Much of the activity with these substances has occurred in the southwestern and midwestern states. MDA analogs have been openly promoted as safe and legal through fliers. N-ethyl MDA has been sold as "Eve" in bars and shops in Texas. DEA has identified several clandestine laboratories which have produced or are capable of producing N-ethyl and N-hydroxy MDA.

The use of MDA and its analogs has been associated with adverse effects on the public health and safety. They are known to cause psychotomimetic effects in man. DAWN (Drug Abuse Warning Network) has reported emergency room mentions of MDA, MDMA and N-ethyl MDA. Two deaths in Texas have been associated with the use of N-ethyl MDA; it was not possible, however, to determine whether N-ethyl MDA directly contributed to the deaths. With the exception of psychotomimetic effects reported from human subjects under controlled experimental conditions, there have been no specific reports of adverse effects, injuries or deaths associated with the use of N-hydroxy MDA. Considering, however, that N-hydroxy MDA has a similar structure and pharmacology to that of MDA and MDMA, it seems likely that adverse effects similar to those produced by MDA and MDMA will also be produced by N-hydroxy MDA.

Another concern arising from the use of N-ethyl MDA and N-hydroxy MDA is their possible neuro-toxicity. It has been well documented that MDA and MDMA destroy specific nerve terminals and, in some cases, nerve cells in the brains of laboratory animals. Recently reported studies have provided evidence that N-ethyl MDA also produces neurotoxic effects resembling those of MDA and MDMA. The question of whether N-hydroxy MDA causes neurotoxicity has not been examined.

The above data show that the clandestine production, distribution and use of analogs of MDA, currently in the form of N-ethyl MDA and N-hydroxy MDA, pose a serious hazard to the public safety. DEA is unaware of any commercial manufacturer or supplier of N-ethyl MDA or N-hydroxy MDA or of any recognized therapeutic use of either of these substances.

The DEA Administrator, based on the information gathered and reviewed by his staff and after consideration of the factors in 21 U.S.C. 811(c), believes that sufficient data exists to propose and to support that 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine be placed into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The specific findings required pursuant to 21 U.S.C. 811 and 812 for a substance to be placed into Schedule I are as follows:

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety for use of the drug or other substance under medical supervision.
4. Before issuing a final rule in this matter, the DEA Administrator will take into consideration the scientific and medical evaluations and scheduling recommendations of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b).

The recommendations of the Secretary regarding scientific and medical matters are binding on the Administrator and if the Secretary recommends that a substance should not be controlled, the DEA Administrator will not control it. The Administrator will also consider relevant comments from other concerned parties.

Interested persons are invited to submit their comments, objections or requests for 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 to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537; Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for a hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for hearing.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the proposed placement of 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine in Schedule I of the CSA will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). The substances proposed for control in this notice have no legitimate use or manufacturer in the United States. In accordance with the provisions of Title 21, United States Code, section 811(a), this proposal to place 3,4-methylenedioxy-N-ethylamphetamine and N-hydroxy-3,4-methylenedioxyamphetamine into Schedule I 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 (48 FR 13193).

List of Subjects in 21 CFR Part 1308


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 proposes that 21 CFR Part 1308 be amended as follows:

PART 1308—[AMENDED]


2. Section 1308.11 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.

(a)(8) 3,4-methylenedioxy-N-ethylamphetamine [also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDEA . . . 7404
(b)(9) N-hydroxy-3,4-methylenedioxyamphetamine [also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA . . . 7402

3. Section 1308.11 is amended by removing paragraphs (g)(3) and (g)(4) and redesignating existing paragraphs (g)(5) and (g)(6) as (g)(3) and (g)(4).

John C. Lawn,

Administrator, Drug Enforcement Administration.

Date: October 12, 1988.

[FR Doc. 88-23929 Filed 10-13-88; 9:51 am]

BILLING CODE 4410-09-M

21 CFR Part 1308

Schedules of Controlled Substances; Proposal To Place 4-methylaminorex Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) proposes that 4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine (4-methylaminorex), a stimulant, be placed into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This proposed action by the DEA Administrator has been initiated following a review of the scientific and forensic data on 4-methylaminorex by DEA. An independent review of the medical and scientific data on 4-methylaminorex and a scheduling recommendation has been requested from the Assistant Secretary for Health, Department of Health and Human Services (DHHS). The scheduling of 4-methylaminorex in Schedule I, if finalized, would impose the regulatory controls and criminal sanctions of a Schedule I substance under the CSA on the manufacture, distribution and possession of 4-methylaminorex.

