PETITION FOR REVIEW OF
DRUG ENFORCEMENT ADMINISTRATION,
DEPARTMENT OF JUSTICE, FINAL ORDER

United States Court of Appeals
for the First Circuit

Lester Grinspoon, M.D.,	]
	]
Petitioner,	]
	]
v.	]
	]
Drug Enforcement Administration,	]
	]
	]
Respondent.	]

PETITION FOR REVIEW

Lester Grinspoon, M.D., hereby petitions the court for review of the final order of the Administrator of the Drug Enforcement Administration, United States Department of Justice, placing the substance 3,4-Methylenedioxymethamphetamine (MDMA) in Schedule I of the Controlled Substances Act. The order is found at 51 Federal Register 36552 and was entered on October 14, 1986. Appellate review is sought pursuant to 21 U.S.C. § 877.

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Pro Se.

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CERTIFICATE OF SERVICE

On November 5, 1986, the undersigned served by hand one copy of the foregoing Petition for Review on the United States Attorney for the District of Massachusetts, 1107 J. W. McCormick, Post Office and Courthouse, Boston, Massachusetts 02101, one copy by mail to the Honorable Edwin Meese, III, Attorney General, Department of Justice, and one copy by mail to Charlotte A. Johnson, Attorney, Office of Chief Counsel, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537.

Lester Grinspoon MD

Lester Grinspoon, M.D.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. 84-48]

Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule placing the drug 3,4-methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act (CSA). MDMA will be classified as a hallucinogenic controlled substance. This action was initiated following the Drug Enforcement Administration's (DEA) review of the abuse and illicit trafficking of MDMA. The Assistant Secretary for Health, Department of Health and Human Services (DHHS), supported DEA's position that the substance be placed into Schedule I of the CSA. The effect of this rule is to impose the criminal sanctions and regulatory controls of Schedule I on the manufacture, distribution and possession of MDMA.

DATE: The effective date of this order is November 13, 1986.

SUPPLEMENTARY INFORMATION: On March 13, 1984, the Administrator of the Drug Enforcement Administration submitted information relevant to the abuse potential and illicit trafficking of 3,4-methylenedioxymethamphetamine (MDMA) to the Assistant Secretary for Health, Department of Health and Human Services. Briefly, the information documented that 3,4-methylenedioxymethamphetamine, trafficked on the street as MDMA or "Ecstasy": (1) Is an analog of the Schedule I controlled substance, 3,4-methylenedioxyamphetamine (MDA), (2) has no legitimate medical use or manufacturer in the United States, (3) has been clandestinely synthesized and encountered in the illicit drug traffic, (4) produces stimulant and psychotomimetic effects in humans similar to those produced by MDA, and (5) has been associated with medical emergencies as reported by the Drug Abuse Warning Network (DAWN).

In accordance with the provisions of 21 U.S.C. 811(b), the DEA Administrator requested a scientific and medical evaluation of the relevant information and a scheduling recommendation for 3,4-methylenedioxymethamphetamine from the Assistant Secretary for Health. On June 6, 1984, the Administrator of the Drug Enforcement Administration received a letter from the Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, stating that 3,4-methylenedioxymethamphetamine (MDMA) has a high potential for abuse and presents a significant risk to the public health, and recommending that it should be placed into Schedule I of the Controlled Substances Act.

On July 27, 1984, the Administrator of the Drug Enforcement Administration, based upon a review of investigations by the Drug Enforcement Administration and relying on the scientific and medical evaluation and the recommendation of the Secretary of Health and Human Services in accordance with 21 U.S.C. 811(c), issued a Notice of Proposed Rulemaking to amend § 1308.11 of Title 21 of the Code of Federal Regulations by placing MDMA in Schedule I as a hallucinogenic controlled substance. 49 FR 30210. MDMA was not, at that time, a controlled substance.

The Notice of Proposed Rulemaking allowed sixty days for interested parties to submit comments, objections or requests for a hearing.

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 of experimental studies involving 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 had 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 was 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 human research with 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 believed that there may be some confusion of this substance with another which is known 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 believed that Schedule I was not the appropriate schedule.

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. The proceeding was

conducted "on the record after opportunity for a hearing" as required by 21 U.S.C. 811(a) and in accordance with the Administrative Procedures Act. 5 U.S.C. 556 and 557.

The authority and criteria for classifying substances into schedules under the Controlled Substances Act is found in 21 U.S.C. 811. This section of the Act sets forth the standards by which the Attorney General and the Secretary of the Department of Health and Human Services are to evaluate substances for control, decontrol or rescheduling. The Secretary of DHHS is charged with making scientific and medical evaluations, including scientific evidence of a substance's pharmacological effects, the state of current scientific knowledge regarding the drug or other substance, what risk there is to the public health, the psychic or physiological dependence liability of the drug, and whether the substance is an immediate precursor of a substance already controlled under the Act. The Attorney General must consider those items presented by the Secretary, and in addition must consider the actual or relative potential for abuse of the substance, the history and current pattern of abuse, and the scope, duration and significance of abuse. MDMA was not a controlled substance. It had not been approved for marketing in the United States by the Food and Drug Administration.

Following prehearing procedures, there remained five parties, including the Agency, participating in the hearing process. The participants were the Agency staff; George Greer, M.D., Lester Grinspoon, M.D., Thomas B. Roberts, Ph.D. and James Bakalar; McNeilab, Inc. and Hoffmann-LaRoche, Inc.; Lyn B. Ehrnstein, Esq.; and David E. Joranson.

Five hearing sessions, compromising nine hearing days, beginning on February 1, 1985, and culminating on November 1, 1985, were conducted before the Administrative Law Judge; the testimony of 33 witnesses was heard and 95 exhibits were received into evidence.

At a preliminary prehearing conference on February 1, 1985, the Administrative Law Judge determined that one of the issues identified presented a purely legal question which might be decided without the need of any evidence and in advance of the other issues in the case. The issue was:

> Assuming that a substance has a potential for abuse and has no currently accepted medical use in treatment in the United States, can the substance be placed in any schedule other than Schedule I?

After studying briefs submitted by the participants, the judge issued a recommended decision on that issue, dated June 1, 1985. He recommended, first, that the language of the Act was such that a substance with a potential for abuse less than a "high" potential, and having no currently accepted medical use in treatment, cannot be placed in *any* of the five schedules. Alternatively, the judge recommended that such a substance should be placed in either Schedule III, IV or V, depending upon its degree of potential for abuse. In a letter to the Administrative Law Judge, dated October 7, 1985, the Administrator advised that he had decided not to issue a final agency ruling on that initial ruling until he had received the entire record at the conclusion of the case.

During the course of the hearing, on July 1, 1985, in an independent action by the Administrator of DEA, MDMA was placed into Schedule I of the CSA pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h)(1), following a determination by the Administrator that this action was necessary to avoid an imminent hazard to the public safety. 50 FR 23118.

On May 22, 1986, the judge issued his Opinion and Recommendations regarding the scheduling of MDMA. The judge recommended that MDMA be placed in Schedule III of the CSA. He reached this conclusion after finding that MDMA has a currently accepted medical use in treatment in the United States, that MDMA does not lack accepted safety for use under medical supervision, and that it has less than a high potential for abuse.

Concerning the issue of "accepted medical use", the judge refused to accept the Agency's argument that if a drug or other substance being considered for scheduling is not approved for marketing in the United States under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.*, then it has no "accepted medical use." He concluded that "accepted medical use" is determined by what is actually going on within the health care community. Using this standard, the judge found that, based on the testimony of a relatively small group of psychiatrists and psychotherapists who have used MDMA in treatment of humans and found it to have certain desirable effects, MDMA had an accepted medical use in treatment in the United States. With regard to the issue of "accepted safety for use", the judge concluded that MDMA does not lack accepted safety for use because the same group of psychiatrists and psychotherapists mentioned above have administered MDMA to willing subjects in uncontrolled, nonresearch studies and would not have done so if such a procedure was unsafe. Finally, with regard to the issue of abuse potential, the judge found that the Agency did not meet its burden in establishing that MDMA has a high potential for abuse.

On June 11, 13 and 24, 1986, respectively, David Joranson, counsel for DEA, and two counsel for Hoffman-LaRoche, Inc. filed exceptions to the Opinion and Recommendations of the Administrative Law Judge. In reply, Grinspoon, Greer, et al. filed a Response to the exceptions on June 27, 1986, and also moved to strike portions of the Government's exceptions alleging the Government's use of the term "bias" with respect to the Administrative Law Judge's opinion was prejudicial. Additionally, they filed a motion for the opportunity for oral presentation to the Administrator. On July 24, 1986, the Administrative Law Judge certified and transmitted the record to the Administrator of DEA. The record included the Opinion and Recommendations of the Administrative Law Judge, the findings of fact and conclusions of law proposed by all parties, the exceptions filed by the parties, the response to those exceptions and motions filed by Grinspoon, Greer, et al., all of the exhibits and affidavits, and all of the transcripts of the hearing sessions.

On August 11, 1986, the Administrator granted the motion to strike portions of the Government exceptions, filed by Grinspoon, Greer, et al., and ordered the Government to refile its exceptions without use of the term "bias" with respect to the Administrative Law Judge's opinion. The Administrator also denied the motion for the opportunity for oral presentation to him filed by Grinspoon, Greer, et al. On August 21, 1986, the Government refiled its exceptions.

The Administrator has carefully reviewed the entire record in this matter and hereby issues this final rule as prescribed by 21 CFR 1316.67. The Administrator declines to accept the recommendations of the Administrative Law Judge and finds that there is substantial evidence in the record to support the decision that MDMA be placed in Schedule I as a hallucinogenic controlled substance. The Administrator finds, consistent with his decision that:

1. A new drug application (NDA) must be approved by the Food and Drug Administration prior to the marketing of a new drug in the United States. The NDA generally consists of data collected during the pre-clinical and

investigational new drug (IND) processes. The data in the NDA must include toxicity studies, carcinogenic studies in animals, reproductive studies in animals, side effects in humans, and sufficient results from controlled studies to show that the drug is safe and effective in humans for the therapeutic purpose advanced by the sponsor. New drug applications have been required prior to marketing since 1938.

2. Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) outlines the new drug application process. The statute provides at section 505(a) that, "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug." The statute further provides that a person filing an application for a new drug must include "full reports of investigations which have been made to show whether such drug is effective in use." (Section 505(b)).

3. Section 505(i) of the Federal Food, Drug and Cosmetic Act allows the Secretary of the Department of Health and Human Services to exempt from the application of the requirements of approval of an NDA prior to marketing "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." The section goes further to delineate certain requirements which must be met by these experts.

4. Before an unmarketed new drug may be tested on humans, an investigational new drug exemption (IND) must be applied for and approved by the Food and Drug Administration. This approval is required for both pharmaceutical companies who ultimately intend to market the drug and physicians or researchers who are interested in using the drug solely as a research tool. These IND requirements are necessary to comply with provisions of the Federal Food, Drug and Cosmetic Act, its implementing regulations, and the basic ethical principles regarding the conduct of research in human subjects. These standards were established as a result of the Nuremberg trials in the Nuremberg Code, and later reiterated in the Helsinki Agreement of 1975.

