

Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on April 6, 1998.

Note 4: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 92-186-014(B)R4, dated December 4, 1996.

Issued in Fort Worth, Texas, on March 12, 1998.

Eric Bries,

*Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.*

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DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 980313063-8063-01]

RIN 0625-AA51

Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Interim final rules; request for comments.

SUMMARY: The Department of Commerce ("the Department") hereby amends its regulations on antidumping and countervailing duty proceedings on an interim basis in order to implement certain provisions of the Uruguay Round Agreements Act ("URAA").

The regulations provide, in particular, for procedures for conducting five-year ("sunset") reviews of antidumping and countervailing duty orders and suspended investigations pursuant to the provisions of sections 751(c) and 752 of the Tariff Act of 1930, as amended ("the Act").

DATES: Interim final regulations effective March 20, 1998. To be assured of consideration, written comments must be received not later than April 20, 1998. Rebuttal comments must be received not later than May 11, 1998.

ADDRESSES: A signed original and six copies of each set of comments, including reasons for any recommendation, along with a cover letter identifying the commenter's name and address, should be submitted to Robert S. LaRussa, Assistant Secretary for Import Administration, Central Records Unit, Room 1870, U.S. Department of Commerce, Pennsylvania

Avenue and 14th Street, NW, Washington, DC 20230; Attention: Sunset Procedural Regulations.

FOR FURTHER INFORMATION CONTACT: Melissa G. Skinner, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, at (202) 482-1560, or Stacy J. Ettinger, Office of the Chief Counsel for Import Administration, U.S. Department of Commerce, at (202) 482-4618.

SUPPLEMENTARY INFORMATION:

Background

The Uruguay Round Agreements Act ("URAA") fundamentally revised the Act by requiring that antidumping ("AD") and countervailing duty ("CVD") orders be revoked, and suspended investigations be terminated, after five years unless revocation would be likely to lead to a continuation or recurrence of (1) dumping or a countervailable subsidy, and (2) material injury to the domestic industry. The URAA assigns to the Department the responsibility of determining whether revocation of an antidumping or countervailing duty order, or termination of a suspended investigation, would be likely to lead to a continuation or recurrence of dumping or a countervailable subsidy, and of providing to the International Trade Commission the magnitude of the margin of dumping or the net countervailable subsidy that is likely to prevail if the order is revoked or the suspended investigation is terminated. The URAA requires that the Department begin initiating sunset reviews in July 1998, that all sunset reviews of "transition orders"—those antidumping and countervailing duty orders and suspended investigations in effect on January 1, 1995, the effective date of the URAA—be initiated by December 31, 1999, and that all reviews of transition orders be completed by June 30, 2001. The URAA further requires that the Department initiate a sunset review of each order or suspended investigation that is not a "transition order" not later than 30 days before the fifth anniversary of publication of the order or suspension agreement in the **Federal Register**. Pursuant to section 751(c)(1) of the Act, initiation of sunset reviews is automatic. The Department intends to notify, in advance, all persons on the service list for each proceeding subject to a sunset review, of the approximate date of publication in the **Federal Register** of the automatic initiation of the sunset review.

The interim regulations described below address the procedures for

participation in, and conduct of, sunset reviews consistent with the statute and with the legislative history's commitment to provide further guidance on procedures. These regulations are effective on their date of publication in the **Federal Register** and apply to sunset reviews initiated on or after July 1, 1998. These rules will remain in effect until the Department adopts final regulations after considering comments in response to this notice of interim final rules.

Request for Comment

The Department solicits comments pertaining to these interim final regulations concerning conduct of sunset reviews. Initial comments should be received by the Assistant Secretary not later than April 20, 1998. Any rebuttals to the initial comments should be received by the Assistant Secretary not later than May 11, 1998. Commenters should file a signed original and six copies of each set of initial and rebuttal comments. All comments will be available for public inspection and photocopying in the Import Administration's Central Records Unit, Room B-099, between the hours of 8:30 am and 5:00 pm on business days.

Each person submitting a comment should include the commenter's name and address, and give reasons for any recommendations. To facilitate their consideration by the Department, initial and rebuttal comments should be submitted in the following format: (1) Number each comment in accordance with the number of the regulation being addressed; (2) begin each comment on a separate page; (3) provide a brief summary of the comment (a maximum of three sentences) and label this section "Summary of the Comment;" and (4) concisely state the issue identified and discussed in the comment and provide reasons for any recommendation.

To help simplify the processing and distribution of comments, the Department requests the submission of initial and rebuttal comments in electronic form to accompany the required paper copies. Comments filed in electronic form should be on a DOS formatted 3.5" diskette in either WordPerfect format or a format that the WordPerfect program can convert and import into WordPerfect. Please make each comment a separate file on the diskette and name each separate file using the number of the regulation being addressed in the comment.

Comments received on diskette will be made available to the public on the Internet at the following address: "http://www.ita.doc.gov/import_admin/

records/". In addition, upon request, the Department will make comments filed in electronic form available to the public on 3.5" diskettes (at cost), with specific instructions for accessing compressed data (if necessary). Any questions concerning file formatting, document conversion, access on the Internet, or other electronic filing issues should be addressed to Andrew Lee Beller, IA Webmaster, (202) 482-0866.

Classification

Administrative Procedure Act

Pursuant to authority at 5 U.S.C. 553(b)(A), the Assistant Secretary for Import Administration waives the requirement to provide prior notice and an opportunity for public comment because this action is a rule of agency procedure. Section 751(c) and section 752 of the Tariff Act of 1930, as amended (19 U.S.C. 1675(c) and 1675a), and the Statement of Administrative Action ("SAA") accompanying the Uruguay Round Agreements Act (H.R. Doc. No. 103-316, vol. 1 (1994)) address the substantive methodological and analytical framework for sunset reviews, as well as procedures for conducting sunset reviews. This action only addresses the procedures for participation in, and conduct of, sunset reviews consistent with the statute and with the SAA's commitment to provide further guidance on procedures. This interim final rule is not subject to a 30-day delay in its effectiveness under 5 U.S.C. 553(d) as it is not a substantive rule. The analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 note) are inapplicable to this rulemaking because it is not one for which a Notice of Proposed Rulemaking is required under 5 U.S.C. 553 or any other statute.

Paperwork Reduction Act

This interim final rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

Executive Order 12866

This interim final rule has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 12612

This interim final rule does not contain federalism implications described in Executive Order 12612 warranting the preparation of a Federalism Assessment.

Explanation of Particular Provisions

Subpart A—Scope and Definitions

Subpart A sets forth the scope of part 351, definitions, and other general

matters applicable to AD/CVD proceedings.

Section 351.102

Section 351.102 sets forth definitions of terms that are used throughout part 351. Most of the terms used in the new sunset regulations have been defined previously in the statute or regulations, and parties should refer to the relevant provisions for guidance. However, we added two new definitions.

Expedited sunset review is used in these regulations as a shorthand expression for the 120-day expedited sunset review conducted by the Department under section 751(c)(3)(B) of the Act. The Department will conduct an expedited sunset review when respondent interested parties provide inadequate responses to a Notice of Initiation under new § 351.218(e)(1)(ii).

