

So as to eliminate any confusion which may arise regarding the basis of the proposed action, the DEA is withdrawing the original NPRM (46 FR 29484) and under a separate notice in this issue of the **Federal Register**, the DEA is publishing a new NPRM which proposes the placement of the substance ketamine, its salts, isomers, and salts of isomers, into Schedule III of the CSA.

DATES: The proposed rule is withdrawn on April 9, 1999.

FOR FURTHER INFORMATION CONTACT:

Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: 202-307-7183; FAX: 202-307-8570.

SUPPLEMENTARY INFORMATION: On June 2, 1981, the DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (46 FR 29484). The NPRM proposed to add the noncontrolled substance ketamine and any salts thereof to Schedule III of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). The DEA received seven letters in response to the NPRM.

Comments in support of the proposed action were received from the American Veterinary Medical Association and a professor at the Texas A & M University, College of Veterinary Medicine.

Comments in opposition were received from the Warner-Lambert Company, the Humane Society of the United States, the Division of Comparative Medicine at the Johns Hopkins University School of Medicine, the Department of Laboratory Animal Medicine at the Southwest Foundation for Research and Education, and the Director of Scientific Support Services, Primate Research Institute at the New Mexico State University. No requests for a hearing were received.

The DEA, after careful consideration, determined to postpone proceeding with the proposed regulatory action. While the substance's potential for abuse was established, the DEA concluded that the number of documented cases of abuse of the substance was insufficient to justify the regulatory action in 1981. The DEA did not withdraw the NPRM and terminate further rulemaking on the proposal, but continued to monitor the diversion and abuse of ketamine. In 1992, an increase in the number of cases of diversion and abuse was first noted. Elsewhere in this issue of the **Federal Register**, the DEA publishes a new NPRM, which results from the current experience as it relates to the diversion and abuse of ketamine. So as to eliminate any confusion which might arise regarding the basis of the proposed action, the DEA is withdrawing the 1981 NPRM (46 FR

29484 June 2, 1981) and terminating further rulemaking on this proposal.

Dated: April 2, 1999.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA-183P]

21 CFR Part 1308

Schedules of Controlled Substances: Proposed Placement of Ketamine Into Schedule III

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA). It proposes the placement of the substance ketamine, including its salts, isomers, and salts of isomers, into Schedule III of the Controlled Substances Act (CSA). This proposed action is based on an evaluation of the relevant data by the DEA and a recommendation from the Assistant Secretary for Health and Surgeon General of the Department of Health and Human Services (DHHS) that ketamine and products containing it be placed into Schedule III of the CSA. The effect of this proposed action will be to discourage the diversion and abuse of ketamine, and subject ketamine to the regulatory, civil and criminal controls of a Schedule III controlled substance.

DATES: Comments and objections must be received on or before June 8, 1999.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537; Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: 202-307-7183; FAX: 202-307-8570.

SUPPLEMENTARY INFORMATION: Ketamine hydrochloride has been marketed in the United States since 1971 as a rapid-acting general anesthetic. It is used in both human and veterinary practice. Chemically, ketamine is related to PCP, a Schedule II controlled substance. The effects produced with use of ketamine are similar, although less intense and

shorter in duration, to those produced by PCP.

The DHHS, by letter of March 18, 1981, recommended to the DEA that ketamine and products containing it be placed into Schedule III of the CSA. The DEA published a notice of proposed rulemaking (NPRM) (46 FR 29484, June 2, 1981) which proposed the placement of the substance ketamine and salts thereof, into Schedule III of the CSA. In response to the NPRM, the DEA received seven letters. Comments in support of the proposed action were received from the American Veterinary Medical Association and a professor at the Texas A & M University, College of Veterinary Medicine. Comments in opposition were received from the Warner-Lambert Company, the Humane Society of the United States, the Division of Comparative Medicine at the Johns Hopkins University School of Medicine, the Department of Laboratory Animal Medicine at the Southwest Foundation for Research and Education, and the Director of Scientific Support Services, Primate Research Institute at the New Mexico State University. On review of the comments and the yearly average of four documented instances of diversion or abuse between 1975 and 1981, the DEA determined that the incidence of actual abuse was not sufficient to sustain the scheduling action. The DEA continued to monitor the situation.

