§ 375.2, complete responsibility and authority for the procurement of needed supplies, equipment, space, communications, transportation, and repair services, are delegated to each regional director for his or her geographic area.

* * * * *

§ 375.7 [Amended]

7. Section 375.7 is amended as follows:

a. In paragraph (a)(2), by removing ''Director of Retirement Claims'' and adding in its place ''Director of Programs''.

b. In paragraph (b)(1)(ii), by removing ''such as claim file folders or magnetic tape master records''.

c. In paragraph (b)(1)(vi), by removing ''and in the regions'' and ''or if those offices become inoperative''.

d. In paragraph (b)(2), by removing ''Director of Unemployment and Sickness Insurance'' and adding in its place ''Director of Programs''.

e. Paragraph (c) is removed.

8. Section 375.8 is revised to read as follows:

§ 375.8 Regulations for employers.

(a) In a national emergency, as described in § 375.2, employers shall continue to follow, to the greatest extent possible, the requirements pertaining to employers in subchapters A, B, and C of this chapter.

(b) Where a national emergency, as described in § 375.2, prevents an employer from following any requirement imposed by paragraph (a) of this section, the employer shall comply with such requirement as soon as possible after the cessation of the national emergency.

(c) In a national emergency, as defined in § 375.2, all communications by employers shall be directed as set forth in § 375.4.

Dated: August 5, 1999.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 99–20912 Filed 8–16–99; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 344

[Docket No. 77N–334S]

RIN 091O–AA01

Topical Otic Drug Products for Over-the-Counter Human Use; Products for Drying Water-Clogged Ears; Proposed Amendment of Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) topical otic drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded). The amendment would add conditions for marketing topical otic drug products for drying water-clogged ears. Concurrently, the agency is proposing to remove water-clogged ears from one part of the regulation that lists conditions that are not generally recognized as safe and effective and that are misbranded. This proposal contains labeling in the new OTC drug format and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments on the proposed regulation by November 15, 1999. Please see section VIII for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Ryland, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 1982 (47 FR 30012), the agency published a tentative final monograph for OTC topical otic drug products used as earwax removal aids. Subsequently, in the **Federal Register** of July 30, 1986 (51 FR 27366), the agency proposed to amend this tentative final monograph to consider OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears. At that time, no topical otic drug products for these conditions were proposed as generally recognized as safe and effective and not misbranded. The agency, however, did propose Category I (monograph) labeling for such products in case data were submitted that resulted in upgrading any ingredient(s) to monograph status in the final rule.

In the **Federal Register** of August 8, 1986 (51 FR 28656), the agency issued a final rule establishing part 344 (21 CFR part 344) for topical otic drug products for OTC human use. The monograph included one active ingredient for use as an earwax removal aid.

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 (hereinafter referred to as the 1990 final rule). The 1990 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. After the 1990 final rule published, only two ingredients remained to be evaluated in this rulemaking: Isopropyl alcohol and anhydrous glycerin.

In the **Federal Register** of February 15, 1995 (60 FR 8916), the agency issued a final rule establishing that OTC topical otic drug products for prevention of swimmer's ear or for drying water-clogged ears were not generally recognized as safe and effective for OTC use and were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The agency listed the ingredients considered in the rulemaking (i.e., glycerin, anhydrous glycerin, and isopropyl alcohol) in § 310.545(a)(15)(ii), with an effective date of August 15, 1995, after which products containing these ingredients for these uses could no longer be initially introduced or initially delivered for introduction into interstate commerce. Acetic acid, which had been listed solely in § 310.545, was now listed in § 310.545(a)(15)(i), with the same effective date of May 7, 1991. This final rule did not affect the conclusion reached in the 1990 final rule that acetic acid was not generally recognized as safe and effective for the prevention of swimmer's ear. The phrase ''approved

as of May 7, 1991'' in § 310.545(a)(15)(i) indicates when this conclusion became effective for acetic acid.

