

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]

BILLING CODE 4160-01-F

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. Gullede, 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

Interstate Land Sales Full Disclosure Act, 15 U.S.C. 1701 *et seq.*, by filing with HUD a certified copy of the state's disclosure report.

Under 24 CFR 1710.508(a), HUD's acceptance of Georgia's Certified Registration will expire 90 days after the date of this notice, unless a Georgia registrant files a registration request with HUD by that date. Under the Act, unless subdivision sales are exempt by statute or regulation, the subdivision must be effectively registered with HUD before the developer may offer to sell or lease any lots.

HUD will try to minimize the burden on Georgia developers by accepting much of the former Georgia State registration. A Georgia registrant previously registered under the State Certification Program that wants to maintain its Federal registration, must submit, within 90 days after this Notice, a modified Statement of Record that includes (1) a current Property Report and (2) an Affirmation pursuant to the instructions found at 24 CFR § 17120.219. There will be no fees required for these changes. The Property Report must be modified to include the following changes:

1. A revised cover page pursuant to the instructions found at 24 CFR 1710.105;
2. A revised Agent, Certification and Cancellation page pursuant to instructions found at 24 CFR 1710.118;
3. Deletion of the Supplemental Receipt for Georgia purchasers; and,
4. Deletion of any other information that is no longer applicable due to changes in Georgia law.

Once these above mentioned materials are accepted by the Department, a new effective date will be issued for the registration. Developers are reminded that within 30 days of each anniversary date of the new effective date, the registrant must submit to the Department an Annual Report of Activity accompanied by the prescribed fee (see 24 CFR 1710.310). Within 120 days after the close of the developer's fiscal year, the developer shall submit financial statements meeting the standards of 24 CFR 1710.212(c) to the Department.

In addition, any additional changes in material fact must be made in conformance with the Interstate Land Sales Full Disclosure Act and its implementing Regulations. For purposes of these filings, Georgia developers need only update the particular sections of the Property Report and supply any required supporting documentation.

Charles Clark, Georgia Real Estate Commissioner, sent a letter, dated May 8, 1995, to all interested parties,

notifying them of changes in Georgia's regulation of land sales development, effective July 1, 1995, pursuant to Georgia House Bills 621 and 622. This Notice of Order of Withdrawal of State Certification for the State of Georgia will be sent to the same parties.

The above constitutes the Order of Withdrawal referred to in 24 CFR 1710.508(a) with respect to the State of Georgia's certification under the Interstate Land Sales Full Disclosure Act.

Authority: 15 U.S.C. 1708.

Dated: August 7, 1995.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 95-20091 Filed 8-15-95; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

West Virginia Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving an amendment to the West Virginia permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment concerns West Virginia's regulations for the design and construction of durable rock fills. The amendment will revise the West Virginia program to be consistent with SMCRA and the Federal regulations.

EFFECTIVE DATE: August 16, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. James C. Blankenship Jr., Director, Charleston Field Office, Office of Mining Reclamation and Enforcement, 1027 Virginia Street East, Charleston, West Virginia 25301, Telephone: (304) 347-7158.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia Program
- II. Submission of the Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the West Virginia Program

SMCRA was passed in 1977 to address environmental and safety problems associated with coal mining.

Under SMCRA, OSM works with States to ensure that coal mines are operated in a manner that protects citizens and the environment during mining, that the land is restored to beneficial use following mining, and that the effects of past mining at abandoned coal mines are mitigated.

Many coal-producing States, including West Virginia, have sought and obtained approval from the Secretary of the Interior to carry out SMCRA's requirements within their borders. In becoming the primary enforcers of SMCRA, these "primacy" States accept a shared responsibility with OSM to achieve the goals of the Act. Such States join with OSM in a shared commitment to the protection of citizens—our primary customers—from abusive mining practices, to be responsive to their concerns, and to allow them full access to information needed to evaluate the effects of mining on their health, safety, general welfare, and property. This commitment also recognizes the need for clear, fair, and consistently applied policies that are not unnecessarily burdensome to the coal industry—producers of an important source of our Nation's energy.

Under SMCRA, OSM sets minimum regulatory and reclamation standards. Each primacy State ensures that coal mines are operated and reclaimed in accordance with the standards in its approved State program. The States serve as the front-line authorities for implementation and enforcement of SMCRA, while OSM maintains a State performance evaluation role and provides funding and technical assistance to States to carry out their approved programs. OSM also is responsible for taking direct enforcement action in a primacy State, if needed, to protect the public in cases of imminent harm or, following appropriate notice to the State, when a State acts in an arbitrary and capricious manner in not taking needed enforcement actions required under its approved regulatory program.

Currently there are 24 primacy states that administer and enforce regulatory programs under SMCRA. These states may amend their programs, with OSM approval, at any time so long as they remain no less effective than Federal regulatory requirements. In addition, whenever SMCRA or implementing Federal regulations are revised, OSM is required to notify the States of the changes so that they can revise their programs accordingly to remain no less effective than the Federal requirements.

A major goal of SMCRA is to ensure adequate reclamation of all areas disturbed by surface coal mining.