

29 of this document. The Panel stated in its safety evaluation of petrolatum preparations (43 FR 34628 at 34639) that "Petrolatum is not absorbed through intact or injured skin and is neither sensitizing nor irritating. Large amounts are essentially nontoxic when ingested in liquid laxative preparations. Clinical and marketing experience has confirmed that petrolatum is safe in the OTC dosage range used as a skin protectant." As noted for cocoa butter, the agency has considered the OTC uses for these ingredients and believes that application to these areas for these uses will likely be infrequent and to limited areas of the body. The agency concludes that petrolatum and white petrolatum have an extremely low risk in actual consumer use situations. Moreover, both products provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings nad no general warnings (e.g., pregnancy or overdose warnings).

V. Stay of § 347.20(d) and Part 352

The agency is lifting the stay for the sunscreen monograph in part 352 for the sole purpose of amending the codified language as set forth in the skin protectant final monograph. Once the codified language is amended, part 352 will remain stayed indefinitely. The agency is also staying § 347.20(d) because it involves combination products that contain sunscreen active ingredients. 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 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 the public interest. The agency complied with the notice and comment procedures in 5 U.S.C. 553 when it issued the skin protectant final monograph set forth in this notice. The agency is lifting the stay for part 352 in order to revise part 352 to be consistent with that monograph. As the agency stated in the **Federal Register** of December 31, 2001 (66 FR 67485), FDA intends to publish a proposal to amend part 352 in order to develop a comprehensive sunscreen monograph that addresses formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection. That amendment will propose a new effective date for part 352 and for § 347.20(d). Thus, there will be an opportunity for

public comment on the new effective date within the proposed amendment to part 352. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this partial stay should be modified or revoked.

VI. Analysis of Impacts

An analysis of the costs and benefits of this regulation, conducted under Executive Order 12291, was discussed in the TFM for OTC skin protectant drug products (48 FR 6820 at 6831). The agency certified that under the Regulatory Flexibility Act the proposed rule would not have a significant economic impact on a substantial number of small entities. No comments were received on the economic impact of this rulemaking.

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 (2 U.S.C. 1501 *et seq.*). 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 may have 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 and economic analysis before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The proposed rules that have led to the development of this final rule were published on February 15, 1983, and October 3, 1989, before the Unfunded Mandates Reform Act of 1995 was enacted. The agency explains in this final rule that the final rule will not result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year.

The agency 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. The Unfunded Mandates Reform

Act 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 establish allowable monograph ingredients and labeling under which OTC skin protectant drug products are generally recognized as safe and effective. Of the 29 active ingredients considered in this final rule, 19 are being included in the final monograph while 10 are not. Of the 10 not included, 1 is deferred to the final rule on OTC skin protectant diaper rash drug products and 1 may be included pending development of a USP/NF monograph for the ingredient.

Products containing the remaining eight active ingredients will need to be reformulated to delete and replace the ingredient(s) with another (monograph) skin protectant active ingredient or an inactive vehicle. As discussed in section II, comment 34 of this document, at least three and maybe five of these eight ingredients also could be used as inactive (vehicle) ingredients in topical drug products. Therefore, some of these manufacturers may be able to relabel their products without reformulations to comply with this rule.

The agency's Drug Listing System identifies approximately 4,000 drug products containing these 8 ingredients; however, only a limited number of these products list these ingredients as active for a skin protectant drug product (table 2) in the next paragraph of this document.

TABLE 2.—NUMBER OF MARKETERS AND PRODUCTS LISTING INGREDIENTS AS ACTIVE

Ingredient	No. of Marketers	No. of Products
Beeswax	2	2
Boric acid	21	22
Cetyl alcohol	3	9

The cost to reformulate a product will vary greatly depending on the nature of the change in formulation, the product, the process, and the size of the firm. Some of the 33 manufacturers of the 50 products containing nonmonograph active ingredients may not have to reformulate. For those products that need reformulation, the cost can be significant. Because of the large number of monograph active ingredients available for reformulation, no manufacturer should need to change its