[4-methylaminorex]. . . Moreover, "... at effective dose levels, all of the anorexigenics display a similar degree of central nervous system stimulation."

Based on the data presently available, 4-methylaminorex appears to have a toxicity associated with its actions in producing central nervous system stimulation. With increasing dosage, 4-methylaminorex produces an overstimulation of the central nervous system that leads to stereotypic behavior activity, seizure activity in the brain and associated convulsions, depression, respiratory failure, and death. It should be noted that a recent death has been attributed to the abuse of 4-methylaminorex. Analyses indicated the presence of high levels of 4-methylaminorex in the blood (21.3 mg/L) and urine (12.3 mg/L) of the victim. Comment from researchers studying 4-methylaminorex has previously stressed that it has a narrow margin of safety in the dog and thus should be tested very cautiously in humans. Review of these pharmacological studies, then, indicates that 4-methylaminorex is a potent amphetamine-like stimulant with a low margin of safety.

DEA has received two reports of clandestine laboratories being seized following synthesis of considerable quantities of 4-methylaminorex. A number of samples of clandestinely manufactured 4-methylaminorex obtained from Florida and California have been positively identified by DEA chemists. DEA is not aware of any commercial manufacturers or suppliers of this compound, nor any approved therapeutic use.

In making a finding of an imminent hazard to the public safety, the Administrator, as delegated by Attorney General, is required to consider only those factors set forth in paragraphs (4), (5) and (6) of section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows:

4. The history and current pattern of abuse.
5. The scope, duration and significance of abuse, and
6. What, if any, risk there is to the public health.

Based on a consideration of these three factors along with the potent stimulant and toxic actions of the substance, and the lack of accepted medical use or established safety for the use of 4-methylaminorex, the Administrator, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, finds that scheduling 4-methylaminorex in Schedule I of the CSA, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety.

The Administrator has transmitted notice of his intention to temporarily place 4-methylaminorex into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services. Comments submitted by the Assistant Secretary for Health in response to the notification, including whether there is an exemption or approval in effect for 4-methylaminorex under the Federal Food, Drug, and Cosmetic Act, shall be taken into consideration by the Administrator before a final order is published. Because the Administrator has found that it is necessary to temporarily place 4-methylaminorex into Schedule I to avoid an imminent hazard to the public safety, the final order, if issued, will be effective on the date of publication in the Federal Register. Further it is the intention of the Administrator to issue such a final order as soon as possible after the expiration of thirty days from the date of publication of this proposal and the date that a notification has been transmitted to the Assistant Secretary for Health.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the temporary placement of 4-methylaminorex into Schedule I of the CSA, as ordered hereunder, 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 temporary control of a substance with no currently approved medical use or manufacture in the United States.

It has been determined that the temporary placement of 4-methylaminorex in Schedule I of the CSA under the emergency scheduling provision is a statutory exception to the requirements of Executive Order 12291 (46 FR 13193).

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(h) of the CSA (21 U.S.C. 811(h)), 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—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b)

2. Paragraph (g)(6) is added to §1308.11 Schedule I

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<th>§ 1308.11</th>
<th>Schedule I</th>
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<tbody>
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<td>(g)</td>
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<tr>
<td>(6) 2-amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex) . . .</td>
<td>1590</td>
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John C. Lawn, Administrator. Drug Enforcement Administration.

[FR Doc. 87-18344 Filed 8-12-87; 8:45 am]
BILLING CODE 4410-09-M

21 CFR Part 1308

Schedules of Controlled Substances
Temporary Placement of N-ethyl MDA and N-hydroxy MDA Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of Intent.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily place N-hydroxy MDA and N-ethyl MDA into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provision of the CSA (21 U.S.C. 801 et seq.). This action is based on a finding by the DEA Administrator that the scheduling of N-hydroxy MDA and N-ethyl MDA in Schedule I is necessary to avoid an imminent hazard to the public safety. Finalization of this action will impose the criminal sanctions and regulatory controls of Schedule I on the manufacturing, distribution and possession of N-hydroxy MDA and N-ethyl MDA.

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

SUPPLEMENTARY INFORMATION: The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the Controlled Substances Act (CSA) (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if he finds that such action is necessary to avoid an imminent hazard to the public safety. A substance may be scheduled under the emergency provision of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no approval.
or exemption in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (28 CFR 0.100). In making a finding of an imminent hazard to the public safety, the Administrator is required to consider only those factors set forth in paragraphs (4), (5) and (6) of section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows:

(4) Their history and current pattern of abuse

(5) The scope, duration and significance of abuse, and

(6) What, if any, risk there is to the public health.

