proposed rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Mecloqualone and the Thiophene Analog of Phencyclidine in Schedule I

On March 15, 1974, the Administrator of the Drug Enforcement Administration requested the Assistant Secretary of Health to submit, in behalf of the Department of Health, Education and Welfare, a scientific and medical evaluation and recommendation that the thiophene analog of phencyclidine (1-[1-(2-thienyl) cyclohexyl] piperidine) be placed in Schedule I of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513).

On October 22, 1974, a similar request was made with respect to mecloqualone.

By a letter dated January 21, 1975, the Assistant Secretary for Health submitted the requested scientific and medical evaluations and recommendations. That letter is set out as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Washington, D.C. 20201

JANUARY 21, 1975.

Mr. JOHN R. BARTELS, Jr.,
Administrator, Drug Enforcement Administration, Department of Justice, 1405 Eye Street NW., Washington, D.C. 20537.

DEAR MR. BARTELS: The appropriate agencies within the Department of Health, Education and Welfare, and the FDA Controlled Substances Advisory Committee, have evaluated the DEA proposals of March 15 and October 22, 1974 to control the thiophene analog of phencyclidine ([1-(1-2-thienyl) cyclohexyl] piperidine) and mecloqualone. We agree that these substances should be controlled in Schedule I of the Controlled Substances Act (Pub. L. 91-513).

Pursuant to the criteria for Schedule I substances described in section 202.(b) of the Controlled Substances Act, the present evidence indicates that these substances have a high potential for abuse, have no currently accepted medical use in treatment in the United Sttaes, and there is lack of accepted safety for use of these substances under medical supervision.

Schedule I control of the thiophene analog of PCP and mecloqualone therefore seems to be clearly in the interest of public health.

Enclosed please find a document supporting these recommendations.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Assistant Secretary for Health.

Upon receipt of this letter, the Drug Enforcement Administration undertook a review of the following: (1) Materials submitted to DEA by the Department of Health, Education and Welfare with the letter of January 21, 1975; (2) materials on file with the Food and Drug Administration; (3) published scientific and medical literature from the United States and other nations regarding these drugs; (4) selected investigatory files compiled for law enforcement purposes by the Drug Enforcement Administration; and (5) the legislative history of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluations and recommendations of the Secretary of Health, Education and Welfare, received pursuant to sections 201(a) and 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, mecloqualone and the thiophene analog of phencyclidine have a high potential for abuse.

2. Mecloqualone and the thiophene analog of phencyclidine have no currently accepted medical use in treatment in the United States.

3. There is a lack of accepted safety for use of mecloqualone and of the thiophene analog of phencyclidine under medical supervision.

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator proposes that § 1308.11 of Title 21 of the Code of Federal Regulations be amended to read:

§ 1308.11 Schedule I.

* * * * *

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):

(1) 4-bromo-2,5-dimethoxyamphetamine ---- 7391
Some trade or other names: 4-bromo - 2,5 - dimethoxy - α - methylphenethylamine; 4-bromo-2,5-DMA.

(2) 2,5-dimethoxyamphetamine ---- 7396
Some trade or other names: 2,5-dimethoxy - α - methylphenethylamine; 2,5-DMA.

(3) 4-methoxyamphetamine ---- 7411
Some trade or other names: 4-methoxy - α - methylphenethylamine; paramethoxyamphetamine; PMA.

(4) 5-methoxy-3,4 - methylenedioxy amphetamine ---- 7401

(5) 4-methyl-2,5,-dimethoxyamphetamine ---- 7395
Some trade and other names: 4 - methyl - 2,5, - dimethoxy - α - methylphenethylamine; "DOM"; and "STP".

(6) 3,4 - methylenedioxy amphetamine ---- 7400

(7) 3,4,5-trimethoxy amphetamine... 7390

(8) Bufotenine ---- 7433
Some trade and other names: 3 - (β - Dimethylaminoethyl) - 5 - hydroxyindole; 3-(2 - dimethylaminoethyl) - 5 - indolol; N,N - dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine.

(9) Diethyltryptamine ---- 7434
Some trade and other names: N,N-Diethyltryptamine; DET.

(10) Dimethyltryptamine ---- 7435
Some trade or other names: DMT.

(11) Ibogaine ---- 7260
Some trade and other names: 7 - Ethyl - 6,6α, 7,8,9,10,12, 13 - octahydro - 2 - methoxy - 6,9 - methano - 5H-pyrido [1',2':1,2] azepino [5,4-b] indole; tabernanthe iboga.

(12) Lysergic acid diethylamide ---- 7315

(13) Marihuana ---- 7360

(14) Mescaline ---- 7381

(15) Peyote ---- 7415

(16) N-ethyl-3-piperidyl benzilate.... 7482

(17) N-methyl-3-piperidyl benzilate... 7484

(18) Psilocybin ---- 7437

(19) Psilocyn ---- 7438

(20) Tetrahydrocannabinols ---- 7370
Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
Δ1 cis or trans tetrahydrocannabinol, and their optical isomers.
Δ6 cis or trans tetrahydrocannabinol, and their optical isomers.
Δ3,4 cis or trans tetrahydrocannabinol, and its optical isomers.
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)

(21) Thiophene Analog of Phencyclidine
Some trade or other names: 1-[1-(2-thienyl) cyclohexyl] piperidine); 2-Thienyl Analog of Phencyclidine, TPCP.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) mecloqualone ---------- 2572

All interested persons are invited to submit their comments or objections in writing regarding this proposal. The comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, Department of Justice, Room 1130, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than July 1, 1975.

