

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.

#### *Incorporation by Reference*

(j) Unless otherwise provided in this AD, the actions shall be done per Boeing Alert Service Bulletin 767-27A0176, Revision 1, dated June 6, 2002. This incorporation by reference was approved previously by the Director of the Federal Register as of August 27, 2002 (67 FR 52401, August 12, 2002). Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

#### **Effective Date**

(k) This amendment becomes effective on July 8, 2003.

Issued in Renton, Washington, on May 27, 2003.

**Vi L. Lipski,**

*Manager, Transport Airplane Directorate,  
Aircraft Certification Service.*

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## **INTERNATIONAL TRADE COMMISSION**

### **19 CFR Parts 201, 204, 206, 207, 210, and 212**

**Rules of General Application;  
Investigations of Effects of Imports on  
Agricultural Programs; Investigations  
Relating to Global and Bilateral  
Safeguard Actions, Market Disruption,  
Trade Diversion and Review of Relief  
Actions; and Investigations of Whether  
Injury to Domestic Industries Results  
From Imports Sold at Less Than Fair  
Value or From Subsidized Exports to  
the United States; Adjudication and  
Enforcement; Implementation of the  
Equal Access to Justice Act**

**AGENCY:** International Trade  
Commission.

**ACTION:** Final rules.

**SUMMARY:** The United States International Trade Commission (Commission) amends its rules of practice and procedure concerning rules of general application, safeguard investigations, antidumping and countervailing duty investigations and reviews, intellectual property-related investigations, and the Equal Access to Justice Act, in 19 CFR parts 201, 206, 207, 210, and 212. The Commission also renumbers two footnotes in 19 CFR part 204. The amendments are necessary to make certain technical corrections, to

clarify certain provisions, to harmonize different parts of the Commission's rules, and to address concerns that have arisen in Commission practice. The intended effect of the amendments is to facilitate compliance with the Commission's rules and improve the administration of agency proceedings.

**DATES:** These rules are effective August 4, 2003, without further action, unless adverse comment is received by July 3, 2003. If adverse comment is received, the Commission will publish a timely withdrawal of the rules in the **Federal Register**.

**ADDRESSES:** A signed original and 8 copies of each set of comments on these amendments to the Commission's Rules, along with a cover letter, should be submitted by mail or hand delivery to Marilyn R. Abbott, Secretary, United States International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436. Comments may be submitted electronically to the extent provided by section 201.8 of the Commission's rules, as amended by 67 FR 68063 (Nov. 8, 2002).

**FOR FURTHER INFORMATION CONTACT:** Paul R. Bardos, Esq., Office of the General Counsel, United States International Trade Commission (telephone 202-205-3102). Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its World Wide Web site (<http://www.usitc.gov>).

**SUPPLEMENTARY INFORMATION:** This preamble provides background information, a regulatory analysis of the amendments, and then a detailed section-by-section analysis of the amendments.

#### **Background**

Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures, rules, and regulations as it deems necessary to carry out its functions and duties. To carry out its functions and duties, the Commission has issued rules of practice and procedure. The passage of time has rendered some provisions of the rules outdated. In addition, Commission practice has revealed the need for improvements in certain rules. This rulemaking updates certain outdated provisions and improves other provisions.

Consistent with its ordinary practice, the Commission is issuing these amendments in accordance with the rulemaking procedure in section 553 of

the Administrative Procedure Act (APA) (5 U.S.C. 553). This procedure entails the following steps: (1) Publication of a notice of proposed rulemaking; (2) solicitation of public comments on the proposed amendments; (3) Commission review of such comments prior to developing final amendments; and (4) publication of final amendments at least thirty days prior to their effective date. The Commission published a notice of proposed rulemaking (67 FR 38614, June 5, 2002) on which the present notice is based. No public comments were received on the notice of proposed rulemaking. Based on a continuing review of the rules to identify references that need correction or clarification, the present notice contains a number of amendments not included in the notice of proposed rulemaking.

A number of the amendments affect interim rules, *i.e.*, sections 201.201, 201.202, 201.204, 206.3. Those interim rules will be replaced with final rules in future rulemakings.

#### **Regulatory Analysis**

The Commission has determined that these amendments do not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, Oct. 4, 1993) and thus do not constitute a significant regulatory action for purposes of the Executive Order.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of rulemaking is required under 5 U.S.C. 553(b) or any other statute. Although the Commission has chosen to publish a notice, these amendments are "agency rules of procedure and practice," and thus are exempt from the notice requirement imposed by 5 U.S.C. 553(b).

These amendments do not contain federalism implications warranting the preparation of a federalism summary impact statement pursuant to Executive Order 13132 (64 FR 43255, Aug. 4, 1999).

No actions are necessary under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) because the amendments 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 will not significantly or uniquely affect small governments.

The amendments are not major rules as defined in the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). Moreover, they are exempt from the reporting requirements of the Contract With America Advancement Act of 1996 (5

U.S.C. 801 *et seq.*) because they concern rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

The amendments are not subject to section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), since they do not contain any new information collection requirements.

## Section-by-Section Analysis of the Amendments

### Part 201—Rules of General Application

#### Subpart A—Miscellaneous

The Commission revises section 201.1 regarding the applicability of part 201 to correctly reference parts 210, 212 and 213 in the reference to rules of special application.

The Commission amends section 201.2 by revising paragraph (c), which defines the term “Tariff Act,” to include citations to 19 U.S.C. 1677m and 1677n.

The Commission amends section 201.3 by revising paragraph (c) to clarify that any document filed after Commission business hours will be considered filed the next business day, and that if filing on that day means the document is untimely filed then the document may not be accepted unless it is accompanied by a request for permission to make a late filing.

The Commission amends section 201.3a by revising paragraph (a) to update the Commission’s designated point of contact for using its penalty mail in locating and recovering missing children.

The Commission amends section 201.4 by revising paragraph (d) to correctly cite to section 202 of the Trade Act of 1974 (19 U.S.C. 2252), eliminate the citation to the former 19 U.S.C. 1303, which has been repealed, and add “*et seq.*” to the citation to 19 U.S.C. 1673 to correctly refer to all of the antidumping provisions.