DATE: Written comments and objections must be received on or before November 14, 1988.

ADDRESS: Comments and objections should be submitted in quintuplicate to the Federal Register Representative, Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537.

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

SUPPLEMENTARY INFORMATION: 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 pursuant to the emergency scheduling provisions of 21 U.S.C. 811(b). 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. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) provides that the emergency scheduling of a substance expires at the end of one year from the effective date of the order. However, if a rulemaking proceeding to schedule the substance has been initiated pursuant to section 201(a)(1) of the CSA (21 U.S.C. 811(a)(1)), the temporary scheduling of 4-methylaminorex may be extended for up to six months. Under this provision, the temporary scheduling of 4-methylaminorex which would expire on October 15, 1988 may be extended until April 15, 1989. This extension is being ordered by the Administrator of DEA in a separate notice.

During the period of temporary control of 4-methylaminorex in Schedule I, DEA has continued to gather information regarding the abuse and abuse potential, the clandestine manufacture and the illicit distribution and trafficking of 4-methylaminorex. The Administrator of DEA has submitted this information by letter to the Assistant Secretary for Health, DHHS and has 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.

The factors considered by the Administrator of DEA with respect to 4-methylaminorex were:

1. Its actual or relative potential for abuse;
2. Scientific evidence of its pharmacological effects, if known;
3. The state of current scientific knowledge regarding the drug (or other substance);
4. Its history and current pattern of abuse;
5. The scope, duration and significance of abuse;
6. What, if any, risk there is to the public health;
7. Its psychic or physiological dependence liability; and
8. Whether the substance is an immediate precursor of a substance already controlled under this title.

Briefly, the information gathered and reviewed by DEA shows that 4-methylaminorex:

1. Is a potent amphetamine-like compound;
2. Produces the stimulant and anorectic effects of typical amphetamine-like substances;
3. Is not approved for marketing by the Food and Drug Administration;
4. Is manufactured in clandestine laboratories;
5. Has been identified by forensic laboratories in submissions of evidence from Florida, California and Pennsylvania;
6. Has been associated with at least two deaths; and
7. Continues to pose a threat to the public safety.

Based on the information gathered and reviewed by DEA, the Administrator of DEA, pursuant to the provisions of 21 U.S.C. 811(a) finds that:

1. According to presently available information, 4-methylaminorex has a high potential for abuse;
2. 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 4-methylaminorex under medical supervision.

The above findings are consistent with the proposed placement of 4-methylaminorex into Schedule I of the CSA. Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief. In the event that comments, objections or requests for a hearing received in response to this proposal raise one or more issues which warrant a hearing, the Administrator will publish in the Federal Register an order for a public hearing which will summarize the issues to be heard and set the time for the hearing that will not be less than 30 days after the date of the order. 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 Administrator, after giving consideration to written comments and objections, will issue a final order pursuant to 21 CFR 1308.48 without a hearing. DEA's final decision concerning the scheduling of 4-methylaminorex will take into account the recommendation of the Assistant Secretary for Health (DHHS), its own review, and any information received in response to this proposal.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator certifies that the scheduling of 4-methylaminorex 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 proposed drug control action relates to the control of a substance (4-methylaminorex) that has no legitimate 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 proposed 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 13185).
List of Subjects in 21 CFR Part 1308


Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)1 and delegated to the Administrator of DEA by regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby proposes to amend 21 CFR Part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR Part 1308 continues to read as follows:


2. Paragraph (f) of § 1308.11 is amended by redesignating the existing paragraph (f)(2) as (f)(3) and adding a new paragraph (f)(2):

   § 1308.11, Schedule I.
   
   (f) * * *

   (f)(2) 4-methylaminorex (4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) . . . 1590.

3. Paragraph (g) of § 1308.11 is amended by removing paragraph (g)(3) and redesignating existing paragraph (g)(4) as (g)(3).

John C. Lawn,
Administrator, Drug Enforcement Administration.


[FR Doc. 88–23930 Filed 10–13–88; 9:53 am]
BILLING CODE 4410–09–M