

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 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.

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.

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(a) * * *

(3) Hypromellose, 0.2 to 2.5 percent.

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