

external analgesic ingredients in a patch, plaster, or poultice dosage form in Category III (more data needed). FDA is proposing to amend the introductory language in §§ 348.10 and 348.12 to include the following language at the end of the currently proposed language, to read as follows: "The active ingredients of the product consist of any of the following, within the established concentration for each ingredient, but not for use in a patch, plaster, or poultice dosage form." FDA will revise this language if any of these active ingredients are found acceptable for use in one of these dosage forms.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and 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).

FDA believes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. FDA has determined that the proposed 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 explained later in this section, FDA believes that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. 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 for inflation. The current inflation adjusted

statutory threshold is about \$110 million.

The purpose of this proposed rule is to determine the monograph status of patch, plaster, and poultice dosage forms for external analgesic drug products for OTC human use. This proposed rule indicates that these dosage forms have not been determined to be generally recognized as safe and effective for any OTC external analgesic drug products at this time.

Manufacturers who wish to market these types of products for external analgesic active ingredients need to provide additional safety and effectiveness data to FDA before the FM for these products is established. If adequate safety and effectiveness data are not provided, FDA will not include these types of dosage forms for external analgesic active ingredients in the FM, to be published in a future issue of the **Federal Register**, and any currently marketed products will no longer be able to be marketed when the FM becomes effective, unless they are the subject of an approved new drug application.

FDA estimates that there is a limited number of OTC patch, plaster, and poultice external analgesic drug products currently in the marketplace. Reformulation will not be possible if these dosage forms are not included in the FM. Thus, manufacturers of these products may incur a loss of revenue. However, these manufacturers may be able to replace these products with other products that contain monograph ingredients in the dosage forms currently proposed for inclusion in the FM, e.g., creams, lotions, ointments. Manufacturers will not incur any costs related to proving safety and effectiveness of the active ingredients in these proposed monograph dosage forms. Based on the lack of adequate scientific information on external analgesic active ingredients in patch, plaster, and poultice dosage forms, FDA does not believe that there are any significant alternatives to the proposed rule that would adequately provide for the safe and effective use of these specific OTC drug products.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would exclude patch, plaster, and poultice dosage forms from the final monograph for OTC external analgesic drug products. A few entities that currently market these products may incur significant impacts if these products are not included in the final

monograph. However, as only a limited number of small firms market these products in the dosage forms that may not be included in the FM, FDA does not believe that this proposed rule will impose a significant economic burden on affected entities. Thus, this economic analysis, together with other relevant sections of this document, serves as FDA's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

FDA invites public comment regarding any substantial or significant economic impact that this rulemaking would have on manufacturers who market these products. Comments regarding the impact of this rulemaking on such manufacturers should be accompanied by appropriate documentation. FDA is providing a period of 90 days from the date of publication of this proposed rulemaking in the **Federal Register** for comments to be developed and submitted. FDA will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

V. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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 proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 tentatively concludes that the proposed 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. Request for Comments

FDA is reopening the administrative record for a period of 90 days for