§ 207.41 Commission review of agreements to eliminate the injurious effect of subsidized imports or imports sold at less than fair value.

If the administering authority determines to suspend an investigation upon acceptance of an agreement to eliminate the injurious effect of subsidized imports or imports sold at less than fair value, the Commission shall, upon petition, initiate an investigation to determine whether the injurious effect of imports of the merchandise which was the subject of the suspended investigation is eliminated completely by the agreement. Petitions may be filed by a party to the investigation which is an interested party described in paragraph (C), (D), (E), (F), or (G) of section 771(9) of the Act. Investigations under this section shall be completed within seventy five (75) days of their initiation.

§ 207.42 Investigation continued upon request.

Upon receipt of advice from the administering authority that it has received a request for the continuation of a suspended investigation pursuant to section 704(g) or 734(g) of the Act, the Commission shall continue the investigation. The procedures set forth in subparts B and C of this part, including applicable time limitations, shall apply to all continued investigations within this rule.

§ 207.43 [Reserved]

§ 207.44 Consolidation of investigations.

The Commission may, when appropriate, consolidate continued investigations under section 704(g) or section 734(g) of the Act with investigations to review agreements for the elimination of injury under section 704(h) or section 734(h) of the Act.

§ 207.45 Investigation to review outstanding determination.

(a) *Request for review.* Any person may file with the Commission a request for the institution of a review investigation under section 751 of the Act. The person making the request shall also promptly serve copies of the request on the parties to the original investigation upon which the review is to be based. All requests shall set forth a description of changed circumstances sufficient to warrant the institution of a review investigation by the Commission.

(b) *Notice of receipt of a request.* Upon the receipt of a properly filed and sufficient request for a review investigation, the Secretary shall publish a notice of having received such a request in the **Federal Register** inviting public comment on the question of whether the Commission should institute a review investigation. Persons shall have at least thirty (30) days from the date of publication in the **Federal Register** within which to submit comments to the Commission.

(c) *Institution of an investigation.* Within thirty (30) days after the close of the period for public comments following publication of the receipt of a request, the Commission shall determine whether the request shows changed circumstances sufficient to warrant a review and, if so, shall institute a review investigation. The Commission may also institute a review investigation on its own initiative. The review investigation shall be instituted by notice published in the **Federal Register** and shall be completed within one hundred twenty (120) days of the date of such publication. If the Commission determines that a request does not show changed circumstances sufficient to warrant a review, the request shall be dismissed and a notice of the dismissal published in the **Federal Register** stating the reasons therefor.

(d) *Conduct of review investigation.* The procedures set forth in subpart C of part 207 shall apply to all investigations instituted under this section.

Subpart E—Judicial Review

§ 207.50 Judicial review.

(a) *In general.* Persons entitled to judicial review under section 516A of the Act may seek review in the U.S. Court of International Trade.

(b) *Transmittal of record.* In the event a Commission determination is appealed to the U.S. Court of International Trade under section 516A, a copy of the record in the investigation before the Commission, as such record is defined in § 207.2(f), or a certified list of all items therein, shall be transmitted to the court by the Secretary in accordance with the rules of the court.

(c) *Service of process.* The Commission's General Counsel shall be the Commission's agent for service of process in cases arising under section 516A of the Act.

§ 207.51 Judicial review of denial of application for disclosure of certain business proprietary information under administrative protective order.

(a) *In general.* Persons entitled to judicial review under section 777(c)(2) of the Commission determination not to disclose business proprietary information may apply to the U.S. Court of International Trade for an order directing the Commission to make the information involved available.

(b) *Transmittal of record.* In the event a court order is sought under section 777(c)(2) requiring the Commission to disclose business proprietary information, the Secretary shall within 20 days after service of a summons and complaint upon the Commission transmit to the court under seal the business proprietary information involved along with pertinent parts of the record.

(c) *Pertinent parts of the record.* The pertinent parts of the record shall consist of:

(1) The application for Commission disclosure together with any documents filed in support thereof or in opposition thereto.

(2) Any Government memoranda relating to the Commission's determination, and

(3) The Commission's action on the application.

(d) *Service of process.* The Commission's General Counsel shall be the Commission's agent for service of process in cases under section 777(c)(2) of the Act.