The Commission amends section 201.6 by revising paragraph (a)(2) to include section 206.17 as a section having special rules for the handling of nondisclosable confidential business information. The Commission also revises paragraph (d) of section 201.6 regarding the approval or denial of requests for confidential treatment. The revision will provide for consistency by stating that approvals, like denials, would be in writing. The Commission also revises paragraph (e)(3) of section 201.6 by replacing “his consideration” with the updated reference “consideration.” The Commission revises paragraph (g) of section 201.6 regarding granting confidential status to business information to clarify when

business information deemed not entitled to confidential treatment will be treated as public information. The revised paragraph (g) will impose a five-day deadline for withdrawing such business information after which time it would become public.

#### Subpart B—Initiation and Conduct of Investigations

The Commission amends section 201.8 by revising paragraph (a) to state that filings made within the Commission’s official hours of operation will be deemed filed on the date received by the Commission, consistent with the revised paragraph (c) of section 201.3 regarding Commission hours. The Commission also amends section 201.8 by revising paragraph (c), to provide that all documents filed, other than one or two-page documents, must be double-spaced, to improve the readability of documents. In addition, the Commission amends paragraph (d) of section 201.8 to require submitters to specify when a document is being filed with no confidential counterpart.

The Commission amends section 201.13 by revising paragraph (f) to provide, for ease of consideration, that supplementary materials in nonadjudicative hearings must be marked with the name of the organization submitting them. The same paragraph is also revised to remove the page limit on supplementary material that can be filed at a hearing, so that parties may present their arguments without such a limitation. The Commission revises paragraph (i)(1) of section 201.13, to delete the unnecessary reference to the requirement to file 14 copies of briefs with the Secretary, since paragraph (d) of section 201.8 already contains a requirement concerning the requisite number of copies to be filed.

The Commission amends section 201.14 by revising paragraph (a) to simplify filing requirements. In the event of an early or all-day closing of the Commission on a business day, the revision will allow the Secretary to accept filings due the day of the early or all-day closing on the next business day, without requiring the submitter to file a request for an extension of time.

#### Subpart C—Availability of Information to the Public Pursuant to 5 U.S.C. 552

The Commission amends section 201.17 by revising paragraph (a)(1) to permit the filing of requests electronically. Similarly, paragraph (b) of section 201.18 is revised to permit the filing of appeals by such means. The Commission has the capability of accepting electronic filing of requests at

its World Wide Web site, at <http://www.usitc.gov/foia.htm>.

The Commission amends section 201.18 by revising paragraphs (b), (d) (introductory text), and (e) to permit electronic filing of requests under the Freedom of Information Act and to correctly state that paragraph (c), and not paragraphs (a) and (b), provides for extension of time for deciding appeals of denials.

The Commission amends section 201.19 by revising paragraph (b) to clarify that the term “[s]ubmitter” includes contractors, bidders, vendors and others who have an administrative relationship with the Commission, and who provide confidential business information to the Commission. Under the amended provision, persons or entities having an administrative relationship to the Commission will qualify to receive notice before release of their confidential submission under FOIA.

The Commission amends section 201.21 by revising paragraph (a) to provide information about the Commission’s World Wide Web site, consistent with the electronic reading room provisions of the FOIA.

#### Subpart D—Safeguarding Individual Privacy Pursuant to 5 U.S.C. 552a

The Commission amends section 201.31 by revising the section heading and adding paragraph (c) to include employee conduct as part of the section and to rename the section heading to reflect this change. Consequently, the Commission removes section 201.33, which currently deals with employee conduct, and adds its text to section 201.31. This eliminates the current duplication of section numbers.

#### Subpart G—Enforcement of Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the U.S. International Trade Commission

The Commission amends section 201.170 by revising paragraph (c) to provide an updated contact point.

#### Subpart H—Debt Collection

The Commission amends subpart H, regarding debt collection, to update all references to “Office of Finance and Budget” to read “Office of Finance.” The Commission also amends subpart H to update citations to applicable statutes and rules, and in particular to take into account the move of the Federal Claims Collection Standards from title 4 of the Code of Federal Regulations to title 31. The revisions affect the authority citation for subpart H; paragraphs (f), (i), and (m) of section 201.201; paragraphs

(a) and (b)(4) of section 201.202; paragraphs (a)(16)(ii), (g)(1), (g)(2), (h)(1)(iii), (h)(2)(iii), (h)(3), (h)(4)(ii), (j), and (n) of section 201.204; paragraphs (d), (f)(3), and (g)(1)(iv) of section 201.206; and paragraph (b)(3) of section 201.207.

*Part 204—Investigations of Effects of Imports on Agricultural Programs*

In section 204.1, the Commission redesignates footnote 5 as footnote 1. In section 204.2, the Commission redesignates footnote 6 as footnote 2. These changes correct a misnumbering of those footnotes. The Commission also revises the authority citation to simplify the citations.

*Part 206—Investigations Relating to Global and Bilateral Safeguard Actions, Market Disruption, Trade Diversion, and Review of Relief Actions*

**Subpart A—General**

The Commission amends section 206.3 by revising paragraph (b) to include in the notice of institution any limits on page lengths for posthearing briefs.

The Commission amends section 206.8 by revising paragraph (b) to provide that the Secretary shall promptly notify a petitioner of approval of an application for disclosure of confidential business information under administrative protective order (APO), and that the petitioner shall then serve a copy of the confidential petition on those approved applicants within two (2) calendar days of receiving that notification. Under the revised paragraph, which is consistent with section 207.10(b)(1)(i), approved applicants will receive a copy of the confidential petition more quickly, and without having to wait for the Secretary's issuance of the service list.

The Commission amends section 206.17 by revising paragraphs (a)(2), (b)(2), (g)(1) and (g)(3). The Commission revises paragraph (a)(2) to require only a signed APO application and five (5) copies to be filed with the Commission. Filing a signed original and fourteen (14) copies pursuant to section 201.8(d) provides the Commission with unnecessary copies. Paragraph (b)(2) is revised to clarify that confidential business information can only be used in representing an interested party. The Commission revises paragraph (g)(1) to include the definition of nondisclosable confidential business information from section 201.6(a)(2) to make the rule easier to understand. The Commission also revises paragraph (g)(3) to make it consistent with existing section 207.7

(g)(3), the analogous provision in part 207.

