DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of N,N-Dimethylamphetamine into Schedule I

AGENCY: Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place N,N-dimethylamphetamine into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This proposed action by the DEA Administrator is based on data gathered and reviewed by DEA. If finalized, this proposed action would impose the regulatory control mechanisms and criminal sanctions of Schedule I on the manufacture, distribution and possession of this substance.

DATE: Comments must be submitted on or before October 2, 1989.

ADDRESS: Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7193.

SUPPLEMENTARY INFORMATION: On August 3, 1988, the Administrator of DEA issued a final rule in the Federal Register (53 FR 29223) temporarily placing N,N-dimethylamphetamine into Schedule I using the temporary scheduling provisions of the CSA (21 U.S.C. 811(h)).

The final rule which became effective on August 3, 1988, was based on a finding by the Administrator that the emergency scheduling of the above-referenced substance 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)) requires that the emergency scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. Under this provision, the temporary scheduling of N,N-dimethylamphetamine which would expire on August 3, 1989, may be extended to February 3, 1990. This extension is being ordered by the DEA Administrator in a separate action.

DEA has gathered and reviewed the available information regarding the actual abuse and relative abuse potential of N,N-dimethylamphetamine. DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of this substance. By letter, the Administrator has submitted data which DEA has gathered regarding N,N-dimethylamphetamine to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the DEA Administrator also requested a scientific and medical evaluation and a scheduling recommendation for N,N-dimethylamphetamine from the Assistant Secretary for Health.

Chemically, N,N-dimethylamphetamine is N,N-alpha-trimethylbenzeneethanamine or N,N-alpha-trimethylpiperidylcaine. It is a close structural analogue of amphetamine, methamphetamine and N-ethylamphetamine, all psychomotor stimulants with demonstrated high abuse potential.

Data exist which show that N,N-dimethylamphetamine exhibits central nervous system stimulant properties in rodents qualitatively similar to those of methamphetamine. N,N-dimethylamphetamine is less potent than methamphetamine. It has discriminative stimulus properties which enable it to be recognized as cocaine by rodents trained to discriminate cocaine from saline. N,N-dimethylamphetamine is reported to be self-administered by monkeys trained to self-administer cocaine. It is about three times less potent than methamphetamine in its lethal effects and produces neurotoxic effects on dopaminergic nerve terminals. Sufficient data exists to support a finding that N,N-dimethylamphetamine, at the proper dose, is an ampheta mine-like central nervous system stimulant with a high potential for abuse.

Since the summer of 1987 law enforcement agencies have seized at least 20 clandestine laboratories (18 in California, 1 each in Iowa and Georgia) which have produced N,N-dimethylamphetamine. Over 57 kg. of N,N-dimethylamphetamine and sufficient precursors to produce an additional 246 kg. were seized at these laboratories. Forensic laboratories have identified N,N-dimethylamphetamine in over 175 exhibits of drug evidence purchased or seized by law enforcement officials since the middle of 1987. It has been identified in evidence submissions from California, Iowa, Alabama, Missouri, Colorado, Utah, Arizona, Kansas, Florida and Idaho.

There have been no reports of deaths or injuries specifically attributed to the abuse of N,N-dimethylamphetamine, to date. It is likely that individuals abusing this substance do not know that they are taking N,N-dimethylamphetamine but think that they are taking methamphetamine. N,N-dimethylamphetamine has been sold and trafficked as methamphetamine or speed. Thus, any injuries or adverse effects associated with the use of N,N-dimethylamphetamine are likely to be
reported as methamphetamine or speed related incidents. N,N-
dimethylamphetamine’s pharmacological and toxicological profiles strongly suggest that abuse of this substance will lead to health and safety risks similar to those produced by amphetamine and methamphetamine. Since N,N-dimethylamphetamine is only manufactured in clandestine laboratories, there are additional risks associated with its abuse. The health and safety hazards associated with the abuse of amphetamine and methamphetamine are well established. According to national estimates of emergency room mentions from the Drug Abuse Warning Network (DAWN), there were over 40,000 emergency room mentions associated with the use of methamphetamine and speed during the period 1986–1988. Abuse of N,N-
dimethylamphetamine is likely to cause similar types of emergency room episodes and may already have contributed to those attributed to methamphetamine or speed.

There are no commercial manufacturers or suppliers of N,N-
dimethylamphetamine. The Food and Drug Administration has notified DEA that there are no exemptions or approvals in effect under section 505 of the Federal Food, Drug and Cosmetic Act for N,N-dimethylamphetamine. A search of the scientific and medical literature revealed no indications of current medical use of N,N-dimethylamphetamine.

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 that N,N-dimethylamphetamine 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.

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 a 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, 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 the hearing.

Pursuant to Title 5, United States Code, section 805(b), the Administrator certifies that the proposed placement of N,N-dimethylamphetamine 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 substance proposed for control in this notice has 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 N,N-dimethylamphetamine 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. 550 and 552 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13103).

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


Under the authority vested in the Attorney General by section 301(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]

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

2. Section 1308.11 is amended by adding paragraph (f)(3) to read as follows:

1308.11 Schedule I.

(f)

(3) N,N-dimethylamphetamine (also known as N,N-trimethylbenzeneethanamine; N,N,alpha-trimethylphenethylamine), 1490.

3. Section 1308.11 is further amended by removing and reserving paragraph (g)(3).

Date: July 27, 1989.

John C. Lawren, Administrator, Drug Enforcement Administration.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Chapter I


RIN 2501–AA85

Advance Notice of Intention To Develop and Publish Fair Housing Accessibility Guidelines

AGENCY: Department of Housing and Urban Development, Office of the Secretary.

ACTION: Advance Notice of Development of Fair Housing Accessibility Guidelines.

SUMMARY: In the final rule implementing the Fair Housing Amendments Act of 1988 (54 FR 3232, January 23, 1989), HUD announced its intention to publish “accessibility guidelines” to provide additional guidance to designers and developers of residential structures, and to the public concerning the requirements of the amended Fair Housing Act as the Act relates to accessibility of dwellings for use by handicapped persons. This document solicits early comment from the public concerning the content of the accessibility guidelines, and outlines the procedures that HUD intends to follow in developing the guidelines.