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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[MDMA, Docket No. 84-48]

Schedules of Controlled Substances Proposed Placement of 3,4-Methylenedioxymethamphetamine into Schedule I Hearing

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of hearing on proposed rulemaking.

SUMMARY: This is notice of a hearing with respect to a proposed rulemaking which would place the substance 3, 4 methylenedioxymethamphetamine in Schedule I of the schedules established by the Controlled Substances Act (21 U.S.C. 801, *et seq.*). Notice of the proposed rulemaking was published in the Federal Register on July 27, 1984 at 49 FR 30210.

DATES: Interested persons desiring to participate in the hearing must give written notice of such desire as set out below within thirty days after the publication of this notice in the Federal Register. The hearing will commence on Friday, February 1, 1985 at 10:00 am. at the place specified below.

ADDRESS: Notices of desire to participate in the hearing are to be sent to: Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, 1405 I Street, NW., Room 221, Washington, D.C. 20537. Hearing location: Room 1213, Drug Enforcement Administration, 1405 I St. NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Ms. Melanie Baltz, Hearing Clerk, Drug Enforcement Administration, Washington, D.C. 20537. Telephone (202) 633-1350.

SUPPLEMENTARY INFORMATION: On July 27, 1984, a Notice of Proposed Rulemaking was published in the **Federal Register** (49 FR 30210) giving notice that the Administrator of the Drug Enforcement Administration (DEA) proposed to place the substance 3, 4 methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801, *et seq.*). This proposed action was based on the investigations and review of information by the DAE and on the scientific and medical evaluation and recommendations of the Secretary of the Department of Health and Human Services. It was pointed out that if this scheduling action were effected by rule, MDMA would be subject to the regulatory control mechanisms and criminal sanctions imposed for the manufacture, distribution and possession of any Sechedule I substance.

Interested persons were invited to submit comments, objections and requests for hearing on or before August 27, 1984.

Sixteen comments were received in response to the notice, seven of which requested a hearing.

These comments and requests for hearing came from a variety of physicians, counselors, instructors and others in medical or health care related professions, as well as from former subjects in experimental studies on the use and effects of MDMA.

All of the persons or entities that submitted comments and/or requests for hearing opposed the proposed placement of the substance into Schedule I. DEA was urged by many to delay this proposed action until after additional research could be completed. Most felt that preliminary usage and studies had shown MDMA to have enormous potential value as an adjunct to psychotherapy, as an analgesic and in the treatment of problems of drug addiction.

Most of the writers vigorously objected to one of DEA's stated bases for the proposed scheduling, that being the finding that MDMA has no currently accepted medical use in treatment in the United States. Some of the responding physicians and psychiatrists reported having used it in their practices with what they felt were positive results. Many disputed the Agency's concept of "currently accepted medical use."

Several stated that the highly restrictive scheduling which is contemplated would effectively end presently ongoing research and scientific experimentation. Some felt that the costs involved in obtaining an Investigational New Drug permit from the Food and Drug Administration to conduct research on a Schedule I drug would be prohibitive to any individual researcher. Another stated that it would be unrealistic to believe that any pharmaceutical company would develop the drug.

Several felt that DEA did not have sufficient information regarding the present and potential uses of this drug and urged that the proposed scheduling action be delayed until DEA had the opportunity to consider additional studies and reports of experimentation and research.

A few of the writers questioned the finding of high abuse potential as a basis for placement into Schedule I. While most of them acknowledged that there is some evidence of unsupervised use of MDMA, they felt the reported instances of abuse were not sufficient in number to warrant the conclusion that it is a substance with a high potential for abuse. Others stated that a potential for abuse had not led DEA to place certain other substances into Schedule I. A few felt that there may be some confusion of this substance with another which is know to be abused, MDA, and that the differences between the two should be closely examined. A number of the writers were not opposed to the placement of MDMA into one of the schedules under the CSA but felt that Schedule I was not appropriate for this substance.

On November 13, 1984, the Deputy Administrator of DEA referred the matter to the Agency's Administrative Law Judge, Francis L. Young, to conduct a hearing for the purpose of receiving factual evidence and expert opinion regarding the proposed scheduling of MDMA. Judge Young was directed to report to the Administrator of DEA his findings and recommended conclusions on the appropriate scheduling action to be taken with respect to MDMA and on the question of whether a drug which has potential for abuse but no currently accepted medical use in treatment can lawfully be placed in any schedule other than Schedule I.

Accordingly, notice is hereby given that the hearing in connection with this proposed scheduling will commence on Friday, February 1, 1985 at 10:00 a.m. in Room 1213, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C., and will continue until all interested persons desiring to participate, who have given notice of such desire as prescribed below, have been heard. The hearing will be conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and 21 CFR 1308.41.

Every interested person desiring to participate in the hearing, including DEA Agency counsel, on behalf of the Agency staff, shall file a written notice of intention to participate, in duplicate, with the Hearing Clerk, Office of the Administrative Law Judge, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537, within thirty days after the date of publication of this notice of hearing in the **Federal Register**. Each notice of intention to participate must be in the

form prescribed in 21 CFR 1316.48. No person who has previously filed a request for hearing need now file a notice of intention to participate.

The proceedings at the first hearing session, on February 1, 1985, will be limited to a preliminary discussion to identify parties and issues and positions, and to determine procedures and set dates and locations for further proceedings.

Dated: December 21, 1984.

Francis M. Mullen, Jr.,

Administrator, Drug Enforcement Administration.

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