

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 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.*

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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 (µg/L) or less of aluminum may state: “Contains no more than 25 µg/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 \_ µg/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 \_ µg/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 µg/L or less of aluminum to state: “Contains no more than 25 µg/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 µg/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 µg/L of aluminum is added to a TPN solution that contains 25 µg/L of aluminum, the concentration of aluminum in the mixture will still be 25 µg/L. Consistent with its approach to LVPs (to which SVPs and PBPs are added) that are permitted to contain 25 µg/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 µg/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