deferred submission.* (1) FDA may, on its own initiative or at the request of an applicant, defer submission of some or all assessments of safety and effectiveness described in paragraph (a) of this section until after licensing of the product for use in adults. Deferral may be granted if, among other reasons, the product is ready for approval in adults before studies in pediatric patients are complete, pediatric studies should be delayed until additional safety or effectiveness data have been collected. If an applicant requests deferred submission, the request must provide an adequate justification for delaying pediatric studies, a description of the planned or ongoing studies, and evidence that the studies are being or will be conducted with due diligence and at the earliest possible time.

(2) If FDA determines that there is an adequate justification for temporarily delaying the submission of assessments of pediatric safety and effectiveness, the product may be licensed for use in adults subject to the requirement that the applicant submit the required assessments within a specified time.

(c) *Waivers*—(1) *General.* FDA may grant a full or partial waiver of the requirements of paragraph (a) of this section on its own initiative or at the request of an applicant. A request for a waiver must provide an adequate justification.

(2) *Full waiver.* An applicant may request a waiver of the requirements of paragraph (a) of this section if the applicant certifies that:

(i) The product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in a substantial number of pediatric patients;

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed; or

(iii) There is evidence strongly suggesting that the product would be ineffective or unsafe in all pediatric age groups.

(3) *Partial waiver.* An applicant may request a waiver of the requirements of paragraph (a) of this section with respect to a specified pediatric age group, if the applicant certifies that:

(i) The product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group, and is not likely to be used in a substantial number of patients in that age group;

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of patients in that age group is so small or geographically dispersed;

(iii) There is evidence strongly suggesting that the product would be ineffective or unsafe in that age group; or

(iv) The applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(4) *FDA action on waiver.* FDA shall grant a full or partial waiver, as appropriate, if the agency finds that there is a reasonable basis on which to conclude that one or more of the grounds for waiver specified in paragraphs (c)(2) or (c)(3) of this section have been met. If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver will cover only those pediatric age groups requiring that formulation. If a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.

(5) *Definition of ''meaningful therapeutic benefit''.* For purposes of this section, a product will be considered to offer a meaningful therapeutic benefit over existing therapies if FDA estimates that:

(i) If approved, the product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared to marketed products adequately labeled for that use in the relevant pediatric population. Examples of how improvement might be demonstrated include, e.g., evidence of increased effectiveness in treatment, prevention, or diagnosis of disease;

elimination or substantial reduction of a treatment-limiting drug reaction; documented enhancement of compliance; or evidence of safety and effectiveness in a new subpopulation; or

(ii) The product is in a class of products or for an indication for which there is a need for additional therapeutic options.

(d) *Exemption for orphan drugs.* This section does not apply to any product for an indication or indications for which orphan designation has been granted under part 316, subpart C, of this chapter.

13. Section 601.37 is added to subpart D to read as follows:

§ 601.37 Annual reports of postmarketing pediatric studies.

Sponsors of licensed biological products shall submit the following information each year within 60 days of the anniversary date of approval of the license, to the Director, Center for Biologics Evaluation and Research:

(a) *Summary.* A brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(b) *Clinical data.* Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(c) *Status reports.* A statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant. The statement shall include whether postmarketing clinical studies in pediatric populations were required or agreed to, and if so, the status of these studies, e.g., to be initiated, ongoing (with projected completion date), completed (including date), completed and results submitted to the BLA (including date).

Dated: November 24, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–31902 Filed 11–27–98; 8:45 am]

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Federal Register

Wednesday
December 2, 1998

Part III

General Services Administration

41 CFR Part 300–3 et al.

Federal Travel Regulation; General and Temporary Duty (TDY) Travel Allowances; Final Rule

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 300–3, 301–11, and 301–12

[FTR Amendment 75—1998 Edition]

RIN 3090–AG86

Federal Travel Regulation; General and Temporary Duty (TDY) Travel Allowances

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: An analysis of lodging and meal cost survey data reveals that the listing of maximum per diem rates for locations within the continental United States (CONUS) should be updated to provide for the reimbursement of Federal employees' expenses covered by per diem. This final rule increases/decreases the maximum lodging amounts in certain existing per diem localities, adds new per diem localities, deletes a number of previously designated per diem localities, removes taxes from lodging rates, allows lodging taxes to be reimbursed as a miscellaneous expense, establishes more than one per diem rate within some counties, lists many previously combined locations separately with different per diem rates, adds additional seasons (up to four) where appropriate, adds one additional meal tier, and allows laundry, cleaning and pressing of clothing expenses (previously included as an incidental expense) as a miscellaneous expense.

EFFECTIVE DATE: This final rule is effective January 1, 1999, and applies to official travel performed on or after January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Jim Harte, telephone (202) 501–0483.

SUPPLEMENTARY INFORMATION:

A. Background

There are significant changes in this final rule, regarding payment of expenses in connection with official travel.

What are the significant changes?

The significant changes are that this rule:

(a) Extracts taxes from lodging rates;

(b) Allows payment of actual costs for lodging taxes as a miscellaneous expense;

(c) Adds additional seasons (up to four) where appropriate;

(d) Provides for more than one per diem rate within a county, where needed;

(e) Separates previously combined locations to provide for separate per diem rates (e.g., Alexandria and Arlington, Virginia, are now listed separately from the District of Columbia);

(f) Provides one new meal and incidental expense (M&IE) tier;

(g) Increases/decreases maximum lodging amounts in certain existing localities;

(h) Removes laundry, cleaning and pressing of clothing from incidental expenses and includes them as reimbursable miscellaneous expenses. The rule requires a minimum of 4 consecutive nights lodging to qualify for miscellaneous laundry expenses reimbursement;

(i) Adds new per diem localities; and

(j) Deletes a number of previously designated per diem localities.

B. Executive Order 12866

The General Services Administration (GSA) has determined that this final rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

C. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed revisions do not impose recordkeeping or information collection requirements, or the collection 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. 501 *et seq.*

E. Small Business Reform Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Parts 300–3, 301–11, and 301–12

Government employees, Travel and transportation expenses.

For the reasons set forth in the preamble, 41 CFR parts 300–3, 301–11, 301–12 and Appendix A to chapter 301 are amended to read as follows:

PART 300–3—GLOSSARY OF TERMS

1. The authority citation for part 300–3 continues to read as follows:

Authority: 5 U.S.C. 5707; 5 U.S.C. 5738; 5 U.S.C. 5741–5742; 20 U.S.C. 905(a); 31 U.S.C. 1353; 40 U.S.C. 486(c); 49 U.S.C. 40118; E.O. 11609, 3 CFR, 1971–1975 Comp., p. 586.

1a. Section 300–3.1 is amended by revising the term ''Per diem allowance'' and removing the term ''Subsistence expenses'', to read as follows:

§ 300–3.1 What do the following terms mean?

* * * * *

Per diem allowance—The per diem allowance (also referred to as subsistence allowance) is a daily payment instead of reimbursement for actual expenses for lodging (excluding taxes), meals, and related incidental expenses. The per diem allowance is separate from transportation expenses and other miscellaneous expenses. The per diem allowance covers all charges, including any service charges where applicable for:

(a) *Lodging.* Includes expenses, except lodging taxes, for overnight sleeping facilities, baths, personal use of the room during daytime, telephone access fee, and service charges for fans, air conditioners, heaters and fires furnished in the room when such charges are not included in the room rate. Lodging does not include accommodations on airplanes, trains, buses, or ships. Such cost is included in the transportation cost and is not considered a lodging expense.

