

directions, such as eyewashes, the labeling should state the proportion of each active ingredient. For eyewashes, the quantity of water should be stated as the percentage of the total product, which is likely to be 98 to 99 percent. It is not necessary to state "in each bottle" or an amount per dosage unit.

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. 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, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 Unfunded Mandates Reform Act of 1995 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. The Unfunded Mandates Reform Act of 1995 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. No further analysis is required under the Regulatory Flexibility Act because the agency has determined that this final rule will not have a significant effect on a substantial number of small entities.

As discussed previously, FDA is implementing this action to clarify the final monograph for OTC ophthalmic drug products. This will facilitate compliance with the labeling provisions in § 201.66. OTC ophthalmic drug products were supposed to be in compliance with this section by May 16, 2002. The agency believes that while some products may have already incorporated the labeling format described in this technical amendment, other products have not.

The agency believes 25 manufacturers produce approximately 40 eyewash products, which are represented by up to 60 stock keeping units (SKUs). To minimize any impacts on any of these manufacturers not currently in compliance, the agency is providing them with up to 24 months (or the date of the first major labeling revision of the product after the effective date of this final rule, whichever occurs first) to relabel their products. The agency believes the cost of a label change to a particular SKU will not exceed \$3,000. Based on this information, the total one-time costs of relabeling would be \$180,000 (\$3,000 per SKU x 60 SKUs). The average cost per manufacturer would be \$7,200 (\$180,000 / 25 manufacturers). These estimates likely overstate the true burden of this rule, as the agency believes some manufacturers may already be in compliance and would incur no additional costs. Also, some manufacturers might be able to make these changes during the implementation period as part of routinely scheduled label revisions.

The Regulatory Flexibility Act requires the agency to analyze whether a rule may have a significant impact on a substantial number of small entities. According to the Small Business Administration, manufacturers of OTC ophthalmic drug products, as part of the North American Industry Classification System (NAICS) code 325412 (pharmaceutical preparations), are small entities if they have fewer than 750 employees. The agency has reviewed information on the manufacturers of OTC eyewash drug products and believes 22 of the 25 manufacturers are small entities. These small entities have average annual revenues of \$10.7 million. The cost of the rule per affected small entity would be 0.067 percent

(\$7,200 / \$10.7 million) of average annual revenues.

The two smallest of these small entities have reported annual revenues of approximately \$1 million. The agency believes one of these manufacturers to have three SKUs. The total cost of the final rule for this particular small entity would be 0.9 percent (3 SKUs x \$3,000 per SKU / \$1 million). Thus, the impact on any of the small entities would be less than 1 percent of annual revenues. The agency therefore certifies that this final rule will not have a significant impact on a substantial number of small entities.

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. Opportunity for 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 to <http://www.fda.gov/dockets/ecomments> or three hard copies