5. In order for an IND to be initially approved by the Food and Drug Administration, the sponsor must provide information regarding the composition, source and manufacturing safeguards of the substance; animal toxicity studies showing that the substance will not produce irreversible damage at the doses used, and that there will be no unreasonable hazard in initiating studies in humans; a detailed research protocol of the proposed clinical investigation, information regarding the training and experiences of the investigators; and an agreement to notify the FDA if any adverse effects arise during animal or human tests.

6. On June 29, 1982, the Food and Drug Administration (FDA) published in the **Federal Register** "Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and its Components and Notice of Public Hearing" (47 FR 28141) in which the Commissioner of Food and Drugs stated:

> FDA interprets the term "accepted medical use" to mean lawfully marketed under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.* . . . A drug may be marketed lawfully under the Federal Food, Drug, and Cosmetic Act after approval of a new drug application (NDA) for that drug. There are, theoretically other ways in which a drug could be marketed legally. The drug could satisfy either the requirements for exemption from the definition of "new drug" in 21 U.S.C. 321(p) or the requirements for a "grandfather clause" from the new drug approval provision. (47 FR 28150)

The Commissioner of FDA continued at page 28151 by saying:

> The mechanism set up by Congress for lawful marketing of a new drug requires submission of an NDA to FDA and FDA approval of that application before marketing. Before FDA can approve an NDA, however, the drug sponsor must submit data from an extensive battery of experimental testing on both animals and humans to establish the drug's safety and effectiveness for its proposed uses. In addition, the sponsor must submit data and manufacturing controls, demonstrating that standards of identity, strength, quality, and purity will be met.

and concludes by saying:

> Thus, the lack of an approved NDA for a drug substance leads FDA to find that a substance lacks an "accepted medical use in treatment" for two reasons. First, if use of the drug is unlawful whenever interstate commerce is involved, medical use of the drug cannot be classified as accepted. Second, in the absence of the data necessary for approval of an NDA, the agency has no basis for concluding that medical use of the drug in treatment can be considered acceptable by medical standards.

7. In March 1984, there was no reference in the files of the Food and Drug Administration to the substance 3,4-methylenedioxymethamphetamine (MDMA); there were no investigational new drug applications or approvals; there were no new drug applications or approvals; and there was no indication that any sponsor had informed FDA that such submission would be forthcoming. It was also determined at that time that MDMA was not a grandfathered drug and that it had not been approved for over-the-counter use.

8. On June 6, 1984, the Acting Assistant Secretary for Health sent a letter to the Administrator of DEA which stated that a scientific and medical evaluation of MDMA had been completed. He further recommended that MDMA be placed in Schedule I of the CSA. Attached to the letter was an "Evaluation of the DEA Recommendation to Control MDMA in Schedule I of the CSA." In this evaluation, the Acting Assistant Secretary for Health stated that he concurred with DEA's recommendation of Schedule I for MDMA. The evaluation included a list of the findings required to be made for Schedule I substances, which included the finding that the drug has no currently accepted medical use in treatment in the United States. The evaluation of the Acting Assistant Secretary for Health stated that he concurred with this finding.

9. The phrase "currently accepted medical use in treatment in the United States" as used in 21 U.S.C. 812, means that the Federal Food and Drug Administration has determined that a drug or other substance can be lawfully marketed in the United States.

10. Since it has been determined that MDMA may not be lawfully marketed in the United States, the Administrator finds that MDMA has no currently accepted medical use in treatment in the United States.

11. The Food and Drug Administration evaluates the safety of a substance throughout the investigational new drug (IND) process, and as part of the new drug application (NDA) approval status.

12. The sponsor of an IND is responsible for supplying FDA with the results of preclinical (animal) studies which show that there will be no unreasonable hazards in initiating studies in humans with the drug. At a minimum, these initial studies must include a pharmacological profile of the drug, acute toxicity studies in several species, and short-term toxicity studies ranging from two weeks to three months.

13. A substance is not deemed "safe" by the Food and Drug Administration unless FDA, after a review of scientific data submitted during the IND process, has determined that the substance can be given to humans without irreversible harm.

14. No scientific data was supplied to the Food and Drug Administration which would demonstrate the safety of MDMA, and a review of the scientific literature led an FDA official who

evaluates the safety and efficacy of drugs to conclude that the literature does not support the safety of MDMA for use under medical supervision.

15. On June 29, 1982, the Food and Drug Administration (FDA) published in the **Federal Register** "Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing" (47 FR 28141) in which the Commissioner of Food and Drugs stated:

> The Federal Food, Drug and Cosmetic Act provides that FDA approve an NDA upon scientific evidence that the drug has been shown to be safe and effective for its proposed uses. See 21 U.S.C. 355(d). Because no drug is ever completely safe in the absolute sense, FDA considers "safe" to mean (in the context of a human drug) that the therapeutic benefits to be derived from the drug outweigh its known and potential risks under the conditions of use in labeling . . .
>
> Another factor considered by FDA in assessing the drug's safety is the proposed labeling which is approved at the time of approval for marketing. A drug might be considered safe for some proposed uses but not others. Only those proposed uses where the benefit/risk ratio is favorable will be included in the indications section of the drug's labeling. . .
>
> But it is only upon approval for marketing, when there has been an institutional decision based upon scientific judgement by the regulatory agency charged with the responsibility of evaluating the safety and efficacy of new drugs, that a drug becomes "accepted" as safe under medical supervision. (47 FR 28152)

16. There is no legitimate commercial manufacturer of MDMA in the United States. Further, the MDMA which has been used by psychiatrists is not labeled with safety or therapeutic considerations.