(b) *Meals.* Expenses for breakfast, lunch, dinner and related tips and taxes (specifically excluded are alcoholic beverage and entertainment expenses, and any expenses incurred for other persons).

(c) *Incidental expenses.* (1) Fees and tips given to porters, baggage carriers, bellhops, hotel maids, stewards or stewardesses and others on ships, and hotel servants in foreign countries.

(2) Transportation between places of lodging or business and places where meals are taken, if suitable meals cannot be obtained at the TDY site; and

(3) Mailing cost associated with filing travel vouchers and payment of Government-sponsored charge card billings.

* * * * *

PART 301–11—PER DIEM EXPENSES

2. The authority citation for part 301–11 continues to read as follows:

Authority: 5 U.S.C. 5707.

2a. In § 301–11.18 the table is revised to read as follows:

§ 301–11.18 What M&IE rate will I receive if a meal(s) is furnished at nominal or no cost by the Government or is included in the registration fee?

* * * * *

M&IE	$30	$34	$38	$42	$46
Breakfast	6	7	8	9	9
Lunch	6	7	8	9	11
Dinner	16	18	20	22	24
Incidentals	2	2	2	2	2

3. Section 301–11.27 is revised to read as follows:

§ 301–11.27 Are taxes included in the lodging portion of the Government per diem rate?

No. Lodging taxes paid by you are reimbursable as a miscellaneous travel expense limited to the taxes on reimbursable lodging costs. For example, if your agency authorizes you a maximum lodging rate of $50 per night, and you elect to stay at a hotel that costs $100 per night, you can only claim the amount of taxes on $50, which is the maximum authorized lodging amount.

4. Section 301–11.30 is revised to read as follows:

§ 301–11.30 What is my option if the Government lodging rate exceeds my lodging reimbursement?

You may request reimbursement on an actual expense basis, not to exceed 300 percent of the maximum per diem allowance.

Approval of actual expenses is usually in advance of travel and at the discretion of your agency. (See § 301–11.302.)

5. Section 301–11.31 is added to read as follows:

§ 301–11.31 Are laundry, cleaning and pressing of clothing expenses reimbursable?

Yes. The expenses incurred for laundry, cleaning and pressing of clothing at a TDY location are reimbursable as a miscellaneous travel expense. However, you must incur a minimum of 4 consecutive nights lodging on official travel to qualify for this reimbursement.

PART 301–12—MISCELLANEOUS EXPENSES

6. The authority citation for part 301–12 continues to read as follows:

Authority: 5 U.S.C. 5707.

6a. Section 301–12.1 is revised to read as follows:

§ 301–12.1 What miscellaneous expenses are reimbursable?

When the following items have been authorized or approved by your agency, they will be reimbursed as a miscellaneous expense. Taxes for reimbursable lodging are deemed approved when lodging is authorized. Examples of such expenses include, but are not limited to the following:

General expenses	Fees to obtain money	Special expenses of foreign travel
Baggage expenses as described in § 301–12.2..	Fees for travelers checks	Commissions on conversion of foreign currency.
Services of guides, interpreters, and drivers.	Fees for money orders	Passport and/or visa fees.
Use of computers, printers, faxing machines, and scanners..	Fees for certified checks	Costs of photographs for passports and visas.
Services of typists, data processors, or stenographers..	Transaction fees for use of automated teller machines (ATMs)-Government contractor-issued charge card.	Foreign country exit fees.
Storage of property used on official business.		Costs of birth, health, and identity certificates.
Hire of conference center room or hotel room for official business..		Charges for inoculations that cannot be obtained through a Federal dispensary.
Official telephone calls/service (see note)..		
Faxes, telegrams, cablegrams, or radiograms..		
Lodging taxes as prescribed in § 301–11.27..		
Laundry, cleaning and pressing of clothing expenses as prescribed in § 301–11.31..		

Note to § 301–12.1: You should use Government provided services for all official communications. When they are not available, commercial services may be used. Reimbursement may be authorized or approved by your agency.

7. Appendix A to chapter 301 is revised to read as follows:

Appendix A To Chapter 301—Prescribed Maximum Per Diem Rates for CONUS

The maximum rates listed below are prescribed under part 301–11 of this chapter for reimbursement of per diem expenses incurred during official travel within CONUS (the continental United States). The amount shown in column (a) is the maximum that will be reimbursed for lodging expenses excluding taxes. The M&IE rate shown in column (b) is a fixed amount allowed for meals and incidental expenses covered by per diem. The per diem payment calculated in accordance with part 301–11 of this chapter for lodging expenses plus the M&IE rate may not exceed the maximum per diem rate shown in column (c). Seasonal rates apply during the periods indicated.

It is the policy of the Government, as reflected in the Hotel Motel Fire Safety Act of 1990 (Pub. L. No. 101–391, September 25, 1990 as amended by Pub. L. No. 105–85, November 18, 1997), referred to as ''the Act'' in this paragraph, to save lives and protect property by promoting fire safety in hotels, motels, and all places of public accommodation affecting commerce. In furtherance of the Act's goals, employees are encouraged to stay in a facility which is fire-safe, i.e., an approved accommodation, when commercial lodging is required. Lodgings that meet the Government requirements are listed on the U.S. Fire Administration's Internet site at *http://www.usfa.fema.gov/hotel/index.htm*.

Note: Major changes in the coverage of per diem rates effective in this amendment are:

- Lodging rates do not include any taxes. They are now room rates only. Actual costs paid for lodging taxes may be reimbursed to the traveler as a miscellaneous expense (see 301–11).
- Additional seasons (up to four) have been added where appropriate.
- There may be more than one rate within a county now. Please read the tables carefully.

- Many previously combined locations are now shown separately with different rates (e.g., Alexandria, Arlington, Montgomery County, Prince Georges County, Fairfax County, and Loudoun County, are now listed separately from Washington, DC).
- There is one new M&IE tier: $46.

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Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
CONUS, Standard rate (Applies to all locations within CONUS not specifically listed below or encompassed by the boundary definition of a listed point. However, the standard CONUS rate applies to all locations within CONUS, including those defined below, for certain relocation subsistence allowances. See parts 302-2, 302-4, and 302-5 of this subtitle.)		$50	$30	$80
ALABAMA				
Birmingham	Jefferson	59	38	97
Gulf Shores	Baldwin			
(May 1-September 30)		116	34	150
(October 1-April 30)		50	34	84
Huntsville	Madison	58	38	96
Mobile	Mobile	50	34	84
Montgomery	Montgomery	51	38	89
ARIZONA				
Casa Grande	Pinal			
(January 1-April 30)		80	34	114
(May 1-December 31)		50	34	84
Chinle	Apache			
(April 1-October 31)		80	34	114
(November 1-March 31)		59	34	93
Flagstaff	All points in Coconino County not covered under Grand Canyon per diem area			
(April 1-October 31)		67	34	101
(November 1-March 31)		50	34	84
Grand Canyon	All points in the Grand Canyon National Park and Kaibab National Forest within Coconino County	94	42	136
Kayenta	Navajo			
(June 1-September 30)		92	30	122
(October 1-May 31)		50	30	80
Phoenix	Maricopa (except			