Full sunset review is used in these regulations as a shorthand expression for the 240-day (or 330-day if fully extended) full sunset review conducted by the Department under section 751(c)(5) of the Act. The Department will conduct a full sunset review when both domestic interested parties and respondent interested parties provide adequate responses to a Notice of Initiation under section 751(c)(3)(B) of the Act and new §§ 351.218(e)(1)(i) and 351.218(e)(1)(ii).

Section 351.104

Section 351.104 defines what constitutes the official and public records of an AD/CVD proceeding.

Administrative record of proceedings. Although no changes have been made to § 351.104 by these regulations, in order to avoid any confusion that might arise from reporting and recordkeeping differences between the International Trade Commission and the Department with respect to grouped transition orders, we are clarifying that a sunset proceeding before the Department is subject merchandise- and country-specific (*i.e.*, order-specific). Therefore, consistent with § 351.104(a)(1), the Department will maintain in the Central Records Unit an official record of each sunset review of an order or suspended investigation, and a party must file separate submissions, consistent with the filing requirements of § 351.303, in each sunset review in which it participates.

Subpart B—Antidumping and Countervailing Duty Procedures

Subpart B deals with AD/CVD procedures.

Section 351.218

Section 351.218 deals with sunset reviews under section 751(c) of the Act. We removed paragraphs (d) and (e) and added new paragraphs (d), (e), and (f). These revisions are intended to streamline sunset reviews by providing guidance on participation in, and conduct of, sunset reviews. In addition, the Department believes that such guidance will allow both the Department and interested parties to begin preparing in advance, in particular, for the approximately 325 sunset reviews of transition orders scheduled to be initiated over an 18-month period beginning in July 1998.

Participation in sunset review.

Paragraph (d) is new and sets forth the procedural requirements for participation in, or waiver of participation in, a sunset review.

Domestic interested party notification of intent to participate. Paragraph (d)(1) sets forth the procedure for domestic interested party participation in a sunset review. Paragraph (d)(1)(i) provides that a domestic interested party that intends to participate in a sunset review must file a Notice of Intent to Participate in a Sunset Review within 15 days of initiation of a sunset review. The requirement that domestic interested parties notify the Department of their intention to participate prior to the deadline for submission of substantive responses to both the Department and the International Trade Commission is intended to alleviate the burden on parties of having to prepare substantive responses in cases where there is no domestic party interest. This is because, where there is no domestic party interest in a particular case, the Department, pursuant to section 751(c)(3)(A) of the Act, automatically will revoke the order or terminate the suspended investigation, as applicable. The Notice of Intent procedure is intended to eliminate needless reviews and promote administrative efficiency, consistent with the explanation in the House Report (H.R. Rep. No. 103-826, pt. 1 (1994)) at 56. As set forth in paragraph (d)(1)(iii), therefore, where no domestic interested party files a Notice of Intent to Participate in the sunset review, the Department will issue a final determination revoking the order or terminating the suspended investigation within 90 days of initiation of the sunset review.

Paragraph (d)(1)(ii) sets forth the information required to be provided in a Notice of Intent to Participate in a Sunset Review. It is the Department's intention to make the Notice of Intent procedure as simple as possible and, as

a result, the information required to be provided is minimal.

Waiver of response by a respondent interested party to a Notice of Initiation. Paragraph (d)(2) deals with the procedure for waiving participation in a sunset review before the Department, consistent with section 751(c)(4) of the Act. As the SAA at 881, and the House Report at 57, explain, allowing respondent interested parties, including foreign governments, to waive participation in a sunset review before the Department is intended to reduce the burden on all parties involved in a sunset review.

Paragraph (d)(2)(i) provides that a Statement of Waiver must be filed within 30 days of initiation of the sunset review, and, consistent with section 751(c)(4)(A) of the Act, clarifies that waiving participation in a sunset review before the Department does not affect a party's opportunity to participate in the sunset review conducted by the International Trade Commission.

Paragraph (d)(2)(iii) clarifies that failure to file a complete substantive response to a Notice of Initiation under paragraph (d)(3) also will be treated as a waiver of participation. It is the Department's intention to make the waiver process as simple as possible and, as reflected in paragraph (d)(2)(ii), the information required to be provided in a Statement of Waiver is minimal.

Paragraph (d)(2)(iv) indicates the effect of waiver by the foreign government in a CVD sunset review. Specifically, paragraph (d)(2)(iv) provides that where the foreign government waives participation in a CVD sunset review, either by filing a Statement of Waiver or by failing to file a complete substantive response to a Notice of Initiation, the Department will conduct an expedited sunset review under section 751(c)(3)(B) of the Act and, consistent with the SAA at 881, and the House Report at 57, normally will conclude that revocation of the order or termination of the suspended investigation would be likely to lead to continuation or recurrence of a countervailable subsidy for all respondent interested parties.

Substantive response to a Notice of Initiation. Section 751(c)(2) of the Act requires the Department to initiate sunset reviews automatically every five years. As part of the initiation, section 751(c)(2) of the Act authorizes the Department to request that interested parties submit certain information needed to conduct the review. Paragraph (d)(3) indicates the information that interested parties are required to submit in response to the Notice of Initiation of a sunset review,

as well as optional information that may be submitted in response to the Notice of Initiation.

Paragraph (d)(3)(i) provides that a complete substantive response to a Notice of Initiation must be submitted to the Department within 30 days of initiation of the sunset review.

Paragraph (d)(3)(ii), consistent with section 751(c)(2) of the Act, indicates the information required to be filed by all interested parties in a sunset review, including a statement expressing the interested party's willingness to participate in the review by providing information requested by the Department, a statement regarding the likely effects of revocation of the order or termination of the suspended investigation, and, if applicable, a summary of the Department's findings regarding duty absorption.

Paragraph (d)(3)(iii) indicates the additional information required to be filed by respondent interested parties in a sunset review, including historical margin or rate information and export volume and value data. In particular, respondent interested parties are required to report their percentage of the total exports of subject merchandise to the United States; this information will be central to the Department's determination as to whether respondent interested parties provided adequate response to a notice of initiation under section 751(c)(3)(B) of the Act.

Paragraph (d)(3)(iv) indicates that parties also may submit information to show good cause for the Department to consider other factors under sections 752(b)(2) (CVD) or 752(c)(2) (AD) of the Act. Paragraph (d)(3)(iv) clarifies, however, that, if an interested party wants the Department to consider these other factors during the course of the sunset review, the party must submit evidence of good cause in its substantive response.

Substantive response from a foreign government in a CVD sunset review.

Paragraph (d)(3)(v) indicates the information required to be filed by the foreign government in a CVD sunset review. This information is a subset of the information required to be filed by other respondent interested parties. However, where the sunset review involves a CVD order where the investigation was conducted on an aggregate basis, paragraph (d)(3)(v)(B) provides for additional information required to be filed by the foreign government. This additional information essentially is identical to the additional required information that normally would be filed by respondent companies. This is because, in an aggregate CVD proceeding, the foreign

government normally is the only respondent.

Substantive responses from industrial users and consumers. Paragraph (d)(3)(vi) indicates the information required to be filed by industrial users and representative consumer organizations that intend to participate in a sunset review.

