

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N-0056]

RIN 0910-AA74

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Certifier R. LEDESMA

Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Amendment; 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 further delaying until January 26, 2004, the effective date of a final rule published in the **Federal Register** of January 26, 2000 (65 FR 4103) (aluminum final rule), and originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency delayed the effective date of the aluminum final rule until January 26, 2003. The aluminum final rule imposes certain requirements for aluminum-containing large volume parenterals (LVPs), small volume parenterals (SVPs), and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). FDA is delaying the effective date of the aluminum final rule to allow time for the agency to finalize an amendment to the aluminum final rule. The agency is also amending the aluminum final rule to change to January 26, 2004, the date that limits the use of historical levels to determine the maximum level of aluminum in SVPs and PBPs; this date corresponds to the effective date of the aluminum final rule, which is delayed until January 26, 2004, by this document.

DATES: This final rule is effective [*insert date 30 days after date of publication in the Federal Register*]. The effective date for § 201.323 (21 CFR 201.323), added at 65 FR 4103, January 26, 2000, is delayed until January 26, 2004.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

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: On January 26, 2000, FDA published final regulations at § 201.323 imposing certain requirements for aluminum-containing LVPs, SVPs, and PBPs used in TPN (65 FR 4103). The aluminum 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 notice delaying the effective date until January 26, 2003.

In the **Federal Register** of August 12, 2002 (67 FR 52429), FDA published a proposed rule to amend § 201.323. The proposed rule would permit SVPs and PBPs containing 25 micrograms per liter ($\mu\text{g}/\text{L}$) or less of aluminum to be labeled with the statement “Contains no more than 25 $\mu\text{g}/\text{L}$ of aluminum”, instead of stating the exact amount of aluminum they contain. Because there is insufficient time to finalize this proposed amendment before January 26, 2003, when § 201.323 is scheduled to become effective, the agency is delaying the effective date of § 201.323 until January 26, 2004.

The agency is also amending § 201.323(c)(3) of the aluminum final rule to reflect the fact that the effective date is now being extended to January 26, 2004. Section 201.323(c)(3) provides that a manufacturer may state the maximum level of aluminum in terms of historical levels, but only until completion of production of the first five batches after January 26, 2001, the date by which manufacturers were to have submitted supplements describing the validated assay method used to determine aluminum content. Because manufacturers now have until January 26, 2004, to submit supplements, this final rule is changing the date in § 201.323(c)(3) to reflect the fact that the effective date of the aluminum final rule has been extended to January 26, 2004.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency is delaying the effective date of § 201.323 because the agency has proposed to amend § 201.323. Given the imminence of the effective date of current § 201.323, seeking prior public comment on this delay is impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the effective date for § 201.323, those companies affected would have to be preparing to relabel to comply with the January 26, 2003, effective date. In accordance with 21 CFR 10.40(e)(1),

FDA is providing an opportunity for comment on which this delay should be modified or revoked.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this action is consistent with the regulatory philosophy and principles identified in the Executive order. This action will ease the burden on industry of compliance with § 201.323 by giving manufacturers more time to relabel affected products. Thus, this action is not a significant action as defined by the Executive order.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

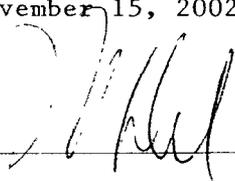
1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.323(c)(3) is amended by removing the date "2001" and replacing it with the date "2004".

Dated: 11-15-02

November 15, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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