

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 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. 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. As discussed in this section, FDA has determined that this final rule will not have a significant economic impact on a substantial number of small entities. 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.

The purpose of this final rule is to revise and improve the statement of identity, warnings, directions, and other required labeling statements for OTC pediculicide drug products. The revised labeling provides more detailed information on the proper use of the product and should improve consumers' self-use.

The final rule requires relabeling of OTC pediculicide drug products containing pyrethrum extract with piperonyl butoxide. FDA's drug listing system identifies about 23 manufacturers and 36 marketers of approximately 75 stockkeeping units (SKU) (individual products, packages, and sizes) of OTC pediculicide drug products. There may be a few additional marketers and products that are not identified in the sources FDA reviewed.

FDA does not believe that manufacturers would need to increase the package size to add the additional labeling information. Almost all of these products are marketed in an outer carton which should have adequate space for the additional information. In addition, manufacturers may include the "Other information" section of the labeling in a package insert, which generally has a nominal cost. Assuming that there are about 75 affected OTC SKUs in the marketplace, FDA estimates (based on information provided by OTC drug manufacturers) that the rule would impose total one-time compliance costs on industry for relabeling of about

\$3,000 to \$4,000 per SKU, for a total cost of \$225,000 to \$300,000.

FDA believes the actual cost could be lower for several reasons. First, most of the labeling changes will be made by private label small manufacturers that tend to use simpler and less expensive labeling.

Second, FDA is providing a period of 18 months (24 months for products with annual sales less than \$25,000) for manufacturers to implement the new labeling. Thus, manufacturers should be able to use up existing labeling stocks and to make the labeling changes in the normal course of business. Further, manufacturers will not incur any expenses determining how to state the product's labeling because the final rule provides that information. The final rule does not require any new reporting and recordkeeping activities. Therefore, no additional professional skills are needed.

FDA considered but rejected several labeling alternatives: (1) A shorter or longer implementation period, and (2) an exemption from coverage for small entities. While the agency believes that consumers would benefit from having this new labeling in place as soon as possible, the agency also acknowledges that a shorter implementation period could significantly increase the compliance costs and these costs could be passed through to consumers. A longer time period would unnecessarily delay the benefit of new labeling to consumers who self-medicate with these drug products. The agency rejects an exemption for small entities because the new labeling information is also needed by consumers who purchase products marketed by those entities. However, a longer compliance date (24 months) is being provided for products with annual sales less than \$25,000.

OTC pediculicide drug products are not the sole products produced by manufacturers affected by this final rule. FDA believes that the incremental costs of this final rule will be less than 1 percent of any of the manufacturer's total sales. Therefore, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

V. Paperwork Reduction Act of 1995

FDA 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 statement of identity, warnings, directions, and other information 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

FDA 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 concludes 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. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Fact sheet from Mason County, Washington State Government Services, "Head Lice (Pediculosis)," <http://www.co.mason.wa.us/health/Headlice.shtml>.

2. Fact sheet from King County, Washington State Government Services, "Communicable Disease Fact Sheet Head Lice (Pediculosis)," <http://www.metrokc.gov/health/prevcont/headlice.htm>.

List of Subjects in 21 CFR Part 358

Labeling, 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 358 is amended as follows: