

SUPPLEMENTARY INFORMATION: FDA is amending § 5.31 *Petitions under Part 10* (21 CFR 5.31) by adding new paragraph (e)(5) that will authorize the Director and Deputy Director, CDRH, to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30 of this chapter. This redelegation of authority will help expedite responses to citizen petitions and will be consistent with authority delegated to other centers within the agency.

Further redelegation of authority is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such a position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552; 7 U.S.C. 2217; 15 U.S.C. 638, 1451 *et seq.*, 3701 *et seq.*; 21 U.S.C. 41 *et seq.*, 61–63, 141 *et seq.*, 301–392, 467f(b), 679(b), 801 *et seq.*, 823(f), 1031 *et seq.*; 35 U.S.C. 156; 42 U.S.C. 219, 241, 242(a), 242a, 242l, 242o, 243, 262, 263, 263b through 263m, 264, 265, 300u *et seq.*, 1395y and 1395y note, 3246b(b)(3), 4831(a), 10007, and 10008; Federal Caustic Poison Act (44 Stat. 1406); Federal Advisory Committee Act (Pub. L. 92–463); E.O. 11490, 11921, 12591.

2. Section 5.31 is amended by adding new paragraph (e)(5) to read as follows:

§ 5.31 Petitions under Part 10.

* * * * *

(5) The Director and Deputy Director, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

* * * * *

Dated: April 5, 1989.

Ronald G. Chesemore,
Acting Commissioner for Regulatory Affairs.
[FR Doc. 89–8654 Filed 4–12–89; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of 3,4-Methylenedioxy-N-ethylamphetamine and N-Hydroxy-3,4-methylenedioxyamphetamine into Schedule I

AGENCY: Drug Enforcement Administration, Justice.
ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is based on findings made by the DEA Administrator, after a review and evaluation of the relevant data by both DEA and the Acting Assistant Secretary for Health, that 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine meet the statutory criteria for inclusion in Schedule I of the CSA. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I are applicable to the manufacture, distribution, importation, exportation and possession of 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine.

EFFECTIVE DATE: April 13, 1989.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: On October 14, 1988, in a notice of proposed rulemaking published in the *Federal Register* (53 FR 40390), after a review of relevant data, the DEA Administrator proposed to place 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). By letter dated April 5, 1989, the DEA Administrator received the scientific and medical evaluation and scheduling recommendation for 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine from the Acting Assistant Secretary for Health, delegate of the Secretary of the Department of Health and Human Services. He recommended that 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-

methylenedioxyamphetamine be placed into Schedule I of the CSA.

The proposed rule provided the opportunity for interested parties to submit comments, objections or requests for a hearing regarding the proposed scheduling of 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine. There was one request to conduct a hearing on the religious use of 3,4-methylenedioxy-N-ethylamphetamine. The DEA Administrator denied the request on the grounds that religious use of a substance is not a relevant factor to be considered in determining whether 3,4-methylenedioxy-N-ethylamphetamine should be controlled under the CSA and into what schedule it should be placed. No comments, objections or requests for hearing were received regarding N-hydroxy-3,4-methylenedioxyamphetamine.

Both drugs have additional names. Other chemical names of 3,4-methylenedioxy-N-ethylamphetamine include N-ethyl-3,4-methylenedioxyamphetamine, N-ethyl-3,4-methylenedioxyphenylisopropylamine, N-ethyl-alpha-methyl-3,4-(methylenedioxy)phenethylamine and N-ethyl-alpha-methyl-1,3-benzodioxole-5-ethanamine. Various chemical names of N-hydroxy-3,4-methylenedioxyamphetamine include 3,4-methylenedioxy-N-hydroxyamphetamine, N-hydroxy-3,4-methylenedioxyphenyliso-propylamine, 1-(3,4-methylenedioxyphenyl)-2-hydroxyaminopropane, N-hydroxy-alpha-methyl-3,4-(methylenedioxy)phenethylamine, and N-hydroxy-alpha-methyl-1,3-benzodioxole-5-ethanamine.

Both 3,4-methylenedioxy-N-ethylamphetamine (MDE) and N-hydroxy-3,4-methylenedioxyamphetamine (N-hydroxy-MDA) are analogs of 3,4-methylenedioxyamphetamine (MDMA). They have been reported to cause psychotomimetic effects in humans. Data collected from various animals studies, utilizing various pharmacological tests, indicate that both substances have a behavioral and self-administration profile that resembles 3,4-methylenedioxyamphetamine (MDA) and MDMA. A number of studies, utilizing laboratory animals, have provided evidence to suggest that MDE causes neurotoxic effects similar to that produced by MDA or MDMA. To date, one study using rats has provided evidence of neurotoxicity induced by N-hydroxy-MDA. Both substances have been found in the illicit drug market. The

street name for MDE is "Eve". Both substances have been produced in clandestine laboratories and identified in drug evidence submissions to forensic laboratories.

Based upon the investigation and review conducted by DEA and upon the scientific and medical evaluation and recommendation of the Acting Assistant Secretary for Health, delegate of the Secretary of the Department of Health and Human Services, received in accordance with 21 U.S.C. 811(b), the DEA Administrator, pursuant to the provisions of 21 U.S.C. 811 (a) and (b), finds that:

(1) 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine have a high potential for abuse;

(2) 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine have not currently accepted medical use in treatment in the United States, and

(3) 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine lack accepted safety for use under medical supervision.

These findings are consistent with the placement of 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine into Schedule I of the CSA.

All regulations applicable to Schedule I substances continue to be effective as of April 13, 1989 with respect to 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine. These substances have been in Schedule I pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h) since October 15, 1987. The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine or who engages in research or conducts instructional activities with respect to these substances, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 3,4-methylenedioxy-*N*-

ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations of all stocks of these substances on hand.

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 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34-1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine.

8. *Order Forms.* All registrants involved in the distribution of 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine must comply with the order form requirements of §§ 1305.01-1305.16 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with respect to 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator certifies that the scheduling of 3,4-methylenedioxy-*N*-ethylamphetamine and *N*-hydroxy-3,4-methylenedioxyamphetamine, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be

considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the control of substances that have no legitimate medical use or manufacturer in the United States.

In accordance with the provisions of section 201(a) of the CSA (21 U.S.C. 811(a)), this scheduling action 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 (46 FR 13193). This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice Regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR 1308 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).

2. Section 1308.11(d) is amended by redesignating paragraphs (d)(8) through (d)(25) to (d)(10) through (d)(27) and by adding new paragraphs (d)(8) and (d)(9) to read as follows:

§ 1308.11 Schedule I.

- * * * * *
- (d) * * *
- (8) 3,4-methylenedioxy-*N*-ethylamphetamine (also known as *N*-ethyl- α -methyl-3,4(methylenedioxy)phenethylamine, *N*-ethyl MDA, MDE, MDEA..... 7404
- (9) *N*-hydroxy-3,4-methylenedioxyamphetamine (also known as *N*-hydroxy- α -methyl-3,4(methylenedioxy)phenethylamine, and *N*-hydroxy MDA..... 7402
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3. Section 1308.11(g) is amended by removing paragraphs (g)(3) and (g)(4)

and redesignating (g)(5) and (g)(6) as (g)(3) and (g)(4).

John C. Lawn,
Administrator.

Date: April 10, 1989.

[FR Doc. 89-8755 Filed 4-12-89; 8:45 am]

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21 CFR Part 1308

Schedules of Controlled Substances; Placement of (±)cis-4-methylaminorex into Schedule I

AGENCY: Drug Enforcement
Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place (±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine ((±)cis-4-methylaminorex), a stimulant, into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is taken following a review and evaluation of the relevant data by both DEA and the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS). Based on these reviews, the DEA Administrator finds that (±)cis-4-methylaminorex meets the statutory criteria for placement into Schedule I of the CSA. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I will be applicable to the manufacture, distribution, importation, exportation and possession of (±)cis-4-methylaminorex.