17. The phrase "accepted safety for use . . . under medical supervision" as used in 21 U.S.C. 812(b) means that a drug has been evaluated for safety by the Food and Drug Administration and approved for marketing in the United States.

18. Accordingly, the Administrator finds that since MDMA has not been evaluated for safety by the Food and Drug Administration, and has not been approved for marketing in the United States, it does not possess "accepted safety for use . . . under medical supervision."

19. MDMA, or 3,4-methylenedioxymethamphetamine, belongs to a class of compounds which can be termed phenethylamines or, narrowly defined, phenylisopropylamines or amphetamines.

20. MDA, or 3,4-methylenedioxyamphetamine, amphetamine and methamphetamine are also phenylisopropylamines.

21. MDA, or 3,4-methylenedioxyamphetamine, is formed by the addition of a methylenedioxy group to amphetamine.

22. MDMA is formed by the addition of a methylenedioxy group to methamphetamine.

23. The addition of a methylenedioxy group to the aromatic nucleus of amphetamines produces compounds with psychotomimetic activity.

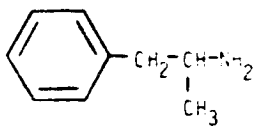
24. Psychotomimetic is a term used to describe a large class of compounds which change or modify a person's mood or mental state. The terms psychotomimetic and hallucinogenic are commonly used interchangeably.

25. MDMA is the N-methyl analog of MDA. This means that MDMA differs structurally from MDA the same way that methamphetamine differs from amphetamine, by the addition of an N-methyl group.

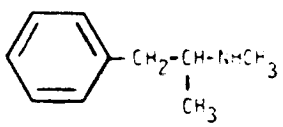
26. N-methylation of MDA yields MDMA which retains the psychotomimetic properties of MDA.

27. N-methylation of amphetamine yields methamphetamine which retains the central nervous system activity of amphetamine.

28. The difference in structure between amphetamine and methamphetamine is illustrated by the following diagram:

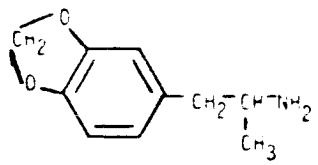


amphetamine

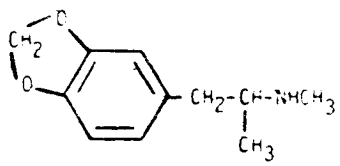


methamphetamine

29. The difference in structure between MDA and MDMA is illustrated by the following diagram:



MDA



MDMA

30. MDMA produces pharmacological effects in common with both central nervous system stimulants like amphetamine, and hallucinogens like MDA in animals.

31. MDA and MDMA both produce central nervous system stimulation as measured by increased locomotor activity in mice.

32. Tests conducted by Braun, Shulgin and Braun show that at an oral dose of 20 mg./kg. in mice, MDA produced a significant increase in locomotor activity. At the same dose, MDMA produced approximately three times the motor activity of MDA during the first three hours after application. They concluded that MDA, MDMA and N-ethyl MDA caused the greatest stimulation and that this is consistent with results of tests in mice of amphetamine compounds with no ring substitution (e.g., amphetamine and methamphetamine). Braun, Shulgin and Braun further conclude that "compounds which cause a sharp increase in motor activity in animals generally prove to have a pronounced central nervous system effect in man."

33. A study conducted by Intox Laboratories reported significantly reduced body weights at 7 and 14 days following initiation of MDMA dosing in rats.

34. The Intox Laboratory study also reported that rats who had been administered MDMA showed hyperactivity, excitability, aggressive behavior and stereotypic behavior.

35. Studies conducted by Dr. Harris at the Medical College of Virginia compared the locomotor activity in mice using d-amphetamine and MDMA. Dr. Harris found that MDMA produces slightly less central nervous system stimulation than amphetamine at peak activity which is 1½ hours after administration. However, at 5–15 minutes and 2–3 hours after administration, the maximum stimulating effect of MDMA is substantially greater than that produced by d-amphetamine.

36. MDA and MDMA produce similar centrally mediated analgesic effects in mice as determined by the hot-plate test, the tail-flick test and the stretch test. The tail-flick test and hot-plate test showed that MDMA produces an increased analgesic effect over that produced by MDA.

37. MDA and MDMA both produce an increase in body temperature when administered to rabbits at similar potencies. Hyperthermia in rabbits is reported to be a measure of central nervous system activity. Dr. Shulgin notes that there is a reasonably good parallel between the hyperthermia response in rabbits and some of the effects of LSD, and that these parallel quite closely the psychopharmacological potency in humans. He believes that it is probably the best animal test at present for estimating psychotomimetic potency.

38. Both MDA and MDMA are potent releasers of serotonin or 5-hydroxytryptamine, a neurotransmitter which has a widely accepted role in the activity of hallucinogens.

39. In mice, dogs and monkeys, MDA and MDMA produce the same spectrum of pharmacological effects when observed during toxicity studies. These effects include hyperactivity, excitability, emesis, apprehension or fright, aggressive behavior, bizarre body attitudes, apparent hallucinations, dyspnea and hyperpnea. Motor activity effects include convulsions, muscular rigidity and tremors and the autonomic activity includes mydriasis, piloerection, salivation and vascular flushing. These effects are part of what is described as the classical pharmacological response of the dog to intravenous mescaline.

40. The lethality of a compound is reported as an LD_{50}, which is the dose of a drug which will kill 50% of the animals treated with that dose.

41. The LD_{50}'s for mescaline, MDA and MDMA were determined by intravenous or intraperitoneal administration in five species of animals. MDMA had LD_{50}'s between 2 and 6 times less than those of mescaline and between 1.5 and 3 times more than MDA. This means that MDMA is more lethal than mescaline but less lethal than MDA.

