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]

BILLING CODE 7020–02–P

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

§ 201.323 until July 26, 2004. This delay applies to all products subject to § 201.323.

III. Changes From the Proposed Rule

The final rule delays the effective date of § 201.323 to July 26, 2004. The final rule also changes § 201.323(c)(3) to reflect the fact that the effective date has been delayed. 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 the effective date of the January 2000 final rule. That effective date is the date by which manufacturers are to submit supplements describing the validated assay method used to determine aluminum content. Because manufacturers now have until July 26, 2004, to submit supplements, the final rule changes the date in § 201.323(c)(3) to July 26, 2004. The final rule also slightly modifies the introductory language in § 201.323(c) to clarify that the language ''except as provided in paragraph (d) of this section'' applies to both the second and third sentences in § 201.323(c). That is, the ''exception'' language applies generally to SVPs and PBPs used in the preparation of TPN and also to SVPs and PBPs that are lyophilized powders that are reconsituted and used in the preparation of TPN.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Analysis of Impacts

FDA has examined the impacts of this amendment to § 201.323 under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order and in these two statutes.

The purpose of this final rule is to relax the requirements of the January 2000 final rule for labeling aluminum content in SVPs and PBPs used in TPN. Specifically, this final rule allows manufacturers to use a standard statement of quantity of aluminum content in place of the exact amount for affected products that contain no more than 25 µg/L of aluminum. FDA determined that the proposed rule would not be a significant action as defined by the Executive order. FDA received one comment to the proposed rule, but the comment did not address the Analysis of Impacts section of the proposed rule.

In the Analysis of Impacts section of the January 2000 final rule, the agency relied on the Eastern Research Group (ERG) report entitled ''Addendum to Compliance Cost Analysis for a Regulation for Parenteral Drug Products Containing Aluminum.'' In that report, ERG calculated the total relabeling costs for SVPs and PBPs to be about $523,000, or about $3,500 per product (equivalent to annualized costs totaling $128,000, or about $850 per product, discounted at 7 percent over 5 years). To the extent that manufacturers of SVPs and PBPs containing no more than 25 µg/L of aluminum use the added flexibility in labeling that this final rule provides, the compliance burden cited above could be reduced.

The single comment to the proposed rule requested that an additional 18 months be added to the effective date of § 201.323. FDA has complied with this request. Since this additional time would allow for more flexibility in implementing the compliance methods for all parts of § 201.323, it could further reduce the compliance burden.

Because this final rule could slightly decrease current compliance costs for the affected industry without imposing any additional costs, FDA has determined that the final rule is not a significant regulatory action as defined by the Executive order and thus is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA made the determination for the January 2000 final rule that very few small firms, if any, would be significantly impacted. Thus, the agency certified that the final rule would not have a significant impact on a substantial number of small entities. This final rule could slightly lessen the economic impact of the January 2000 final rule. Accordingly, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (as amended).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before finalizing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

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 is amended by revising the first sentence of the introductory text of paragraph (c); by removing from paragraph (c)(3) the word ''January'' and adding in its place the word ''July''; by redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively; and by adding new paragraph (d) to read as follows:

§ 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

* * * * *

(c) Except as provided in paragraph (d) of this section, the maximum level of aluminum present at expiry must be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages (PBPs) used in the preparation of TPN solutions.* * *

(d) If the maximum level of aluminum is 25 µg/L or less, instead of stating the exact amount of aluminum as required in paragraph (c) of this section, the immediate container label may state: ''Contains no more than 25 µg/L of aluminum.'' If the SVP or PBP is a lyophilized powder, the immediate container label may state: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than 25 µg/L''.

* * * * *

Dated: May 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13752 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 349

[Docket No. 03N–0193]

RIN 0910–AA01

Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) ophthalmic drug products are generally recognized as safe and effective and not misbranded. This amendment updates the monograph to incorporate a United States Pharmacopeia (USP) name change for one active ingredient included in the monograph. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This final rule is effective July 3, 2003. Submit written or electronic comments by August 4, 2003.

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*.

FOR FURTHER INFORMATION CONTACT: Michael T. Benson, 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

In the **Federal Register** of March 4, 1988 (53 FR 7076), FDA issued a final monograph for OTC ophthalmic drug products in part 349 (21 CFR part 349). Section 349.12 of that monograph included the active ingredient hydroxypropyl methylcellulose. In 2000, the USP proposed (for inclusion in the Third Supplement to *USP* 24) a name change for this ingredient based on a name adopted by the United States Adopted Names Council (Ref. 1). The new name for hydroxypropyl methylcellulose is hypromellose. This name change became official on March 1, 2001, and was subsequently included in the *USP* with an effective date of September 1, 2002 (Ref. 2).

II. Naming Process

The Federal Food, Drug, and Cosmetic Act (the act) in section 502(e)(1)(A)(i) (21 U.S.C. 352(e)(1)(A)(i)) requires the label of a drug to bear the established name of the drug to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula). The established name of the drug is defined as:

* * * (A) the applicable official name designated pursuant to section 508 [of the act], or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient * * *.

21 U.S.C. 352(e)(3).

Section 508 of the act (21 U.S.C. 358) authorizes FDA to designate an official name for any drug if FDA determines ''that such action is necessary or desirable in the interest of usefulness and simplicity.'' FDA does not, however, routinely designate official names for drug products under section 508 of the act (§ 299.4(e) (21 CFR 299.4(e))). In the absence of designation by FDA of an official name, interested persons may rely on the current compendial name as the established name (§ 299.4(e)).

III. The Technical Amendment

FDA has not designated an official name for the active ingredient hydroxypropyl methylcellulose. Thus, its established name is the current compendial name. The USP has now changed the compendial name for hydroxypropyl methylcellulose to hypromellose. To be consistent with the change in this official compendial name, the agency is changing this name in § 349.12 in the ingredient listing. As noted previously, this USP name change became official on March 1, 2001, with a USP effective date of September 1, 2002.

Because section 502(e)(1) and (e)(3) of the act requires the established name of a drug to be used, any ophthalmic drug product initially introduced or initially delivered for introduction into interstate commerce after September 1, 2002, would need to bear the new established name ''hypromellose.'' However, the agency is aware that many manufacturers of OTC ophthalmic drug products have not yet implemented this name change in their product labeling. Therefore, elsewhere in this issue of the **Federal Register**, as a matter of its enforcement discretion, the agency is issuing guidance stating its intent to provide manufacturers of affected OTC ophthalmic drug products until September 1, 2003 (1 extra year from the USP effective date), to implement this labeling change. Accordingly, on or after September 1, 2003, any OTC ophthalmic drug product initially introduced or initially delivered for introduction into interstate commerce that contains the ingredient hypromellose (formerly known as hydroxypropyl methylcellulose) must bear labeling that contains the new name for this ingredient.

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 agency 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 public interest. This labeling revision