

prevention of swimmer's ear or for the drying of water-clogged ears, the agency will promulgate an appropriate regulation at that time.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II or III, the term "nonmonograph conditions" is used.

In the tentative final monograph for OTC topical otic drug products (51 FR 27366 at 27367), the agency advised that the conditions under which the drug products are subject to the monograph would be generally recognized as safe and effective and not misbranded would be effective 12 months after the date of publication of the final monograph in the **Federal Register**. Although data and information were submitted in response to the proposed rule, they were not sufficient to support monograph conditions, and no monograph is being established at this time. Therefore, topical otic drug products that are subject to this rule are not generally recognized as safe and effective and are misbranded (nonmonograph conditions). Because no OTC drug monograph is being established for this class of drug products, the agency is adopting its standard 6-month effective date for the nonmonograph conditions in this final rule. Therefore, on or after August 15, 1995, no OTC drug products that are subject to this final rule may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application.

In response to the proposed rule on OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears, two drug manufacturers submitted comments on isopropyl alcohol and anhydrous glycerin, and one physician submitted a comment on isopropyl alcohol and acetic acid. Copies of the comments received are on public display in the Dockets Management Branch (address

above). Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

A. General Comments

1. One comment contended that products for the treatment of "water-clogged ears" are not drugs within the meaning of section 201(g) of the act (21 U.S.C. 321(g)) and, thus, are not the proper subject of an OTC drug monograph. The comment stated that section 201(g)(1) of the act defines a drug, in part, as " * * * (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals * * * ." The comment argued that these products are not intended for use in connection with "any disease," do not affect the structure or any function of the body, and are not meant to have any effect on the body. The comment mentioned that FDA had previously stated that "water-clogged ears is not a recognized clinical entity or a term found in textbooks," (Refs. 1 and 2) and thus, in FDA's view, the condition "water-clogged ears" is not a disease.

The comment added that if FDA concluded that such products are intended for use in connection with a "disease" or affect the structure or a function of the body, then the products should be regulated as a device rather than as a drug. The comment stated that section 201(h) of the act (21 U.S.C. 321(h)) states that a device "does not achieve its primary intended purposes through chemical action within or on the body * * * and * * * is not dependent upon being metabolized for the achievement of its primary intended purposes." The comment contended that products that function by drying excess water work by a purely physical process and that the product is not metabolized.

Despite the comment's arguments, the agency considers products "for the drying of water in the ears" or "to help relieve the discomfort of water-clogged ears by drying excess water" to be drugs and not devices. All drugs do not need to be metabolized. Some work by a purely physical process, such as a skin protectant that forms a physical barrier.

The act defines a device, in section 201(h), in part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or

other similar or related article, including any component, part, or accessory, which is: (1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The agency has determined that these products do not meet the definition of a device because they are not an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article.

As discussed in the Panel's report (42 FR 63556 at 63565), external otitis, an infection of the skin lining the external auditory canal, is one of the most common diseases of the ear. One type of external otitis is called "diffuse external otitis" and is commonly known as "swimmer's ear." It occurs with greater frequency during hot, humid weather and has been reported to occur in divers and swimmers. "Swimmer's ear" is apparently due to excessive moisture in the external auditory meatus, which may be the result of various causes. The external auditory canal is a cul-de-sac, well suited for the collection of moisture, thus providing a basis for infection. Disruption of the skin lining of the external auditory canal by the action of the accumulated moisture, or by the use of instruments to clear the ear canal of water after bathing or swimming, may cause maceration, fissuring, or laceration of the skin lining and provide a favorable environment for the growth of bacteria or fungi. Although the action of products that dry water in the ear is limited to removal of the excess water, if this condition is left untreated, it could result in "swimmer's ear."

In the tentative final monograph (51 FR 27366 at 27367), the agency stated that it recognized a population that is prone to develop swimmer's ear and that the availability of OTC drug products to prevent the occurrence of this condition would benefit the consumer. Products that dry water in the ear may prevent the occurrence of "swimmer's ear" and, thus, help prevent disease. As discussed in the tentative final monograph (51 FR 27366 at 27370), the agency also believes that