Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Removal of Loperamide From Control

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes the removal of the drug, loperamide, and salts thereof, from control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*). This action results from the Acting Administrator of the Drug Enforcement Administration finding that loperamide hydrochloride has a currently accepted medical use in treatment in the United States and does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule.

DATE: Comments and objections must be received on or before September 27, 1982.

ADDRESS: Comments and objections may be submitted in quintuplicate to the Acting Administrator, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

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

In 1976, the Assistant Secretary for Health, Department of Health, Education and Welfare, pursuant to 21 U.S.C. 811(f), requested that the drug, loperamide, be placed into Schedule V of the Controlled Substances Act (CSA). The Administrator of the Drug Enforcement Administration, in accordance with 21 U.S.C. 811(a) and 811(b), determined that loperamide should be placed into Schedule V of the CSA and ordered that accomplished in a notice published in the **Federal Register** (42 FR 25498, May 18, 1977).

In 1979, Ortho Pharmaceutical Corporation petitioned the Administrator to remove loperamide from control under the CSA. The Administrator, in accordance with 21 U.S.C. 811(b), requested from the Department of Health and Human Services (the successor agency to the Department of Health, Education and Welfare) a scientific and medical evaluation and recommendation as to the merits of the petition. In a letter dated March 24, 1982, the Assistant Secretary for Health, acting on behalf of the Secretary, provided the Acting Administrator with his evaluation and recommended that loperamide be removed from control. The letter is set forth below:

March 24, 1982.

Mr. Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement Administration, 1405 Eye Street, N.W., Washington, D.C. 20537

Dear Mr. Mullen: Pursuant to Section 201(b) of the Controlled Substances Act, 21 U.S.C. 811(b), this letter is notification of the following recommendations prepared by the Food and Drug Administration: 1) to remove loperamide hydrochloride from Schedule V of the Act into a noncontrolled, prescription status, and 2) to monitor loperamide actively in your agency's drug abuse indicator systems for a period of three years after the decontrol action has become effective. A Summary of the Basis of Recommendation for the change in control is enclosed with this letter.

I concur with the Food and Drug Administration's recommendations. I further recommend that these actions become effective as soon as practical.

Should you have any questions concerning these recommendations, the appropriate staff is prepared to respond.

Sincerely yours,

Edward N. Brandt, Jr., M.D.,
Assistant Secretary for Health.

Enclosure.

Based upon the investigations of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of the Department of Health and Human Services, received pursuant to 21 U.S.C. 811(b), the Acting Administrator finds that loperamide hydrochloride has a currently accepted medical use in treatment in the United States and does not have sufficient potential for abuse to justify its continued control in any schedule of the CSA.

Therefore, under the authority vested in the Attorney General by Section 201(a) of the Act (21 U.S.C. 811(a)) and delegated to the Acting Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Acting Administrator hereby proposes that 21 CFR 1308.15 be amended by removing paragraph (c).

Interested persons are invited to submit their comments, objections or requests for a hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted in quintuplicate to the Acting Administrator, Drug Enforcement Administration, 1405 I Street, N.W. Washington, D.C. 20537, Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for a hearing raise one or more issues which the Acting Administrator finds warrant a hearing, the Acting Administrator shall order a public hearing by notice in the **Federal Register** summarizing the issues to be heard and setting the time for the hearing which will not be less than 30 days after the date of the notice.

If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Acting Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Pursuant to 5 U.S.C. 605(b), the Acting Administrator certifies that removal of loperamide from control under the Controlled Substances Act is a deregulation action which will have no adverse impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354).

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to remove

loperamide from Schedule V is a formal rulemaking "on the record after opportunity for a 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 requirements of Executive Order 12291.

Dated: July 22, 1982.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 886 and 938

Abandoned Mine Land Reclamation Program

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

ACTION: Receipt of the Abandoned Mine Land Reclamation (AMLR) Grant Application from the State of Pennsylvania.