EFFECTIVE DATE: April 13, 1989.

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

SUPPLEMENTARY INFORMATION: (±)cis-4-methylaminorex is a potent central nervous system stimulant that is similar in its pharmacological action to amphetamine, a Schedule II substance. This substance has been produced in clandestine laboratories, identified in drug evidence submissions and associated with at least two overdose deaths.

On October 15, 1987, the Administrator of DEA issued a final rule in the Federal Register temporarily placing 4-methylaminorex into Schedule I of the CSA for one year pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h). This action was based on a finding by the Administrator of DEA that the emergency scheduling of 4-

methylaminorex was necessary to avoid an imminent hazard to the public safety. Emergency control was extended until April 15, 1989 through issuance of an additional final rule (53 FR 40061).

On October 14, 1988, in a notice of proposed rulemaking published in the Federal Register (53 FR 40391), the DEA Administrator proposed to place 4-methylaminorex (4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) in Schedule I of the CSA. This proposal followed a review of the relevant data by DEA pursuant to 21 U.S.C. 811(a). The proposed rule provided the opportunity for interested parties to submit comments, objections or requests for a hearing regarding the proposed scheduling of 4-methylaminorex. There was one comment submitted on October 18, 1988 by an individual who expressed an interest in the use of 4-methylaminorex as a nasal decongestant. Since receipt of that comment, two requests for a hearing were received from the same individual on January 30 and February 3, 1989. Since the requests for a hearing were not filed in a timely manner and did not follow the procedures set forth in 21 CFR 1303.44 and 1303.45, they have been denied.

During the period of temporary control of 4-methylaminorex in Schedule I, DEA gathered information regarding the abuse and abuse potential, the clandestine manufacture and the illicit distribution and trafficking of 4-methylaminorex. The Administrator of DEA submitted this information by letter to the Assistant Secretary for Health (DHHS) and recommended that 4-methylaminorex be placed into Schedule I of the CSA. Enclosed with the letter was a document prepared by the DEA entitled "Scheduling Recommendation for 4-methylaminorex." The document contained a review of the factors which the CSA requires the Attorney General (delegated to the Administrator of DEA) to consider (21 U.S.C. 811(b)) and the summarized recommendations regarding the scheduling of 4-methylaminorex.

As stated in the proposed rulemaking, DEA's final decision concerning the scheduling of 4-methylaminorex took into account the recommendation of the Acting Assistant Secretary for Health (DHHS), its own review, and any information received in response to this proposal. By letter dated April 5, 1989, the DEA Administrator received the scientific and medical evaluation and scheduling recommendation for 4-methylaminorex from the Acting Assistant Secretary for Health (DHHS). The recommendation stated that (±)cis-4-methylaminorex has actions that are consistent with central nervous system

stimulation of the amphetamine type and that it should be placed into Schedule I of the CSA.

Based on the information gathered and reviewed by DEA and the recommendation of the Acting Assistant Secretary for Health (DHHS), the Administrator of DEA, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

- (1) (±)cis-4-methylaminorex has a high potential for abuse;
- (2) (±)cis-4-methylaminorex has no currently accepted medical use in treatment in the United States; and
- (3) There is a lack of accepted safety for use of (±)cis-4-methylaminorex under medical supervision.

The above findings are consistent with the placement of (±)cis-4-methylaminorex into Schedule I of the CSA. In accordance with 21 U.S.C. 811(h)(5), the emergency scheduling order for (±)cis-4-methylaminorex shall be vacated on the effective date of this final rule, with the placement of (±)cis-4-methylaminorex into Schedule I of the CSA pursuant to 21 U.S.C. 811(a).

Since (±)cis-4-methylaminorex is already under temporary control in Schedule I, all regulations applicable to Schedule I substances continue to be effective as of April 13, 1989.

The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports (±)cis-4-methylaminorex or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* (±)cis-4-methylaminorex must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels and labeling for commercial containers of (±)cis-4-methylaminorex must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for (±)cis-4-methylaminorex shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of (±)cis-4-methylaminorex shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the