

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 310**

[Docket NO. 77N-334S]

RIN 0905-AA06

**Topical Drug Products for Over-the-Counter Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Final Rule**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule establishing that any over-the-counter (OTC) topical otic drug product for the prevention of swimmer's ear or for the drying of water-clogged ears is not generally recognized as safe and effective and is misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC topical otic drug products for these uses that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

**EFFECTIVE DATE:** August 15, 1995.

**FOR FURTHER INFORMATION CONTACT:** William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 16, 1977 (42 FR 63556), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical otic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in topical otic drug products. Interested persons were invited to submit comments by March 16, 1978. Reply comments in response to comments filed in the initial comment period could be submitted by April 14, 1978.

In accordance with § 330.10(a)(10), the data and information considered by the Panel, after deletion of a small

amount of trade secret information, were placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

In the December 16, 1977 advance notice of proposed rulemaking on OTC topical otic drug products, the Panel discussed the treatment of swimmer's ear (42 FR 63556 at 63565), but the Panel did not address the prevention of swimmer's ear or the drying of water-clogged ears.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears was published in the **Federal Register** of July 30, 1986 (51 FR 27366). Interested persons were invited to file by September 29, 1986, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by November 28, 1986. New data could have been submitted until July 30, 1987, and comments on the new data until September 30, 1987.

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency published a final rule establishing that certain active ingredients that had been 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) (21 CFR 310.545(a)(15)) the active ingredient acetic acid, which had been under consideration as part of this rulemaking for OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears. This ingredient was determined to be nonmonograph because no additional data had been submitted following publication of the tentative final monograph to determine whether acetic acid is generally recognized as safe and effective as a topical otic drug products for the prevention of swimmer's ear or for the drying of water-clogged ears. After that final rule published, only two ingredients remained to be evaluated in this rulemaking: Isopropyl alcohol and anhydrous glycerin. Final agency action on all other OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears occurs with the publication of this final rule.

In the tentative final monograph for OTC topical otic drug products for the prevention of swimmer's ear and for the

drying of water-clogged ears (51 FR 27366), the agency did not propose any active ingredient as generally recognized as safe and effective and not misbranded. However, the agency proposed monograph labeling in the event that data were submitted that resulted in the upgrading of any ingredient to monograph status. In this final rule, however, no active ingredient has been determined to be generally recognized as safe and effective for use in OTC topical otic drug products for the prevention of swimmer's ear or for the drying of water-clogged ears. Therefore, proposed §§ 344.3(c) through (f), 344.12, 344.14, 344.52, and 344.54 for OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears are not being issued as a final regulation.

This final rule declares OTC drug products containing active ingredients for the prevention of swimmer's ear or for the drying of water-clogged ears to be new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), for which an application or abbreviated application (hereinafter called application) approved under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 is required for marketing. In the absence of an approved application, products containing these drugs for this use also would be misbranded under section 502 of the act (21 U.S.C. 352). In appropriate circumstances, a citizen petition to establish a monograph may be submitted under § 10.30 (21 CFR 10.30) in lieu of an application.

This final rule amends part 310 (21 CFR part 310) to include OTC topical otic drug products containing active ingredients for the prevention of swimmer's ear or for the drying of water-clogged ears by adding new paragraph (a)(15)(ii) to § 310.545 to include the ingredients covered by this final rule, by redesignating the text of paragraph (a)(15) as (a)(15)(i), by revising the heading of newly redesignated paragraph (a)(15)(i), and by revising the heading of paragraph (a)(15) to clarify that products for the drying of water-clogged ears are also included. The inclusion of OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears in part 310 is consistent with FDA's established policy for regulations in which there are no monograph conditions. (See, e.g. §§ 310.510, 310.519, 310.525, 310.526, 310.532, 310.533, 310.534, and 310.536.) If, in the future, any ingredient is determined to be generally recognized as safe and effective for use in an OTC topical otic drug product for the