

■ 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.*

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## 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