

section 1131 of the Act. If the claimant filed for the lump-sum death payment on the social security account of a relative, SSA sends the claimant the pension information on the deceased individual. In either case, SSA sends the notice after it has made a decision on the claim for benefits. The notice shows the type, payment frequency, and amount of pension benefit, as well as the name and address of the plan administrator as reported to the IRS. This information can then be used by the claimant to claim any pension benefits still due from the pension plan.

(b) *Requesting deferred vested pension benefit information from SSA files.* Section 1131 of the Act also requires SSA to provide available pension benefit information on request. SSA will provide this pension benefit information only to the individual who has the pension coverage (or a legal guardian or parent, in the case of a minor, on the individual's behalf). However, if the individual is deceased, the information may be provided to someone who would be eligible for any underpayment of benefits that might be due the individual under section 204(d) of the Act. All requests for such information must be in writing and should contain the following information: the individual's name, social security number, date of birth, and any information the requestor may have concerning the name of the pension plan involved and the month and year coverage under the plan ended; the name and address of the person to whom the information is to be sent; and the requester's signature under the following statement: "I am the individual to whom the information applies (or "I am related to the individual as his or her _____"). I know that if I make any representation which I know is false to obtain information from Social Security records, I could be punished by a fine or imprisonment or both." Such requests should be sent to: Social Security Administration, Office of Central Records Operations, P.O. Box 17055, Baltimore, Maryland 21235.

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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; Partial Stay of Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of regulation.

SUMMARY: The Food and Drug Administration (FDA) is staying part of a final rule that established that any over-the-counter (OTC) topical otic drug products 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. This action, which is being taken in response to new clinical data and a petition for stay of action, applies only to topical otic drug products for the drying of water-clogged ears. This action is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: June 22, 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:

I. Background

In the **Federal Register** of August 8, 1986 (51 FR 28656), the agency published a final rule establishing conditions under which OTC topical otic drug products are generally recognized as safe and effective. That final rule applied only to earwax removal aids. Products for the prevention of swimmer's ear and for the drying of water-clogged ears were not considered by the agency at that time.

In the **Federal Register** of February 15, 1995 (60 FR 8916), the agency declared that OTC drug products containing active ingredients for the prevention of swimmer's ear or for the drying of water-clogged ears were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). To be marketed, such products would require an application or abbreviated application approved under section 505

of the act (21 U.S.C. 355) and 21 CFR part 314. In the absence of an approved application, products for this use also would be misbranded under section 502 of the act (21 U.S.C. 352). The agency also stated that, 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.

Subsequently, Buc Levitt & Beardsley, on behalf of Del Pharmaceuticals, Inc., filed a citizen petition (Ref. 1) to: (1) Permit the marketing of 95 percent isopropyl alcohol in 5 percent anhydrous glycerin for the drying of water-clogged ears, and (2) remove glycerin, anhydrous glycerin, and isopropyl alcohol from the list of active ingredients in § 310.545(a)(15)(ii) (21 CFR 310.545(a)(15)(ii)). This petition included the results of a double-blinded, 3-arm parallel study to evaluate the efficacy and tolerability of isopropyl alcohol in drying water-clogged ears in 90 adult volunteers. Buc Levitt & Beardsley, on behalf of Del Pharmaceuticals, Inc., also filed a petition (Ref. 2), pursuant to 21 CFR 10.35, requesting a stay of the August 15, 1995, effective date of the final rule to allow time for the agency to review the results of the new study.

The agency reviewed the results of this study and determined that 95 percent isopropyl alcohol in a 5 percent anhydrous glycerin base is safe and effective for OTC use for drying water-clogged ears. The agency's detailed comments and evaluations of this study are on file in the Dockets Management Branch (Ref. 3).

On June 22, 1995, FDA agreed to stay the effective date of the final rule for OTC swimmer's ear and the drying of water-clogged ear drug products (Ref. 4). The agency intends to propose to amend the final monograph for OTC topical otic drug products to include conditions under which drug products for the drying of water-clogged ears are generally recognized as safe and effective and not misbranded.

The agency has determined that the stay of action applies only to topical otic drug products for the drying of water-clogged ears. The new study did not involve the prevention of swimmer's ear. Therefore, the August 15, 1995, effective date for § 310.545(a)(15)(ii) remains in effect for topical otic drug products for the prevention of swimmer's ear. The August 15, 1995, effective date is stayed only for topical otic drug products for the drying of water-clogged ears.