House Report 96-835 which accompanied Pub. L. 98-473 states that "This new procedure [emergency scheduling] is intended by the Committee to apply to what has been called 'designer drugs', new chemical analogs or variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant or depressant effect and have a high potential for abuse." N-hydroxy MDA and N-ethyl MDA are analogs of MDA and MDMA, Schedule I hallucinogens/stimulants, and as such are the type of substances which Congress intended to be considered for emergency scheduling.

N-ethyl MDA and N-hydroxy MDA are the most recent in a series of methylenedioxyamphetamine derivatives produced in clandestine laboratories for distribution and abuse in the United States. The parent compound in this class, 3,4-methylenedioxyamphetamine (MDA) has been controlled in Schedule I of the CSA since its passage in 1970. More recently 3,4-methylenedioxy-methamphetamine (MDMA), because of widespread abuse and studies showing that it is a neurotoxin in rodents, was placed into Schedule I pursuant to the emergency scheduling provision of the CSA effective July 1, 1985 (50 FR 23118).

MDMA has since been placed into Schedule I of the CSA pursuant to the scheduling provisions of 21 U.S.C. 811 (a) and (b) effective November 13, 1986 (51 FR 38552). Since the control of MDMA, N-ethyl MDA and N-hydroxy MDA have been identified in the illicit drug traffic in several areas of the United States.

N-ethyl MDA, also known as MDE or MDEA, is N-ethyl-alpha-methyl-3,4-(methylenedioxy)phenethylamine. It is also usually found as the hydrochloride salt in powder, tablet or capsule forms. Both N-ethyl MDA and N-hydroxy MDA are structural analogs of MDA and MDMA.

N-ethyl MDA and N-hydroxy MDA behave as central nervous system stimulants in animals and as psychotomimetic substances in man. Available scientific data show that these substances produce pharmacological effects common with MDA and MDMA. All four substances produce centrally mediated analgesic effects in the mouse as measured in several different tests. Both N-ethyl MDA (20 mg/kg) and N-hydroxy MDA (100 mg/kg) produce an increase in spontaneous locomotor activity in the mouse which is indicative of central nervous system stimulation. During the first three hours after administration, N-ethyl MDA increases spontaneous locomotor activity three times as much as MDA. Preliminary data from drug discrimination tests in rats show that although N-hydroxy MDA is not recognized as either amphetamine or DOM by appropriately trained animals it is recognized as MDMA in rats trained to discriminate MDMA from saline. Preliminary data also indicate that baboons trained to self-administer cocaine also self-administer N-ethyl MDA when it is substituted for cocaine. Similar reinforcing properties are observed for MDA, MDMA and other abusable central nervous system stimulants.

In man, N-ethyl MDA at oral doses of 140-200 mg, and N-hydroxy MDA at oral doses of 60-120 mg, produce psychomimetic effects. The scientific literature indicates that MDA, MDMA, N-ethyl MDA and N-hydroxy MDA produce a very similar spectrum of psychopharmacological effects in humans. They produce a change in consciousness, an increase in acoustic, visual and tactile sensory perceptions, mood changes and a drive-increasing effect. Effects appear about 30 minutes after ingestion and last for several hours.

N-ethyl MDA and N-hydroxy MDA have been identified by forensic laboratories in drug evidence submissions from many sections of the country. N-ethyl MDA was found infrequently in drug evidence from 1978 to 1982. With the control of MDMA in Schedule I of the CSA, N-ethyl MDA has been identified with increasing frequency by forensic laboratories. At the same time, N-hydroxy MDA began to show up in forensic drug evidence. Much of the activity with these substances has occurred in the Southwest and Midwestern states. MDA analogs have been openly promoted as safe and legal through flyers. 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 MDA and N-hydroxy MDA.

The use of MDA and its analogs has been associated with adverse effects on the public health and safety. N-ethyl MDA has been found in the blood of several individuals who were stopped by police for speeding, driving while intoxicated or involvement in accidents. Emergency room personnel have reported the admission of several individuals who had used N-ethyl MDA as determined by toxicological analyses. Reasons for admission range from bizarre behavior to loss of consciousness. Two deaths in Texas have also been associated with the use of N-ethyl MDA. Although as yet there have been no specific reports of injuries or deaths associated with the use of N-hydroxy MDA, its similar pharmacology makes it very likely that similar adverse effects will be reported. Another concern arising from the use of N-ethyl MDA and N-hydroxy MDA is their possible neurotoxicity. It has been well documented that both MDA and MDMA destroy serotonergic nerve terminals and, in some cases, nerve cells in the brains of laboratory animals. Neither N-ethyl MDA nor N-hydroxy MDA have undergone toxicity testing. Their similar chemical structures and pharmacological profiles to those of MDA and MDMA and their possible metabolism by N-dealkylation or decomposition of MDA, however, suggest a cause for serious concern regarding their possible neurotoxicity.