Rebuttal to substantive response to a Notice of Initiation. Paragraph (d)(4) allows parties that filed a substantive response to a Notice of Initiation to file rebuttals to other parties' substantive responses within five days. Paragraph (d)(4) also explicitly provides that the Department normally will not accept or consider any additional information from a party after the time for filing rebuttals has expired unless the Secretary requests additional information from parties after determining to proceed to a full sunset review.

Conduct of sunset review. Paragraph (e) is new and deals with the conduct of sunset reviews, including the determination of whether interested party responses are adequate.

Adequacy of response to a Notice of Initiation. The SAA at 880, provides that the determination of adequacy is committed to the Department's (and, separately, the International Trade Commission's) discretion. Paragraph (e)(1), therefore, sets forth the guidelines by which the Department will determine whether interested parties' substantive responses to a Notice of Initiation are adequate. Responses will be evaluated for adequacy on an individual basis, i.e., whether a party has timely submitted a complete substantive response to a Notice of Initiation. A complete substantive response is one which contains all of the information required under paragraph (d)(3). The Department may consider a substantive response that does not contain all of the information required under paragraph (d)(3) to be complete where a party is unable to report certain required information and provides a reasonable explanation as to why it is unable to provide such information. In addition, responses will be evaluated for adequacy on an aggregate basis. In assessing the adequacy of responses in the aggregate, the Department will consider only those responses that individually are considered adequate. The Department will determine separately the adequacy of responses of domestic interested parties and respondent interested parties. Consistent with the Senate Report at 46, the Department will make its determination of adequacy on a case-by-case basis.

Adequacy of response from domestic interested parties. Paragraph (e)(1)(i)(A) provides that the Department normally will conclude that domestic interested parties have provided adequate response where at least one domestic interested party files a complete substantive response. Paragraph (e)(1)(i)(B) provides that the Department may consider whether a domestic interested party is related to a foreign producer or exporter, or is an importer or related to an importer of the subject merchandise, in determining adequacy of response from domestic interested parties.

Paragraph (e)(1)(i)(C) clarifies that, where the Department disregards a response from a domestic interested party, either because the response is not complete or because of the domestic interested party's relationship with a foreign producer, foreign exporter, or importer, and where no other domestic interested party has responded to the Notice of Initiation, the Department will find no domestic interested party response under section 751(c)(3)(A) of the Act and issue final results revoking the order or terminating the suspended investigation within 90 days after initiation of the sunset review.

Adequacy of response from respondent interested parties. Paragraph (e)(1)(ii)(A) provides that the Department normally will conclude that respondent interested parties have provided adequate response where respondent interested party responses account for more than 50 percent, by volume, of the total exports of subject merchandise to the United States. Paragraph (e)(1)(ii)(C) provides that where respondent interested parties provide inadequate response, the Department will conduct an expedited sunset review under section 751(c)(3)(B) of the Act and issue final results of review based on the facts available. In addition, the Department will notify the International Trade Commission of its adequacy determination within 50 days of initiation of the sunset review.

Adequacy of response from a foreign government in a CVD sunset review. Consistent with the SAA at 880, and the Senate Report at 46, paragraph (e)(1)(ii)(B) provides that if the foreign government does not file a complete substantive response to a Notice of Initiation in a CVD sunset review, the Department will find inadequate response from *all* respondent interested parties under section 751(c)(3)(B) of the Act and will conduct an expedited sunset review.

Full sunset review upon adequate response from domestic and respondent interested parties. Paragraph (e)(2)(i)

provides that where the Department receives adequate responses from both domestic and respondent interested parties, it normally will conduct a full sunset review. Consistent with the SAA at 891, and the House Report at 64, paragraph (e)(2)(i) also provides that only under the most extraordinary circumstances will the Department rely on a countervailing duty rate or dumping margin other than those it calculated and published in its prior determinations. As a result, paragraph (e)(2)(i) provides that the Department will not calculate a net countervailable subsidy or dumping margin for a new shipper in the context of a sunset review. Paragraph (e)(2)(ii) clarifies that the Department will consider other factors, if at all, normally only in the context of a full sunset review.

Time limits. Paragraph (f) is new and deals with time limits for verification, issuance of preliminary and final results of full sunset review, and issuance of the Department's determination to continue, revoke, or terminate an order or suspended investigation, as applicable, after the publication of the International Trade Commission's final determination concluding a sunset review.

Paragraph (f)(1) provides that the Department normally will issue its preliminary results of full sunset review not later than 110 days after initiation of the sunset review.

Paragraph (f)(2)(i) clarifies that the Department normally will conduct verification, if at all, only in a full sunset review. In addition, paragraph (f)(2)(i) provides that the Department will conduct verification normally only if, in its preliminary results, the Department determines that revocation of the order or termination of the suspended investigation is *not* likely to lead to continuation or recurrence of a countervailable subsidy or dumping (see section 752(b) and section 752(c) of the Act), *and* the Department's determination is *not* based on countervailing duty rates or dumping margins from the original investigation or subsequent reviews. There may be other situations in which the Department would not need to conduct verification. Paragraph (f)(2)(ii) indicates that the Department normally will conduct verification, if at all, approximately 120 days after initiation of the sunset review, i.e., normally after the Department issues its preliminary results of review. Because the Department cannot anticipate the extent of its workload during the conduct of sunset reviews, particularly during the 18-month period in which the Department must begin conducting

sunset reviews of approximately 325 transition orders, the Department may need to schedule verification either before or after the 120-day time frame. Paragraph (f)(2)(ii) allows for this type of flexibility in scheduling.

Paragraph (f)(3) provides that the Department normally will issue its final results of full sunset review not later than 240 days after initiation of the sunset review and may extend the period for issuing final results in an extraordinarily complicated sunset review by up to 90 days.

Paragraph (f)(4) provides that the Department normally will issue its determination to continue, revoke, or terminate an order or suspended investigation, as applicable, within seven days after the date of publication of the International Trade Commission's final determination concluding the sunset review, and subsequently publish notice of the Department's determination in the **Federal Register**.

Section 351.221

Section 351.221 deals with review procedures. We amended paragraph (c)(5)(i) to take into account changes in these regulations. Paragraph (c)(5)(i) provides, therefore, that the notice of initiation of a sunset review will contain a request for the information described in § 351.218(d).

Section 351.222

Section 351.222 deals with the revocation of orders and the termination of suspended investigations. We removed paragraph (i) and added new paragraph (i). These revisions are intended to clarify the circumstances under which the Department will revoke an order or terminate a suspended investigation and the effective date of revocation.

Circumstances under which the Secretary will revoke an order or terminate a suspended investigation. Paragraph (i)(1) is new and clarifies the circumstances under which the Department will revoke an order or terminate a suspended investigation. Paragraph (i)(1)(i) provides for revocation or termination within 90 days after initiation of the sunset review where no domestic interested party files a Notice of Intent to Participate in the sunset review or where the Department determines that domestic interested parties provided inadequate response to the Notice of Initiation. Paragraph (i)(1)(ii) provides for revocation or termination within 240 days (or 330 days where a full sunset review is fully extended) after initiation of the sunset review where the Department determines that revocation or

termination is not likely to lead to continuation or recurrence of a countervailable subsidy or dumping, as applicable. Finally, paragraph (i)(1)(iii) provides for revocation or termination within seven days after the date of publication of a final determination by the International Trade Commission that revocation or termination is not likely to lead to continuation or recurrence of material injury.