*Part 207—Investigations of Whether Injury to Domestic Industries Results From Imports Sold at Less Than Fair Value or From Subsidized Exports to the United States*

**Subpart A—General Provisions**

The Commission removes section 207.6 regarding reports of progress of investigation as unnecessary as duplicative of the statute. Moreover, amendments to the statute, the Commission's rules, and Commission practice have resulted in information being disseminated as a matter of course about an investigation's schedule and status. The section number is reserved.

The Commission amends section 207.7 by revising paragraph (a)(2) to require only a signed APO application and five (5) copies to be filed with the Commission, consistent with the changes in part 206. The Commission further revises paragraph (a)(2) of section 207.7 for consistency to include a deadline for adding attorneys under the APO in remanded investigations. Paragraph (b)(2) is revised to clarify that business proprietary information can only be used in representing an interested party.

**Subpart F—Five-Year Reviews**

The Commission amends section 207.62 by revising paragraph (b)(2) to delete the reference to "per group," as unnecessary, since a grouped review only involves one "group."

The Commission amends section 207.64 by revising paragraph (b), regarding staff reports, to conform with agency practice by providing that the final staff report will be placed in the record.

*Part 210—Adjudication and Enforcement*

The Commission revises paragraph (f)(2) of section 210.4 and paragraph (a) of section 210.8 to reduce the number of copies submitters must file of documents to the minimum needed by the agency. Submitters must file an original and 12—rather than 14—copies of each submission if the investigation or related proceeding is before the Commission, except that a submitter shall file the original and 6 copies of any exhibits filed with a request or petition for related proceedings. The Commission previously had effected a partial version of this reduction in the number of required copies by publishing notice of a waiver of its rules at 66 FR 58523 (Nov. 21, 2001).

*Part 212—Implementation of the Equal Access to Justice Act*

The Commission amends section 212.29, regarding payment of awards, to update all references to "Finance and Budget Division" to read "Office of Finance."

**List of Subjects in 19 CFR Parts 201, 204, 206, 207, 210**

Administrative practice and procedure, investigations.

■ For the reasons stated in the preamble, the Commission amends 19 CFR parts 201, 204, 206, 207, and 210 as set forth below:

**PART 201—RULES OF GENERAL APPLICATION**

■ 1. The authority citation for part 201 continues to read as follows:

**Authority:** Sec. 335 of the Tariff Act of 1930 (19 U.S.C. 1335), and sec. 603 of the Trade Act of 1974 (19 U.S.C. 2482), unless otherwise noted.

■ 2. Revise § 201.1 to read as follows:

**§ 201.1 Applicability of part.**

This part relates generally to functions and activities of the Commission under various statutes and other legal authority. Rules having special application appear separately in parts 202 through 207, inclusive, and parts 210, 212 and 213, of this chapter. In case of inconsistency between a rule of general application and a rule of special application, the latter is controlling.

■ 3. Amend § 201.2 to revise paragraph (c) to read as follows:

**§ 201.2 Definitions.**

\* \* \* \* \*

(c) *Tariff Act* means the Tariff Act of 1930, 19 U.S.C. 1202–1677j, 1677m–n;

\* \* \* \* \*

■ 4. Amend § 201.3 to revise paragraph (c) to read as follows:

**§ 201.3 Commission offices, mailing address, and hours.**

\* \* \* \* \*

(c) *Hours.* The business hours of the Commission are from 8:45 a.m. to 5:15 p.m., eastern standard or daylight savings time, whichever is in effect in Washington, DC. Any document filed with the Secretary of the Commission after 5:15 p.m. will be considered filed the next business day. If filing on that day would be untimely, the filing may not be accepted unless a request is made for acceptance of a late filing for good cause shown pursuant to 201.14(b)(2).

■ 5. Amend § 201.3a to revise paragraph (a) to read as follows:

**§ 201.3a Missing children information.**

(a) Pursuant to 39 U.S.C. 3220, penalty mail sent by the Commission may be used to assist in the location and recovery of missing children. This section establishes procedures for such use and is applicable on a Commission-wide basis. The Commission's Office of Facilities Management, telephone 202-205-2741, shall be the point of contact for matters related to the implementation of this section.

\* \* \* \* \*

■ 6. Amend § 201.4 to revise paragraph (d) to read as follows:

**§ 201.4 Performance of functions.**

\* \* \* \* \*

(d) Presentation of matter that may come within the purview of other laws. Whenever any party or person, including the Commission staff, has reason to believe that (1) a matter under investigation pursuant to section 337 of the Tariff Act of 1930, or (2) a matter under an investigation pursuant to section 202 of the Trade Act of 1974 (19 U.S.C. 2252), which is causing increased imports may come within the purview of another remedial provision of law not the basis of such investigation, including but not limited to the antidumping provisions (19 U.S.C. 1673 *et seq.*) or the countervailing duty provisions (19 U.S.C. 1671 *et seq.*) of the Tariff Act of 1930, then the party or person may file a suggestion of notification with the Commission that the appropriate agency be notified of such matter or circumstances, together with such information as the party or person has available. The Secretary shall promptly thereafter publish notice of the filing of such suggestion and information, and make them available for inspection and copying to the extent permitted by law. Any person may comment on the suggestion within 10 days after the publication of said notice. Thereafter, the Commission shall determine whether notification is appropriate under the law and, if so, shall notify the appropriate agency of such matters or circumstances. The Commission may at any time make such notification in the absence of a suggestion under this rule when the Commission has reason to believe, on the basis of information before it, that notification is appropriate under law.

■ 7. Amend § 201.6 to revise paragraphs (a)(2), (d), (e)(3) and (g) to read as follows:

**§ 201.6 Confidential business information.**

(a) \* \* \*

(2) *Nondisclosable confidential business information* is privileged

information, classified information, or specific information (*e.g.*, trade secrets) of a type for which there is a clear and compelling need to withhold from disclosure. Special rules for the handling of such information are set out in § 206.17 and § 207.7 of this chapter.