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.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Administrator of DEA has considered the following factors relative to making a determination of whether N-ethyl MDA and N-hydroxy MDA pose an imminent hazard to the public safety:

(1) Their history and current pattern of abuse.

(2) The scope, duration and significance of abuse, and

(3) The potential for abuse of the substance.
(3) What, if any, risk there is to the public health.

Based on a consideration of these factors and other relevant information, the Administrator, pursuant to section 201(h) of the CSA [21 U.S.C. 811(h)] and 28 CFR 0.100, finds that scheduling N-ethyl MDA and N-hydroxy MDA in Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

As required by section 201(h)(4) of the CSA [21 U.S.C. 811(h)(4)], the Administrator has notified the Assistant Secretary for Health, delegate of the Secretary of the Department of Health and Human Services of his intention to temporarily place N-ethyl MDA and N-hydroxy MDA into Schedule I of the CSA. Comments submitted by the Assistant Secretary in response to this notification, including whether there is an exemption or approval in effect for N-ethyl MDA or N-hydroxy MDA under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration by the Administrator before a final order is published. Because the Administrator has found that it is necessary to temporarily place N-ethyl MDA and N-hydroxy MDA into Schedule I to avoid an imminent hazard to the public safety, the final order, if issued, will be effective on the date of publication in the Federal Register. Further, it is the intention of the Administrator to issue such a final order as soon as possible after the expiration of thirty days from the date of publication of this proposal and the date that a notification has been transmitted to the Assistant Secretary for Health.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the temporary placement of N-ethyl MDA and N-hydroxy MDA into Schedule I of the Controlled Substances Act will have no 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 temporary control of substances with no legitimate medical use or manufacture in the United States. It has been determined that the temporary placement of N-ethyl MDA and N-hydroxy MDA in Schedule I of the CSA under the emergency scheduling provision is a statutory exception to the requirements of Executive Order 12291 (46 FR 13193).

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(h) of the CSA [21 U.S.C. 811(h)], 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]

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


2. Paragraphs (g)(4) and (g)(5) are added to § 1308.11 to read as follows:

§ 1308.11 Schedule I.

4. N-ethyl-alpha-methyl-3,4-(methyleneedioxy)phenethylamine (N-ethyl MDA, 3,4-methyleneedioxyethylamphetamine, MDA, MDEA) 7404

5. N-hydroxy-alpha-methyl-3,4-(methyleneedioxy)phenethylamine (N-hydroxy MDA) 7402


John C. Lunn,
Administrator, Drug Enforcement Administration.

[FR Doc. 87-18345 Filed 8-12-87; 8:45 am]
BILLING CODE 4410-09-M

DEPARTMENT OF TREASURY
INTERNAL REVENUE SERVICE

26 CFR Part 301

[LR-34-87]

Abatement of Interest; Definition of Ministerial Act

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue of the Federal Register, the Internal Revenue Service is issuing temporary amendments to the procedure and administration regulations relating to the definition of ministerial act for purposes of abatement of interest. Changes to the law were made by the Tax Reform Act of 1986. The text of those temporary regulations also serves as the comment document for this proposed rulemaking.

DATES: The regulations contained in this document are proposed to be effective for interest accruing with respect to deficiencies and payments for taxable years beginning after December 31, 1978. Written comments and requests for a public hearing must be delivered or mailed by October 13, 1987.

ADDRESS: Send comments and requests for public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-34-87), Washington, DC 20224.


SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (designated by a T following the section citation) in the Rules and Regulations portion of this issue of the Federal Register amend Part 301 of Title 26 of the Code of Federal Regulations. These amendments reflect the provisions of section 6404(e)(1) of the Internal Revenue Code of 1986 as added by section 1563(a) of the Tax Reform Act of 1986 (Pub. L. 99-514, 100 Stat. 2762). For the text of the temporary regulations, see FR Doc. (T.D. 8150) published in the Rules and Regulations portion of this issue of the Federal Register. A general discussion of the temporary regulations is contained in the preamble to the regulations. The final regulations, which this document proposes to base on the temporary regulations, would amend Part 301 of Title 26 of the Code of Federal Regulations.

Special Analyses

The Commissioner of Internal Revenue has determined that this proposed rule is not a major rule as defined in Executive Order 12291. Accordingly, a Regulatory Impact Analysis is not required. Although this document is a notice of proposed rulemaking that solicits public comments, the Internal Revenue Service has concluded that the proposed regulations are interpretative and that the notice and public procedure requirements of 5 U.S.C. 553 do not apply. Accordingly, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act (5 U.S.C. chapter 6).

The collection of information requirements contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget (OMB) for review under section 3504(h) of the Paperwork Reduction Act. Comments on the requirements should be sent to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer...