(g) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation (NELAC), the International Organizations for Standardization's (ISO) Committee on Conformity Assessment (CASCO), conformity assessment related activities of the American National Standards Institute (ANSI), and ICSP working groups dealing with conformity assessment issues.

(h) Work with other agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities. Examples: An agency can participate in another agency's conformity assessment activities by conducting joint procurement audits/inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: Conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.

(i) Encourage domestic and international recognition of U.S. conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/agreements.

(j) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(k) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.

(l) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products.

(m) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.

(n) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

§ 287.5 Responsibilities of an Agency Standards Executive.

In addition to carrying out the duties described in OMB Circular A–119 related to standards activities, an Agency Standards Executive should:

(a) Promote the following goals:

(1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest.

(2) Development and dissemination of agency technical and policy positions.

(3) Development of agency positions on conformity assessment related issues that are in the public interest.

(b) Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.

(c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.

(d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.

(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.

(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.

(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and Budget (OMB) on the agency's implementation of OMB Circular A–119.

[FR Doc. 00–20262 Filed 8–9–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 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; Amendment of Monograph; Lift of Partial Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; lift of partial stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the 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 adds conditions for marketing topical otic drug products for drying water-clogged ears and includes labeling in the new OTC drug format. The agency is amending its final regulations for OTC drug labeling requirements to include the new flammability warning for topical otic drug products for drying water-clogged ears. The agency is also lifting a partial stay of the effective date of certain provisions of the regulations for topical otic drug products for the drying of water clogged ears. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES:

Effective Date: This rule is effective May 17, 2002. The stay of § 310.545 (a)(15)(ii) for topical otic drug products for the drying of water-clogged ears that published at 60 FR 42436 on August 16, 1995, and effective June 22, 1995, is lifted effective September 11, 2000.

Compliance Date: The compliance date for products with annual sales less that $25,000 is May 17, 2003. The compliance date for all other OTC drug products is May 17, 2002.

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.

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 a 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), (hereinafter referred to as the 1990 final rule) 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. 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 and 1995 final rules that acetic acid was not generally recognized as safe and effective for the prevention of swimmer's ear or for the drying of water-clogged ears. 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 determined that the data supported 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 agency is lifting the partial stay of the August 15, 1995, effective date of certain provisions of the regulations for topical otic drug products for the drying of water clogged ears. 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.

In the **Federal Register** of August 17, 1999 (64 FR 44671), the agency published a proposed amendment of the monograph for OTC topical otic drug products to add conditions for marketing products with isopropyl alcohol and anhydrous glycerin for drying water-clogged ears. The proposal contained labeling in the new OTC drug format in § 201.66 (21 CFR 201.66). Concurrently, the agency proposed to remove the drying of water-clogged ears from one part of § 310.545(a)(15) by revising the headings of paragraphs (a)(15), (a)(15)(i), and (a)(15)(ii).

Interested persons were invited to submit comments on the proposal and on the agency's economic impact determination by November 15, 1999. The agency did not receive any comments in response to the proposal.

II. The Agency's Final Conclusions

The agency concludes that a product consisting of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base is generally recognized as safe and effective for OTC use for the drying of water-clogged ears and that such a product is not misbranded when it contains the labeling in new § 344.52 and is consistent with § 330.1 (21 CFR 330.1). No other product or ingredient has been found to be generally recognized as safe and effective for this use.

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 are changed to ''Earwax removal aid active ingredient'' and ''Labeling of earwax removal aid drug products,'' respectively. The agency is including new §§ 344.12 and 344.52 as ''Ear drying aid active ingredient,'' and ''Labeling of ear drying aid drug products,'' respectively. The agency is deleting § 344.50(e), which refers to substitution of the word ''physician'' for the word ''doctor,'' because this is now included in § 330.1(i)(23). The agency is listing the flammability warning in § 344.52(c) in § 201.66(c)(5)(ii)(C).

