

§ 5.115 of this chapter for transmittal to the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such a notification unless it has information, from FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

- (a) The recalling firm's distributors have failed to retrieve the recalled infant formula.
- (b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

#### § 7.74 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

- (a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.
- (b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.
- (c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information, demonstrate that the original notifications were not received, or were disregarded, in a significant number of cases.

#### § 7.75 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonably calculated to meet the obligations set forth in this Subpart D. The recall guidelines in Subpart C of Part 7 specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

#### § 7.76 Records retention.

Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

Dated: June 12, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-18441 Filed 8-12-87; 8:45 am]

BILLING CODE 4160-01-M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

#### Schedules of Controlled Substances; Temporary Placement of 2-Amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex) into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of intent.

**SUMMARY:** This notice of intent is issued by the Administrator of the Drug Enforcement Administration (DEA) in order to temporarily place 2-amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex) into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provisions of the CSA. This action is based on a finding that the scheduling of 4-methylaminorex is necessary to avoid an imminent hazard to the public safety. When this action is finalized, the regulatory controls and criminal sanctions of a Schedule I substance under the CSA will be applicable to the manufacture, distribution and possession of 4-methylaminorex.

**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 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 provisions 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).

House Report 98-835 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." 2-Amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex) is a new substance that is clandestinely produced, that is distributed in the illicit traffic, and that produces stimulant effects. This drug, 4-methylaminorex, is certainly the type of drug which Congress intended to be considered for emergency scheduling.

The pharmacological profile of 4-methylaminorex closely resembles that of amphetamine. 4-methylaminorex has been described as "a potent central nervous system stimulant." Its spectrum of pharmacological actions is similar in several respects to that produced by amphetamine. In particular, it has been determined that 4-methylaminorex (5mg/kg i.v. in dogs) produces substantial increases in mean blood pressure by way of sympathomimetic actions. Following doses of 1-2 mg/kg to dogs, 4-methylaminorex produces signs of restlessness, alertness, dilated pupils, and increases in coordinated motor activity. Higher doses elicit stereotyped behavior (repetitive motor movements), followed by seizures, loss of consciousness, respiratory depression and death. Amphetamine produces a similar pattern of behavioral changes in the dog. In other experimental studies, it has been reported that cross tolerance develops between 4-methylaminorex and amphetamine with respect to pressor actions. Furthermore the researchers noted that, like amphetamine, 4-methylaminorex produces these pressor actions indirectly by way of released catecholamines.

Experimental studies of the anorectic actions of 4-methylaminorex have shown that it potently suppresses appetite in rats in a manner similar to amphetamine. It was noted that "Of the 10 drugs tested 4 were very potent: d-amphetamine, methamphetamine, and two oxazolines; . . . McN-742 . . . and

[4-methylaminorex]. . . " Moreover, ". . . at effective dose levels, all of the anorexigens 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 stereotyped motor 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. Commentary 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 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 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 to read as follows:

#### § 1308.11 Schedule I

\* \* \* \* \*

(g) \* \* \*

(6) 2-amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex) . . . 1590

Dated: August 6, 1987.

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