\* \* \* \* \*

(d) *Approval or denial of requests for confidential treatment.* Approval or denial of requests shall be made only by the Secretary or Acting Secretary. An approval or a denial of a request for confidential treatment shall be in writing. A denial shall specify the reason therefor, and shall advise the submitter of the right to appeal to the Commission.

(e) \* \* \*

(3) The justification submitted to the Commission in connection with an appeal shall be limited to that presented to the Secretary with the original or amended request. When the Secretary or Acting Secretary has denied a request on the ground that the submitter failed to provide adequate justification, any such additional justification shall be submitted to the Secretary for consideration as part of an amended request. For purposes of paragraph (e)(1) of this section, the twenty (20) day period for filing an appeal shall be tolled on the filing of an amended request and a new twenty (20) day period shall begin once the Secretary or Acting Secretary has denied the amended request, or the approval or denial has not been forthcoming within ten (10) days of the filing of the amended request. A denial of a request by the Secretary on the ground of inadequate justification shall not obligate a requester to furnish additional justification and shall not preclude a requester from filing an appeal with the Commission based on the justification earlier submitted to the Secretary.

\* \* \* \* \*

(g) *Granting confidential status to business information.* Any business information submitted in confidence and determined to be entitled to confidential treatment shall be maintained in confidence by the Commission and not disclosed except as required by law. In the event that any business information submitted to the Commission is not entitled to confidential treatment, the submitter will be permitted to withdraw the tender within five days of its denial of confidential treatment unless it is the subject of a request under the Freedom of Information Act or of judicial discovery proceedings. After such five day period, the business information deemed not entitled to confidential

treatment, and not withdrawn, will be treated as public information.

\* \* \* \* \*

■ 8. Amend § 201.8 to revise paragraphs (a), (c) and (d) to read as follows:

**§ 201.8 Filing of Documents.**

(a) *Where to file; date of filing.*

Documents shall be filed at the office of the Secretary of the Commission in Washington, DC. Such documents, if properly filed within the hours of operation specified in § 201.3(c), will be deemed to be filed on the date on which they are actually received in the Commission.

\* \* \* \* \*

(c) *Specifications for documents.* Each document filed under this chapter shall be double-spaced, clear and legible, except that a document of two pages or less in length need not be double-spaced.

\* \* \* \* \*

(d) *Number of copies.* A signed original (or a copy designated as an original) and fourteen (14) copies of each document shall be filed. All submissions shall be on letter-sized paper (8½ inches by 11 inches), except copies of documents prepared for another agency or a court (*e.g.* patent file wrappers or pleadings papers). The original and at least one copy of all submissions shall be printed on one side only and shall be unbound (although they may be stapled or held together by means of a clip). In the event that confidential treatment of the document is requested under Sec. 201.6, at least four (4) additional copies shall be filed, in which the confidential business information shall have been deleted and which shall have been conspicuously marked "nonconfidential" or "public inspection." In the event that confidential treatment is not requested, the document shall be conspicuously marked "No confidential version filed." The name of the person signing the original shall be typewritten or otherwise reproduced on each copy.

\* \* \* \* \*

■ 9. Amend § 201.13 to revise paragraphs (f) and (i)(1) to read as follows:

**§ 201.13 Conduct of nonadjudicative hearings.**

\* \* \* \* \*

(f) *Supplementary material.* A party to the investigation may file with the Secretary supplementary material, other than remarks read into the record, for acceptance into the record. The party shall file any such material with the Secretary at the hearing. Supplementary materials must be marked with the

name of the organization submitting it. As used herein, the term *supplementary material* refers to (1) additional graphic material such as charts and diagrams used to illuminate an argument or clarify a position and (2) information not available to a party at the time its prehearing brief was filed.

\* \* \* \* \*

(i) *Briefs*—(1) *Parties*. Briefs of the information produced at the hearing and arguments thereon may be presented to the Commission by parties to the investigation. Time to be allowed for submission of briefs will be set after conclusion of testimony and oral argument, if any.

\* \* \* \* \*

■ 10. Amend § 201.14 to revise paragraph (a) to read as follows:

**§ 201.14 Computation of time, additional hearings, postponements, continuances, and extensions of time.**

(a) *Computation of time*. Computation of any period of time prescribed or allowed by the rules in this chapter, by order of the Commission, or by order of the presiding officer under part 210 of this chapter shall begin with the first business day following the day on which the act or event initiating such period of time shall have occurred. The last day of the period so computed is to be included, unless it is a Saturday, Sunday, or Federal legal holiday, in which event the period runs until the end of the next business day. When the period of time prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and Federal legal holidays shall be excluded from the computation. As used in this rule, a Federal legal holiday refers to any full calendar day designated as a legal holiday by the President or the Congress of the United States. In the event of an early or all-day closing of the Commission on a business day, the Secretary is authorized to accept on the next full business day filings due the day of the early or all-day closing, without requiring the granting of an extension of time by the Chairman of the Commission, or such other person designated to conduct the investigation.

\* \* \* \* \*

■ 11. Amend § 201.17 to revise paragraph (a)(1) to read as follows:

**201.17 Procedures for requesting access to records.**

(a) *Requests for records*. (1) A request for any information or record shall be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436 and shall indicate clearly in the

request, and if the request is in paper form on the envelope, that it is a "Freedom of Information Act Request." A written request may be made either (1) in paper form, or (2) electronically by contacting the Commission at <http://www.usitc.gov/foia.htm>.

\* \* \* \* \*

■ 12. Amend § 201.18 to revise paragraphs (b), (d) introductory text, and (e) to read as follows:

**§ 201.18 Denial of requests, appeals from denial.**

\* \* \* \* \*

(b) An appeal from a denial of a request must be received within sixty days of the date of the letter of denial and shall be made to the Commission and addressed to the Chairman, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. Any such appeal shall be in writing, and shall indicate clearly in the appeal, and if the appeal is in paper form on the envelope, that it is a "Freedom of Information Act Appeal." An appeal may be made either in paper form, or electronically by contacting the Commission at <http://www.usitc.gov/foia.htm>.

\* \* \* \* \*

(d) The extensions of time mentioned in paragraph (c) of this section shall be made only for one or more of the following reasons:

\* \* \* \* \*

(e) The extensions of time mentioned in paragraph (c) of this section shall not exceed ten working days in the aggregate.