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(January 1-April 30)	Scottsdale)	106	38	144
(May 1-August 31)		62	38	100
(September 1-December 31)		86	38	124
Prescott	Yavapai	50	38	88
Scottsdale	City limits of			
(January 1-April 30)	Scottsdale (see	107	42	149
(May 1-August 31)	Maricopa County)	56	42	98
(September 1-December 31)		79	42	121
Tucson	Pima County;			
(January 1-May 31)	Davis-Monthan	79	38	117
(June 1-December 31)	AFB	58	38	96
Yuma	Yuma	52	34	86
ARKANSAS				
Little Rock	Pulaski	55	34	89
CALIFORNIA				
Barstow	San Bernardino	58	34	92
Bridgeport	Mono (except			
(April 1-October 31)	Mammoth Lakes)	66	42	108
(November 1-March 31		53	42	95
Clearlake	Lake			
(April 1-September 30)		59	38	97
(October 1-March 31)		50	38	88
Contra Costa County	Contra Costa County	69	42	111
Death Valley	Inyo	85	46	131
Eureka	Humboldt			
(May 1-September 30)		59	38	97
(October 1-April 30)		50	38	88
Fresno	Fresno	53	38	91
Gualala	City limits of Gualala (see Mendicino County)	114	38	152
Kern County	Kern County	59	38	97
Los Angeles	Los Angeles; Edwards AFB; Naval Weapons Center and Ordnance Test Station, China Lake	95	46	141
Madera	Madera (except	50	34	84

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	Oakhurst)			
Mammoth Lakes	City limits of			
(November 1-April 30)	Mammoth Lake	85	46	131
(May 1-October 31)	(see Mono County)	62	46	108
Marin County	Marin County	82	42	124
Merced	Merced	58	38	96
Modesto	Stanislaus	58	34	92
Monterey	Monterey			
(June 1-October 31)		94	42	136
(November 1-May 31)		71	42	113
Napa	Napa			
(April 1-October 31)		98	42	140
(November 1-March 31)		75	42	117
Oakhurst	City limits of Oakhurst (except Madera)	76	38	114
Oakland	Alameda	93	38	131
Ontario	San Bernardino	55	38	93
Orange County	Orange County	75	46	121
Palm Springs	Riverside			
(January 1-May 31)		73	42	115
(June 1-August 31)		50	42	92
(September 1-December 31)		55	42	97
Palo Alto	City limits of Palo Alto (see Santa Clara County)	115	42	157
Point Arena	Mendicino (except Gualala)	100	38	138
Redding	Shasta	52	38	90
Redwood City	City limits of Redwood City (see San Mateo County)	94	42	136
Sacramento	Sacramento	79	42	121
San Diego	San Diego	89	46	135
San Francisco	San Francisco	129	46	175
San Jose	Santa Clara (except Palo Alto)	99	46	145
San Luis Obispo	San Luis Obispo	54	38	92
San Mateo	San Mateo (except Redwood	74	42	116

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	City)			
Santa Barbara	Santa Barbara			
(June 1-September 30)		110	38	148
(October 1-May 31)		92	38	130
Santa Cruz	Santa Cruz			
(June 1-September 30)		75	42	117
(October 1-May 31)		55	42	97
Santa Rosa	Sonoma	67	42	109
Stockton	San Joaquin	50	38	88
Sunnyvale	City limits of Sunnyvale (see Santa Clara County)	116	42	158
Tahoe City	Placer	86	42	128
Ventura County	Ventura County	99	38	137
Victorville	City limits of Victorville	60	34	94
Visalia	Tulare	58	38	96
West Sacramento	Yolo	64	30	94
Yosemite Nat'l Park	Mariposa			
(April 1-October 31)		189	46	235
(November 1-March 31)		79	46	125
COLORADO				
Adams County	Adams County	60	38	98
Arapahoe County	Arapahoe County	83	38	121
Aspen	Pitkin			
(January 1-March 31)		163	46	209
(April 1-May 31)		68	46	114
(June 1-December 31)		140	46	186
Boulder	Boulder			
(May 1-October 31)		74	42	116
(November 1-April 30)		64	42	106
Colorado Springs	El Paso			
(May 1-October 31)		73	38	111
(November 1-April 30)		58	38	96
Cortez	Montezuma			
(June 1-September 30)		64	34	98
(October 1-May 31)		50	34	84
Denver	Denver	80	42	122
Durango	La Plata			
(June 1-October 31)		84	38	122
(November 1-May 31)		54	38	92
Fort Collins	Larimer (except			

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(May 1-September 30)	Loveland)	53	34	87
(October 1-April 30)		50	34	84
Glenwood Springs	Garfield	50	38	88
Gunnison	Gunnison			
(June 1-September 30)		69	34	103
(October 1-May 31)		50	34	84
Jefferson County	Jefferson County	61	34	95
Loveland	Qity limits of			
(April 1-September 30)	Loveland (see	65	30	95
(October 1-March 31)	Larimer County)	55	30	85
Montrose	Montrose			
(June 1-September 30)		59	34	93
(October 1-May 31)		50	34	84
Pueblo	Pueblo			
(June 1-September 30)		75	34	109
(October 1-May 31)		67	34	101
Silverstone/Keystone	Summit			
(January 1-April 30)		81	38	119
(May 1-December 31)		62	38	100
Steamboat Springs	Routt			
(December 1-March 31)		59	38	97
(April 1-November 30)		50	38	88
Telluride	San Miguel			
(November 1-March 31)		117	46	163
(April 1-October 31)		75	46	121
Trinidad	Las Animas			
(June 1-October 31)		62	30	92
(November 1-May 31)		50	30	80
Vail	Eagle			
(November 1-March 31)		183	46	229
(April 1-May 31)		104	46	150
(June 1-October 31)		106	46	152
CONNECTICUT				
Bridgeport	City limits of Bridgeport (see Fairfield County)	85	34	119
Danbury	Fairfield (except Bridgeport)	77	38	115
Groton	New London (except New London)	65	30	95

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Hartford	Hartford	85	42	127
Lakeville	Litchfield (except Salisbury)	85	38	123
Middlesex County	Middlesex County	50	34	84
New Haven	New Haven	70	38	108
New London	City limits of New London (see New London County)	93	34	127
Putnam/Danielson	Windham	56	30	86
Salisbury	City limits of Salisbury (see Litchfield County)	95	46	141
Vernon	Tolland	56	34	90
DELAWARE				
Dover	Kent	64	34	98
Lewes	Sussex			
(June 1-August 31)		73	42	115
(September 1-May 31)		50	42	134
Wilmington	New Castle	93	34	127
DISTRICT OF COLUMBIA Washington, DC	District of Columbia	115	46	161
FLORIDA				
Altamonte Springs	Seminole	71	38	109
Boca Raton	City limits of			
(January 1-April 30)	Boca Raton (see	105	38	143
(May 1-December 31)	Palm Beach County)	69	38	107
Bradenton	Manatee			
(January 1-May 31)		52	34	86
(June 1-December 31)		50	34	84
Cocoa Beach	Brevard	77	34	111
Daytona Beach	Volusia			
(February 1-August 31)		64	38	102
(September 1-January 31)		54	38	92
Delray Beach	City limits of			
(November 1-March 31)	Delray Beach	239	42	281
(April 1-October 31)	(see Palm Beach County)	67	42	109