The DEA summarized the relatively little actual abuse information available to it, and by letter of August 14, 1984, asked the DHHS if its previous recommendation for control of ketamine as a Schedule III controlled substance should stand. The DHHS, by letter of November 29, 1984, requested the information of abuse to which the DEA had referred. The DEA furnished the information to the DHHS by letter of February 18, 1985. By letter of September 8, 1986, the DHHS reaffirmed the recommendation to place ketamine into Schedule III of the CSA. On this occasion, as earlier, the DEA determined that the incidence of actual abuse, roughly five documented cases of diversion or abuse per year for the 1980-1986 period, was not sufficient to sustain the scheduling action and continued to monitor the situation.

Since 1992, 775 reports of ketamine diversion or abuse have been received by the DEA. The incidence of law enforcement encounters of individuals selling the drug, under its influence, or who had it in their possession, along with the wide geographic distribution of the encounters, the involvement of teenagers and young adults, the occurrence of veterinary clinic

burglaries directed at ketamine, the spreading notoriety of ketamine as a party drug, "Special K" or "K", and the number of ketamine abuse related hospital emergency department visits have caused the DEA to reconsider the noncontrolled status of the drug.

In 1998, the DEA submitted the DHHS information relevant to each of the eight factors which are determinative of control under the CSA. By letter of December 17, 1998, the Assistant Secretary for Health and Surgeon General responded recommending that ketamine be added to Schedule III. Enclosed with the letter was a document which summarized the findings related to the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(c)].

The factors considered by the Assistant Secretary for Health and Surgeon General and the DEA with respect to ketamine were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect;
- (3) The state of current scientific knowledge regarding the drug or other substance;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

Ketamine is used in human and veterinary medicine to produce a unique anesthetic state characterized by sedation, immobility, marked analgesia, and amnesia. Since 1992, the DEA has documented more than 568 incidents of the sale and/or use of the drug in schools by minors, on college campuses, at night clubs and rave dances, incidents of public intoxication and improper operation of a motor vehicle while under the influence of ketamine, burglaries of veterinary clinics in which ketamine was the sole item targeted, and the sale of ketamine as a drug of abuse to undercover police. During the same period of time, 207 ketamine abuse related visits to hospital emergency departments were recorded by the Drug Abuse Warning Network.

The pharmacological and behavioral effects of ketamine are similar, but somewhat less intense and shorter in duration, to those of PCP. Low dose intoxication with ketamine results in impaired attention, learning, and memory functions. Higher doses may

result in ataxia, dizziness, elevated blood pressure, mental confusion, hyperexcitability, catalepsy (the inability to move), convulsions, a delusional dream-like, hallucinations, and psychosis. Long-term use of ketamine is associated with hallucinatory flashbacks and as inability to concentrate. Several case reports suggest that psychological dependence and tolerance develop in humans after long-term use of ketamine. Behavioral and physical dependence have been demonstrated in animals.

Diversion of ketamine pharmaceutical products from practitioners has been the most frequently documented source of the drug, with the primary sources being veterinary clinics. The liquid pharmaceutical product is injected or, more commonly, evaporated and the resultant powder inhaled (snorted). Clandestine manufacture of ketamine has not been encountered. In contrast to that of PCP, the synthesis of ketamine is difficult.

Ketamine is presently regulated as a controlled substance in 18 states; 15 states have placed it into Schedule III, two states have placed it into Schedule IV, and Massachusetts has designated it as a Class A substance. By letter of July 10, 1996, the President of Fort Dodge Animal Health asked the DEA to place ketamine into Schedule III of the CSA. That position reflected the belief "that moving the product to a Schedule III classification is in the best interest of the veterinary industry and the public." In letters to the DEA earlier that same year, the New Jersey Veterinary Medical Association and 43 veterinarians licensed by that State urged the DEA to place ketamine into Schedule III, as a means to limit the abuse of the drug while ensuring its continued availability for appropriate veterinary use.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health in accordance with section 201(b) of the CSA [21 U.S.C. 811(b)], and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the CSA [21 U.S.C. 811(a) and 811(b)], finds that:

- (1) Based on information now available, ketamine has a potential for abuse less than the drugs or other substances in Schedules I and II.
- (2) Ketamine hydrochloride has a currently accepted medical use in treatment in the United States; and
- (3) Abuse of ketamine may lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Deputy Administrators of the DEA concludes

that ketamine, its isomers, salts, and salts of isomers, should be placed into Schedule III of the CSA.

