

an adverse event, and FDA does not so find. Nor does FDA's mandate of a warning repudiate the OTC drug monograph under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that this revised warning is necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

FDA's decision to act in an instance such as this one need not meet the standard of proof required to prevail in a private tort action (*Glatte v. Novartis Pharmaceuticals, Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)). To mandate a warning, or take similar regulatory action, FDA need not show, nor do we allege, actual causation.

The agency is proposing to revise the directions in § 347.52(d)(1)(i) for aluminum acetate used as a soak to read: "For use as a soak: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use". The agency is proposing to revise the directions in § 347.52(d)(1)(ii) for aluminum acetate used as a compress or wet dressing to read: "For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use". The agency is also proposing to shorten the directions in § 347.52(d)(3) for products containing witch hazel to read: "apply as often as needed".

The agency is proposing to add new § 347.52(e) for products containing aluminum sulfate formulated as a styptic pencil. This section allows products that meet the criteria established in § 201.66(d)(10) to be marketed with reduced labeling.

### III. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments

received under the companion proposed rule will be treated as comments regarding the direct final rule.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document stating that the direct final is effective as of 135 days after the date of publication in the **Federal Register**. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this companion rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. FDA will not provide additional opportunity for comment. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

### IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 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 and economic analysis 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 concludes that this proposed rule is consistent with the principles set out in the Executive order and in these two statutes. 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. FDA has determined that the proposed rule does 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 make some minor labeling revisions in the previously issued astringents portion of the skin protectant drug products monograph to make the labeling consistent with the rest of the monograph and to add small package labeling provisions for aluminum sulfate marketed as a styptic pencil.

Current manufacturers of these products should incur only minor costs to relabel their products to meet the monograph. Some manufacturers will have to add a warning and revise the directions in their labeling. The agency will provide either 24 months from the date of publication of a final rule or the date of the first major labeling revision after the effective date of the final rule, whichever occurs first, for the manufacturers to use up existing labeling and to print new labeling that incorporates the labeling included in any final rule that may publish based on this proposal. Further, the labeling in the proposed rule is in the new OTC drug labeling format. Therefore, no additional professional skills are needed and manufacturers will not incur expenses determining how to state the product's labeling.

The agency believes that relabeling costs of the type required by this proposed rule generally average about \$2,000 to \$3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). Assuming that there are about 25 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be \$50,000 to \$75,000. The agency believes that the actual cost could be lower for the reasons stated in the previous paragraph.

For the reasons stated above and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.