42. Intraperitoneal LD_{50}'s for MDA and MDMA were determined in mice by Dr. Davis. The LD_{50}'s of MDMA and MDA were substantially the same with the LD_{50} for MDA equalling 90.0 mg./kg. and the LD_{50} for MDMA equalling 106.5 mg./kg. Dr. Hardman found the LD_{50} of MDA to be 92 mg./kg. Davis also found that both MDA and MDMA showed the amphetamine-like property of increased lethality under aggregated housing conditions compared to isolated housing conditions.

43. In the study conducted by Intox Laboratories the oral LD_{50} for MDMA in rats was estimated to be approximately 325 mg./kg. No oral value was reported for MDA, but based on the data from Intox Laboratories, Dr. Hardman estimated it to be approximately 150 mg./kg.

44. MDMA, MDA, amphetamine and methamphetamine produce neurotoxic effects when administered to animals. MDMA and MDA are neurotoxic in rats at doses which are very low compared to the neurotoxic doses of amphetamine and methamphetamine.

45. MDMA and MDA both produce long term reduction in serotonin levels and serotonin uptake sites in the rat brain. These neurochemical depletions are due to the destruction of serotonin nerve terminals as determined by visual staining techniques.

46. In humans, serotonin nerve terminals are believed to play a major role in mood, emotion, pain perception, sleep and affect the regulation of aggressive and sexual behavior.

47. Although single injections of MDMA may be slightly less neurotoxic than MDA, MDMA, used chronically, appears to be more neurotoxic than MDA.

48. The neurotoxicity of amphetamine and methamphetamine has been determined in rats, guinea pigs and monkeys.

49. MDMA and MDA may produce the same neurotoxic effects to serotonergic nerves in humans.

50. Drug discrimination studies in animals allow one to determine if a particular dose of a test substance produces effects which are recognized as the same as those produced by a particular dose of another substance. It is believed that the effects recognized by the animals in these studies are central nervous system effects and hence this paradigm is very useful in characterizing centrally acting compounds.

51. If a test drug in animal drug discrimination studies elicits similar responses to a standard drug, both the test drug and the standard drug are assumed to have similar abuse potential if the reinforcing properties and adverse effects of the standard and test drugs are similar.

52. In drug discrimination paradigms, complete generalization indicates that the test compound is similar enough for the animal to recognize it as the training drug by responding on the appropriate drug lever at least 80% of the time. No generalization indicates that the test compound is unlike the training compound so that a low number of responses will be made on the drug lever. Partial generalization indicates that there may be pharmacological effects common to both test and training drug, but that some doses of the test and training drug are similar and that, at the tested doses, another type of pharmacological effect may predominate.

53. MDMA shares discriminative stimulus properties in common with amphetamine and MDA in drug discrimination studies in rats.

54. In a drug discrimination test described by Dr. Glennon, rats trained to recognize amphetamine also recognized MDA and MDMA. MDMA was slightly more potent than MDA in being recognized as amphetamine. Other compounds which generalized to the amphetamine stimulus included methamphetamine, cocaine and para-methoxyamphetamine.

55. Rats trained to recognize MDA recognized MDMA in drug discrimination studies conducted by Dr. Glennon.

56. MDA completely generalized (83% correct response) in rats trained to recognize 4-methyl-2,5-dimethoxyamphetamine (DOM), a substance with known hallucinogenic properties, but only within a very narrow dosage range.

57. MDMA showed partial generalization (52% correct response) in rats trained to recognize DOM, at a specific dose.

58. A standard abuse liability test for assessing the reinforcing properties of a drug is the substitution procedure. It is the most common and reliable method for determining whether a drug will be self-administered. In this procedure, new drugs are tested to determine whether or not they will maintain the responding of animals trained to press a lever for intravenous delivery of a known drug reinforcer.

59. In tests conducted with rhesus monkeys and baboons trained to self-administer cocaine, the monkeys and baboons continued to self-administer

when MDMA was substituted for cocaine.

60. Of three baboons that self-administered MDMA, two exhibited unusual behavior. One appeared to track nonexistent objects, and another exhibited aggressive behavior. Levels of self-administration in all three baboons tested were in the same range as those of MDA and slightly less than those of cocaine, amphetamine and phencyclidine.

61. Drs. Shulgin and Nichols first reported that MDMA produces psychotomimetic effects in man in 1976. These effects are described as intoxication, altered state of consciousness and sympathomimetic stimulation.

62. The racemic mixture of MDMA, which is a combination of both optical isomers, is the drug which is clandestinely produced, found in the illicit traffic and used by psychiatrists.

63. In a 1978 publication, Dr. Shulgin reported that racemic MDMA produced a high level of intoxication in man at doses of 100-160 mg. Color enhancement as well as physical symptoms of mydriasis and jaw clenching were noted. MDMA was described as maintaining the same potency as MDA but exhibiting subtle differences in the qualitative nature of the intoxication.

64. In a 1980 publication, Dr. Shulgin and others describe MDA and MDMA as having both stimulant and psychotomimetic properties in humans. Racemic MDA and MDMA were administered orally to five volunteers at doses up to 160 mg. The effective dose of MDA was 60-120 mg., while that of MDMA was 100-160 mg. Dr. Shulgin and others noted a drive increasing effect, a change in expression and an apparent increase in the acoustic, visual and tactile sensory perceptions, as well as a tension-decreasing, mood-lightening effect in the human subjects. Mydriasis and sympathomimetic stimulation were noted during the entire period. The effects of MDA and MDMA were apparent beginning 30 minutes after ingestion and continuing for approximately four hours, except that a noted increase in motor activity lasted several more hours. Shulgin concluded that the "psychopharmacological profiles of MDA and MDMA are very similar."

