CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Withdrawal of Proposed Exemption for Certain Medroxyprogesterone Acetate Tablets

AGENCY: Consumer Product Safety Commission.

ACTION: Withdrawal of proposed rule.

SUMMARY: In this notice the Commission withdraws a proposed amendment of regulations implementing the Poison Prevention Packaging Act that would have exempted medroxyprogesterone acetate tablets in mnemonic packages containing no more than 100 milligrams of the drug from requirements for childresistant packaging. (A mnemonic package is designed to administer one oral dose at a time and incorporates a feature to remind the user to take the dosage at specified intervals throughout the period during which the medication is to be administered.) The Commission is withdrawing this proposed amendment because it has issued an amendment to the regulations which exempts all packages of medroxyprogesterone acetate tablets. including mnemonic packages, without limitation on the amount of drug contained in each exempted package.

FOR FURTHER INFORMATION CONTACT:

Charles Jacobson, Division of Regulatory Management, Consumer Product Safety Commission. Washington, DC 20207; telephone (301) 492–6400.

SUPPLEMENTARY INFORMATION: Among other substances, oral prescription drugs intended for human use are subject to requirements for child-resistant packaging issued under the Poison Prevention Packaging Act (PPPA) (15 U.S.C. 1471-1476). The regulation which requires child-resistant packaging of oral dose prescription drugs is condified at 16 CFR 1700.14(a)(10). By letter dated April 27, 1987, Ayerst Laboratories petitioned the Commission to exempt medroxyprogesterone acetate (MPA) tablets in mnemonic packages containing not more than 100 milligrams of the drug from special packaging requirements. This petition was docketed as PP 878-3.

MPA, a progestin, is a prescription hormonal drug used for the treatment of a variety of female hormonal imbalance disorders. As justification for the exemption, the petitioner submitted evidence of the low oral toxicity of progestins and data showing the

absence of acute toxicity from ingestion of progestins by young children.

After consideration of the information provided by the petition and other available human and animal data, the Commission proposed an exemption from special packaging requirements for MPA tablets in mnemonic packages containing no more than 100 milligrams of the drug in a notice published in the Federal Register of October 20, 1988 (53 FR 41202).

Thereafter, the Commission granted a petition (PP 88-1) from The Upjohn Company which requested exemption of all packages of MPA tablets without regard to the type of package or the amount of the drug contained in each exempted package. The Commission published a notice to propose the exemption requested by the Upjohn petition in the Federal Register of January 12, 1989 (54 FR 1187).

Elsewhere in this issue of the Federal Register the Commission has issued a final amendment of the regulations implementing the PPPA to exempt all packages of MPA tablets, without regard to the type of package, and without limitation on the amount of the drug contained in each exempted package. Because the amendment issued today includes the packages which were the subject of PP 87-3, issuance of the amendment proposed on October 20, 1988, is no longer necessary.

For this reason, the Commission hereby withdraws the amendment proposed in the notice of October 20, 1988 (53 FR 41202).

Dated: April 3, 1990. Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 90-8014 Filed 4-6-90; 8:45 am]

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

Coal Product Valuation Regulations

April 3, 1990.

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule: Notice of meeting and extension of public comment period.

SUMMARY: The Minerals Management Service (MMS) hereby gives notice that it is soliciting comments at a public meeting and is extending the public comment period on its Notice of Proposed Rule, which was published in the Federal Register on February 13, 1990 (55 FR 5024), that amends the coal product valuation regulations. Comments may be submitted at the public meeting and/or in writing to MMS. In response to requests for additional time, MMS will extend the comment period from Apri 16, 1990, to May 15, 1990.

DATES: The public meeting will be held on May 9, 1990, from 9:30 a.m. to 5 p.m. Written comments must be received by 4 p.m., mountain time, May 15, 1990.

ADDRESSES: The public meeting will be held at the Edgewater Hotel, 666 Wisconsin Avenue, Madison, Wisconsin, telephone (608) 256–9071. Written comments should be sent to the Minerals Management Service, Royalty Management Program, Denver Federal Center, Building 85, P.O. Box 25165, Mail Stop 662, Denver, Colorado 80225, Attention; Dennis C. Whitcomb.

FOR FURTHER INFORMATION CONTACT: Dennis C. Whitcomb, Chief. Rules and Procedures Branch, telephone (303) 231– 3432 or (FTS) 326–3432.

SUPPLEMENTARY INFORMATION:

I. Background

On January 13, 1989 (54 FR 1492). MMS adopted new coal product value regulations codified at 30 CFR part 206 to replace the regulations in 30 CFR part 203. The regulations that were adopted were the product of a lengthy public process including a proposed rulemaking on January 15, 1987 (52 FR 1840). a further notice of proposed rulemaking on July 15, 1988 (53 FR 26942), and numerous public meetings, including representatives of the affected States. Indian tribes, and the coal and electric utility industries.

