

Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-866, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 15 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701-1766, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 282, 283, 284, 265, 300u-300u-5, 300aa-1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. Section 5.25 is amended by adding new paragraph (a)(7) to read as follows:

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) * * *

(7) The Director, Office of Orphan Products Development.

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Dated: September 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-23746 Filed 9-30-92; 8:45 am]

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21 CFR Part 310

[Docket No. 89N-0525]

Status of Certain Over-the-Counter Drug Category II and III Active Ingredients; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations regarding the status of certain over-the-counter (OTC) drug Category II and III active ingredients. This final rule makes a nonsubstantive correction to the final regulations that were published in the Federal Register of November 7, 1990 (55 FR 46914). That final rule listed the name of an active ingredient incorrectly. This document corrects that error and provides clarification of the final rule for certain OTC drug products.

EFFECTIVE DATE: October 1, 1992.

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, 301-295-8000.

SUPPLEMENTARY INFORMATION: This document amends the final rule concerning drug products containing certain active ingredients offered OTC for certain uses in 21 CFR part 310 (as set forth in the Federal Register of November 7, 1990 (55 FR 46914)). That final rule listed an active ingredient

incorrectly. This final rule corrects that error in the regulations. As noted above, this amendment institutes a change that is nonsubstantive in nature. Because the amendment is not controversial and because, when effective, it provides clarification of a final rule for OTC drug products, FDA finds that the usual notice and comment procedures and delayed effective date are unnecessary.

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, 301, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 706 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, 376); 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 [Amended]

2. Section 310.545 *Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses* is amended in paragraph (a)(3) by removing the entry "Carboxymethylcellulose" and adding in its place the entry "Carboxymethylcellulose sodium".

Dated: September 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-23648 Filed 9-30-92; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Regulatory Program; Definitions; Exemption for Coal Extraction Incidental to Extraction of Other Minerals; Coal Exploration; Kentucky Bond Pool; Backfilling and Grading; and Postmining Land Use

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with exceptions, of a proposed program amendment to the Kentucky regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of proposed modifications to a number of Kentucky rules in various subject areas for the purpose of maintaining consistency with revised Federal requirements, clarifying ambiguities, improving operational efficiency and implementing the additional flexibility afforded by Federal regulatory revisions.

EFFECTIVE DATE: October 1, 1992.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone (606) 233-2896.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Information pertinent to the general background and revisions to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, Federal Register (47 FR 21404-21435). Subsequent actions concerning the conditions of approval and proposed amendments are identified at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Submission of Amendments

By letter dated June 28, 1991 (Administrative Record Number KY-1059), Kentucky submitted a proposed program amendment modifying 19 regulations and incorporating two Technical Reclamation Memorandum (No. 19 and No. 20).

OSM announced receipt of the proposed amendment in the July 22, 1991, Federal Register (56 FR 33398), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on August 21, 1991.

By letter dated November 11, 1991 (Administrative Record Number KY-1079), Kentucky resubmitted that portion