SUMMARY: On June 18, 1982, the State of Pennsylvania submitted to the Office of Surface Mining Reclamation and Enforcement (OSM) its proposed Abandoned Mine Land Reclamation (AMLR) grant application under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM is seeking public comment on the adequacy of the State grant application. The grant will not be approved until the Secretary has approved the Title V Regulatory Program and the Title IV Reclamation Program.

DATES: Written comments on the application must be received on or before 5:00 p.m. August 12, 1982.

ADDRESS: Copies of the full text of the proposed Pennsylvania grant application are available for review during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Pennsylvania State Office, 100 Chestnut Street, Suite 300, Harrisburg, Pennsylvania 17101, and

Department of Environmental Resources, Office of Resources Management, Evangelical Press Building, Third and Riley Streets, Harrisburg, Pennsylvania 17120.

Written comments should be sent to:

Robert Biggi, State Office Director, Office of Surface Mining Reclamation and Enforcement, 100 Chestnut Street, Suite 300, Harrisburg, Pennsylvania 17101.

FOR FURTHER INFORMATION CONTACT: Robert Biggi, (717) 782-4036.

SUPPLEMENTARY INFORMATION: A State reclamation plan was submitted to the Secretary. Action by the Secretary on the Plan has been delayed because Pennsylvania does not have an approved State regulatory program under Title V of SMCRA. Under Section 405(c) of the SMCRA, the Secretary cannot approve a State AMLR program unless that State has an approved State regulatory program pursuant to Section 503 of the SMCRA.

On June 18, 1982, OSM received an AMLR grant application from the State of Pennsylvania.

Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. 95-87, 30 U.S.C. 1201 *et seq.*, establishes an AMLR program for the purposes of reclaiming and restoring land and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. Lands and water eligible for reclamation under the program are those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there is no continuing reclamation responsibility under State and Federal law.

Each State having within its borders coal mined lands eligible for reclamation under Title IV of SMCRA may submit to the Secretary a State reclamation grant application to implement the provisions of the approved State Reclamation Plan. However, grants for reclamation may be issued only to States with an approved Title V Regulatory Program for active mine reclamation and an approved Title IV Reclamation Program. The grant application received from the State of Pennsylvania will be reviewed and held pending a final approval by the Secretary on the State's Title V and Title IV programs in accordance with SMCRA.

This notice describes the nature of the proposed projects and sets forth information concerning public participation in the development of the projects.

This publication does not represent any decision by the Secretary on the Title V Regulatory Program or the Title IV Reclamation Program, but is published solely for the purpose of expediting the review process and the implementation of the reclamation program if the Title V and Title IV programs of the State of Pennsylvania are approved.

All written comments must be mailed or hand carried to the State Director's Office above.

The comment period will close at 5:00 p.m. on August 12, 1982. Comments received after that time will not be considered. During the comment period representatives of the State Director's office will be available to meet between 8:00 a.m. and 4:00 p.m. at the request of members of the public to receive their advice and recommendations concerning the proposed State AMLR application.

Persons wishing to meet with representatives of the State Director's office during this time period may place such requests with Robert Biggi, State Director, telephone (717) 782-4036, at the State Director's Office above.

Meetings may be scheduled between 9 a.m. and noon and 1 p.m. and 4 p.m. Monday through Friday excluding holidays.

OSM intends to continue to discuss the State's application with representatives of the State throughout the review process.

In order to comply with the requirements of the National Environmental Policy Act, OSM will assess the environmental effects of all State reclamation projects. The primary basis for this assessment will be the environmental information provided in the project grant application.

The Pennsylvania AMLR grant application can be approved if:

1. The Director finds that the public has been given adequate notice and opportunity to comment, and the record does not reflect major unresolved controversies.
2. Views of other Federal agencies have been solicited and considered.
3. The application meets all the requirements of the OSM, AMLR program provisions and the required Federal circulars.
4. The State has an approved regulatory program and an approved State reclamation plan.

The following constitutes a summary of the contents of the submission:

1. Designation of authorized State Agency to administer the program.
2. Objectives and need for the assistance.
3. Project ranking and selection.
4. Coordination with other reclamation programs.
5. Results and benefits expected.
6. Plan of action pertaining to the scope.
7. Monthly or quarterly projections of accomplishments to be achieved.