65. The Haight-Ashbury Free Medical Clinic in San Francisco treats approximately three to four clients per month who seek help for problems arising from the use of MDMA, MMDA or MDA. Individuals seen at the clinic have taken up to 15 doses of MDMA in one day, likely to be 50 to 150 mg. each. The use of higher doses produces rapid pulse and heartbeat, severe anxiety, paranoia, fear, insomnia, psychological craving for the drug and depression.

66. Dr. Siegel, in his interviews with 171 individuals who claim to have used MDMA in the Los Angeles, California area, reports that effects of MDMA at low doses approximate those of low doses of mescaline, and that effects reported for higher doses of MDMA (200 mg.) produce effects similar to those of LSD. The high dose effects include hallucinations, either visual, tactile, olfactory or auditory.

67. Low to moderate doses of MDMA have been given to individuals by psychiatrists. Some of these psychiatrists claimed that the MDMA administered was made by them under the supervision of Dr. Shulgin in his laboratory in California.

68. MDMA has been reported, by the psychiatrists administering to themselves and others, and by other individuals to produce the following physical effects: jaw clenching, anorexia, insomnia, flight of ideas, increased heart and pulse rate, mydriasis, nystagmus, blurred vision, enhanced deep tendon reflexes, fatigue after use, ataxia, nausea, vomitting, headache and shakiness.

69. Psychological effects reported for low to moderate doses of MDMA include euphoria, sense of well-being, increases in physical and emotional energy, focus on the here and now, impaired judgment, heightened sensual awareness, anxiety, brief short-term memory loss, distortion in depth perception, brief hallucination, visual illusion, nervousness, mild depression, mental fatigue, confusion and altered state of consciousness.

70. MDMA was first identified by a DEA laboratory in 1972. Between 1972 and April 1985, DEA laboratories identified 41 exhibits of MDMA consisting of over 60,000 dosage units.

71. Since its temporary placement into Schedule I on July 1, 1985, MDMA has been identified in at least 14 exhibits submitted to DEA laboratories from Texas alone. These 14 exhibits contained over 35,000 dosage units of MDMA.

72. MDMA is available in tablets, capsules and powders with recent analyses indicating approximately 110 mg. of racemic MDMA per dosage unit. MDMA has been encountered in many sections of the United States and other countries.

73. Since 1978, non-Federal forensic laboratories have reported over 41 exhibits of MDMA to DEA.

74. Pharm Chem Laboratories and Toxicology Testing Service are laboratories which provide confidential analysis of drug samples voluntarily submitted to them. Their data provides information on the availability of street drugs and trends in drug abuse patterns.

75. Between 1973 and 1983, Pharm Chem Laboratories reported MDA and MDMA in the same category. The total number of submissions of MDA/MDMA between 1973 and 1983 was 610, ranging from 21 in 1974 to 88 in 1978.

76. Pharm Chem reported 20 submissions of MDMA between May 1983 and May 1984, when it discontinued its testing service.

77. Toxicology Testing Service reported 19 submissions of MDMA between April 1984 and March 1985.

78. In its investigation of the clandestine manufacture of controlled substances, DEA has encountered five laboratories producing or possessing the necessary chemicals to produce MDMA. Each laboratory had produced or had the capability of producing kilogram (10,000 dosage units) quantities of MDMA. Impurities found in the MDMA analyzed by forensic laboratories indicate that MDMA is produced in clandestine laboratories.

79. A DEA investigation conducted in June 1984 of a suspected cocaine distributor resulted in information concerning the widespread availability of "Ecstasy," or MDMA, in the Dallas Texas area.

80. "Ecstasy," or MDMA, with a claimed origination of California, was being distributed in the Dallas area in 100 tablet bottles by organized groups. The tablets were found to contain approximately 110 mg. of MDMA.

81. Street prices for MDMA in 1985 were found to be $750 for 1,000 doses in Austin, Texas; $12.50 per dose in Boulder, Colorado; $70 per gram in New York; $85 per gram in California, and $10–$20 per dose in New Hampshire.

82. Dr. Inaba from the Haight-Ashbury Clinic in San Francisco reports medically unsupervised use of MDMA in San Francisco by the gay male population, young professionals and individuals with a history of hallucinogenic drug use.

83. Dr. Siegel of UCLA estimates that the street distribution of MDMA has risen from 10,000 dosage units in 1976 to 30,000 dosage units per month in 1985.

84. Students at the University of Texas in Austin indicate that MDMA is easily available on campus at about $5 to $20 per tablet.

85. Dr. Ingrasci, a psychiatrist who has himself used MDMA on patients, has interviewed over 500 individuals who have used MDMA over the past seven to eight years. More than half of these individuals had used MDMA in a non-

therapeutically motivated setting for curiosity or recreation.

86. Dr. Joseph J. Downing, a practicing psychiatrist in San Francisco, California, conducted a pilot study in 1984 into the effects in healthy humans of a single exposure to MDMA. The 21 subjects in Dr. Downing's MDMA study had all used MDMA previously. One had used MDMA 15 times, one 10 times, and one only once. The mean frequency of use of the 21 subjects was once every 2.2 months.

87. Dr. Lester Grinspoon reports that MDMA is being taken by a growing number of people, particularly students and young professionals in a casual and recreational manner.

88. Dr. George Greer, a practicing psychiatrist in Santa Fe, New Mexico, has used MDMA as an adjunct to psychotherapy in clinical work. He reported that one of his subjects, after taking the unusually high dosage of 350 mg. of MDMA, reported visual hallucinations, illusions, hearing impairment, brief memory loss and distortion in depth perception.