Effective date of revocation. Paragraph (i)(2) is new and clarifies the effective date of revocation. With respect to non-transition orders, paragraph (i)(2)(i) provides that revocation or termination will be effective on the fifth anniversary of the date of publication of the order or suspended investigation, as applicable. With respect to transition orders, paragraph (i)(2)(ii) provides that revocation or termination will be effective on January 1, 2000.

Subpart C—Information and Argument

Subpart C deals with collection of information and presentation of arguments to the Department.

Section 351.308

Section 351.308 deals with determinations on the basis of the facts available. We added new paragraph (f) to take into account changes in these regulations.

Use of facts available in a sunset review. Paragraph (f) is new and, consistent with the SAA at 879, provides that, where the Department determines to issue final results of review on the basis of the facts available, it normally will rely on calculated rates or margins, as applicable, from prior Department determinations and information contained in parties' substantive responses to the Notice of Initiation.

Section 351.309

Section 351.309 deals with written argument. We made minor changes to paragraphs (c)(1)(i) and (c)(1)(iii), and added new paragraph (e) to take into account changes in these regulations.

Case and rebuttal briefs. Paragraph (c)(1)(i) provides that case briefs for the final results of full sunset reviews may be filed 50 days after the date of publication of the preliminary results. Only an interested party (or industrial user or consumer organization) that filed a complete substantive response to the Notice of Initiation may submit a case brief. Paragraph (d)(1) (which is unchanged) provides that rebuttal briefs may be filed five days after the time limit for filing the case brief.

Comments on adequacy of response and appropriateness of expedited sunset

review. Paragraph (e) is new and provides for filing of comments on adequacy of response and the appropriateness of conducting an expedited sunset review. Paragraph (e)(i) provides that, where the Secretary determines that respondent interested parties provided inadequate response to a Notice of Initiation and has notified the International Trade Commission as such, interested parties (and industrial users and consumer organizations) that submitted complete substantive responses to the Notice of Initiation may file comments on whether an expedited sunset review is appropriate based on the adequacy of response. Paragraph (e)(i) clarifies that the comments may not include any new factual information or evidence and are limited to five pages. Paragraph (e)(ii) provides that comments on adequacy and appropriateness of expedited sunset review may be filed within 70 days after initiation of the sunset review.

Section 351.310

Section 351.310 deals with matters related to hearings.

Hearings. Although no changes have been made to § 351.310 by these regulations, we are clarifying that the provisions of § 351.310 are applicable in a full sunset review.

Section 351.312

Section 351.312 clarifies the regulatory provisions under which industrial users and consumers are entitled to provide information and comments.

Opportunity for industrial users and consumer organizations to submit relevant information and argument. We have made minor changes to paragraph (b) to take into account changes in these regulations. Specifically, paragraph (b) has been amended to allow industrial users and consumers to file substantive responses to a Notice of Initiation and comments concerning adequacy of response and appropriateness of expedited review. All such submissions must be filed in accordance with § 351.303.

Annex VIII—A, -B, and -C

Schedule for sunset review. We have added new Annex VIII—A, -B, and -C, which provides the schedules for 90-day, expedited, and full sunset reviews, respectively.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping duties, Business and industry, Cheese, Confidential business information, Countervailing duties, Investigations,

Reporting and recordkeeping requirements.

Dated: March 13, 1998

Robert S. LaRussa,
Assistant Secretary for Import Administration.

For the reasons stated, 19 CFR part 351 is amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

Subpart A—Scope and Definitions

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.*; and 19 U.S.C. 3538.

2. Section 351.102 is amended by adding new definitions to read as follows:

§ 351.102 Definitions.

* * * * *

(b) * * *

Expedited sunset review. "Expedited sunset review" means an expedited sunset review conducted by the Department where respondent interested parties provide inadequate responses to a notice of initiation under section 751(c)(3)(B) of the Act and § 351.218(e)(1)(ii).

* * * * *

Full sunset review. "Full sunset review" means a full sunset review conducted by the Department under section 751(c)(5) of the Act where both domestic interested parties and respondent interested parties provide adequate response to a notice of initiation under section 751(c)(3)(B) of the Act and §§ 351.218(e)(1)(i) and 351.218(e)(1)(ii).

* * * * *

Subpart B—Antidumping and Countervailing Duty Procedures

3. Section 351.218 is amended by revising paragraph (d) and (e) and adding paragraph (f) to read as follows:

§ 351.218 Sunset reviews under section 751(c) of the Act.

* * * * *

(d) **Participation in sunset review—(1) Domestic interested party notification of intent to participate—(i) Filing of notice of intent to participate.** Where a domestic interested party intends to participate in a sunset review, the interested party must, not later than 15 days after the date of publication in the **Federal Register** of the notice of initiation, file a notice of intent to participate in a sunset review with the Secretary.

(ii) *Contents of notice of intent to participate.* Every notice of intent to participate in a sunset review must include a statement expressing the domestic interested party's intent to participate in the sunset review and the following information:

(A) The name, address, and phone number of the domestic interested party (and its members, if applicable) that intends to participate in the sunset review and the statutory basis (under section 771(9) of the Act) for interested party status;

(B) A statement indicating whether the domestic producer:

(1) Is related to a foreign producer or to a foreign exporter under section 771(4)(B) of the Act; or

(2) Is an importer of the subject merchandise or is related to such an importer under section 771(4)(B) of the Act;

(C) The name, address, and phone number of legal counsel or other representative, if any;

(D) The subject merchandise and country subject to the sunset review; and

(E) The citation and date of publication in the **Federal Register** of the notice of initiation.

(iii) *Failure of domestic interested party to file notice of intent to participate in the sunset review.* (A) A domestic interested party that does not file a notice of intent to participate in the sunset review will be considered not willing to participate in the review and the Secretary will not accept or consider any unsolicited submissions from that party during the course of the review.

(B) If no domestic interested party files a notice of intent to participate in the sunset review, the Secretary will:

(1) Conclude that no domestic interested party has responded to the notice of initiation under section 751(c)(3)(A) of the Act;

(2) Notify the International Trade Commission in writing as such normally not later than 20 days after the date of publication in the **Federal Register** of the notice of initiation; and

(3) Not later than 90 days after the date of publication in the **Federal Register** of the Notice of Initiation, issue a final determination revoking the order or terminating the suspended investigation (see §§ 351.221(c)(5)(ii) and 351.222(i)).

(2) *Waiver of response by a respondent interested party to a notice of initiation—(i) Filing of statement of waiver.* A respondent interested party may waive participation in a sunset review before the Department under section 751(c)(4) of the Act by filing a statement of waiver with the

Department, not later than 30 days after the date of publication in the **Federal Register** of the notice of initiation. If a respondent interested party waives participation in a sunset review before the Department, the Secretary will not accept or consider any unsolicited submissions from that party during the course of the review. Waiving participation in a sunset review before the Department will not affect a party's opportunity to participate in the sunset review conducted by the International Trade Commission.

(ii) *Contents of statement of waiver.* Every statement of waiver must include a statement indicating that the respondent interested party waives participation in the sunset review before the Department and the following information:

(A) The name, address, and phone number of the respondent interested party waiving participation in the sunset review before the Department;

(B) The name, address, and phone number of legal counsel or other representative, if any;

(C) The subject merchandise and country subject to the sunset review; and

(D) The citation and date of publication in the **Federal Register** of the notice of initiation.