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 Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537. Attention: DEA Federal Register Representative/CCR. In the event that comments, objections, or requests for a hearing raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy 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.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action 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. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. Ketamine products are prescription drugs used as anesthetics in hospitals and clinics. Handlers of ketamine are likely to handle other controlled substances which are already subject to the regulatory requirements of the CSA.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule, as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based companies to compete with foreign based

companies in domestic and export markets.

This rule will not have substantial direct effects on the United States, on the relationship between the national government and the United States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

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

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

2. Section 1308.13 is proposed to be amended by redesignating the existing paragraphs (c)(5) through (c)(11) as (c)(6) through (c)(12).

3. Section 1308.13 is proposed to be amended by adding a new paragraph (c)(5) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(c) Depressants.

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(5) Ketamine, its salts, isomers, and salts of isomers . . . 7285 [Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone.

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Dated: April 2, 1999.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 990

[Docket No. FR-4425-N-03]

Negotiated Rulemaking Committee on Operating Fund Allocation; Meetings

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Negotiated Rulemaking Committee Meetings.

SUMMARY: This notice announces the second and third meetings of the Negotiated Rulemaking Committee on Operating Fund Allocation. These meetings are sponsored by HUD for the purpose of discussing and negotiating a proposed rule that would change the current method of determining the payment of operating subsidies to public housing agencies (PHAs).

DATES: The second committee meeting will be held on April 13 and April 14, 1999. On April 13, 1999, the meeting will begin at approximately 9:30 am and run until completion; on April 14, 1999, the meeting will begin at approximately 9:00 am and run until approximately 4:00 pm.

The third committee meeting will be held on May 13 and may 14, 1999. On May 13, 1999, the meeting will begin at approximately 9:30 am and run until completion; on May 14, 1999 the meeting will begin at approximately 9:00 am and run until approximately 4:00 pm.

ADDRESSES: The second and third committee meetings will take place at the Hyatt Dulles Hotel (Concorde Ballroom), 2300 Dulles Corner Boulevard, Herndon, VA 22071.

FOR FURTHER INFORMATION CONTACT: Joan DeWitt, Director, Funding and Financial Management Division, Public and Indian Housing, Room 4216, Department of Housing and Urban Development, 431 Seventh Street, SW, Washington, DC 20410-0500; telephone (202) 708-1872 ext. 4035 (this telephone numbers is not toll-free). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: The Secretary of HUD has established the Negotiated Rulemaking Committee on Operating Fund Allocation to negotiate and develop a proposed that would change the current method of determining the payment of operating subsidies to PHAs. The establishment of the committee is required by the Quality

Housing and Work Responsibility Act of 1996 (Pub.L. 105-276, approved October 21, 1998; 112 Stat. 2461) (the "Public Housing Reform Act"). The Public Housing Reform Act makes extensive changes to HUD's public and assisted housing programs. These changes include the establishment of an Operating Fund for the purpose of making assistance available to PHAs for the operation and management of public housing. The Public Housing Reform Act requires that the assistance to be made available from the new Operating Fund be determined using a formula developed through negotiated rulemaking procedures.

On March 16, 1999 (64 FR 12920), HUD published a notice in the **Federal Register** that announced: (1) The establishment of the negotiated rulemaking committee; (2) the names of the committee members; and (3) the dates, location, and agenda for the first committee meeting. The second and third meetings of the negotiated rulemaking committee will take place as described in the **DATES** and **ADDRESSES** section of this notice.

The agenda planned for the committee meetings includes: (1) The adoption of committee protocols, as appropriate; (2) defining the goals for the operating fund formula; (3) discussing the various methods for translating these goals into a formula-based allocation system; and (4) the scheduling of future meetings.

In accordance with the General Services Administration (GSA) regulations implementing the Federal Advisory Committee Act, HUD normally publishes a **Federal Register** meeting notice at least 15 calendar days before the date of an advisory committee meeting. The GSA regulations, however, also provide that an agency may give less than 15 days notice if the reasons for doing so are included in the **Federal Register** meeting notice. (See 41 CFR 101-6.1015(b).) Due to the difficulty in obtaining suitable hotel and conference room accommodations in the Washington, DC area during April, 1999, it has not been possible for HUD to announce the date and location of the second committee meeting before today. Given the strict statutory deadline for implementation of the Operating Fund formula, HUD believes it is imperative that the negotiations for development of the formula not be delayed. Failure to publish the Operating Fund final rule on a timely basis will delay the provision of operating subsidies to PHAs. Accordingly, rather than defer the negotiations, HUD has decided to proceed with the second committee meeting on April 13 and April 14, 1999.