■ 13. Amend § 201.19 to revise paragraph (b) to revise the definition of *submitter* to read as follows:

**§ 201.19 Notification regarding requests for confidential business information.**

\* \* \* \* \*

(b) *Definitions*. \* \* \*

*Submitter* means any person or entity who provides confidential business information, directly or indirectly, to the Commission. The term includes, but is not limited to, corporations, producers, importers, and state and federal governments, as well as others who have an administrative relationship with the Commission such as contractors, bidders and vendors.

\* \* \* \* \*

■ 14. Amend § 201.21 to revise paragraph (a) to read as follows:

**§ 201.21 Availability of specific records.**

(a) *Records available*. The following information, on request to the Secretary of the Commission, is available for public inspection and copying: (1) final

opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases; (2) those statements of policy and interpretations which have been adopted by the agency; and (3) administrative staff manuals and instructions to staff that affect a member of the public. Available information includes, but is not limited to: (i) Applications, petitions, and other formal documents filed with the Commission, (ii) notices to the public concerning Commission matters, (iii) transcripts of testimony taken and exhibits submitted at hearings, (iv) reports to the President, to either or both Houses of Congress, or to Committees of Congress, release of which has been authorized by the President or the legislative body concerned, (v) reports and other documents issued for general distribution. Much of the information described above also is available on the Commission's World Wide Web site. The Commission's home page is at <http://www.usitc.gov>. The Web site also includes information subject to repeated Freedom of Information Act requests. Persons accessing the Web site can find instructions on how to locate Commission information by following the "Freedom of Information Act" link on the home page.

\* \* \* \* \*

■ 15. Amend § 201.31 to revise the section heading and add paragraph (c) to read as follows:

**§ 201.31 Fees and Employee conduct.**

\* \* \* \* \*

(c) The Privacy Act Officer shall establish rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records, or in maintaining any record, and periodically instruct each such person with respect to such rules and the requirements of the Privacy Act including the penalties for noncompliance.

■ 16. Remove § 201.33 of subpart D.

**§ 201.33 [Removed]**

■ 17. Amend § 201.170 to revise paragraph (c) to read as follows:

**§ 201.170 Compliance procedures.**

\* \* \* \* \*

(c) The Director, Office of Equal Employment Opportunity, shall be responsible for coordinating implementation of this section. Complaints may be sent to the Director, Office of Equal Employment Opportunity, United States International

Trade Commission, 500 E Street SW., Washington, DC 20436.

\* \* \* \* \*

■ 18. Amend the authority citation for subpart H of part 201 to read as follows:

**Authority:** 19 U.S.C. 1335; 5 U.S.C. 5514(b)(1); 31 U.S.C. 3716(b); 31 U.S.C. 3720A(b)(4); 31 CFR chapter IX; 26 CFR 301.6402-6(b).

■ 19. Amend § 201.201 to revise paragraphs (f), (i), and (m) to read as follows:

**§ 201.201 Definitions.**

\* \* \* \* \*

(f) *Director* means the Director, Office of Finance of the Commission or an official designated to act on the Director's behalf.

\* \* \* \* \*

(i) *Federal Claims Collection Standards (FCCS)* means standards published at 31 CFR chapter IX.

\* \* \* \* \*

(m) *Office of Finance* means the Office of Finance of the Commission.

■ 20. Amend § 201.202 to revise paragraphs (a) and (b)(4) to read as follows:

**§ 201.202 Purpose and scope of salary and administrative offset rules.**

(a) *Purpose.* The purpose of sections 201.201 through 201.207 is to implement 5 U.S.C. 5514, 31 U.S.C. 3716, and 31 U.S.C. 3720A which authorize the collection by salary offset, administrative offset, or tax refund offset of debts owed by persons, organizations, or entities to the Federal government. Generally, however, a debt may not be collected by such means if it has been outstanding for more than ten years after the agency's right to collect the debt first accrued. These proposed regulations are consistent with the Office of Personnel Management regulations on salary offset, codified at 5 CFR Part 550, subpart K, and with regulations on administrative offset codified at 31 CFR part 901.

\* \* \* \* \*

(b) \* \* \*

(4) Nothing in Sections 201.201 through 201.207 precludes the compromise, suspension, or termination of collection actions where appropriate under the standards implementing the Federal Claims Collection Act (31 U.S.C. 3711 *et seq.*), namely, 31 CFR chapter IX.

■ 21. Amend § 201.204 to revise paragraphs (a)(16)(ii), (g)(1), (g)(2), (h)(1)(iii), (h)(2)(iii), (h)(3), (h)(4)(ii), (j), and (n) to read as follows:

**§ 201.204 Salary offset.**

(a) \* \* \*

(16) \* \* \*

(ii) Penalties under the False Claims Act, 31 U.S.C. 3729-3733, or under any other applicable statutory authority; or

(g) Notice of salary offset where the Commission is the paying agency.

(1) Upon issuance of a proper certification by the Director (for debts owed to the Commission) or upon receipt of a proper certification from another creditor agency, the Office of Finance shall send the employee a written notice of salary offset. Such notice shall advise the employee:

(i) Of the certification that has been issued by the Director or received from another creditor agency;

(ii) Of the amount of the debt and of the deductions to be made; and

(iii) Of the initiation of salary offset at the next officially established pay interval or as otherwise provided for in the certification.

(2) The Office of Finance shall provide a copy of the notice to the creditor agency and advise such agency of the dollar amount to be offset and the pay period when the offset will begin.

\* \* \* \* \*

(h) \* \* \*

(1) \* \* \*

(iii) Deductions shall begin the pay period following the issuance of the certification by the Director or the receipt by the Office of Finance of the certification from another agency or as soon thereafter as possible.

\* \* \* \* \*

(2) \* \* \*

(iii) Lump-sum deductions from final check. In order to liquidate a debt, a lump-sum deduction exceeding 15 percent of disposable pay may be made pursuant to 31 U.S.C. 3716 and 5 U.S.C. 5514(a)(1) from any final salary payment due a former employee, whether the former employee was separated voluntarily or involuntarily.