Subpart F—[Reserved]

* * * * *

Issued: March 14, 1991.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 91-6554 Filed 3-20-91; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Transfer of Glutethimide from Schedule III to Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This rule transfers glutethimide from Schedule III to Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). As a result of this transfer, the regulatory controls and criminal sanctions of Schedule II of the CSA will apply to the manufacture, distribution, importation, exportation, and possession of any material, compound, mixture, or preparation of the substance, glutethimide. Glutethimide is an ingredient in pharmaceutical products which are being diverted and abused. This action is based on data gathered

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and reviewed by the Drug Enforcement Administration and the Department of Health and Human Services.

EFFECTIVE DATE: March 21, 1991.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: A proposal to transfer glutethimide from Schedule III to Schedule II of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) was published in the Federal Register on July 26, 1990 (55 FR 30472). Glutethimide is the ingredient in several pharmaceutical products which are being diverted in large quantities and abused in several areas of the country. Interested parties were given until September 24, 1990, to submit comments or objections regarding the proposal. None were received.

The Administrator of the Drug Enforcement Administration (DEA), based on the investigations and review conducted by his staff, and relying on the scientific and medical evaluation and recommendation of the Assistant Secretary of Health of the Department of Health and Human Services, acting on behalf of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b), finds that pursuant to the provisions of 21 U.S.C. 811(a):

1. Glutethimide has a high potential for abuse;

2. Glutethimide has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and

3. Glutethimide may lead to severe psychological or physical dependence.

The above findings are consistent with placement of glutethimide into Schedule II of the CSA.

The transfer of the substance from Schedule III to Schedule II is effective on March 21, 1991 with selected implementation dates as indicated. In the event that this imposes special hardships on any registrant, the Drug Enforcement Administration will entertain any justified request for an extension of time to comply with the Schedule II regulations. The applicable regulations are as follows:

1. Registration

Any person who manufactures, distributes, dispenses, imports or exports glutethimide or who engages in research or conducts instructional activities or chemical analysis with respect to this substance must be registered to conduct such activities in accordance with 21 CFR parts 1301 and 1311 as of April 22, 1991. Any person currently registered to handle glutethimide in Schedule III may continue activities under that registration until approved or denied registration in Schedule II, provided such registrant has filed an application for registration in Schedule II with DEA on or before April 22, 1991. Any persons not currently registered and proposing to engage in such activities may not conduct activities with the substance until properly registered in Schedule II.

2. Security

Glutethimide must be manufactured, distributed and stored in accordance with 21 CFR 1301.71–1301.76 on or before April 22, 1991.

3. Labeling and Packaging

All labels and labeling for commercial containers of glutethimide, packaged on or after September 18, 1991, shall comply with the requirements of 21 CFR part 1302 and shall be submitted in accordance with the 21 CFR 1308.04. Products manufactured, distributed, or dispensed for approved purposes and labeled as Schedule III products prior to September 18, 1991 may be distributed and dispensed until March 21, 1992.

4. Quotas

All persons required to obtain quotas for glutethimide shall submit applications pursuant to 21 CFR 1303.11, 1303.12, and 1303.22. The initial 1991 manufacturing and procurement quotas will be based on those DEA Forms 189 and 250 which are received on or before April 22, 1991.

5. Inventory

Every registrant required to keep records and who possesses any quantity of glutethimide shall take inventories in accordance with the requirements of 21 CFR 1304.11–1304.19 on or before April 22, 1991.

6. Records

All registrants required to keep records pursuant to 21 CFR 1304.21–1304.27 shall maintain such records on glutethimide commencing April 22, 1991.

7. Reports

All registrants required to submit reports pursuant to 21 CFR 1304.34–1304.37 shall do so regarding glutethimide commencing with the fourth quarter of calendar year 1991.

8. Order Forms

All registrants involved in the distribution of glutethimide shall comply with the order form requirements of 21 CFR part 1305 on and after the date on which the initial inventory of this Schedule II controlled substance is taken, on or before April 22, 1991.

9. Prescriptions

All prescriptions for glutethimide drug products shall comply with 21 CFR part 1306. All prescriptions for products containing glutethimide issued before April 22, 1991, if authorized for refilling, shall not be refilled on or after May 21, 1991.

10. Importation and Exportation

All importation and exportation of glutethimide shall be in compliance with 21 CFR parts 1311 and 1312 on and after April 22, 1991.

11. Criminal Liability

Any activity with respect to glutethimide not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties on and after March 21, 1991, shall be those of a Schedule II substance.

12. Other

In all other respects, this order is effective on March 21, 1991.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the transfer of glutethimide from Schedule III to Schedule II of the CSA will have no significant economic impact on a substantial number of small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). The provisions which accompany the placement of glutethimide into Schedule II are identical to those which apply to any Schedule II substance. Six of the seven companies which manufacture and market pharmaceutical glutethimide products already are registered to handle Schedule II products.

In accordance with the provisions of 21 U.S.C. 811(a), this scheduling action is a formal rulemaking "on the record after opportunity for hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirement of Executive Order 12291 (46 FR 13193).

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 (52 FR 41685), and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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List of Subjects in 21 CRR Part 1308

Administrative practice and procedure, Drug Enforcement Administration, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act [21 U.S.C. 811(a)] and delegated to the Administrator of the DEA by Department of Justice Regulations (28 CFR 0.100), and for the reasons set forth above, the Administrator hereby orders that title 21, part 1308 of the Code of Federal Regulations be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.12 is amended by redesignating paragraphs (e)(2) through (e)(4) to read (e)(3) through (e)(5) and by adding paragraph (e)(2) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(e) * * *

(2) Glutethimide.....2550

* * * * *

§ 1308.13 [Amended]

3. Section 1308.13 is amended by removing paragraph (c)(5) and redesignating paragraphs (c)(6) through (c)(12) to read (c)(5) through (c)(11).

Dated: March 15, 1991.

Robert C. Bonner,

Administrator, Drug Enforcement Administration.

[FR Doc. 91-6667 Filed 3-20-91; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Permanent Regulatory Program; Definitions

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment (Program Amendment Number 90-1) was intended to restructure the Definition section of the State rules and to satisfy a required program amendment concerning coal preparation plants to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: March 21, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. Richard D. Rieke, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204, Telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.15 and 914.16.

II. Submission of the Amendment

By letter dated December 11, 1990, (Administrative Record No. IND-0811), the Indiana Department of Natural Resources (IDNR) submitted proposed Program Amendment Number 90-1 to modify the Indiana Administrative Code (IAC). The proposed amendment creates new article 310 IAC 12-0.5, transfers the existing State definitions from section 310 IAC 12-1-3 to article 310 IAC 12-0.5, restructures the existing State definitions and adds them to separate sections within new article 310 IAC 12-0.5, and repeals section 310 IAC 12-1-3. New article 310 IAC 12-0.5 has been structured to allow for more expeditious future changes to and additions of definitions. The proposed amendment also responds to the OSM required amendment identified at 30 CFR 914.16(a) which requires that clarification be added to the exclusion statement associated with the definition of "coal preparation plant" to make it clear that crushing, screening, and sizing facilities will be regulated as coal preparation plants whenever they are operated in connection with a coal mine. OSM announced receipt of the proposed amendment in the January 18, 1991, **Federal Register** (56 FR 1959-1960), 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 public comment period ended on February 19, 1991.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Indiana program.

310 IAC 12-0.5, Definitions

(a) Indiana proposes to add new article 310 IAC 12-0.5, transfer the existing State definitions from section 310 IAC 12-1-3 to article 310 IAC 12-0.5, repeal section 310 IAC 12-1-3, and recodify and restructure the existing definitions within new article 310 IAC 12-0.5. The new article would be structured to allow for more expeditious future changes to and additions of definitions by assigning a separate section within the article for each term. The Director finds that the addition of new article 310 IAC 12-0.5, the transfer of existing definitions from section 310 IAC 12-1-3 to article 310 IAC 12-0.5, the repeal of section 310 IAC 12-1-3, and the recodification and restructuring of existing definitions at new article 310 IAC 12-0.5 do not render the Indiana definitions less effective than the Federal definitions at 30 CFR 700.5, 30 CFR 701.5, 30 CFR 705.5, 30 CFR 707.5, 30 CFR 761.5, 30 CFR 762.5, 30 CFR 816.46, 30 CFR 843.5, and 30 CFR 850.5.

As discussed below in finding (c), this finding does not include approval for any changes to Indiana's previously approved program definitions which were not identified as part of this amendment by Indiana in its letter of December 11, 1990 (Administrative Record No. IND-0811).

(b) The definition for "coal preparation plant" was recodified and restructured at 310 IAC 12-0.5-25. Indiana amended the exemption statement associated with the definition of "coal preparation plant" at 310 IAC 12-0.5-25(c) in response to a required amendment identified by OSM at 30 CFR 914.16(a) by adding the language "does not crush, size, or screen coal." Indiana also chose to delete the language "does not separate coal from its impurities." The amended exemption now reads as follows:

(c) Exempted from the meaning of coal preparation plant is an operation which:

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