89. Between 1977 and 1981, the Drug Abuse Warning Network (DAWN) reported eight emergency room episodes associated with the use of MDMA.

90. MDMA is reported to have been associated with two overdose deaths. One death occurred in Seattle, Washington in 1979, and one in Santa Monica, California.

91. The Assistant Secretary of Health, Department of Health and Human Services, in his scientific and medical evaluation of MDMA, concluded that MDMA has a high potential for abuse.

92. Therefore, the Administrator finds that MDMA has a high potential for abuse.

Discussion

The phrase "currently accepted medical use in treatment in the United States" is found in 21 U.S.C. 812(b). It is one of the three findings required for placement of a substance into one of the five Schedules of the Controlled Substances Act. Whereas placement of a drug or other substance into Schedules II through V requires a finding that the substance has a currently accepted medical use in treatment in the United States, placement of a substance into Schedule I requires a finding that the substance "has no currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(1)(B). The Controlled Substances Act does not define this term.

The Administrator concludes that the term "currently accepted medical use in treatment in the United States" means that the drug or other substance is lawfully marketed in the United States pursuant to the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. 355. The FDCA establishes procedures regarding approval of drugs for marketing in the United States, and an exemption for investigational use of approved drugs prior to marketing. These procedures require that FDA must approve a new drug as being safe and effective before it may be introduced into interstate commerce in the United States.

If a substance is not marketed in interstate commerce in the United States, it is not manufactured by the pharmaceutical manufacturers who are licensed by the FDA to produce the vast array of medications currently available in this country; it is not distributed by pharmaceutical wholesalers licensed to sell pharmaceuticals, it is not stocked in retail pharmacies, hospitals and other medical facilities which daily dispense drugs to patients; and it cannot be prescribed by the hundreds of thousands of physicians and other practitioners who are authorized by their licenses and registrations to prescribe pharmaceuticals, including controlled substances, in the course of their professional practices. Such a substance cannot be said to have a "currently accepted medical use in *treatment* in the United States." (Emphasis added)

The complex system of approval for marketing and conditions for use of non-approved drugs for investigational purposes is designed to protect the health of the humans to whom the drug is to be given. A drug must be shown to be safe and effective before any manufacturer can market it in this country. Approval of a substance makes it "acceptable" and available for medical use. Any other meaning of "currently accepted medical use in treatment in the United States", other than approval for marketing by the Food and Drug Administration, would make the NDA process a sham and would require pure conjecture on the part of the Secretary and the Administrator in determining if a substance had an "accepted medical use." This interpretation is also consistent with that of the Uniform Controlled Substances Act, which has been adopted by almost all of the 50 states.

The Administrative Law Judge, in recommending that the Administrator find that MDMA has an accepted medical use in treatment, urged that the Administrator look at "what is actually going on within the health care community" in order to make this determination. The Administrator cannot accept this recommendation. The Administrator cannot, consistent with his responsibility to protect the American public from the abuse and misuse of dangerous drugs, declare legitimate a substance which has not been found safe and effective under the procedures required by the FDCA. He cannot find that a drug, which is not available through commercial, legitimate channels to the medical community, has an "accepted medical use in treatment in the United States." The fact that a handful of physicians are of the opinion that a substance may have therapeutic value is not an acceptable alternative to the thorough clinical and preclinical evaluation which precedes the approval of an NDA.

Another finding required to be made by the Administrator for placement of a substance in Schedule I is that "there is a lack of accepted safety for use of the drug or other substance under medical supervision." The same rationale discussed with regard to "accepted medical use" applies to "accepted safety for use . . . under medical supervision."

MDMA has not been approved for marketing in the United States by the Food and Drug Administration. MDMA has not been approved for investigational use by the Food and Drug Administration. No studies have been submitted to the Food and Drug Administration which would demonstrate the safety of MDMA with reliable scientific data. There is no basis upon which to conclude that MDMA has "accepted safety for use . . . under medical supervision."

Instead of relying on scientific data, or the opinion of the Food and Drug Administration, the Administrative Law Judge chose to rely upon the "world of health care practitioners" to determine "accepted safety for use." He chose to disregard scientific, controlled studies conducted by scientific researchers which have shown MDMA to be neurotoxic when administered to rats, and instead substituted the anecdotal judgments of a handful of physicians who observed the behavior of human animals under the influence of MDMA.

A drug's safety for use in humans, both at the investigational stage and at the marketing approval stage, can only be established through controlled scientific studies which are submitted to and evaluated by the FDA. These determinations are given great weight by the Administrator in evaluating scientific and medical matters.

For placement of a substance in Schedule I, the Administrator is also required to find that "the drug or other substance has a high potential for abuse."

The available scientific data clearly show that MDMA produces physical and psychological effects in common with central nervous system stimulants like amphetamine, and with known hallucinogens or psychotomimetics like MDA in both animals and humans. The chemical structure of MDMA is very closely related to MDA and to methamphetamine. Its pharmacological properties are almost identical to those of MDA. In preliminary studies, MDMA has been shown to be neurotoxic in animals, just as MDA has been shown to be neurotoxic. In the studies conducted specifically to determine abuse liability, MDMA has been shown to have an abuse liability similar to stimulants such as cocaine and amphetamine, both substances with an established high potential for abuse. MDMA is a substance which is clandestinely produced and trafficked on the street in the United States, and is taken for its pleasurable effects.

Animal and human studies which completely characterize the pharmacology, safety and efficacy of MDMA are not available.

The Administrator finds that the Agency sustained its burden that MDMA has a high potential for abuse. It has a similar chemical structure and pharmacological properties nearly identical to substances already found to have a high potential for abuse. It is clandestinely manufactured, trafficked, and actually abused. Its lack of established safety and potential neurotoxicity make it a serious risk to the public health and safety.