One of the provisions in the new regulations permitted Federal coal lessees to deduct or exclude the costs of Federal Black Lung excise taxes. abandoned mine lands (AML) fees, and State and local severance taxes from the value for royalty purposes. Since the rules were issued, the States (who receive 50 percent of the royalties from coal production from Federal lands) and Indian tribes (who feel they are affected indirectly despite the express exemption in the regulations) have requested that the exclusions for taxes and fees be removed from the regulations. The MMS has completed a review of the impact of the exclusions and is now proposing to amend its coat product valuation regulations to remove the exclusion from royalty value for amounts representing production-related taxes and fees. The proposed rule was published in the Federal Register (55 FR 5024) on

February 13, 1990. Because of the significance of this issue to all affected parties, the Secretary of the Interior has decided to provide an opportunity for the States, Indian tribes, industry, and the public to provide comments to the Depertment of the Interior. A public meeting is scheduled in St. Louis, Missouri, on April 11, 1990. See the Federal Register dated March 9, 1990 (55 FR 8964).

The MMS is soliciting both written comments and statements from interested parties at a public meeting. The public meeting will be an open discussion among representatives from industry, States, Indian tribes, and all other interested persons, including the public, for the purpose of gathering information.

II. Public comment procedures

A. Public Meeting

1. Procedures for requests to make oral presentations. The time and place for the meeting are identified in the DATES and ADDRESSES sections of this Notice.

You may request to make an oral presentation. Request to make a presentation should be made to Mr. Dennis Whitcomb, Chief, Rules and Procedures Branch, telephone (303) 231–3432, (FTS) 326–3432 by May 4, 1990.

2. Conduct of the meeting. The MMS reserves the right to select the persons to be heard at the meeting (in the event there are more requests to be heard than time allows), to schedule their respective presentations, and to establish the procedures governing the conduct of the meeting. The length of each presentation may be limited, based upon the number of persons requesting to be heard. A Department official will be designated to preside at the meeting.

A transcript of the meeting will be made. The entire record of the meeting, including the transcript, will be retained by MMS and made available for inspection in Room C420, Denver Federal Center, Building 85, Lakewood, Colorado, between the hours of 8 a.m. and 4 p.m., Monday through Friday. You may purchase a copy of the transcript from the reporter.

B. Written Comments

The public is also invited to participate in this proceeding by submitting data and comments in writing. All written comments should be submitted by 4 p.m. of the day specified in the DATES section to the appropriate address indicated in the ADDRESSES section of this Notice and should be identified on the outside envelope and on documents submitted with the

designation "Comments on Coal Product Valuation Regulations." All comments received by MMS will be available for public inspection in Room C420, Denver Federal Center, Building 85, Lakewood, Colorado, between the hours of 8 a.m. and 4 p.m., Monday through Friday.

Any information or data submitted which is considered to be confidential must be so identified and submitted in writing, one copy only. The MMS reserves the right to determine the confidential status of the information or data and to treat it according to its independent determination.

Dated: April 3, 1990.

Milton K. Dial,

Acting Associate Director for Royalty Management.

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Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Regulatory Program— Remining

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

ACTION: Notice of disapproval of proposed amendment.

disapproval of a proposed amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky Program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment would have established special permitting and performance requirements for operations that affect previously disturbed lands. The proposed amendment was intended to implement the remining statute enacted by the 1986 Kentucky General Assembly as Senate Bill No. 374.

DATES: The effective date of this notice is: April 9, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. Roger Calhoun, Acting Director, Lexington Field Office, Telephone (606)

SUPPLEMENTARY INFORMATION:

1. Background on the Kontucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. The approval was effective upon publication in the May 18, 1982, Federal Register (47 FR 21404–21435). General background information on the Kentucky 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. Subsequent actions concerning the Kentucky program, including amendments to the program are identified at 30 CFR 917.11, 917.13, 917.15, 917.16 and 917.17.

II. Submission of Amendment

By letter dated July 29, 1986 (Administrative Record No. KY-717), the Kentucky Department for Surface Mining Reclamation and Enforcement (DSMRE) submitted to OSM regulations to implement Senate Bill No. 374. OSM announced receipt of and solicited public comments on the proposed regulations on September 11, 1986 (51 FR 32336). On October 14, 1986, Kentucky withdrew the July 29, 1986 amendment. On November 24, 1986, OSM announced Kentucky's action to withdraw the proposed amendment (51 FR 42267).

On August 4, 1987 (Administrative Record No. KY-751), Kentucky resubmitted to OSM, proposed regulations on remining. OSM announced receipt of and solicited public comments on the proposed amendment on September 16, 1987 (52 FR 34932).

By letter dated January 22, 1988 (Administrative Record No. KY-789), OSM informed Kentucky that the proposed amendment was less effective than the Federal regulations and could not be approved.

On November 22, 1988 (Administrative Record No. KY-840). Kentucky informally proposed a revised amendment on remining. By letter dated January 12, 1989 (Administrative Record No. KY-843), OSM informed Kentucky that the proposed regulations were less effective than the Federal regulations and could not be approved. On February 28, 1989 (Administrative Record No. KY-855), Kentucky withdrew the August 4, 1987, proposed amendment.

On April 24, 1989 (Administrative Record No. KY-879). Kentucky resubmitted proposed regulations to implement Senate Bill No. 374. This proposal would add Sections 405 KAR 8:060 and 405 KAR 20:090 to the Kentucky program and is substantially identical to the amendment informally proposed by Kentucky on November 22. 1988. OSM announced receipt of the proposed regulations in the May 26, 1989, Federal Register (54 FR 22782-22783), and in the same notice, requested public comments. The public comment period closed on June 26, 1989. A summary of comments received and their disposition appears in the section