

comment on the direct final rule. FDA stated that the effective date of the direct final rule would be December 8, 2003, and, if the agency received no significant adverse comments, it would publish a notice of confirmation of the effective date no later than June 11, 2003. FDA received no significant adverse comments within the comment period. Therefore, FDA is confirming that the effective date of the direct final rule is December 8, 2003. As noted in the direct final rule, FDA is publishing this confirmation document 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their bottled water products into compliance with the quality standard imposed by the new rule.

Dated: June 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 350, and 369

[Docket No. 78N-0064]

RIN 0910-AA01

Antiperspirant Drug Products For Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) antiperspirant drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products. FDA is issuing this final rule after considering public comments on its proposed regulation, issued as a tentative final monograph (TFM), and all new data and information on antiperspirant drug products that have come to the agency's attention.

DATES: *Effective Date:* This rule is effective December 9, 2004.

Compliance Dates: The compliance date for products with annual sales less than \$25,000 is June 9, 2005. The compliance date for all other products is December 9, 2004.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug

Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

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I. Background

In the **Federal Register** of October 10, 1978 (43 FR 46694), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC antiperspirant drug products, together with the recommendations of the Advisory Review Panel on OTC Antiperspirant Drug Products (the Panel), which evaluated the data on these products. The agency's proposed regulation (TFM) for OTC antiperspirant drug products was published in the **Federal Register** of August 20, 1982 (47 FR 36492).

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency issued a final rule establishing that certain active ingredients in OTC drug products are not generally recognized as safe and effective and are misbranded. These ingredients included seven antiperspirant ingredients, which are included in § 310.545(a)(4) (21 CFR 310.545(a)(4)). In this rulemaking, the agency is adding one additional ingredient to this section. (See section III.1 of this document.)

In the **Federal Register** of March 23, 1993 (58 FR 15452), the agency requested public comment on two citizen petitions, and a response to one of the petitions, related to the safety of aluminum compounds in OTC antiperspirant drug products. This final monograph completes the TFM and

provides the substantive response to the citizen petitions.

Twenty-four months after the date of publication in the **Federal Register**, for products with annual sales less than \$25,000, and 18 months after the date of publication in the **Federal Register**, for all other products, no OTC drug product that is subject to this final rule and that contains a nonmonograph condition may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application (NDA) or abbreviated new drug application. Further, any OTC drug product subject to this final monograph that is repackaged or relabeled after the compliance dates of the final rule must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily as soon as possible.

In response to the TFM on OTC antiperspirant drug products and the request for comment on the citizen petitions, the agency received 20 comments. One manufacturer requested an oral hearing before the Commissioner of Food and Drugs on six different issues. Copies of the information considered by the Panel, the comments, and the hearing request are on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. "OTC Volumes" cited in this document refer to information on public display.

The agency received some "feedback" communications under the OTC drug review procedures (see the **Federal Registers** of September 29, 1981 (46 FR 47740) and April 1, 1983 (48 FR 14050)). The agency has included these communications in the administrative record and addressed them in this document.

The safety issues raised by the citizen petitions are discussed in section II.F of this document. The agency believes it has adequately responded to the six issues related to the hearing request; therefore, a hearing is not necessary.

II. The Agency's Conclusions on the Comments

A. General Comments on OTC Antiperspirant Drug Products

(Comment 1) One comment requested that FDA reconsider its position that OTC drug monographs are substantive, as opposed to interpretive, regulations.

The agency addressed this issue and reaffirms its conclusions as stated in