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Fort Lauderdale	Broward			
(December 1-April 30)		99	42	141
(May 1-November 30)		63	42	105
Fort Myers	Lee			
(January 1-April 30)		89	42	131
(May 1-December 31)		50	42	92
Fort Walton Beach	Okaloosa			
(May 1-August 31)		61	38	99
(September 1-April 30)		68	38	106
Gainesville	Alachua	61	34	95
Gulf Breeze	Santa Rosa	61	38	99
Jacksonville	Duval County; Naval Station Mayport	63	34	97
Jupiter	City limits of Jupiter (see Palm Beach County)			
(January 1- April 30)		126	34	160
(May 1-December 31)		59	34	93
Key West	Monroe			
(December 1-April 30)		143	46	189
(May 1-November 30)		95	46	141
Kissimmee	Osceola			
(February 1-April 30)		65	34	99
(May 1-January 31)		50	34	84
Lakeland	Polk			
(January 1-April 30)		55	34	89
(May 1-December 31)		50	34	84
Miami	Dade			
(January 1-April 30)		75	42	117
(May 1-December 31)		71	42	113
Naples	Collier			
(December 1-April 30)		94	38	132
(May 1-November 30)		53	38	91
Orlando	Orange	75	42	117
Palm Beach	City limits of Palm Beach (see Palm Beach County)			
(January 1-April 30)		116	46	162
(May 1-December 31)		79	46	125
Palm Beach Gardens	Bay	69	38	107
Palm Beach Shores	Palm Beach (except Jupiter, Palm Beach, Delray Beach, West Palm Beach,			
(May 1-December 31)		85	38	123
(January 1-April 30)		52	38	90

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	Boca Raton, and Singer Island)			
Panama City	Bay			
(May 1-August 31)		60	38	98
(September 1-April 30)		50	38	88
Pensacola	Escambia	52	34	86
Punta Gorda	Charlotte			
(January 1-April 30)		65	38	103
(May 1-December 31)		50	38	88
St. Augustine	St. Johns			
(February 1-August 31)		58	38	96
(September 1-January 31)		50	38	88
St. Petersburg	Hillsborough			
(January 1-April 30)		59	38	97
(May 1-December 31)		50	38	88
Sarasota	Sarasota			
(January 1-May 31)		94	38	132
(June 1-December 31)		53	38	91
Singer Island	City limits of Singer Island (see Palm Beach County)			
(January 1-April 30)		121	38	159
(May 1-December 31)		67	38	105
Stuart	Martin			
(January 1-April 30)		62	38	100
(May 1-December 31)		55	38	93
Tallahassee	Leon	52	34	86
Tampa	Pinellas			
(January 1-April 30)		103	38	141
(May 1-December 31)		81	38	119
Vero Beach	Indian River			
(February 1-April 30)		72	38	110
(May 1-January 31)		50	38	88
West Palm Beach	City limits of West Palm Beach (see Palm Beach County)			
(January 1-April 30)		81	38	119
(May 1-December 31)		55	38	93
GEORGIA				
Albany	Dougherty	57	34	91
Athens	Clarke	51	34	85
Atlanta	Fulton	90	38	132
Augusta	Richmond	55	38	93
Cobb County	Cobb County	56	34	90
Columbus	Muscogee	56	34	90

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Conyers	Rockdale	65	34	99
DeKalb County	DeKalb County	59	34	93
Gwinnett County	Gwinnett County	84	30	80
Macon	Bibb	51	34	85
Savannah	Chatham	63	38	101
Warner Robins	Houston	50	34	84
IDAHO				
Boise	Ada	55	38	93
Coeur d'Alene	Kootenai			
(June 1-September 30)		56	34	90
(October 1-May 31)		50	34	84
Ketchum	Blaine (except Sun Valley)	58	42	100
McCall	Valley	59	38	97
Stanley	Custer	50	38	97
Sun Valley	City limits of			
(June 1-September 30)	Sun Valley (see	164	42	206
(April 1-May 31)	Blaine County)	124	42	166
(October 1-March 31)		89	42	131
ILLINOIS				
Champaign/Urbana	Champaign	50	34	84
Chicago	Cook	104	46	150
DeCatur	Macon	50	34	84
Du Page County	Du Page County	89	38	127
Lake County	Lake County	108	42	150
Peoria	Peoria	50	38	92
Rock Island	Rock Island	59	30	89
Rockford	Winnebago	55	34	85
Springfield	Sangamon	51	38	89
INDIANA				
Bloomington/Crane	Monroe and Martin	50	34	84
Carmel	Hamilton	65	38	103
Fort Wayne	Allen	52	34	86
Indianapolis	Marion County; Fort Benjamin Harrison	70	42	112
Michigan City	La Porte	50	34	84
Muncie	Delware	50	34	84
Nashville	Brown			

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(June 1-October 31)		75	38	113
(November 1-May 31)		50	38	88
South Bend	St. Joseph	58	34	103
Valparaiso/Burlington Beach	Porter	69	34	103
IOWA				
Cedar Rapids	Linn	52	34	86
Davenport/Bettendorf	Scott	55	34	89
Des Moines	Polk	67	34	101
KANSAS				
Kansas City	Johnson and Wyandotte (see also Kansas City, MO)	51	30	81
Overland Park	Kenton	78	38	116
Wichita	Sedgwick	58	38	96
KENTUCKY				
Covington	Kenton	80	38	118
Florence	Boone	60	34	94
Lexington	Fayette	55	34	89
Louisville	Jefferson	60	38	98
LOUISIANA				
Baton Rouge	East Baton Rouge Parish	59	38	97
Bossier City	Bossier Parish	54	34	88
Gonzales	Ascension Parish	55	34	88
Lake Charles	Calcasieu Parish	77	34	111
New Orleans	City limits of New Orleans	88	42	130
Opelouses	St. Landry	55	30	85
Slidell	St. Tammany	55	34	89
St. Francisville	West Feliciana	50	38	88
MAINE				
Bangor	Penobscot	56	30	86
Bar Harbor	Hancock			
(July 1-August 31)		139	38	177
(September 1-June 30)		119	38	157
Bath	Sagadahoc			

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(June 1-September 30)		57	34	91
(October 1-May 31)		50	34	84
Kennebunk	York			
(July 1-August 31)		96	38	134
(September 1-June 30)		65	38	103
Kittery	Portsmouth Naval			
(May 1-October 31)	Shipyard (see	70	34	104
(November 1-April 30)	also Portsmouth, NH)	50	34	84
Portland	Cumberland			
(July 1-October 31)		82	38	120
(November 1-June 30)		58	38	96
Rockport	Knox			
(July 1-August 31)		90	42	132
(September 1-June 30)		55	42	97
Wiscasset	Lincoln	59	38	97
MARYLAND				
Annapolis	Anne Arundel	90	42	132
Baltimore	Baltimore	110	42	152
Columbia	Howard	89	42	131
Easton	Talbot	69	34	103
Frederick	Frederick	53	38	91
Grasonville	Queen Annes	56	38	94
Hagerstown	Washington	56	34	90
Harford County	Harford County	55	38	93
Lexington Park/Leonardtown/Lusby	St. Mary's	59	34	93
Montgomery County	Montgomery County	115	38	153
Ocean City	Worcester			
(April 1-August 31)		129	46	175
(September 1-March 31)		52	46	98
Prince Georges County	Prince Georges County	109	38	147
Salisbury	Wicomico	55	34	89
St. Michaels	City limits of St. Michaels	100	42	142
MASSACHUSETTS				
Andover	Essex	83	38	121
Boston	Suffolk	105	46	151
Cambridge	City limits of Cambridge (see	105	46	151

