

dosage form; however, it will have to redo the validation (product, process, new supplier), conduct stability tests, and change master production records. The agency estimates the cost of reformulation to range from \$100,000 to \$500,000. Therefore, if all 50 products are reformulated, the midpoint of the cost estimate implies total costs of \$15 million. However, the agency believes the total costs will be much smaller because not all manufacturers will have to reformulate and some may choose to discontinue a product line if sales are too low to justify the added cost and/or they also produce substitute products that do not require reformulation.

Because these products must be manufactured in compliance with the pharmaceutical current good manufacturing practices (21 CFR parts 210 and 211), all firms would have the necessary skills and personnel to perform these tasks either in-house or by contractual arrangement. No additional professional skills are needed.

This final rule establishes the monograph for OTC skin protectant drug products and will require relabeling of all products covered by the monograph. The agency's Drug Listing System identifies approximately 1,300 OTC skin protectant drug products containing the 29 ingredients covered by this final rule. It is likely that there are a number of additional products that are not currently included in the agency's system. Also, as indicated previously, a number of the skin protectant ingredients can be and often are used as inactive ingredients in many of the OTC drug products included in the Drug Listing System. While it is difficult to determine an exact number, the agency estimates that 2,000 to 2,500 OTC stockkeeping units (SKUs) (individual products, packages, and sizes) will need to be relabeled based on this final rule. Based on information in the Drug Listing System, the agency estimates there are at least 200 manufacturers and 700 marketers of these products. Marketers, however, generally do not incur these costs because manufacturers of OTC drug products are usually responsible for product labeling, testing, and formulation.

Estimates of relabeling costs for the type of changes required by this rule vary greatly and range from \$500 to \$15,000 per SKU depending on whether the products are nationally branded or private label. The agency assumes the same weighted average cost to relabel (i.e., \$3,600 per SKU) that it estimated for the final rule requiring uniform label formats of OTC drug products (64 FR

13254 at 13279 to 13281). Assuming 2,000 to 2,500 affected OTC SKUs in the marketplace, total one-time costs of relabeling would be \$7.2 to \$9.0 million. Because frequent labeling redesigns are a recognized cost of doing business in the OTC drug industry, these costs may be less. Manufacturers that make voluntary market-driven changes to their labeling during the implementation period can implement the regulatory requirements for a nominal cost. The final rule would not require any new reporting or recordkeeping activities.

This final rule may have an economic impact on some small entities. The agency's Drug Listing System indicates that about 700 marketers will need to relabel, and that this relabeling will be prepared by about 200 manufacturers, most of which are private label or contract manufacturers. Based on the Small Business Administration's determination that a small firm in this industry has fewer than 750 employees, roughly 70 percent of the firms are considered small. The economic impact on any particular firm is very difficult to measure, because it will vary with the type and number of products affected, the number of SKUs per product, and the ability to coordinate these label changes with those required for other purposes. For example, assuming average industry costs, a small company that had 5 products with 3 SKUs each, for a total of 15 SKUs, would experience a one-time cost of \$54,000 (15 x \$3,600). A small private label manufacturer with the same product line and 10 customers per SKU, for a total of 150 SKUs, would experience a one-time cost of \$540,000 (150 x \$3,600). If one or more products needed to be reformulated, the costs would increase by \$100,000 to \$500,000 per reformulation. Some of these relabeling costs may be mitigated to the extent that manufacturers can coordinate this relabeling with relabeling requirements for the standardized format and content labeling requirements of OTC drug products (§ 201.66) and the sunscreen rule. Products with annual sales less than \$25,000 have 1 additional year. Therefore, many of the labeling revisions may be done in the normal course of business. These steps should help to minimize the impact on small entities by providing enough time for implementation to enable entities to use up existing labeling stock. The agency believes that these actions provide substantial flexibility and reductions in cost for small entities.

The agency 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, a longer time period would unnecessarily delay the benefit of new labeling and revised formulations, where applicable, to consumers. The agency rejected an exemption for small entities because the new labeling and revised formulations, where applicable, are also needed by consumers who purchase products marketed by those entities. However, a longer (24-month) compliance date is being provided for products with annual sales less than \$25,000.

This analysis shows that the agency has undertaken important steps to reduce the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

VII. 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 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)).

VIII. 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 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.

IX. 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