(iii) *No response from a respondent interested party.* The Secretary will consider the failure by a respondent interested party to file a complete substantive response to a notice of initiation under paragraph (d)(3) of this section as a waiver of participation in a sunset review before the Department.

(iv) *Waiver of participation by a foreign government in a CVD sunset review.* Where a foreign government waives participation in a CVD sunset review under paragraph (d)(2)(i) or (d)(2)(iii) of this section, the Secretary will:

(A) Conclude that respondent interested parties have provided inadequate response to the notice of initiation under section 751(c)(3)(B) of the Act;

(B) Notify the International Trade Commission and conduct an expedited sunset review and issue final results of review in accordance with paragraph (e)(1)(ii)(C) of this section; and

(C) Base the final results of review on the facts available in accordance with § 351.308(f), which normally will include a determination that revocation of the order or termination of the suspended investigation, as applicable, would be likely to lead to continuation or recurrence of a countervailable subsidy for all respondent interested parties.

(3) *Substantive response to a notice of initiation.—(i) e limit for substantive response to a notice of initiation.* A complete substantive response to a notice of initiation, filed under this section, must be submitted to the Department not later than 30 days after the date of publication in the **Federal Register** of the notice of initiation.

(ii) *Required information to be filed by all interested parties in substantive response to a notice of initiation.* Except as provided in paragraph (d)(3)(v)(A) of this section, each interested party that intends to participate in a sunset review must file a submission with the Department containing the following:

(A) The name, address, and phone number of the interested party (and its members, if applicable) that intends to participate in the sunset review and the statutory basis (under section 771(9) of the Act) for interested party status;

(B) The name, address, and phone number of legal counsel or other representative, if any;

(C) The subject merchandise and country subject to the sunset review;

(D) The citation and date of publication in the **Federal Register** of the notice of initiation;

(E) A statement expressing the interested party's willingness to participate in the review by providing information requested by the Department, which must include a summary of that party's historical participation in any segment of the proceeding before the Department related to the subject merchandise;

(F) A statement regarding the likely effects of revocation of the order or termination of the suspended investigation under review, which must include any factual information, argument, and reason to support such statement;

(G) Factual information, argument, and reason concerning the dumping margin or countervailing duty rate, as applicable, that is likely to prevail if the Secretary revokes the order or terminates the suspended investigation, that the Department should select for a particular interested party(s);

(H) A summary of the Department's findings regarding duty absorption, if any, including a citation to the **Federal Register** notice in which the Department's findings are set forth; and

(I) A description of any relevant scope clarification or ruling, including a circumvention determination, or changed circumstances determination issued by the Department during the proceeding with respect to the subject merchandise.

(iii) *Additional required information to be filed by respondent interested*

parties in substantive response to a notice of initiation. Except as provided in paragraph (d)(3)(v)(A) of this section, the submission from each respondent interested party that intends to participate in a sunset review must also contain the following:

(A) That party's individual weighted average dumping margin or countervailing duty rate, as applicable, from the investigation and each subsequent completed administrative review, including the final margin or rate, as applicable, where such margin or rate was changed as a result of a final and conclusive court order;

(B) For each of the five calendar years (or fiscal years, if more appropriate) preceding the year of publication of the notice of initiation, that party's volume and value (normally on an FOB basis) of exports of subject merchandise to the United States;

(C) As applicable, for the calendar year (or fiscal year, if more appropriate) preceding the year of initiation of the dumping investigation, that party's volume and value (normally on an FOB basis) of exports of subject merchandise to the United States;

(D) For each of the five calendar years (or fiscal years, if more appropriate) preceding the year of publication of the notice of initiation, on a volume basis (or value basis, if more appropriate), that party's percentage of the total exports of subject merchandise (defined in section 771(25) of the Act) to the United States; and

(E) For each of the three most recent years, including the year of publication of the notice of initiation, that party's volume and value (normally on an FOB basis) of exports of subject merchandise to the United States during the two fiscal quarters as of the month preceding the month in which the notice of initiation was published.

(iv) *Optional information to be filed by interested parties in substantive response to a notice of initiation—(A) Showing good cause.* An interested party may submit information or evidence to show good cause for the Secretary to consider other factors under section 752(b)(2) (CVD) or section 752(c)(2) (AD) of the Act and paragraph (e)(2)(ii) of this section. Such information or evidence must be submitted in the party's substantive response to the notice of initiation under paragraph (d)(3) of this section.

(B) *Other information.* A substantive response from an interested party under paragraph (d)(3) of this section also may contain any other relevant information or argument that the party would like the Secretary to consider.

(v) *Required information to be filed by a foreign government in substantive response to the notice of initiation in a CVD sunset review—(A) In general.* The foreign government of a country subject to a CVD sunset review (see section 771(9)(B) of the Act) that intends to participate in a CVD sunset review must file a submission with the Department under paragraph (d)(3)(i) of this section containing the information required under paragraphs (d)(3)(ii) (A) through (E) of this section.

(B) *Additional required information to be filed by a foreign government in a CVD sunset review involving an order where the investigation was conducted on an aggregate basis.* The submission from the foreign government of a country subject to a CVD sunset review, involving an order where the investigation was conducted on an aggregate basis, must also contain:

(1) The information required under paragraphs (d)(3)(ii)(F), (d)(3)(ii)(G), and (d)(3)(ii)(I) of this section;

(2) The countervailing duty rate from the investigation and each subsequent completed administrative review, including the final rate where such rate was changed as a result of a final and conclusive court order; and

(3) For each of the five calendar years (or fiscal years, if more appropriate) preceding the year of publication of the notice of initiation, the volume and value (normally on an FOB basis) of exports of subject merchandise to the United States.

(vi) *Substantive responses from industrial users and consumers.* An industrial user of the subject merchandise or a representative consumer organization, as described in section 777(h) of the Act, that intends to participate in a sunset review must file a submission with the Department under paragraph (d)(3)(i) of this section containing the information required under paragraphs (d)(3)(ii) (A) through (D) of this section and may submit other relevant information under paragraphs (d)(3)(ii) and (d)(3)(iv) of this section.

(4) *Rebuttal to substantive response to a notice of initiation.* Any interested party that files a substantive response to a notice of initiation under paragraph (d)(3) of this section may file a rebuttal to any other party's substantive response to a notice of initiation not later than five days after the date the substantive response is filed with the Department. Except as provided in § 351.309(e), the Secretary normally will not accept or consider any additional information from a party after the time for filing rebuttals has expired, unless the Secretary requests additional information from parties after

determining to proceed to a full sunset review under paragraph (e)(2) of this section.

(e) *Conduct of sunset review.—(1) Adequacy of response to a notice of initiation. (i) Adequacy of response from domestic interested parties.—(A) In general.* The Secretary will make its determination of adequacy of response on a case-by-case basis; however, the Secretary normally will conclude that domestic interested parties have provided adequate response to a notice of initiation where it receives a complete substantive response under paragraph (d)(3) of this section from at least one domestic interested party.