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	Middlesex County)			
Falmouth	City limits of Falmouth	105	38	143
Greenfield	Franklin			
(May 1-October 31)		55	30	85
(November 1-April 30)		50	30	80
Hyannis	Barnstable			
(July 1-September 30)		94	38	132
(October 1-June 30)		72	38	110
Lowell	Middlesex (except Cambridge)	89	34	123
Martha's Vineyard	Dukes			
(June 1-September 30)		159	46	205
(October 1-May 31)		92	46	138
Nantucket	Nantucket			
(June 1-September 30)		90	46	136
(October 1-May 31)		85	46	131
New Bedford	City limits of New Bedford (see Bristol County)	65	34	99
Northampton	Hampshire	68	34	102
Pittsfield	Berkshire	56	38	94
Plymouth	Plymouth			
(June 1-October 31)		87	34	121
(November 1-May 31)		56	34	90
Quincy	Norfolk	74	38	112
Springfield	Hampden	61	34	95
Taunton	Bristol (except New Bedford)	58	30	88
Worcester	Worcester	79	34	113
MICHIGAN				
Ann Arbor	Washtenaw	70	38	108
Auburn Hills	Bay	59	38	97
Charlevoix	Charlevoix			
(July 1-September 30)		125	38	163
(October 1-June 30)		56	38	94
Detroit	Wayne	77	46	123
East Lansing	City limits of East Lansing (see Ingham	72	38	110

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	County)			
Flint	Genesee	50	34	84
Frankfort	Benzie			
(June 1-September 30)		95	34	129
(October 1-May 31)		63	34	97
Gaylord	Otsego	55	38	93
Grand Rapids	Kent	59	34	93
Grayling	Crawford			
(April 1-November 30)		59	34	93
(December 1-March 31)		50	34	84
Holland	Ottawa			
(May 1-September 30)		72	34	106
(October 1-April 30)		64	34	98
Lansing	Ingham (except East Lansing)	56	34	90
Leland	Leelanau			
(June 1-August 31)		75	34	109
(September 1-May 31)		60	34	94
Mackinac Island	Mackinac	140	46	186
Manistee	Manistee			
(June 1-September 30)		62	30	92
(October 1-May 31)		50	30	80
Midland	Midland	59	34	93
Mount Pleasant	Isabella	71	34	105
Petoskey	Emmet	65	38	103
Pontiac	City limits of Pontiac (see Oakland County)	93	34	127
Sault Ste Marie	Chippewa	65	34	99
South Haven	Van Buren	50	34	84
Traverse City	Grand Traverse			
(June 1-September 30)		97	42	139
(October 1-May 31)		60	42	102
Troy	Oakland (except Pontiac)	84	38	122
Warren	Macomb	62	34	96
MINNESOTA				
Anoka County	Anoka County	50	34	84
Dakota County	Dakota County	52	34	86
Duluth	St. Louis	58	42	100
Minneapolis	Hennepin and Ramsey Counties;	85	46	131

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
	Fort Snelling Military Reservation and Navy Astronautics Group (Detachment BRAVO), Rosemount			
Rochester	Olmsted	69	34	103
St. Paul County	St. Paul County	64	38	102
MISSISSIPPI				
Bay St. Louis	Hancock	68	38	106
Biloxi	City limits of Biloxi (see Harrison County)	72	38	110
Gulfport	Harrison (except Biloxi)			
(May 1-August 31)		60	34	94
(September 1-April 30)		53	34	87
Jackson	Hinds	59	34	93
Pascagoula	Jackson	50	34	84
Ridgeland	Madison	51	38	89
Robinsonville	Tunica	55	34	89
Vicksburg	Warren	50	34	84
MISSOURI				
Branson	Taney			
(June 1-September 30)		60	34	94
(October 1-May 31)		50	34	84
Cape Girardeau	Cape Girardeau	51	34	85
Clay County	Clay	82	30	112
Hannibal	Marion			
(June 1-September 30)		54	30	84
(October 1-May 31)		50	30	80
Jefferson City	Cole	52	34	86
Kansas City	Jackson and Platte (see also Kansas City, KS)	85	42	127
Lake Ozark	Miller	50	34	84
Osage Beach	Camden			
(June 1-Sepember 30)		64	34	98
(October 1-May 31)		50	34	84

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Platte County	Platte County	65	34	99
St. Charles County	St. Charles County	51	34	85
St. Louis	St. Louis	66	46	112
MONTANA				
Polson/Kalispell	Lake			
(May 1-September 30)		54	34	88
(October 1-April 30)		50	34	84
West Yellowstone Park	Gallatin			
(May 1-October 31)		64	34	98
(November 1-April 30)		60	34	94
NEBRASKA				
Lincoln	Lancaster	50	34	84
Omaha	Douglas	55	38	93
NEVADA				
Elko	All points in Elko County excluding Wendover	52	30	82
Incline Village	All points in the Northern Lake Tahoe area within Washoe County			
(June 1-September 30)		94	38	132
(October 1-May 31)		74	38	112
Las Vegas	Clark County; Nellis AFB	55	38	93
Reno	All points in Washoe County not covered under Incline Village per diem locality	50	38	88
Stateline	Douglas (see also South Lake Tahoe, CA)	108	42	150
Winnemucca	Humboldt	54	34	88
NEW HAMPSHIRE				
Concord	Merrimack	57	34	91
Conway	Carroll			
(June 1-October 31)		90	38	128

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(November 1-May 31)		50	38	88
Durham	Strafford			
(May 1-October 31)		71	30	101
(November 1-April 30)		63	30	93
Hanover	Grafton			
(June 1-October 31)		96	42	138
(November 1-May 31)		59	42	101
Laconia	Belknap			
(June 1-October 31)		65	34	99
(November 1-May 31)		55	34	89
Manchester	Hillsborough	78	34	112
Portsmouth/Newington	Rockingham			
(June 1-October 31)	County; Pease	75	42	117
(November 1-May 31)	AFB (see also Kittery, ME)	59	42	101
Sullivan County	Sullivan County	50	34	84
NEW JERSEY				
Atlantic City	Atlantic			
(July 1-August 31)		98	42	140
(September 1-November 30)		76	42	118
(December 1-April 30)		65	42	107
(May 1-June 30)		79	42	121
Bergen County	Bergen County	94	38	132
Cape May	Cape May (except			
(June 1-September 30)	Ocean City)	132	42	174
(October 1-May 31)		80	42	122
Cherry Hill/Camden/Moorestown	Camden/ Burlington	74	42	116
Eatontown	Monmouth County; Fort Monmouth	84	38	122
Edison	Middlesex (except Piscataway)	61	34	108
Flemington	Hunterdon	74	34	108
Freehold	City limits of			
(May 1-September 30)	Freehold	95	34	129
(October 1-April 30)		75	34	109
Hudson County	Hudson County	99	38	137
Millville	Cumberland	51	38	89
Newark	Essex	94	42	136
Ocean City	City limits of			
(June 1-August 31)	Cape May County	215	38	253

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(September 1-May 31)	(see Cape May County)	80	38	118
Parisippany/Dover	Morris County; Picatinny Arsenal	80	38	118
Passaic County	Passaic County	95	38	133
Piscataway	City limits of Piscataway	129	38	167
Princeton	City limits of Princeton (see Mercer County)	107	42	149
Trenton	Mercer (except Princeton)	84	38	122
Union County	Union County	125	38	163
NEW MEXICO				
Albuquerque	Bernalillo	60	38	98
Cloudcroft	Otero	74	30	104
Los Alamos	Los Alamos	71	34	105
Santa Fe	Santa Fe			
(May 1-October 31)		85	46	131
(November 1-April 30)		78	46	124
Taos	Taos	63	34	97
NEW YORK				
Albany	Albany	68	42	110
Batavia	Genesee	57	34	91
Binghamton	Broome	50	38	88
The Bronx	The Bronx	159	46	209
Brooklyn	Brooklyn	159	46	209
Buffalo	Erie	78	42	120
Corning	Steuben	54	38	92
Elmira	Chemung	50	34	84
Glens Falls	Warren			
(June 1-October 31)		74	34	108
(November 1-May 31)		50	34	84
Ithaca	Tompkins	50	34	86
Kingston	Ulster	51	38	89
Lake Placid	Essex			
(June 1-October 31)		80	38	118
(November 1-May 31)		59	38	97
Manhattan	Manhattan	195	46	241
Nassau County	Nassau County	70	38	108

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Niagara Falls	Niagara			
(June 1-October 31)		65	34	99
(November 1-May 31)		55	34	89
Nyack/Palisades	Rockland	62	38	100
Owego	Tioga	63	30	93
Plattsburgh	Clinton	50	34	84
Poughkeepsie	Dutchess	74	38	112
Queens Borough	Queens	159	46	205
Rochester	Monroe	55	42	97
Saratoga Springs	Saratoga			
(August 1-August 31)		147	38	185
(September 1-March 31)		50	38	88
(April 1-July 31)		71	38	109
Schenectady	Schenectady	55	34	89
Staten Island Borough	Richmond	94	42	136
Suffolk	Suffolk	68	38	106
Tarrytown	Westchester (except White Plains)	114	42	156
Utica	Oneida	51	34	85
Waterloo/Romulus	Seneca	89	34	123
Watkins Glen	Schuyler			
(May 1-October 31)		60	34	94
(November 1-April 30)		50	34	84
West Point	Orange	121	34	155
White Plains	City limits of White Plains (see Westchester County)	165	42	207
NORTH CAROLINA				
Asheville	Buncombe			
(June 1-October 31)		56	34	90
(November 1-May 31)		50	34	84
Chapel Hill	Orange	69	38	107
Charlotte	Mecklenburg	69	38	107
Durham	Durham	69	42	111
Fayetteville	Cumberland	55	34	89
Greensboro	Guilford	60	38	98
Kill Devil	Dare			
(May 1-August 31)		125	38	163
(September 1-October 31)		68	38	106
(November 1-February 28)		50	38	88

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(March 1-April 30)		72	38	110
New Bern	Craven	71	34	105
Raleigh	Wake	74	38	112
Research Triangle Park	City limits of Research Triangle Park	85	38	123
Wilmington	New Hanover			
(March 1-September 30)		60	34	94
(October 1-February 29)		53	34	87
Winston-Salem	Forsyth	64	38	102
NORTH DAKOTA (See footnote 5)				
OHIO				
Akron	Summit	56	38	94
Bellevue	City limits of			
(June 1-August 31)	Bellevue	55	30	85
(September 1-May 31)		50	30	80
Cambridge	Guernsey			
(April 1-October 31)		60	34	94
(November 1-March 30)		50	34	84
Canton	Stark	55	34	89
Cincinnati	Hamilton	69	46	115
Cleveland	Cuyahoga	85	42	127
Columbus	Franklin	70	38	108
Dayton	Montgomery, Wright-Patterson AFB	54	38	92
Elyria	Lorain			
(May 1-September 30)		67	34	101
(October 1-April 30)		50	34	84
Fairborn	Greene	66	34	100
Geneva/Hamilton	Ashtabula	58	34	92
Lancaster	Fairfield	60	34	94
Port Clinton/Oakharbor	Ottawa			
(June 1-August 31)		80	34	114
(September 1-May 31)		50	34	84
Portsmouth	Scioto	50	34	84
Sandusky	Erie			
(May 1-September 30)		83	38	121
(October 1-April 30)		53	38	91
Springfield	Clark	50	34	121
Toledo	Lucas	50	38	88

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Warren County	Warren County	59	30	89
OKLAHOMA				
Oklahoma City	Oklahoma	59	38	97
Tulsa	Osage, Tulsa and Washington	50	38	88
OREGON				
Ashland	Jackson	59	42	101
Beaverton	Washington	69	38	107
Bend	Deschutes	59	38	97
Clackamas	Clackamas	59	34	93
Coos Bay	Coos	51	34	85
Crater Lake	City limits of Crater Lake	74	38	112
Eugene	Lane (except Florence)	64	38	102
Florence	City limits of Florence (see Lane County)	87	34	121
Gold Beach	Curry			
(June 1-September 30)		65	34	99
(October 1-May 31)		50	34	84
Klamath Falls	Klamath	54	30	84
Lincoln City/Newport	Lincoln			
(July 1-September 30)		80	34	114
(October 1-June 30)		69	34	103
Portland	Multnomah	72	38	110
Salem	Marion	53	34	87
Seaside	Clatsop			
(May 1-September 30)		85	34	119
(October 1-April 30)		60	34	94
PENNSYLVANIA				
Allentown	Lehigh	59	38	97
Easton	Northampton	59	34	93
Erie	Erie			
(May 1-September 30)		65	30	95
(October 1-April 30)		50	30	80
Chester/Radnor	Delaware	69	34	103
Gettysburg	Adams			
(May 1-October 31)		82	34	116
(November 1-April 30)		53	34	87

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Harrisburg	Dauphin (except Hershey)	56	42	98
Hershey	City limits of Hershey			
(May 1-October 31)		125	42	167
(November 1-April 30)		53	42	95
King Prussia/Ft. Washington	Montgomery County, except Bala Cynwyd (see also Philadelphia, PA)	84	42	126
Lancaster	Lancaster	65	38	103
Malvern/Downingtn/Valley Forge	Chester	100	38	138
Mechanicsburg	Cumberland			
		79	34	113
		65	34	99
Philadelphia	Philadelphia County; city of Bala Cynwyd in Montgomery County	113	46	159
Pittsburgh	Allegheny	79	46	125
Reading	Berks	57	38	95
Scranton	Lackawanna	60	30	90
Warminster	Bucks County; Naval Air Development Center	75	42	117
Wayne	City limits of Wayne	95	42	137
RHODE ISLAND				
Block Island	Washington	94	42	136
East Greenwich	Kent County; Naval Construction Battalion Center, Davisville	69	38	107
Newport	Newport			
(June 1-September 30)		111	42	153
(October 1-May 31)		77	42	119
North Kingston	Washington			
(June 1-Septemer 30)		60	30	90
(October 1-May 31)		50	30	80