In the event that an interested party submits objections to this proposal which present grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that a hearing on these objections will be held as soon as the matter may be heard at the Drug Enforcement Administration, 1405 Eye Street NW., Washington, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may, without a hearing, and, after giving consideration to written comments, issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: May 9, 1975.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.75-13818 Filed 5-28-75;8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[50 CFR Part 18]

MARINE MAMMALS

Procedures for Hearings on Proposed Regulations

The Marine Mammal Protection Act authorizes the Secretary to prescribe regulations and to waive the moratorium on the taking and/or importation of marine mammals and marine mammal products and, for such prescription or waiver, refers the Secretary to section 103 of the Act (16 U.S.C. 1373). Section 103(d) requires that regulations be made on the record after opportunity for an agency hearing on such regulations and, in the case of a waiver, on a determination by the Secretary to waive the moratorium.

On July 12, 1974 proposed regulations to govern hearings on the record as required by section 103 of the Act (16 U.S.C. 1373) were published in the FEDERAL REGISTER, 39 FR 25664-25667, by the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce. Thirty days were provided for comments on the proposed regulations.

The only comment received was from the Environmental Protection Agency (EPA). The EPA suggested that provision be made for introducing the environmental impact statement into the record of the hearing. To comply with that suggestion, §§ 216.73(b)(6) and 216.85(b) have been amended. Furthermore, if an environmental impact statement is necessary, the statement will be considered when the Director determines the issues of fact published in the notice of hearing pursuant to § 216.73(b)(5).

The regulations to govern hearings on the record as required by section 103 of the Marine Mammal Protection Act (16 U.S.C. 1373) were published in final form in the FEDERAL REGISTER, 40 FR 10182-10186, March 5, 1975.

It is the intent of the Director, U.S. Fish and Wildlife Service to adopt the regulations published in final form by the NMFS on March 5, 1975 [40 FR 10182-10182]. The purpose of adopting these regulations would be to allow the two Departments to handle joint requests for a waiver of the moratorium and hearings simultaneously.

The basic format for the proposed hearing procedures to govern section 103 hearings consist of:

(1) Publication of notice in the FEDERAL REGISTER of (i) an intent to waive the moratorium and/or to prescribe regulations and (ii) issues which may be involved in the hearing;

(2) Submission in writing of all direct testimony to be introduced at the hearing. Such submission must be accomplished by a date specified in the notice;

(3) As soon as possible after the date specified in (2) above, the presiding officer shall consider all the direct testimony offered and make a preliminary determination of the issues presented;

(4) The presiding officer shall then conduct a prehearing conference and cause to be published in the FEDERAL REGISTER a final hearing agenda;

(5) If the presiding officer determines at the prehearing conference that no issues of fact are presented by the written direct testimony, the presiding officer shall publish in the FEDERAL REGISTER such determination and notice that no hearing will be held and that any person may submit written comments for the presiding officer's consideration prior to his rendering of a recommended decision;

(6) When a hearing is held, only direct testimony previously submitted may be introduced. Direct testimony not submitted as provided in these regulations and introduced at the hearing shall not be considered a part of the record;

(7) The hearing shall be limited to cross-examination of witnesses introducing direct testimony. Oral arguments may be allowed at the presiding officer's discretion;

(8) After the hearing, written comments may be submitted by any interested person;

(9) After the time provided for submission of written comments, the presiding officer shall make a recommended decision and transmit such decision with the transcript and comments to the Director for a final determination.

Written comments, views and objections with respect to this proposed adoption of regulations may be submitted to the Director, U.S. Fish and Wildlife Service (MNB), Washington, D.C. 20240. All material received on or before June 30, 1975 will be considered.

The Fish and Wildlife Service published the present subpart G in the FEDERAL REGISTER on February 13, 1975 (40 FR 6661-6663) for the hearing to waive the Moratorium and return the Management of Walrus to the State of Alaska. This proposal will replace the earlier publication as the new subpart G will broaden the hearing procedures from walrus to all marine mammals.

Accordingly, it is hereby proposed to amend Subpart G, Part 18, Subchapter B, Chapter I of Title 50, CFR by deleting it in its entirety and replacing it with the following new language.

LYNN A. GREENWALT,
Director.

MAY 21, 1975.

Subpart G—Notice and Hearing on Section 103 Regulations

Sec.
18.70 Basis and purpose.
18.71 Definitions.
18.72 Scope of regulations.
18.73 Notice of hearing.
18.74 Notification by interested persons.
18.75 Presiding officer.
18.76 Direct testimony submitted as written documents.
18.77 Mailing address.
18.78 Inspection and copying of documents.
18.79 Ex parte communications.
18.80 Prehearing conference.
18.81 Final agenda of the hearing.
18.82 Determination to cancel the hearing.
18.83 Rebuttal testimony and new issues of fact in final agenda.
18.84 Waiver of right to participate.
18.85 Conduct of the hearing.
18.86 Direct testimony.
18.87 Cross-examination.
18.88 Oral and written arguments.
18.89 Recommended decision, certification of the transcript and submission of comments on the recommended decision.
18.90 Director's decision.

AUTHORITY: Title I of the Marine Mammal Protection Act of 1972, 86 Stat. 1027 (16 U.S.C. 1361-1407), Pub. L. No. 92-522.

Subpart G—Notice and Hearing on Section 103 Regulations

§ 18.70 Basis and purpose.

(a) Sections 101(a)(2), 101(a)(3)(A), and 101(b) (16 U.S.C. §§ 1371(a)(2), 1371(a)(3)(A), 1371(b) (1972)) of the Act and these regulations authorize the Director, U.S. Fish and Wildlife Service,