\* \* \* \* \*

(3) Multiple debts. Where two or more creditor agencies are seeking salary offset, or where two or more debts are owed to a single creditor agency, the Office of Finance may, at its discretion, determine whether one or more debts should be offset simultaneously within the 15 percent limitation.

(4) \* \* \*

(ii) In the event that a debt to the Commission is certified while an employee is subject to salary offset to repay another agency, the Office of Finance may, at its discretion, determine whether the debt to the Commission should be repaid before the debt to the other agency, repaid

simultaneously, or repaid after the debt to the other agency.

\* \* \* \* \*

(j) Interest, Penalties, and Administrative Costs. Where the Commission is the creditor agency, it shall assess interest, penalties, and administrative costs pursuant to 31 U.S.C. 3717 and 31 CFR 901.9.

\* \* \* \* \*

(n) Exception to due process procedures. The procedures set forth in this section shall not apply to adjustments described in 5 U.S.C. 5514(a)(3) and 5 CFR 550.1104(c).

■ 22. Amend § 201.206 to revise paragraphs (d), (f)(3), and (g)(1)(iv) to read as follows:

**§ 201.206 Administrative offset.**

\* \* \* \* \*

(d) Interest. Pursuant to 31 U.S.C. 3717 and 31 CFR 901.9, the Commission shall assess interest, penalties and administrative costs on debts owed to the United States. The Commission is authorized to assess interest and related charges on debts that are not subject to 31 U.S.C. 3717 to the extent authorized under the common law or other applicable statutory authority.

(f) \* \* \*

(3) That the Commission has complied with the requirements of its own administrative offset regulations and the applicable provisions of 31 CFR part 901 with respect to providing the debtor with due process.

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(iv) That the agency has complied with its own administrative offset regulations and with the applicable provisions of 31 CFR part 901, including providing any required hearing or review.

■ 23. Amend § 201.207 to revise paragraph (b)(3) to read as follows:

**§ 201.207 Administrative offset against amounts payable from Civil Service Retirement and Disability Fund.**

\* \* \* \* \*

(b) \* \* \*

(3) The Commission has complied with the requirements of 31 CFR 901.3, including any required hearing or review.

\* \* \* \* \*

**PART 204—INVESTIGATIONS OF EFFECTS OF IMPORTS ON AGRICULTURAL PROGRAMS**

■ 1. Revise the authority citation for part 204 to read as follows:

**Authority:** 19 U.S.C. 1335.

- 2. In § 204.1, redesignate footnote 5 as footnote 1.
- 3. In § 204.2, redesignate footnote 6 as footnote 2.

**PART 206—INVESTIGATIONS RELATING TO GLOBAL AND BILATERAL SAFEGUARD ACTIONS, MARKET DISRUPTION, TRADE DIVERSION, AND REVIEW OF RELIEF ACTIONS**

- 1. The authority citation for part 206 continues to read as follows:

**Authority:** 19 U.S.C. 1335, 2251–2254, 3351–3382; secs. 103, 301–302, Pub. L. 103–465, 108 Stat. 4809.

- 2. Amend § 206.3 to revise paragraph (b) to read as follows:

**§ 206.3 Institution of investigations; publication of notice; and availability for public inspection.**

\* \* \* \* \*

(b) *Contents of notice.* The notice will identify the petitioner or other requestor, the imported article that is the subject of the investigation and its tariff subheading, the nature and timing of the determination to be made, the time and place of any public hearing, dates of deadlines for filing briefs, statements, and other documents, limits on page lengths for posthearing briefs, the place at which the petition or request and any other documents filed in the course of the investigation may be inspected, and the name, address, and telephone number of the office that may be contacted for more information. The Commission will provide the same sort of information in its notice when the investigation was instituted following receipt of a resolution or on the Commission's own motion.

\* \* \* \* \*

- 3. Amend § 206.8 to revise paragraph (b) to read as follows:

**§ 206.8 Service, filing and certification of documents.**

\* \* \* \* \*

(b) *Service.* Any party submitting a document for the consideration of the Commission in the course of an investigation to which this part pertains shall, in addition to complying with § 201.8 of this chapter, serve a copy of the public version of such document on all other parties to the investigation in the manner prescribed in § 201.16 of this chapter, and, when appropriate, serve a copy of the confidential version of such document in the manner provided for in § 206.17(f). The Secretary shall promptly notify a petitioner when, before the establishment of a service list under § 206.17(a)(4), an application under

§ 206.17(a) is approved. When practicable, this notification shall be made by facsimile transmission. A copy of the petition including all confidential business information shall then be served by petitioner on those approved applicants in accordance with this section within two (2) calendar days of the time notification is made by the Secretary. If a document is filed before the Secretary's issuance of the service list provided for in § 201.11 of this chapter or the administrative protective order list provided for in § 206.17, the document need not be accompanied by a certificate of service, but the document shall be served on all appropriate parties within two (2) days of the issuance of the service list or the administrative protective order list and a certificate of service shall then be filed. Notwithstanding § 201.16 of this chapter, petitions, briefs, and testimony filed by parties shall be served by hand or, if served by mail, by overnight mail or its equivalent. Failure to comply with the requirements of this rule may result in removal from status as a party to the investigation. The Commission shall make available, upon request, to all parties to the investigation a copy of each document, except transcripts of hearings, confidential business information, privileged information, and information required to be served under this section, placed in the docket file of the investigation by the Commission.

\* \* \* \* \*

- 4. Amend § 206.17 to revise paragraphs (a)(2), (b)(2), (g)(1), and (g)(3) to read as follows:

**§ 206.17 Limited disclosure of certain confidential business information under administrative protective order.**

(a) \* \* \*

(2) *Application.* An application under paragraph (a)(1) of this section must be made by an authorized applicant on a form adopted by the Secretary or a photocopy thereof. A signed application and five (5) copies thereof shall be filed. An application on behalf of an authorized applicant must be made no later than the time that entries of appearance are due pursuant to § 201.11 of this chapter. In the event that two or more authorized applicants represent one interested party who is a party to the investigation, the authorized applicants must select one of their number to be lead authorized applicant. The lead authorized applicant's application must be filed no later than the time that entries of appearance are due. Provided that the application is accepted, the lead authorized applicant shall be served with confidential business information pursuant to

paragraph (f) of this section. The other authorized applicants representing the same party may file their applications after the deadline for entries of appearance but at least five days before the deadline for filing posthearing briefs in the investigation, and shall not be served with confidential business information.