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Providence	Providence	79	42	121
SOUTH CAROLINA				
Charleston	Charleston	64	42	106
Columbia	Richland	50	38	88
Greenville	Greenville	62	38	100
Hilton Head	Beaufort			
(March 1-August 31)		110	42	152
(September 1-February 29)		63	42	105
Myrtle Beach	Horry County;			
(June 1-September 30)	Myrtle Beach AFB	114	42	156
(October 1-May 31)		50	42	92
Spartanburg	Spartanburg	50	34	84
SOUTH DAKOTA				
Custer	Custer			
(June 1-August 31)		69	34	103
(September 1-May 31)		50	34	84
Hot Springs	Fall River			
(June 1-August 31)		85	30	115
(September 1-May 31)		50	30	80
Rapid City	Pennington			
(June 1-August 31)		72	34	106
(September 1-May 31)		50	34	84
TENNESSEE				
Chattanooga	Hamilton	50	34	84
Gatlinburg	Sevier	70	38	108
Knoxville	Knoxville County	50	38	88
Memphis	Shelby	79	38	117
Nashville	Davidson	72	42	114
Townsend	Blount	70	34	104
TEXAS				
Arlington	Tarrant	76	34	110
Austin	Travis	80	38	118
Brownsville	Cameron	50	34	84
College Station	Brazos	55	34	89
Corpus Christi	Nueces and San Patricio	56	38	94
Dallas	Dallas	89	46	135
Eagle Pass	Maverick	54	30	84
El Paso	El Paso	78	38	116

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Fort Davis	Jeff Davis	65	30	95
Fort Worth	City limits of Fort Worth	69	38	107
Galveston	Galveston			
(May 1-August 31)		56	42	98
(September 1-April 30)		50	42	92
Houston	Harris County; L. B. Johnson Space Center and Ellington AFB	72	42	114
Killeen	Bell	52	30	82
Laredo	Webb	50	34	84
Lubbock	Lubbock	53	34	87
McAllen	Hidalgo	80	34	114
Odessa/Plano	Collin	55	34	89
San Antonio	Bexar	91	42	133
South Padre Island	Cameron			
(March 1-August 31)		58	38	96
(September 1-April 30)		50	38	88
Tyler	Smith	51	34	85
Victoria	Victoria	53	30	83
UTAH				
Bullfrog	Garfield			
(April 1-October 31)		104	30	142
(November 1-March 31)		73	38	111
Cedar City	Iron			
(June 1-August 31)		71	34	105
(September 1-May 31)		59	34	93
Davis County	Davis County	63	34	97
Moab	Grand	70	34	104
Ogden	Weber	54	34	88
Park City	Summit			
(December 1-March 31)		155	46	201
(April 1-November 30)		84	46	130
Provo	Utah	57	38	95
Salt Lake City	Salt Lake and Dugway Proving Ground and Tooele Army Depot	76	42	118
VERMONT				

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
Burlington/St. Albans	Chittenden and Franklin	82	38	120
Manchester	Bennington	95	42	137
Middlebury	Addison			
(May 1-October 31)		93	38	131
(November 1-April 30)		90	38	128
Rutland	Rutland			
(December 1-March 31)		64	34	98
(April 1-November 30)		50	34	84
White River Junction	Windsor			
(July 1-October 31)		74	34	108
(November 1-June 30)		60	34	94
VIRGINIA				
Alexandria*		126	42	168
Arlington	Arlington	115	42	157
Blacksburg	Montgomery	54	34	88
Charlottesville*		52	42	94
Chesterfield County	Chesterfield County	63	38	101
Loudoun County	Loudoun	75	38	113
Lynchburg*		62	38	100
Manassas	Prince William County (except Woodbridge)	62	34	96
Fairfax County	Fairfax County (includes the cities of Falls Church and Fairfax)	118	42	160
Richmond*	Henrico, also Defense Supply Center	76	38	114
Roanoke*		50	34	84
Shenandoah County	Shenandoah County	50	34	84
Virginia Beach*	Virginia Beach			
(June 1-August 31)	(also Norfolk,	97	38	135
(September 1-May 31)	Portsmouth and Chesapeake)*	54	38	92
Wallops Island	Accomack			
(June 1-September 30)		77	34	111
(October 1-May 31)		54	34	88
Williamsburg*	Williamsburg			

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount (room rate only-no taxes) (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
(June 1-October 31)	(also Hampton, Newport News, York County, Naval Weapons Station, Yorktown)*	91	38	129
(November 1-May 31)		59	38	97
Wintergreen	Nelson			
(June 1-October 31)		110	46	156
(November 1-May 31)		95	46	141
Woodbridge	City limits of Woodbridge	67	38	105
*Denotes independent cities.				
WASHINGTON				
Anacortes	Skagit	74	38	112
Bellingham	Whatcom	50	34	84
Bremerton	Kitsap	61	34	95
Everett	Snohomish (except Lynnwood)	59	38	97
Friday Harbor	San Juan			
(Junel-September 30)		82	42	124
(October 1-May 31)		59	42	101
Island County	Island County	84	34	118
Lynnwood	City limits of Lynnwood (see Snohomish County)	79	34	113
Ocean Shores	Grays Harbor			
(April 1-September 30)		82	38	120
(October 1-March 31)		72	38	110
Olympia/Tumwater	Thurston	58	38	96
Port Angeles	Clallam			
(June 1-September 30)		65	38	103
(October 1-May 31)		54	38	92
Port Townsend	Jefferson	65	34	99
Seattle	King	104	46	150
Sequim	Clallam			
(May 1-September 30)		59	34	93
(October 1-April 30)		50	34	84
Spokane	Spokane	61	38	99
Tacoma	Pierce	54	38	92
Vancouver	Clark	55	38	93

Per diem locality: Key city 1	County and/or other defined location 2,3	Maximum lodging amount **(room rate only-no taxes)** (a)	+ M&IE rate (b)	= Maximum per diem rate 4 (c)
WEST VIRGINIA				
Berkeley Springs	Morgan	69	34	103
Charleston	Kanawha	77	38	115
Harpers Ferry	Jefferson	50	34	84
Morgantown	Monongalia	64	34	98
Parkersburg	Wood	52	34	86
Wheeling	Ohio	55	34	89
WISCONSIN				
Brookfield	Waukesha	66	38	104
Eau Claire	Eau Claire	52	34	86
Green Bay	Brown	54	34	88
Kenosha	Kenosha	52	30	82
La Crosse	La Crosse	52	30	82
Lake Geneva	Walworth	86	38	124
Madison	Dane	59	38	97
Milwaukee	Milwaukee	72	42	114
Minocqua/Rhinelander	Oneida	52	38	90
Oshkosh	Winnebago	56	34	90
Sturgeon Bay	Door			
(July 1-August 31)		73	34	107
(September 1-June 30)		50	34	84
Wisconsin Dells	Columbia			
(June 1-September 30)		71	38	109
(October 1-May 31)		50	38	88
WYOMING				
Cody	Park			
(June 1-September 30)		79	30	109
(October 1-May 31)		50	30	80
Jackson	Teton			
(June 1-September 30)		88	42	130
(October 1-May 31)		59	42	101
Thermopolis	Hot Springs			
(June 1-August 31)		54	30	84
(September 1-May 31)		50	30	80

/1/ Unless otherwise specified, the per diem locality is defined as "all locations within, or entirely surrounded by, the corporate limits of the key city, including independent entities located within those boundaries."