II. References

The following references are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Citizen's Petition, Buc Levitt & Beardsley, filed on behalf of Del Pharmaceuticals, Inc., coded CP1, Docket No. 77N-334S, Dockets Management Branch.

(2) Citizen's Petition to Stay Action, Buc Levitt & Beardsley, filed on behalf of Del Pharmaceuticals, Inc., coded PSA 1, Docket No. 77N-334S, Dockets Management Branch.

(3) Letter from W. E. Gilbertson, FDA, to Buc Levitt & Beardsley, attorneys for Del Pharmaceuticals, Inc., coded LET 12, Docket No. 77N-334S, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA to Buc Levitt & Beardsley, attorneys for Del Pharmaceuticals, Inc., coded LET 13, Docket No. 77N-334S, Dockets Management Branch.

List of Subjects in 21 CFR Part 310

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-16, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; secs. 215, 301, 302(a) 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

§ 310.545 [Partial stay]

2. Section 310.545 *Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses* is stayed in paragraph (a)(15)(ii) only for topical otic drug products for the drying of water-clogged ears.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.
[FR Doc. 95-20315 Filed 8-15-95; 8:45 am]

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Parts 1309 and 1310**

[DEA No. 112C]

Implementation of the Domestic Chemical Diversion Control Act of 1993 (PL 103-200); Correction

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations which were published on Thursday, June 22, 1995 (60 FR 32447). The regulations related to the registration, recordkeeping and reporting requirements for manufacturers, distributors, importers and exporters of listed chemicals.

EFFECTIVE DATE: August 21, 1995.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Division Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION: The final regulations that are the subject of these corrections implement the Domestic Chemical Diversion Control Act of 1993 (PL 103-200) (DCDCA). The regulations amend Title 21, Code of Federal Regulations, to add a new Part 1309 and revise certain sections in Parts 1310, 1313 and 1316. As published, the final regulations contain errors that could cause confusion in the regulated industry.

Accordingly, the publication on June 22, 1995 of the final regulations to implement the DCDCA, which were the subject of **Federal Register** Document 95-14978, is corrected as follows:

§ 1309.02 [Corrected]

1. On page 32455, in the first column, in section 1309.02, paragraphs (f) through (h) are redesignated as paragraphs (e) through (g).

§ 1310.04 [Corrected]

2. On page 32461, in the first column at the top, in section 1310.04, paragraphs (f)(1)(xxii) and (f)(1)(xxiii) are redesignated as paragraphs (f)(1)(xxi) and (f)(1)(xxii).

Dated: July 28, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 95-20108 Filed 8-15-95; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**Office of the Assistant Secretary for Housing-Federal Housing Commissioner****24 CFR Part 1710**

[Docket No. FR-3925-N-01]

Interstate Land Sales Registration Program—Notice of Order of Withdrawal of State Certification for State of Georgia

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice of Order of Withdrawal of State Certification for Georgia.

SUMMARY: A special feature of the Interstate Land Sales Full Disclosure Act, permits subdivisions to be registered under the Act through a State Certification Program. Due to changes in Georgia law, the State of Georgia, which had been one of five certified States, has withdrawn from the certification program, effective July 1, 1995.

DATES: In accordance with HUD regulations, HUD's acceptance of all Georgia Certified Registrations expires 90 days after the date of publication in the **Federal Register**. Unless a registrant submits a modified registration in accordance with this Notice or requests a voluntary suspension of its registration, its registration will be terminated at the end of the 90-day period.

FOR FURTHER INFORMATION CONTACT: Maurice D. Gulledge, Acting Director, Interstate Land Sales Registration Division, Office of Housing, Room 9160, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-0502, ext. 2073 or (202) 708-4594 (TDD).

SUPPLEMENTARY INFORMATION: The Secretary may certify a State disclosure equivalency pursuant to subpart C of 24 CFR part 1710. Five States, Arizona, California, Florida, Georgia and Minnesota, have been participating in HUD's certification program. Georgia is the first state to withdraw from this certification program. The benefit of certification is that a developer operating in compliance with a certified state's law does not have to file a comprehensive, duplicate registration with HUD. Thus, once the Secretary has certified a State's land sales program, the developer of a subdivision located in that state may satisfy the Federal registration requirements of the