\* \* \* \* \*

(b) \* \* \*

(2) Use such confidential business information solely for the purposes of representing an interested party in the Commission investigation then in progress;

\* \* \* \* \*

(g) *Exemption from disclosure—(1) In general.* Any person may request exemption from the disclosure of confidential business information under administrative protective order, whether the person desires to include such information in a petition filed under this Subpart B, or any other submission to the Commission during the course of an investigation. Such a request shall only be granted if the Secretary finds that such information is nondisclosable confidential business information. As defined in § 201.6(a)(2) of this chapter, nondisclosable confidential business information is privileged information, classified information, or specific information (e.g., trade secrets) of a type for which there is a clear and compelling need to withhold from disclosure.

(2) \* \* \*

(3) *Procedure if request is approved.* If the request is approved, the person shall file three versions of the submission containing the nondisclosable confidential business information in question. One version shall contain all confidential business information, bracketed in accordance with § 201.6 of this chapter and § 206.8(c), with the specific information as to which exemption from disclosure was granted enclosed in triple brackets. This version shall have the following warning marked on every page: "CBI exempted from disclosure under APO enclosed in triple brackets." The other two versions shall conform to and be filed in accordance with the requirements of § 201.6 of this chapter and § 206.8(c), except that the specific information as to which exemption from disclosure was granted shall be redacted from those versions of the submission.

\* \* \* \* \*



## PART 207—INVESTIGATIONS OF WHETHER INJURY TO DOMESTIC INDUSTRIES RESULTS FROM IMPORTS SOLD AT LESS THAN FAIR VALUE OR FROM SUBSIDIZED EXPORTS TO THE UNITED STATES

■ 1. The authority citation for part 207 continues to read as follows:

**Authority:** 19 U.S.C. 1336, 1671–1677n, 2482, 3513.

■ 2. Remove and reserve § 207.6.

### § 207.6 [Removed]

■ 3. Amend § 207.7 by revising paragraphs (a)(2), (b)(2), and (g)(1) to read as follows:

#### § 207.7 Limited disclosure of certain business proprietary information under administrative protective order.

(a) \* \* \*

(2) *Application.* An application under paragraph (a)(1) of this section must be made by an authorized applicant on a form adopted by the Secretary or a photocopy thereof. A signed application and five (5) copies thereof shall be filed. An application on behalf of a petitioner, a respondent, or another party must be made no later than the time that entries of appearance are due pursuant to § 201.11 of this chapter. In the event that two or more authorized applicants represent one interested party who is a party to the investigation, the authorized applicants must select one of their number to be lead authorized applicant. The lead authorized applicant's application must be filed no later than the time that entries of appearance are due. Provided that the application is accepted, the lead authorized applicant shall be served with business proprietary information pursuant to paragraph (f) of this section. The other authorized applicants representing the same party may file their applications after the deadline for entries of appearance but at least five days before the deadline for filing posthearing briefs in the investigation, or the deadline for filing briefs in the preliminary phase of an investigation, or the deadline for filing submissions in a remanded investigation, and shall not be served with business proprietary information.

\* \* \* \* \*

(b) \* \* \*

(2) Use such business proprietary information solely for the purposes of representing an interested party in the Commission investigation then in progress or during judicial or other review of such Commission investigation;

\* \* \* \* \*

(g) *Exemption from disclosure*—(1) *In general.* Any person may request exemption from the disclosure of business proprietary information under administrative protective order, whether the person desires to include such information in a petition filed under § 207.10, or any other submission to the Commission during the course of an investigation. Such a request shall only be granted if the Secretary finds that such information is nondisclosable confidential business information. As defined in § 201.6(a)(2) of this chapter, nondisclosable confidential business information is privileged information, classified information, or specific information (e.g., trade secrets) of a type for which there is a clear and compelling need to withhold from disclosure. The request will be granted or denied not later than thirty (30) days (ten (10) days in a preliminary phase investigation) after the date on which the request is filed.

\* \* \* \* \*

■ 4. Amend § 207.62 to revise paragraph (b)(2) to read as follows:

#### § 207.62 Rulings on adequacy and nature of Commission review.

\* \* \* \* \*

(b) \* \* \*

(2) Comments shall be submitted within the time specified in the notice of institution. In a grouped review, only one set of comments shall be filed per party. Comments shall not exceed fifteen (15) pages of textual material, double spaced and single sided, on stationery measuring 8½ x 11 inches. Comments containing new factual information shall be disregarded.

\* \* \* \* \*

■ 5. Amend § 207.64 to revise paragraph (b) to read as follows:

#### § 207.64 Staff Reports.

\* \* \* \* \*

(b) *Final staff report.* After the hearing, the Director shall revise the prehearing staff report and submit to the Commission, prior to the Commission's determination, a final version of the staff report. The final staff report is intended to supplement and correct the information contained in the prehearing staff report. The Director shall place the final staff report in the record. A public version of the final staff report shall be made available to the public and a business proprietary version shall also be made available to persons authorized to receive business proprietary information under § 207.7.

## PART 210—ADJUDICATION AND ENFORCEMENT

■ 1. The authority citation for part 210 continues to read as follows:

**Authority:** 19 U.S.C. 1333, 1335, and 1337.

■ 2. Amend § 210.4 to revise paragraph (f)(2) to read as follows:

#### § 210.4 Written submissions; representations; sanctions.

\* \* \* \* \*

(f) \* \* \*

(2) Unless the Commission or this part specifically states otherwise,

(i) The original and 6 true copies of each submission shall be filed if the investigation or related proceeding is before an administrative law judge, and

(ii) The original and 12 true copies of each submission shall be filed if the investigation or related proceeding is before the Commission, except that a submitter shall file the original and 6 copies of any exhibits filed with a request or petition for related proceedings.