(B) *Disregarding response from a domestic interested party.* In making its determination concerning the adequacy of response from domestic interested parties under paragraph (e)(1)(i)(A) of this section, the Secretary may disregard a response from a domestic producer:

(1) Related to a foreign producer or to a foreign exporter under section 771(4)(B) of the Act; or

(2) That is an importer of the subject merchandise or is related to such an importer under section 771(4)(B) of the Act (see paragraph (d)(1)(ii)(B) of this section).

(C) *Inadequate response from domestic interested parties.* Where the Secretary determines to disregard a response from a domestic interested party(s) under paragraph (e)(1)(i)(A) or (e)(1)(i)(B) of this section and no other domestic interested party has filed a complete substantive response to the notice of initiation under paragraph (d)(3) of this section, the Secretary will:

(1) Conclude that no domestic interested party has responded to the notice of initiation under section 751(c)(3)(A) of the Act;

(2) Notify the International Trade Commission in writing as such normally not later than 40 days after the date of publication in the **Federal Register** of the Notice of Initiation; and

(3) Not later than 90 days after the date of publication in the **Federal Register** of the Notice of Initiation, issue a final determination revoking the order or terminating the suspended investigation (see §§ 351.221(c)(5)(ii) and 351.222(i)).

(ii) *Adequacy of response from respondent interested parties.* (A) *In general.* The Secretary will make its determination of adequacy of response on a case-by-case basis; however, the Secretary normally will conclude that respondent interested parties have provided adequate response to a notice of initiation where it receives complete substantive responses under paragraph (d)(3) of this section from respondent

interested parties accounting on average for more than 50 percent, on a volume basis (or value basis, if appropriate), of the total exports of subject merchandise to the United States over the five calendar years preceding the year of publication of the notice of initiation.

(B) *Failure of a foreign government to file a substantive response to a notice of initiation in a CVD sunset review.* If a foreign government fails to file a complete substantive response to a notice of initiation in a CVD sunset review under paragraph (d)(3)(v) of this section or waives participation in a CVD sunset review under paragraph (d)(2)(i) or (d)(2)(iii) of this section, the Secretary will:

(1) Conclude that respondent interested parties have provided inadequate response to the Notice of Initiation under section 751(c)(3)(B) of the Act;

(2) Notify the International Trade Commission and conduct an expedited sunset review and issue final results of review in accordance with paragraph (e)(1)(ii)(C) of this section; and

(3) Base the final results of review on the facts available in accordance with § 351.308(f), which normally will include a determination that revocation of the order or termination of the suspended investigation, as applicable, would be likely to lead to continuation or recurrence of a countervailable subsidy for all respondent interested parties.

(C) *Inadequate response from respondent interested parties.* If the Secretary determines that respondent interested parties provided inadequate response to a notice of initiation under paragraph (d)(2)(iv), (e)(1)(ii)(A), or (e)(1)(ii)(B) of this section, the Secretary:

(1) Will notify the International Trade Commission in writing as such normally not later than 50 days after the date of publication in the **Federal Register** of the Notice of Initiation; and

(2) Normally will conduct an expedited sunset review and, not later than 120 days after the date of publication in the **Federal Register** of the notice of initiation, issue, without further investigation, final results of review based on the facts available in accordance with § 351.308(f) (see section 751(c)(3)(B) of the Act and § 351.221(c)(5)(ii)).

(2) *Full sunset review upon adequate response from domestic and respondent interested parties.*—(i) *In general.* Normally, only where the Department receives adequate response to the notice of initiation from domestic interested parties under paragraph (e)(1)(i)(A) of this section and from respondent interested parties under paragraph

(e)(1)(ii)(A) of this section, will the Department conduct a full sunset review. Even where the Department conducts a full sunset review, only under the most extraordinary circumstances will the Secretary rely on a countervailing duty rate or a dumping margin other than those it calculated and published in its prior determinations, and in no case will the Secretary calculate a net countervailable subsidy or a dumping margin for a new shipper in the context of a sunset review.

(iii) *Consideration of other factors under section 752(b)(2) (CVD) or section 752(c)(2) (AD) of the Act.* The Secretary will consider other factors under section 752(b)(2) (CVD) or section 752(c)(2) (AD) of the Act if the Secretary determines that good cause to consider such other factors exists. The Secretary normally will consider such other factors only where it conducts a full sunset review under paragraph (e)(2)(i) of this section.

(f) *Time limits.*—(1) *Preliminary results of full sunset review.* The Department normally will issue its preliminary results in a full sunset review not later than 110 days after the date of publication in the **Federal Register** of the notice of initiation.

(2) *Verification.*—(i) *In general.* The Department will verify factual information relied upon in making its final determination normally only in a full sunset review (see section 782(i)(2) of the Act and § 351.307(b)(1)(iii)) and only where needed. The Department will conduct verification normally only if, in its preliminary results, the Department determines that revocation of the order or termination of the suspended investigation, as applicable, is not likely to lead to continuation or recurrence of a countervailable subsidy or dumping (see section 752(b) and section 752(c) of the Act), as applicable, and the Department's preliminary results are not based on countervailing duty rates or dumping margins, as applicable, determined in the investigation or subsequent reviews.

(ii) *Timing of verification.* The Department normally will conduct verification, under paragraph (f)(2)(i) of this section and § 351.307, approximately 120 days after the date of publication in the **Federal Register** of the notice of initiation.

(3) *Final results of full sunset review and notification to the International Trade Commission.*—(i) *Timing of final results of review and notification to the International Trade Commission.* The Department normally will issue its final results in a full sunset review and notify the International Trade Commission of

its results of review not later than 240 days after the date of publication in the **Federal Register** of the notice of initiation (see section 751(c)(5)(A) of the Act).

(ii) *Extension of time limit.* If the Secretary determines that a full sunset review is extraordinarily complicated under section 751(c)(5)(C) of the Act, the Secretary may extend the period for issuing final results by not more than 90 days (see section 751(c)(5)(B) of the Act).

(4) *Notice of continuation of an order or suspended investigation; notice of revocation of an order or termination of a suspended investigation.* Except as provided in paragraph (d)(1)(iii)(B)(3) of this section and § 351.222(i)(1)(i), the Department normally will issue its determination to continue an order or suspended investigation, or to revoke an order or terminate a suspended investigation, as applicable, not later than seven days after the date of publication in the **Federal Register** of the International Trade Commission's determination concluding the sunset review. The Department immediately thereafter will publish notice of its determination in the **Federal Register**.

4. Section 351.221(c)(5)(i) is revised to read as follows:

§ 351.221 Review procedures.

* * * * *

(c) * * *

(5) * * *

(i) The notice of initiation of a sunset review will contain a request for the information described in § 351.218(d); and

* * * * *

5. Section 351.222 is amended by revising paragraph (i) to read as follows:

§ 351.222 Revocation of orders; termination of suspended investigations.