Subsequently, a drug manufacturer submitted new data (Ref. 1) to support the use of a product containing 95 percent isopropyl alcohol in a 5 percent anhydrous glycerin base for drying water-clogged ears. The agency has determined that the data support the use of this product for drying water-clogged ears (Ref. 2). Accordingly, in the **Federal Register** of August 16, 1995 (60 FR 42435), the agency issued a partial stay of the August 15, 1995, effective date for § 310.545(a)(15)(ii) for products containing 95 percent isopropyl alcohol in a 5 percent anhydrous glycerin base used for the drying of water-clogged ears. This partial stay applied only to products with these ingredients for drying water-clogged ears. The new data and the stay did not involve other ingredients, such as acetic acid, and did not pertain to the prevention of swimmer's ear. The August 15, 1995, effective date for § 310.545(a)(15)(ii) remains in effect for the listed ingredients when used in topical otic drug products for the prevention of swimmer's ear.

II. The Agency's Proposal

A. Evaluation of the Data

The new data (Ref. 1) included the results of a double-blinded, three-arm, parallel study to evaluate the effectiveness and tolerability of isopropyl alcohol in drying water-clogged ears in 90 adult volunteers. Subjects were recruited if they were otherwise healthy but had a history of water-clogged ears. A screening test was performed by instilling five drops of water into the ear designated for testing and then examining the ear using an operating microscope. Subjects who had only mild residual fluid, or none, were disqualified from the study. Subjects with moderate fluid retention (defined as having an amount of liquid that placed the meniscus up to one-half of the visible height of the eardrum to the umbo) or greater were then randomized into one of the three treatment arms: Isopropyl alcohol 95 percent in anhydrous-glycerin 5 percent, isopropyl alcohol 100 percent, and no treatment. While subjects in the no-treatment control arm received no drug, the study nurse conveyed a sense of treatment by adding five drops of air from an empty dropper to the subjects' ears.

The results of the study showed that isopropyl alcohol (with and without glycerin) is effective in drying excess water in the subjects' ear canal compared to no treatment, even though the size was insufficient to detect a statistical difference in efficacy between the two isopropyl alcohol treatment arms. Many subjects in both alcohol arms complained of burning/warming after even a single treatment. The intensity of this sensation (as determined by each subject) was up to 40 on a visual analog score (VAS) 50-point scale. No irritation (excessive burning) was documented after a single use. Overall, the results showed that subjects who received isopropyl alcohol with glycerin had better numerical scores than those on isopropyl alcohol alone relative to both effectiveness and tolerability. Subjects on isopropyl alcohol with glycerin had lower burning scores than those on isopropyl alcohol alone, even though the power of this study was insufficient to show a statistically significant difference. Thus, the agency has determined that it would be preferable for consumers to use a product containing 95 percent isopropyl alcohol in 5 percent anhydrous glycerin instead of a product containing 100 percent isopropyl alcohol. The agency's detailed comments and evaluations of the data (Ref. 2) are on file in the Dockets Management Branch (address above).

Based on these new data, the agency is proposing to amend part 344 to include ''ear drying aid'' drug products. The monograph active ingredient for these products is 95 percent isopropyl alcohol in 5 percent anhydrous glycerin base.

B. Labeling

In the July 30, 1986, proposal (51 FR 27366 at 27373), the agency proposed Category I labeling in the event that data were submitted that resulted in upgrading any ingredient(s) to monograph status in the final rule. The agency stated that although the term ''water-clogged ears'' is not a recognized clinical entity, it is a term consumers use to refer to the temporary retention of water in the ears after swimming, showering, washing the hair, bathing, etc. (51 FR 27366 at 27370). The agency also stated that claims such as ''helps relieve the discomfort of water-clogged ears by drying excess water,'' and ''helps dry water in the ear,'' would be acceptable because these claims relate to the relief of the symptoms as described in the previous sentence. At this time, the agency is proposing language that is consistent with the earlier version but is more concise, that is, ''Dries water in the ear,'' or that incorporates some of the common causes of water-clogged ears, that is, ''Dries and relieves water-clogged ears after swimming, showering, bathing, or washing the hair.'' The agency is also allowing other truthful and nonmisleading statements to be used as provided in § 330.1(c)(2) (21 CFR 330.1(c)(2)). The proposed statement of identity for these products is ''ear drying aid.''

The agency is proposing the same warnings previously proposed in § 344.52(c)(1), (c)(2), (c)(3), and (c)(5) of the July 30, 1986, tentative final monograph (51 FR 27366 at 27373) but is proposing them in the new OTC drug labeling format (see 64 FR 13254, March 17, 1999). The agency is changing the warning previously proposed in § 344.52(c)(4), which stated: ''Discontinue use and consult a doctor if undue irritation or sensitivity occurs.'' The agency is expanding the term ''irritation'' to include ''too much burning'' and is deleting the term ''sensitivity'' because the alcohol treatment products in the clinical study (Ref. 1) produced some burning (intensity was moderate to severe during a single use (up to 40 on a 50-point scale)). The agency is concerned about repeated use and long-term use. Accordingly, the agency is revising the language in the proposed warning in § 344.52(c)(4) to now read: ''Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs''. One manufacturer expressed disagreement (Ref. 3) with the inclusion of the phrase ''too much [or excessive] burning,'' and the agency requested the manufacturer to provide additional data on this subject (Ref. 2). However, no data were ever provided. Based on the clinical study (Ref. 1), the agency is proposing the following directions: ''apply 4 to 5 drops in each affected ear''.

Existing part 344 currently includes only topical otic drug products used as earwax removal aids. The current headings for §§ 344.10 and 344.50 refer to a topical otic active ingredient and labeling of topical otic drug products, respectively. Accordingly, §§ 344.10 and 344.50 will become ''Earwax removal aid active ingredient'' and ''Labeling of earwax removal aid drug products,'' respectively. The agency is proposing new §§ 344.12 and 344.52 as ''Ear drying aid active ingredient,'' and ''Labeling of ear drying drug products,'' respectively. The agency is proposing to delete § 344.50(e), which refers to substitution of the word ''physician'' for the word ''doctor'' because this is now covered in § 330.1(i)(23) (21 CFR 330.1(i)(23)). Likewise, the agency is not proposing previously proposed § 344.52(e) (concerning substitution of ''physician'' for ''doctor'') (51 FR 27366 at 27373) because it is also covered by § 330.1(i)(23).

III. Summary of Agency Changes

1. Section 344.52(b), under the heading ''Use,'' follows the new OTC drug labeling format in § 201.66(d)(4) (21 CFR 201.66(d)(4)) and provides several options to customize the uses.

2. Section 344.52(c), under the heading ''Warnings,'' follows the new OTC drug labeling format in § 201.66(c)(5) (21 CFR 201.66(c)(5)) and states all of the warnings after the new appropriate subheadings.

3. The agency has revised the format of the headings for § 310.545(a)(15), (a)(15)(i), and (a)(15)(ii).

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq*.) 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 agency believes that this proposed rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this proposed rule is to establish conditions for drug products used to dry water-clogged ears containing alcohol and glycerin. This proposed rule amends the final monograph for OTC topical otic drug products containing alcohol and glycerin for the drying of water-clogged ears and will require some product relabeling. The agency's Drug Listing System identifies only one manufacturer/marketer of one stockkeeping unit (SKU) (individual product, package, and size) of OTC topical otic drug products with these ingredients for drying water-clogged ears. There may be other manufacturers/marketers not identified in sources FDA reviewed, but the agency believes there are a limited number.

The agency has been informed that relabeling costs of the type required by this proposal generally average about $2,000 to $3,000 per SKU. Assuming there could be as many as five affected OTC SKU's in the marketplace, total one-time costs of relabeling would be $10,000 to $15,000. The agency believes that actual costs would be lower for several reasons.

First, the agency has proposed the revised labeling in the new OTC drug labeling format (64 FR 13254). Therefore, manufacturers will not incur expenses determining how to state the new information in product labeling. Manufacturers, however, will incur some expense to redesign product labeling. Manufacturers will be able to incorporate the revised labeling changes with the new general OTC drug labeling final rule, implementing all labeling changes at one time. Thus, the relabeling costs resulting from two different but related final rules will be individually reduced by implementing both required changes at the same time.

The agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The one identified manufacturer/marketer is a small entity using the U.S. Small Business Administration designations for this industry (750 employees). The agency believes that any other unidentified manufacturer of these products is probably also a small entity. Based on the limited number of SKU's (usually only one) each manufacturer has to relabel, the cost for each manufacturer should be minimal.

This analysis shows that this proposed rule is not economically significant under Executive Order 12866. Finally, this analysis shows that the Unfunded Mandates Reform Act does not apply to the proposed rule because it would 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.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.). Rather, the proposed labeling requirements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(c) 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.

VII. Request for Comments

Interested persons may, on or before November 15, 1999, submit written comments to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before November 15, 1999. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 12 months after its date of publication in the **Federal Regiser**.

IX. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP1, Docket No. 77N–334S, Dockets Management Branch.

2. Letter from W. E. Gilbertson, FDA, to N. Buc, Buc Levitt & Beardsley, attorneys for Del Pharmaceuticals, Inc., coded LET13, Docket No. 77N–334S, Dockets Management Branch.

3. Comment No. C7, Docket No. 77N–334S, Dockets Management Branch.

List of Subjects

21 CFR Part 310

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

21 CFR Part 344

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310 and 344 be amended as follows:

PART 310—NEW DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by revising the headings of paragraphs (a)(15), (a)(15)(i), and (a)(15)(ii) 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*—(i) *For the prevention of swimmer's ear and for the drying of water-clogged ears, approved as of May 7, 1991.*

(ii) *For the prevention of swimmer's ear, approved as of August 15, 1995.*

* * * * *

PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

3. The authority citation for 21 CFR part 344 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 344.3 is amended by adding paragraphs (c) and (d) to read as follows:

§ 344.3 Definitions.

* * * * *

(c) *Water-clogged ears.* The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) *Ear drying aid.* A drug used in the external ear canal to help dry water-clogged ears.

5. Section 344.10 is amended by revising the section heading to read as follows:

§ 344.10 Earwax removal aid active ingredient.

* * * * *

6. Section 344.12 is added to subpart B to read as follows:

§ 344.12 Ear drying aid active ingredient.

The active ingredient of the product consists of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base.

7. Section 344.50 is amended by revising the section heading and by removing paragraph (e) to read as follows:

§ 344.50 Labeling of earwax removal drug products.

* * * * *

8. Section 344.52 is added to subpart C to read as follows:

§ 344.52 Labeling of ear drying aid drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''ear drying aid.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''dries water in the ears'' (optional, which may be followed by: ''and relieves water-clogged ears'') (which may be followed by any or all of the following: ''after: [bullet][1] swimming [bullet] showering [bullet] bathing [bullet] washing the hair''). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''Flammable [in bold type]: Keep away from fire or flame.''

(2) ''Do not use [in bold type] in the eyes.''

(3) ''Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.''

(4) ''Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.''

(d) *Directions.* The labeling of the product contains the following statement under the heading ''Directions'': [optional, bullet] ''apply 4 to 5 drops in each affected ear.''

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21252 Filed 8–16–99; 8:45 am]

BILLING CODE 4160–01–F

[1] See § 201.66(b)(4) of this chapter.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL–097–FOR]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; withdrawal of a previously proposed amendment and public comment period and opportunity for public hearing for a new proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing the withdrawal of a previously proposed amendment and the receipt of a new amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Illinois is replacing its previously proposed amendment dated November 24, 1998, with a new amendment dated August 2, 1999. Both amendments include changes to Illinois' regulations to reflect changes required by the Energy Policy Act of 1992 regarding repair or compensation for material damage caused by subsidence from underground coal mining operations and replacement of drinking, domestic, and residential water supplies that have been adversely impacted by underground coal mining operations. The new amendment also includes revisions to and additions of regulations concerning performance bond adjustment; siltation structures; impoundments; hydrologic balance; disposal of noncoal mine wastes; revegetation; backfilling and grading; prime farmland; and State inspections. Illinois intends to revise its program to be consistent with the corresponding Federal regulations, to provide additional safeguards, to clarify ambiguities, and to improve operational efficiency.

This document gives the times and locations that the Illinois program and the new amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., e.s.t., September 16, 1999. If requested, we will hold a public hearing on the amendment on September 13, 1999. We will accept