CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

A notice of proposed rulemaking issued May 9, 1975 by the Administrator of the Drug Enforcement Administration, and published in the FEDERAL REGISTER on May 29, 1975 (40 FR 23306) proposed that Schedule I of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513) be amended to include mecloqualone, and the thiophene analog of phencyclidine (1-[1 - (2 - thienyl) cyclohexyl] piperidine). All interested persons were given until July 1, 1975 to submit comments, objections and requests for a hearing in the matters. The notice further provided that if all interested persons waive their opportunity to request or participate in a hearing, the Administrator may, without a hearing, issue his final order pursuant to 21 CFR 1308.48 after giving consideration to any comments submitted.

In view of the fact that no comments, objections, or requests for a hearing have been received, the Acting Administrator has determined that all interested persons are deemed to have waived their opportunity for a hearing in the matters, and a final order with respect to controlling the above substances shall be issued without a hearing pursuant to 21 CFR 1308.48.

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 Acting Administrator of the Drug Enforcement Administrations 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, and further, having been duly designated as Acting Administrator by Order No. 607-75 of the Attorney General, dated May 30, 1975, in accordance with the authority stated therein, and pursuant to the authority delegated to the Acting Administrator by § 0.132(d) of Title 28 of the Code of Federal Regulations, the Acting Administrator hereby orders 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-methory-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 - 6,6β,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 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

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Effective dates. Based on investigations conducted by the Drug Enforcement Administration, the Acting Administrator hereby finds that mecloqualone, in the past, has been clandestinely manufactured for purposes of distribution and diversion outside legitimate drug channels. A most recent investigation has revealed that this clandestine manufacturing activity continues.

The Acting Administrator finds that Congress intended that the Attorney General "* * * should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the [Act] * * *" H.R. Rep. No. 91-1444 (part 1) 91st Cong. 2d Sess. 35 (1970).

Considering the danger inherent in mecloqualone as a drug meeting the criteria for inclusion into Schedule I, and considering that Congress intended that controls apply to drugs in a preventative manner, the Acting Administrator hereby finds, based upon the above, that the public health, as well as safety, necessitate the placement of Schedule I controls

upon mecloqualone at a date earlier than thirty days from the date of publication of this order in the FEDERAL REGISTER.

Therefore, pursuant to § 1308.48 of Title 21 of the Code of Federal Regulations, the dates on which this order is to take effect are as follows:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports mecloqualone, or the thiophene analog of phencyclidine, or who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1311 of title 21 of the Code of Federal Regulations on or before August 11, 1975, with respect to the thiophene analog of phencyclidine, and on or before July 10, 1975, with respect to mecloqualone.

2. *Security.* Mecloqualone, and the thiophene analog of phencyclidine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (a), 1301.73, 1301.74(a)–(c), (e)–(f), 301.75(a), (c), and 1301.76 of Title 21 of the Code of Federal Regulations. Compliance with the above shall be required on or before August 11, 1975 with respect to the thiophene analog of phencyclidine, and shall be required on or before July 10, 1975 with respect to mecloqualone. In the event this imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for an extension of time submitted to it on or before the respective required dates of compliance.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of mecloqualone, packaged after July 10, 1975, and all labels on commercial containers of, and all labeling of the thiophene analog of phencyclidine, packaged after August 11, 1975, shall comply with the requirements of §§ 302. 1-03–1302.05, and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations. In the event this effective date imposes special hardships on any manufacturer, as defined in section 102(14) of the Controlled Substances Act) 21 U.S.C. 802 (14)), the Drug Enforcement Administration will entertain any justified requests for an extension of time submitted to it before the respective required dates of compliance.

4. *Quotas.* All persons required to obtain quotas with respect to the thiophene analog of phencyclidine, and mecloqualone, shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations on or before August 11, 1975 as to the thiophene analog of phencyclidine, and on or before July 10, 1975 as to mecloqualone.

5. *Inventory.* Every registrant required to keep records who possesses any quantity of mecloqualone, or of the thiophene analog of phencyclidine, shall take an inventory pursuant to §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of the thiophene analog of phencyclidine on hand, on August 11, 1975, and of all stocks of mecloqualone on hand, on July 10, 1975.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21–1304.27 of Title 21 of the Code of Federal Regulations, shall maintain such records on the thiophene analog of phencyclidine, and on mecloqualone, on the respective dates on which inventories of such substances are required to be taken, as hereinabove provided.

7. *Reports.* All registrants required to file reports with the Drug Enforcement Administration pursuant to §§ 1304.37–1304.41 of Title 21 of the Code of Federal Regulations, shall file such reports on the thiophene analog of phencyclidine, and on mecloqualone, on the respective dates on which inventories of such substances are required to be taken, as hereinabove provided, and on all subsequent transactions.

8. *Order forms.* Each distribution of the thiophene analog of phencyclidine after August 11, 1975, and of mecloqualone after July 10, 1975, shall be pursuant to an order form in accordance with Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Importation and exportation.* All importation and exportation of the thiophene analog of phencyclilone on and after August 11, 1975, and of mecloqualone on and after July 10, 1975, shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal liability.* Pursuant to Title 21 of the Code of Federal Regulations, § 1308.48, the Acting Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to mecloqualone which is not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after publication of this order, shall be unlawful, except that any person not now registered to handle mecloqualone, but who is entitled to registration and who has submitted an application to the Drug Enforcement Administration for registration, on or before July 10, 1975, as herein before provided, shall be permitted to conduct normal business or professional practice with mecloqualone between the date on which this order is published and the date on which he obtains or is denied registration.

The provisions of this paragraph shall apply with respect to the thiophene analog of phencyclidine, except that any person not now registered to handle the thiophene analog of phencyclidine, but who is entitled to registration and who has submitted an application on or before August 11, 1975, as hereinabove provided, shall be permitted to conduct normal business or professional practice with the thiophene analog of phencyclidine between the date on which this order is published and the date on which he obtains or is denied registration.

11. *Other.* In all other respects, this order is effective on August 11, 1975 with respect to the thiophene analog of pencyclidine, and on July 10, 1975 with respect to mecloqualone.

Dated: July 3, 1975.

HENRY S. DOGIN,
Acting Administrator,
Drug Enforcement Administration.

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