■ 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

represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. As discussed previously in this document, manufacturers must relabel their products as a result of the USP name change to remain in compliance with the act. This amendment updates the name of one active ingredient in the final monograph for OTC ophthalmic drug products to reflect this official name change that has already been implemented by the USP. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether the regulation should be modified or revoked.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. FDA has determined that the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The UMRA does not require FDA to prepare a statement of costs and benefits for this final rule, because the final 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 about $110 million.

The purpose of this final rule is to update the final monograph for OTC ophthalmic drug products to incorporate a USP name change for one active ingredient included in the monograph. As discussed in section II of this document, section 502(e)(1) and (e)(3) of the act requires that the established name of a drug be used. Under § 299.4(e), because FDA does not routinely designate official names under section 508 of the act, the established name under section 502(e) of the act ordinarily is the compendial name of the drug. Therefore, because FDA has not designated an official name under section 508 of the act, manufacturers must relabel their products as a result of the USP name change to remain in compliance with the act. Updating the name of the active ingredient in the ophthalmic monograph to reflect its current established name will eliminate possible confusion by the public. Because manufacturers must relabel their products as a result of the USP name change to remain in compliance with the act, this rule does not impose any additional costs on industry. Consequently, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, no further analysis is required.

V. Paperwork Reduction Act of 1995

The agency concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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.

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 [illegible] 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.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or three paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Pharmacopeial Forum,'' The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 702–705, May and June 2000.

2. ''Third Supplement,'' *United States Pharmacopeia* 24, National Formulary 19, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 3041–3042, January 2, 2001.

List of Subjects in 21 CFR Part 349

Labeling, Ophthalmic goods and services, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 349 is amended as follows:

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 1. The authority citation for 21 CFR part 349 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. Section 349.12 is amended by revising paragraph (a)(3) to read as follows:

§ 349.12 Ophthalmic demulcents.

* * * * *

(a) * * *

(3) Hypromellose, 0.2 to 2.5 percent.

Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13827 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 878

[Docket No. 02N–0288]

Medical Devices; Designation of Special Control for Eight Surgical Suture Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the classification regulations for eight surgical suture devices previously reclassified into class II to specify a special control for those devices. The special control is an FDA guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA'' that identifies performance, testing, and labeling recommendations for the devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control. FDA is taking these actions on its own initiative because it believes they are necessary to provide reasonable assurance of the safety and effectiveness of surgical suture devices. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: This rule is effective July 3, 2003.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107–250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

The 1976 amendments also broadened the definition of ''device'' in 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class III all transitional devices, i.e., those devices previously regulated as new drugs, including surgical sutures.

II. Regulatory History of the Devices

In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice that identified sutures as class III devices under the transitional provisions of the act. Section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)) provides that the manufacturer or importer of a device classified in class III under the transitional provisions may file a petition for reclassification of the device into class I or class II. Procedures for filing and review of classification petitions are set forth in § 860.136 (21 CFR 860.136).

In accordance with section 520(l)(2) of the act and § 860.136, and after consulting with members of the General and Plastic Surgery Devices Panel, FDA reclassified surgical suture devices from class III to class II as follows:

1. Absorbable poly(glycolide/L-lactide) surgical suture (21 CFR 878.4493), reclassification order (letter) dated September 14, 1989;
2. Stainless steel suture (21 CFR 878.4495), reclassification order (letter) dated July 30, 1986;
3. Absorbable surgical gut suture (21 CFR 878.4830), reclassification order (letter) dated September 19, 1988;
4. Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000), reclassification order (letter) dated July 5, 1990;
5. Nonabsorbable polypropylene surgical suture (21 CFR 878.5010), reclassification order (letter) dated July 5, 1990;
6. Nonabsorbable polyamide surgical suture (21 CFR 878.5020), reclassification order (letter) dated February 15, 1990;
7. Natural nonabsorbable silk surgical suture (21 CFR 878.5030), reclassification order (letter) dated November 9, 1990; and
8. Nonabsorbable expanded polytetrafluoroethylene surgical suture (21 CFR 878.5035), reclassification order (letter) dated September 9, 1999.

In the **Federal Register** of December 19, 2002 (67 FR 77678), FDA published a proposed rule to designate a special control for eight surgical suture devices already classified into class II. FDA proposed that surgical suture devices would remain in class II, but would be subject to a special control. The proposed rule identified the special control as an FDA guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' In the same edition of the **Federal Register**, FDA announced the availability of the draft guidance that, when final, was intended to serve as a special control (67 FR 77797). FDA invited interested persons to comment on the proposed rule and on the proposed special control guidance document by March 19, 2003.

III. FDA's Conclusion

FDA received no comments on the proposed rule or on the guidance document proposed as the special control. Therefore, under the SMDA authority, FDA is amending the classification regulations for eight surgical suture devices previously reclassified into class II, to designate a special control for those devices. The special control capable of providing reasonable assurance of safety and effectiveness for these devices is a guidance document entitled ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA'' that identifies