Because the Administrator has found that MDMA has no accepted medical use in treatment and has a high potential for abuse, it is unnecessary to address the issue 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."

In reaching the conclusion that MDMA should be placed in Schedule I of the Controlled Substances Act, the Administrator has also considered the following information. In 1983, the World Health Organization recommended that MDMA be placed in Schedule I of the Convention on Psychotropic Substances (CPS), 1971, and the United Nations Commission on Narcotic Drugs subsequently placed MDMA in Schedule I.

In addition, MDMA is controlled in Schedule H of the Canadian Food and Drug Act, along with MDA and LSD. Reports of clandestine manufacture and distribution of MDMA continues in Canada. The Federal Republic of Germany has also reported the clandestine manufacture and distribution of MDMA.

The Administrator has read with interest the comments from various parties in the record concerning what effect placement of MDMA into Schedule I would have on legitimate research into the substance.

The Controlled Substances Act contains specific provisions for research with Schedule I substances. The registration provisions are found in 21 U.S.C. 823(f). The major difference in the regulatory requirements imposed upon researchers handling Schedule I controlled substances and those conducting research with Schedule II, III, IV and V controlled substances is the registration requirements which require review of a protocol by the Secretary of the Department of Health and Human Services.

The information required to be contained in this protocol is outlined with specificity in 21 CFR 1301.33. The protocol requirements also make reference to the investigational new drug (IND) procedures. They provide a mechanism for researchers wishing to conduct clinical (human) investigations with controlled substances in Schedule I.

All researchers utilizing controlled substances must be registered by the Drug Enforcement Administration. All researchers must keep records, and all researchers must maintain the controlled substances in a "securely locked, substantially constructed cabinet." The records required to be kept by researchers in Schedule I are not substantially different from the records required to be kept by a researcher or dispenser of Schedule II, III, IV or V controlled substances.

A review of the above regulations demonstrates that those who wish to conduct research with MDMA have available avenues by which to pursue such research.

Placement of a substance into Schedule I and designating it as a hallucinogenic imposes certain regulatory requirements on those handling the substance. Since MDMA has been a Schedule I controlled substance since July 1, 1985, the requirements imposed by the CSA and implementing regulations continue as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports MDMA, or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* MDMA must be manufactured, distributed and stored in accordance with §§ 1301.71 through 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of MDMA must comply with the requirements of §§ 1302.03 through 1302.05, 1302.7 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for MDMA shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of MDMA shall take an inventory pursuant to 1304.11 through1304.19 of Title 21 of the Code of Federal Regulations of all stocks of this substance on hand.

6. *Records.* All registrants required to keep records pursuant to 1304.21–1301.27 of Title 21 of the Code of Federal Regulations shall do so regarding MDMA.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.37 through 1304.41 of Title 21 of the Code of Federal Regulations shall do so regarding MDMA.

8. *Order Forms.* All registrants involved in distribution of MDMA shall comply with the order form requirements of §§ 1305.01 through 1305.16 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of MDMA shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with respect to MDMA not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act continues to be unlawful. The criminal penalties are those of a Schedule I hallucinogenic.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of MDMA 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 control of a substance with no currently approved medical use or manufacture in the United States.

In accordance with the provisions of section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to provisions of the Administrative Procedures Act, 5 U.S.C. 556 and 557, and as such have been exempted from the consultation 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(a) of the Controlled Substances Act (21 U.S.C. 811(a)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice, 28 CFR 0.100(b), the Administrator hereby orders that Part 1308, Title 21, Code of Federal Regulations, be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES [AMENDED]

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

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

2. Section 1308.11 is amended by redesignating the existing paragraphs (d)(7) through (d)(24) as (d)(8) through (d)(25) and adding a new paragraph (d)(7) as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(7) 3,4-methylenedioxymethamphetamine (MDMA). . . . 7405

* * * * *

3. Section 1308.11 is amended by removing paragraph (g)(1) and redesignating the existing paragraphs (g)(2) through (g)(12) as (g)(1) through (g)(11).

* * * * *

Dated: October 8, 1986.

John C. Lawn,

Administrator.

[FR Doc. 86–23080 Filed 10–10–86; 8:45 am]

BILLING CODE 4410-09-M

Harvard Medical School
Department of Psychiatry

Massachusetts Mental Health Center
74 Fenwood Road, Boston 02115

December 22, 1986

Lyn B. Ehrnstein, Esq.
257 North Weatherly Drive
Beverly Hills, CA 90211

Dear Attorney Ehrnstein:

Dr. Lester Grinspoon has asked me to send you a copy of the enclosed Petition for Review for your information.

Sincerely,

Evelyn Guillette

Evelyn Guillette
Adm. Assistant

enclosure

Harvard Medical School
Department of Psychiatry

Massachusetts Mental Health Center
74 Fenwood Road, Boston 02115

December 22, 1986

Robert T. Angarola, Esq.
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Dear Mr. Angarola:

Dr. Lester Grinspoon asked me to send you a copy of the enclosed petition for review for your information.

Sincerely,

Evelyn Guillette

Evelyn Guillette
Adm. Assistant

enclosure

Harvard Medical School
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December 22, 1986

David E. Joranson, Esq.
Wisconsin Dept. of Health &
Social Services
Controlled Substances Board
One West Wilton St.
PO 7851
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Dear Mr. Joranson:

Dr. Lester Grinspoon has asked me to send you a copy of the enclosed Petition for Review for your information.

Sincerely,

Evelyn Guillette

Evelyn Guillette
Adm. Assistant

enclosure