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4.). 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 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 concludes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order. FDA has determined that the final rule does not have a significant economic impact on a substantial number of small entities. Further, since this final rule makes no mandates on government entities and will result in expenditures less than $100 million in any one year, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to establish conditions for OTC drug products containing alcohol and glycerin used to dry water-clogged ears. This final rule amends the final monograph for OTC topical otic drug products 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 believes that relabeling costs of the type required by this final rule 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 the actual cost could be lower for several reasons.

First, the labeling in the monograph is in the new OTC drug labeling format found in § 201.66. Therefore, manufacturers will not incur any expenses determining how to state the product's labeling. Second, manufacturers will be able to incorporate product labeling changes required by the final monograph and the new general OTC drug labeling requirements 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, thereby reducing the labeling cost of this final rule.

Third, 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. Small entities tend to use simpler and less expensive labeling. In addition, based on the limited number of SKU's (usually only one) each manufacturer has to relabel, the cost for each manufacturer should be minimal. Finally, the final rule will not require any new reporting and recordkeeping activities. Thus, no additional professional skills are needed.

The agency rejected an exemption for small entities because the new labeling information is also needed by consumers who purchase products marketed by those entities. However, a longer effective date until May 17, 2003, is being provided for products with annual sales less than $25,000.

For the reasons stated above and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner certifies that this rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule 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 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)).

V. Environmental Impact

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

VI. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

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 secs. 201–907 of the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the partial stay for § 310.545(a)(15)(ii) for topical otic drug products for the drying of water-clogged ears that published in the **Federal Register** of August 16, 1995 (60 FR 42436), is lifted effective September 11, 2000, and 21 CFR parts 201, 310, and 344 are amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.66 is amended by revising paragraph (c)(5)(ii)(C) to read as follows:

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

* * * * *

(c) * * *

(5) * * *

(ii) * * *

(C) Flammability warning, with appropriate flammability signal word(s) (e.g., §§ 341.74(c)(5)(iii), 344.52(c), 358.150(c), and 358.550(c) of this chapter). This warning shall follow a subheading containing the appropriate flammability signal word(s) described in an applicable OTC drug monograph or approved drug application.

* * * * *

PART 310—NEW DRUGS

3. 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.

4. Section 310.545 is amended by revising the headings of paragraphs (a)(15) and (a)(15)(i), and by revising paragraph (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.*

Glycerin and anhydrous glycerin

Isopropyl alcohol

* * * * *

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

5. 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.

6. 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.

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

§ 344.10 Earwax removal aid active ingredient.

* * * * *

8. 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.

9. 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 aid drug products.

* * * * *

10. 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: July 31, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19992 Filed 8–9–00; 8:45 am]

BILLING CODE 4160–01–F

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

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1335

[Docket No. NHTSA–98–4532]

RIN 2127–AH43

State Highway Safety Data and Traffic Records Improvements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule the regulations that were published in an interim final rule to implement a new program established by the Transportation Equity Act for the 21st Century (TEA–21), with modifications to clarify the program's maintenance of effort requirement. Under the final rule, States can qualify for incentive grant funds for improved highway safety data and traffic records systems if they meet the eligibility requirements.

DATES: This final rule becomes effective on September 11, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Wendi Wilson-John, Office of State and Community Services, NSC–01, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590, telephone (202) 366–2121; or Ms. Heidi L. Coleman, NCC–30, NHTSA, 400 Seventh Street, SW., Washington, DC 20590; telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: The Transportation Equity Act for the 21st Century (TEA–21) was signed into law on June 9, 1998, as Public Law 105–178. Section 2005 of TEA–21 established a new Section 411, entitled State Highway Safety Data Improvements, in Title 23, United States Code (Section 411). Under this new program, States may qualify for incentive grant funds by adopting and implementing effective highway safety data and traffic records improvement programs that meet specified statutory criteria.

Components Required by Section 411

Section 411 provides that a State's highway safety data and traffic records system should have three basic components, all of which must be present if the State is to receive multiple-year grants: a committee to coordinate the development and use of highway safety data and traffic records; a systematic assessment of the State's highway safety data and traffic records;