/2/ Per diem localities with county definitions shall include "all locations within, or entirely surrounded by, the corporate limits of the key city as well as the boundaries of the listed counties, including

independent entities located within the boundaries of the key city and the listed counties (unless otherwise listed separately)."

/3/ When a military installation or Government-related facility (whether or not specifically named) is located partially within more than one city or county boundary, the applicable per diem rate for the entire installation or facility is the higher of the two rates which apply to the cities and/or counties, even though part(s) of such activities may be located outside the defined per diem locality.

/4/ Federal agencies may submit a request to GSA for review of the costs covered by per diem in a particular city or area where the standard CONUS rate applies when travel to that location is repetitive or on a continuing basis and travelers' experiences indicate that the prescribed rate is inadequate. Other per diem localities listed in this appendix will be reviewed on an annual basis by GSA to determine whether rates are adequate. Requests for per diem rate adjustments shall be submitted by the agency headquarters office to the General Services Administration, Office of Governmentwide Policy, Attn: Travel and Transportation Management Policy Division (MTT), Washington, DC 20405. Agencies should designate an individual responsible for reviewing, coordinating, and submitting to GSA any requests from bureaus or subagencies. Requests for rate adjustments shall include a city designation, a description of the surrounding location involved (county or other defined area), and a recommended rate supported by a statement explaining the circumstances that cause the existing rate to be inadequate. The request also must contain an estimate of the annual number of trips to the location, the average duration of such trips, and the primary purpose of travel to the location. Agencies should submit their requests to GSA no later than May 1 in order for a city to be included in the annual review.

/5/ The standard CONUS rate of $80 ($50 for lodging and $30 for M&IE) applies to all per diem localities in the State of North Dakota.

NOTE: Recognizing that all locations are not incorporated cities, the term "city limits" has been used as a general phrase to denote the commonly recognized local boundaries of the location cited.

Dated: November 27, 1998.

David J. Barram,

Administrator of General Services.

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Federal Register

Vol. 63, No. 231

Wednesday, December 2, 1998

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FEDERAL REGISTER PAGES AND DATES, DECEMBER

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT DECEMBER 2, 1998

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Atlantic swordfish; published 12-2-98

ENVIRONMENTAL PROTECTION AGENCY
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Cymoxanil; published 12-2-98
Imidacloprid; published 12-2-98
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities
Metolachlor; published 12-2-98
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Primisulfuron-methyl; published 12-2-98
Tebuconazole; published 12-2-98
Triasulfuron; published 12-2-98

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Animal drugs, feeds, and related products:
Butorphanol tartrate; published 12-2-98
Chlortetracycline and salinomycin; published 12-2-98

PERSONNEL MANAGEMENT OFFICE
Prevailing rate systems; published 11-2-98

SECURITIES AND EXCHANGE COMMISSION
Securities:
Transfer agents; Year 2000 readiness reports; published 11-2-98

TRANSPORTATION DEPARTMENT
Coast Guard
Ports and waterways safety:
Atlantic Intracoastal Waterway, Marine Corps Base Camp Lejeune, NC; safety zone; published 11-2-98

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Aerospatiale; published 10-28-98
Dassault; published 10-28-98
McDonnell Douglas; published 10-28-98

TREASURY DEPARTMENT
Internal Revenue Service
Income taxes:
Reasonable basis; definition; published 12-2-98

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Celery grown in—
Florida; comments due by 12-8-98; published 10-9-98

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Interstate transportation of animals and animal products (quarantine):
Brucellosis in cattle and bison—
State and area classifications; comments due by 12-7-98; published 10-7-98
Brucellosis in swine—
State and area classifications; comments due by 12-7-98; published 10-7-98
Plant-related quarantine, domestic:
Mediterranean fruit fly; comments due by 12-7-98; published 10-8-98

AGRICULTURE DEPARTMENT
Farm Service Agency
Farm marketing quotas, acreage allotments, and production adjustments:
Peanuts; comments due by 12-8-98; published 11-25-98
Program regulations:
Manufactured housing thermal requirements; comments due by 12-7-98; published 10-6-98

AGRICULTURE DEPARTMENT
Food Safety and Inspection Service
Meat and poultry inspection:
Consumer protection standards—
Washing and chilling processes; retained water in raw meat and poultry products; poultry chilling performance standards; comments due by 12-10-98; published 9-11-98
Washing and chilling processes; retained water in raw meat and poultry products; poultry chilling performance standards; correction; comments due by 12-10-98; published 10-26-98

AGRICULTURE DEPARTMENT
Grain Inspection, Packers and Stockyards Administration
Packers and Stockyards Act:
Non-reporting of price as condition of purchase or sale of livestock; prohibition; comments due by 12-9-98; published 9-10-98

AGRICULTURE DEPARTMENT
Rural Business-Cooperative Service
Program regulations:
Manufactured housing thermal requirements; comments due by 12-7-98; published 10-6-98

AGRICULTURE DEPARTMENT
Rural Housing Service
Program regulations:
Manufactured housing thermal requirements; comments due by 12-7-98; published 10-6-98

AGRICULTURE DEPARTMENT
Rural Utilities Service
Electric and telephone loans:
Fidelity and insurance requirements; comments due by 12-8-98; published 10-9-98
Program regulations:
Manufactured housing thermal requirements; comments due by 12-7-98; published 10-6-98

AGRICULTURE DEPARTMENT
Nondiscrimination in federally conducted programs and activities; comments due by 12-10-98; published 11-10-98

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Atka mackerel; comments due by 12-9-98; published 11-9-98
Atlantic swordfish; comments due by 12-7-98; published 10-13-98
Northeastern United States fisheries—
Atlantic surf clam and ocean quahog; comments due by 12-7-98; published 11-13-98
Marine Mammals:
Endangered fish or wildlife—
Sea turtles; shrimp trawling requirements; comments due by 12-7-98; published 11-10-98

ENERGY DEPARTMENT
Acquisition regulations:
Performance guarantees; comments due by 12-9-98; published 11-9-98

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Natural gas companies (Natural Gas Act):
Energy facility applications; collaborative procedures; comments due by 12-7-98; published 10-7-98

ENVIRONMENTAL PROTECTION AGENCY
Air programs; approval and promulgation; State plans for designated facilities and pollutants:
Oklahoma; comments due by 12-7-98; published 11-6-98
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 12-7-98; published 11-6-98
Maryland; comments due by 12-7-98; published 11-5-98
Pennsylvania; comments due by 12-7-98; published 11-6-98
Air quality planning purposes; designation of areas:
Arizona; comments due by 12-7-98; published 11-20-98
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Avermectin; comments due by 12-7-98; published 10-7-98
Bifenthrin; comments due by 12-7-98; published 10-7-98

LIST OF PUBLIC LAWS

Note: The list of Public Laws for the second session of the 105th Congress has been completed and will resume when bills are enacted into law during the first session of the 106th Congress, which convenes on January 6, 1999.

A cumulative list of Public Laws for the second session of the 105th Congress was published in the **Federal Register** on November 30, 1998.