

310, establishing that certain ingredients under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective. That final rule was effective on May 7, 1991, and included in § 310.545(a)(15) the ingredient acetic acid that had been previously considered under this rulemaking for use as a topical otic drug product for the prevention of swimmer's ear and for the drying of water-clogged ears. The agency is revising § 310.545(a)(15) to clarify that products for the drying of water-clogged ears are also included in the regulation and to add new paragraph (a)(15)(ii) to include the ingredients covered by this final rule.

III. Analysis of Impacts

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (51 FR 27366 at 27371). FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory

options that would minimize any significant impact of a rule on small entities. This particular rulemaking for OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears is not expected to pose such an impact on small businesses. As noted above, the ingredient acetic acid has already been removed from OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears. The agency is only aware of several OTC topical otic drug products containing isopropyl alcohol and anhydrous glycerin labeled for these uses. Accordingly, based on the number of affected products, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

2. Section 310.545 is amended by revising paragraphs (a)(15) and (d)(1) and by adding new paragraph (d)(18) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(15) *Topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears—(i)*
Approved as of May 7, 1991.

Acetic acid

(ii) *Approved as of August 15, 1995.*

Glycerin and anhydrous glycerin

Isopropyl alcohol

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(d) * * *

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(9) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv), and (a)(14) through (a)(18)(i) of this section.

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(18) August 15, 1995, for products subject to paragraph (a)(15)(ii) of this section.

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Dated: January 31, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

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