

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 (*Glastetter 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 revising 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 revising 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 shortening the directions in § 347.52(d)(3) for products containing witch hazel to read: "apply as often as needed".

The agency is adding 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. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule revises several older labeling warnings and directions for OTC skin protectant astringent drug products for consistency with recently issued labeling for OTC skin protectant drug products and updates the labeling to the new OTC drug labeling format. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment by 75 days after the date of publication in the **Federal Register**, the agency will publish a document in the **Federal Register** confirming the effective date of the direct final rule. 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. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the proposed rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this direct final rule and that part may be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on the direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

IV. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866, 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 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 rule that led to the development of this direct final rule was published on October 21, 1993, before the Unfunded Mandates Reform Act of 1995 was enacted. The agency explains in this direct final rule that the direct final rule will not 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.

The agency concludes that this direct final rule is consistent with the principles set out in the Executive order and in these two statutes. The direct 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. FDA has determined that the direct final 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 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 direct final 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 is providing either 24 months from the date of publication of this direct final rule or the date of the first major labeling revision after the 135-day effective date of this direct final rule, whichever occurs first, for the manufacturers to use up existing labeling and print new labeling that incorporates the labeling in this direct final rule. Further, the labeling in the direct final rule is in the new OTC drug labeling format. Therefore, no additional professional skills are needed and manufacturers will not incur expenses