* * * * *

(i) *Revocation or termination based on sunset review.*—(1) *Circumstances under which the Secretary will revoke an order or terminate a suspended investigation.* In the case of a sunset review under § 351.218, the Secretary will revoke an order or terminate a suspended investigation:

(i) Under section 751(c)(3)(A) of the Act, where no domestic interested party files a Notice of Intent to Participate in the sunset review under § 351.218(d)(1), or where the Secretary determines under § 351.218(e)(1)(i)(C) that domestic interested parties have provided inadequate response to the Notice of Initiation, not later than 90 days after the date of publication in the **Federal Register** of the notice of initiation;

(ii) Under section 751(d)(2) of the Act, where the Secretary determines that revocation or termination is not likely to lead to continuation or recurrence of a countervailable subsidy or dumping (see section 752(b) and section 752(c) of the Act), as applicable, not later than 240 days (or 330 days where a full sunset review is fully extended) after the date of publication in the **Federal Register** of the notice of initiation; or

(iii) Under section 751(d)(2) of the Act, where the International Trade Commission makes a determination, under section 752(a) of the Act, that revocation or termination is not likely to lead to continuation or recurrence of material injury, not later than seven days after the date of publication in the **Federal Register** of the International Trade Commission's determination concluding the sunset review.

(2) *Effective date of revocation.*—(i) *In general.* Except as provided in paragraph (i)(2)(ii) of this section, where the Secretary revokes an order or terminates a suspended investigation, pursuant to section 751(c)(3)(A) or section 751(d)(2) of the Act (see paragraph (i)(1) of this section), the revocation or termination will be effective on the fifth anniversary of the date of publication in the **Federal Register** of the order or suspended investigation, as applicable. This paragraph also applies to subsequent sunset reviews of transition orders (see paragraph (i)(2)(ii) of this section and section 751(c)(6)(A)(iii) of the Act).

(ii) *Transition orders.* Where the Secretary revokes a transition order (defined in section 751(c)(6)(C) of the Act) pursuant to section 751(c)(3)(A) or section 751(d)(2) of the Act (see paragraph (i)(1) of this section), the revocation or termination will be effective on January 1, 2000. This paragraph does not apply to subsequent sunset reviews of transition orders (see section 751(c)(6)(A)(iii) of the Act).

Subpart C—Information and Argument

6. Section 351.308 is amended by adding new paragraph (f) to read as follows:

§ 351.308 Determinations on the basis of the facts available.

* * * * *

(f) *Use of facts available in a sunset review.* Where the Secretary determines to issue final results of sunset review on the basis of facts available, the Secretary normally will rely on:

(1) Calculated countervailing duty rates or dumping margins, as applicable, from prior Department determinations; and

(2) Information contained in parties' substantive responses to the Notice of Initiation filed under § 351.218(d)(3), consistent with section 752(b) or 752(c) of the Act, as applicable.

7. Section 351.309 is amended by revising paragraph (c)(1)(i), by revising paragraph (c)(1)(iii), and by adding new paragraph (e), to read as follows:

§ 351.309 Written argument.

* * * * *

(c) * * *

(1) * * *

(i) For a final determination in a countervailing duty investigation or antidumping investigation, or for the final results of a full sunset review, 50 days after the date of publication of the preliminary determination or results of review, as applicable, unless the Secretary alters the time limit;

* * * * *

(iii) For the final results of an expedited antidumping review, Article 8 violation review, Article 4/Article 7 review, or section 753 review, a date specified by the Secretary.

* * * * *

(e) *Comments on adequacy of response and appropriateness of expedited sunset review.* (i) *In general.* Where the Secretary determines that respondent interested parties provided inadequate response to a Notice of Initiation (see § 351.218(e)(1)(ii)) and

has notified the International Trade Commission as such under § 351.218(e)(1)(ii)(C), interested parties (and industrial users and consumer organizations) that submitted a complete substantive response to the Notice of Initiation under § 351.218(d)(3) may file comments on whether an expedited sunset review under section 751(c)(3)(B) of the Act and § 351.218(e)(1)(ii)(B) or 351.218(e)(1)(ii)(C) is appropriate based on the adequacy of response to the notice of initiation. These comments may not include any new factual information or evidence (such as supplementation of a substantive response to the notice of initiation) and are limited to five pages.

(ii) *Time limit for filing comments.* Comments on adequacy of response and appropriateness of expedited sunset review must be filed not later than 70 days after the date of publication in the **Federal Register** of the notice of initiation.

8. Section 351.312 is amended by revising paragraph (b) to read as follows:

§ 351.312 Industrial users and consumer organizations.

* * * * *

(b) *Opportunity to submit relevant information and argument.* In an antidumping or countervailing duty proceeding under title VII of the Act and this part, an industrial user of the subject merchandise or a representative consumer organization, as described in section 777(h) of the Act, may submit relevant factual information and written argument to the Department under paragraphs, (d)(3)(ii), (d)(3)(vi), and (d)(4) of § 351.218, paragraphs (b), (c)(1), and (c)(3) of § 351.301, and paragraphs (c), (d), and (e) of § 351.309 concerning dumping or a countervailable subsidy. All such submissions must be filed in accordance with § 351.303.

* * * * *

9. New Annex VIII–A, –B, and –C is added after Annexes I–VII to read as follows:

ANNEX VIII–A—SCHEDULE FOR 90-DAY SUNSET REVIEWS

Day ¹	Event	Regulation
0	Initiation	§ 351.218(c).
15	Filing of Notice of Intent to Participate by domestic interested parties.	§ 351.218(d)(1)(i) (not later than 15 days after the date of publication of the Notice of Initiation).
20	Notification to the ITC that no domestic interested party has responded to the Notice of Initiation.	§ 351.218(d)(1)(iii)(B)(2) (normally not later than 20 days after the date of publication of the Notice of Initiation).
30	Filing of substantive response to the Notice of Initiation by all interested parties and industrial users and consumers.	§§ 351.218(d)(3)(i) and 351.218(d)(3)(vi) (not later than 30 days after the date of publication of the Notice of Initiation).
35	Filing of rebuttal to substantive response to the Notice of Initiation.	§ 351.218(d)(4) (not later than 5 days after the substantive response is filed with the Department).

ANNEX VIII—A—SCHEDULE FOR 90-DAY SUNSET REVIEWS—Continued

Day ¹	Event	Regulation
40	Notification to the ITC that no domestic interested party has responded to the Notice of Initiation (based on inadequate response from domestic interested parties).	§ 351.218(e)(1)(i)(C)(2) (normally not later than 40 days after the date of publication of the Notice of Initiation).
90	Final determination revoking an order or terminating a suspended investigation where no domestic interested party responds to the Notice of Initiation.	§§ 351.218(d)(1)(iii)(B)(3) and 351.222(i)(1)(i) (not later than 90 days after the date of publication of the Notice of Initiation).

¹ Indicates the number of days from the date of publication in the **Federal Register** of the Notice of Initiation.

ANNEX VIII—B—SCHEDULE FOR EXPEDITED SUNSET REVIEWS

Day ¹	Event	Regulation
0	Initiation	§ 351.218(c).
15	Filing of Notice of Intent to Participate by domestic interested parties.	§ 351.218(d)(1)(i) (not later than 15 days after the date of publication of the Notice of Initiation).
30	Filing of Statement of Waiver by respondent interested parties.	§ 351.218(d)(2)(i) (not later than 30 days after the date of publication of the Notice of Initiation).
30	Filing of substantive response to the Notice of Initiation by all interested parties and industrial users and consumers.	§§ 351.218(d)(3)(i) and 351.218(d)(3)(vi) (not later than 30 days after the date of publication of the Notice of Initiation).
35	Filing of rebuttal to substantive response to the Notice of Initiation.	§ 351.218(d)(4) (not later than 5 days after the substantive response is filed with the Department).
50	Notification to the ITC that respondent interested parties provided inadequate response to the Notice of Initiation.	§ 351.218(e)(1)(ii)(C)(1) (normally not later than 50 days after the date of publication of the Notice of Initiation).
70	Comments on adequacy of response and appropriateness of expedited sunset review.	§ 351.309(e)(ii) (not later than 70 days after the date of publication of the Notice of Initiation).
120	Final results of expedited sunset review where respondent interested parties provide inadequate response to the Notice of Initiation.	§§ 351.218(e)(1)(ii)(B) and 351.218(e)(1)(ii)(C)(2) (not later than 120 days after the date of publication of the Notice of Initiation).

