

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 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 believes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule because the proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted annually for inflation. The current inflation adjusted statutory threshold is approximately \$110 million.

With respect to the Regulatory Flexibility Act, FDA does not believe that the proposed rule would have a significant economic impact on a substantial number of small entities. However, the agency recognizes the uncertainty of its estimates with respect to the number of affected small entities as well as the economic impact of the rule on those small entities. The agency therefore requests detailed public comment regarding any substantial or significant economic impact that this rulemaking would have on manufacturers of OTC emergency first aid eyewash drug products.

The purpose of this proposed rule is to amend the final monograph for OTC ophthalmic drug products to include OTC emergency first aid eyewash drug products. This proposed rule may increase OTC availability of these products and may, as a result, lower the costs to industrial facilities and individuals that use such products.

Manufacturers of the affected products should incur only minor costs to relabel their products to meet the monograph requirements. These manufacturers can make the required changes whenever they are ready to order new product labeling within the 12 months after the final rule is issued. Manufacturers of products with annual sales of less than \$25,000 will have 24 months to complete the required relabeling. The agency has been

informed that this type of relabeling generally costs approximately \$3,000 to \$4,000 per stockkeeping unit (SKU) (i.e., individual products, packages, and sizes). The agency estimates that there are approximately 25 manufacturers or marketers of 40 to 45 products and 50 to 60 SKUs that would be affected by this proposed rule.

Based on this information, the total one-time costs of relabeling would be between \$150,000 (\$3,000 per SKU x 50 SKUs) and \$240,000 (\$4,000 per SKU x 60 SKUs). Assuming an equal distribution of these costs across the 25 affected entities results in an average cost burden of \$6,000 to \$9,600 per firm. The agency believes that actual costs would be lower for several reasons. First, most of the required changes will be made by private label manufacturers that tend to use relatively simple and less expensive labeling. Second, the agency is proposing a 12-month implementation period that would allow manufacturers to coordinate the required changes with routinely scheduled label printing and/or revisions. Labeling changes for these products would not be required until 12 months after the monograph amendment is issued as a final rule and becomes effective. Furthermore, products with less than \$25,000 per year in sales would not need to be relabeled until 24 months after the rule becomes final. Thus, manufacturers would have time to use up existing labeling stocks and plan for new labeling, thereby mitigating some of the costs of this proposed rule. Third, manufacturers may be able to implement the new labeling required by this proposal at the same time that they implement the new standardized format and content labeling required by 21 CFR 201.66. Thus, the total relabeling costs associated with two different but related final rules may be reduced by implementing the required changes at the same time.

According to standards established by the Small Business Administration, a small pharmaceutical preparations manufacturer (NAICS code 325412) employs fewer than 750 people. FDA has determined that approximately 88 percent (22 out of 25) of OTC ophthalmic drug product manufacturers meet these criteria and can therefore be categorized as small entities. The average annual revenue of small entities affected by this rule was found to be approximately \$10.7 million. Thus, the cost of the rule per affected small entity would be between 0.056 percent (\$6,000 ÷ \$10.7 million) and 0.09 percent (\$9,600 ÷ \$10.7 million) of average annual revenues. FDA is aware of one

small entity that has average annual revenues of approximately \$1 million and produces 3 SKUs. The total cost of the final rule for this small entity would be between 0.9 percent (3 SKUs x \$3,000 per SKU ÷ \$1 million) and 1.2 percent (3 SKUs x \$4,000 per SKU ÷ \$1 million) of annual revenues. Thus the economic impact of the proposed rule on the majority of small entities is expected to be much less than 1 percent of annual revenues. While these estimates are uncertain, it appears that this proposed rule would not have a significant economic impact on a substantial number of small entities.

The agency considered but rejected several alternatives: (1) A shorter or longer implementation period, and (2) an exemption from the requirements for small entities. While the agency believes that industries and accident victims who use these products would benefit from having the new labeling in place as soon as possible, the agency also acknowledges that coordination of the labeling changes with implementation of the new OTC "Drug Facts" labeling may significantly reduce the costs associated with this proposed rule. Thus, an alternative specifying a shorter implementation period was rejected due to its inflexibility and potentially greater cost. A longer implementation period was also rejected because it would unnecessarily delay the benefits of new labeling and revised formulations, where applicable, to parties who use these OTC drug products. The agency also rejected an exemption for small entities because the new labeling and revised formulations, where applicable, would also generate benefits for parties who purchase products marketed by those entities. Furthermore, the vast majority of firms affected by this proposed rule can be classified as small entities. However, an additional year is being allowed for products with annual sales of less than \$25,000 to implement the required changes in order to reduce the potential impact of the rule on small entities.

This proposed rule allows for continued marketing of affected products without the risk of regulatory action provided the following conditions are met: (1) The product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC drug review on May 11, 1972, a date that was later extended to on or before December 4, 1975 (see 21 CFR 330.13); (2) such product does not constitute a hazard to health; (3) the product formulation is not regarded to be a prescription drug within the meaning of section 503(b) of the Federal Food, Drug, and Cosmetic