\* \* \* \* \*

■ 3. Amend § 210.8 to revise paragraph (a) to read as follows:

#### § 210.8 Commencement of preinstitution proceedings.

(a) Upon receipt of complaint. A preinstitution proceeding is commenced by filing with the Secretary a signed original complaint and the requisite number of true copies. The complainant shall file 12 confidential copies of the complaint along with 6 copies of any exhibits filed with the complaint, 12 nonconfidential copies of the complaint along with 6 copies of any exhibits filed with the complaint, plus one confidential copy and one nonconfidential copy of the complaint and exhibits for each person named in the complaint as violating section 337 of the Tariff Act of 1930, and one nonconfidential copy for the government of each foreign country of any person or persons so named. The same requirements apply for the filing of a supplement to the complaint. If the complainant is seeking temporary relief, the complainant must file 12 confidential copies of the motion along with 6 copies of any exhibits filed with the motion, 12 nonconfidential copies along with 6 copies of any exhibits filed with the motion, plus one additional confidential copy and one additional nonconfidential copy of the motion and exhibits for each proposed respondent, and one nonconfidential copy for the government of the foreign country of the proposed respondent. The additional copies of the complaint and motion for



temporary relief for each proposed respondent and the appropriate foreign government are to be provided notwithstanding the procedures applicable to a motion for temporary relief, which require service of the complaint and motion for temporary relief by the complainant.

## PART 212—IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT

- 1. The authority citation for part 212 continues to read as follows:

**Authority:** Sec. 203(a)(1), Pub. L. 96–481, 94 Stat. 2325 (5 U.S.C. 504(c)(1)).

- 2. Amend § 212.29 to read as follows:

### § 212.29 Payment of award.

An applicant seeking payment of an award shall submit to the Office of Finance of the Commission a copy of the Commission's final determination granting the award, accompanied by a statement that the applicant will not seek review of the decision in the United States courts. The address for submission to the Commission is: United States International Trade Commission, Office of Finance, 500 E Street SW., Washington, DC 20436. The Commission will pay the amount to the applicant within 60 days, unless judicial review of the award or of the underlying determination of the adversary adjudication has been sought by the applicant or any other party to the proceeding.

Issued: May 27, 2003.

By Order of the Commission.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 03–13688 Filed 6–2–03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 201

[Docket No. 02N–0241]

#### Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Delay of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to change the labeling requirements concerning aluminum in

small volume parenterals (SVPs) and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). The immediate container labels of SVPs and PBPs containing 25 micrograms per liter ( $\mu\text{g/L}$ ) or less of aluminum may state: “Contains no more than 25  $\mu\text{g/L}$  of aluminum” instead of stating the exact amount of aluminum they contain. In addition, the final rule revises the aluminum regulations to reflect the fact that the effective date of the final rule published in the **Federal Register** of January 26, 2000 (65 FR 4103) (the January 2000 final rule) is delayed until July 26, 2004. The agency is taking these actions in response to a request from industry.

**DATES:** This final rule is effective July 26, 2004. The effective date for § 201.323, added at 65 FR 4103, January 26, 2000, is delayed until July 26, 2004.

**FOR FURTHER INFORMATION CONTACT:** Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the January 2000 final rule, FDA amended its regulations in § 201.323 (21 CFR 201.323) to enact certain requirements regarding aluminum levels in large volume parenterals (LVPs), SVPs, and PBPs used in TPN. The January 2000 final rule was originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency published a document delaying the effective date to January 26, 2003. In the **Federal Register** of November 26, 2002 (67 FR 70691), the agency published a document further delaying the effective date to January 26, 2004.

Section 201.323(c) of the January 2000 final rule required the product's maximum level of aluminum at expiry to be stated on the immediate container label of SVPs and PBPs used in the preparation of TPN solutions. The January 2000 final rule required that the statement on the immediate container label read as follows: “Contains no more than  $\mu\text{g/L}$  of aluminum.” For those SVPs and PBPs that are lyophilized powders used in the preparation of TPN solutions, the January 2000 final rule required that the maximum level of aluminum at expiry be printed on the immediate container label as follows: “When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than  $\mu\text{g/L}$ .” The January 2000

final rule also required that the maximum level of aluminum be stated as the highest of: (1) The highest level for the batches produced during the last 3 years, (2) the highest level for the latest five batches, or (3) the maximum historical level, but only until completion of production of the first five batches after the effective date of the rule.

In the **Federal Register** of August 12, 2002 (67 FR 52429), FDA proposed to amend § 201.323 to permit the immediate container labels of SVPs and PBPs containing 25  $\mu\text{g/L}$  or less of aluminum to state: “Contains no more than 25  $\mu\text{g/L}$  of aluminum” instead of stating the exact amount of aluminum they contain (the 2002 proposed rule). The proposed amendment was prompted by a request from the Health Industry Manufacturers Association (HIMA, now called AdvaMed). A complete discussion of HIMA's arguments in support of the revision can be found in the 2002 proposed rule.

The agency agreed with HIMA's request for the following reasons. FDA has already determined that 25  $\mu\text{g/L}$  is a safe upper limit for manufacturers to include in LVPs and believes that it is similarly appropriate for SVPs and PBPs. If an SVP or PBP that contains 25  $\mu\text{g/L}$  of aluminum is added to a TPN solution that contains 25  $\mu\text{g/L}$  of aluminum, the concentration of aluminum in the mixture will still be 25  $\mu\text{g/L}$ . Consistent with its approach to LVPs (to which SVPs and PBPs are added) that are permitted to contain 25  $\mu\text{g/L}$ , FDA believes health care practitioners will be provided with sufficient information on the aluminum content of SVPs and PBPs if the label states that the product contains no more than 25  $\mu\text{g/L}$  of aluminum.

In the 2002 proposed rule, the agency also announced its intent to extend the effective date for § 201.323 as necessary to provide time for the proposal to be finalized.

##### II. Comments on the Proposed Rule

The agency received one comment on the 2002 proposed rule. The comment agreed with the proposal. The comment supported the agency's plan to extend the effective date of § 201.323 until the proposed rule could be finalized. The comment asked that the effective date be extended at least 18 months after January 26, 2003, to give industry sufficient time to comply with § 201.323. The comment also asked FDA to clarify that a delay of the effective date would apply to all products subject to § 201.323.

In response to this comment, the agency is delaying the effective date of