¹ Indicates the number of days from the date of publication in the **Federal Register** of the Notice of Initiation.

ANNEX VIII—C—SCHEDULE FOR FULL SUNSET REVIEWS

Day ¹	Event	Regulation
0	Initiation	§ 351.218(c).
15	Filing of Notice of Intent to Participate by domestic interested parties.	§ 351.218(d)(1)(i) (not later than 15 days after the date of publication of the Notice of Initiation).
30	Filing of Statement of Waiver by respondent interested parties.	§ 351.218(d)(2)(i) (not later than 30 days after the date of publication of the Notice of Initiation).
30	Filing of substantive response to the Notice of Initiation by all interested parties and industrial users and consumers.	§§ 351.218(d)(3)(i) and 351.218(d)(3)(vi) (not later than 30 days after the date of publication of the Notice of Initiation).
35	Filing of rebuttal to substantive response to the Notice of Initiation.	§ 351.218(d)(4) (not later than 5 days after the substantive response is filed with the Department).
110	Preliminary results of full sunset review	§ 351.218(f)(1) (normally not later than 110 days after the date of publication of the Notice of Initiation).
120	Verification in a full sunset review, where needed	§ 351.218(f)(2)(ii) (approximately 120 days after the date of publication of the Notice of Initiation).
160	Filing of case brief in full sunset review	§ 351.309(c)(1)(i) (50 days after the date of publication of the preliminary results of full sunset review).
165	Filing of rebuttal brief in full sunset review	§ 351.309(d)(1) (5 days after the time limit for filing a case brief).
167	Hearing in full sunset review if requested	§ 351.310(d)(i) (2 days after the time limit for filing a rebuttal brief).
240	Final results of full sunset review	§ 351.218(f)(3)(i) (not later than 240 days after the date of publication of the Notice of Initiation).
330	Final results of full sunset review if fully extended	§ 351.218(f)(3)(ii) (if full sunset review is extraordinarily complicated, period for issuing final results may be extended by not more than 90 days).

¹ Indicates the number of days from the date of publication in the **Federal Register** of the Notice of Initiation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 94N-0355]

Drug Products Containing Quinine for the Treatment and/or Prevention of Malaria for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that over-the-counter (OTC) drug products containing quinine for the treatment and/or prevention of malaria are not generally recognized as safe and are misbranded. FDA is issuing this final rule after considering public comment on the agency's notice of proposed rulemaking and all data and information that have come to the agency's attention on the safety of quinine.

EFFECTIVE DATE: April 20, 1998.

FOR FURTHER INFORMATION CONTACT: John D. Lipnicki, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The agency's proposed rule for OTC drug products for the treatment and/or prevention of malaria was published in the **Federal Register** of April 19, 1995 (60 FR 19650). In that proposed rule, the agency summarized the history of quinine in the OTC drug review for use as an analgesic, antipyretic, and muscle relaxant (for the treatment and/or prevention of nocturnal leg muscle cramps). The agency also recognized that quinine has been marketed for decades, on both an OTC and a prescription basis, as an anti-infective agent for the treatment and/or prevention of malaria, a serious and potentially life-threatening disease that at one time was endemic in this country. However, data and information reviewed by the agency during the rulemaking for OTC drug products for the treatment and/or prevention of nocturnal leg muscle cramps raised serious safety concerns about the continued OTC availability of quinine

for the treatment and/or prevention of malaria. The agency also discussed serious safety and efficacy concerns about the continued OTC availability of quinine for the self-treatment of malaria without the care and supervision of a doctor. Interested persons were invited to file comments by July 3, 1995.

For reasons discussed in this document, FDA is classifying OTC drug products containing quinine or any quinine salt (e.g., quinine sulfate) and labeled for the treatment and/or prevention of malaria as not generally recognized as safe, as misbranded, and as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), for which an application or abbreviated application (hereinafter called application) approved under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 is required for marketing. In the absence of an approved application, these products are considered misbranded under section 502 of the act (21 U.S.C. 352). The final rule is being incorporated into 21 CFR part 310, Subpart E—Requirements for Specific New Drugs or Devices, by adding new § 310.547.

As discussed in the preamble to the proposed rule for OTC drug products containing quinine for the treatment and/or prevention of malaria, the conditions under which the drug products that are subject to this rule are not generally recognized as safe and effective and are misbranded would be effective 30 days after the date of publication of the final rule in the **Federal Register**. On or after April 20, 1998, no OTC drug product that is subject to the final rule may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the final rule that is repackaged or relabeled after the effective date of the final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

In response to the proposed rule, one comment from a drug distributor was submitted. The comment (Ref. 1) is on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

Reference

(1) Comment No. C1, Docket No. 94N-0355, Dockets Management Branch.

II. The Agency's Conclusion on the Comment

The comment contended that the agency had failed to distinguish between the safety of quinine used for malaria and quinine used for leg cramps. The comment contended that the agency appeared to commingle its safety concerns about quinine for these two uses. The comment noted the agency's discussion of adverse reaction reports on file for quinine: 110 reports over 22 years from 1969 through 1990. The comment noted that this was an average of only five cases per year. The comment added that only 26 of the 110 reports were identified as cases where it can be reasonably concluded that quinine was the causative agent and that only 5 of the 26 reports involved quinine products used for the treatment of malaria. The comment concluded that this is an extremely low incidence of adverse reaction reports for quinine used for malaria: On average, 0.25 reports per year from 1969 through 1990. The comment further noted an agency statement in the **Federal Register** of August 22, 1994 (59 FR 43234 at 43252), that approximately "two-thirds of these quinine-containing products are marketed for antimalarial use (with approximately one-third for the treatment and/or prevention of nocturnal leg muscle cramps)." The comment concluded that OTC quinine products are safe and effective for the treatment of malaria due to the very low incidence of reports of adverse reactions for quinine products used for the treatment of malaria and the two-thirds marketing of quinine products for malaria. The comment argued that these facts demonstrate a lack of scientific support for this proposed rule.

The agency does not agree with the comment. The Center for Disease Control and Prevention stated that approximately 1,000 cases of malaria are reported each year in the United States (60 FR 19650 at 19651). It is not known how many of these people might have used quinine as part of their treatment. As discussed in section III of this document, quinine is not the drug of choice for malaria. Although many quinine products are marketed for the treatment of malaria, many of these products may have been used to treat leg muscle cramps. In 1987, a U.S. manufacturer of quinine estimated (based on sales figures) that there are well over 1 million users of quinine for leg muscle cramps in the United States (Ref. 1). Based on the large number of people using quinine for leg muscle cramps, a larger number of adverse drug experiences would be expected to occur