Paperwork Reduction Act

The proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials (see 7 CFR part 3015, subpart V).

List of Subjects in 9 CFR Part 112

Animal biologics.

Accordingly, 9 CFR part 112 is amended as follows:

PART 112—PACKAGING AND LABELING

1. The authority citation for 9 CFR part 112 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 112.1 would be revised to read as follows:

§ 112.1 General.

(a) Unless otherwise authorized or directed by the Administrator, each biological product prepared at a licensed establishment or imported shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided*, That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements in § 112.9. *Provided further*, That unless otherwise exempted, all preparation, including packaging and labeling, of biological products shall only be done in a licensed establishment under an approved Outline of Production.

(b) No person shall apply or affix to or include with, or cause to be applied or affixed to or included with, any carton or final container of a biological product, any label, stamp, mark or statement that is false or misleading in any particular, is not in compliance with the regulations, or is not approved by APHIS.

(c) No person shall alter, mark or remove any approved labeling affixed to or included with any biological product prior to selling or otherwise distributing such product. In addition, no person shall mark any carton, other container, or final container of a biological product so as to falsify the labeling, make it misleading, or cause it to be illegible.

(d) Labels that are stamped, printed or glued directly on cartons, other containers, or final containers shall be legible throughout the dating period. Biological products bearing labels, which have been altered, mutilated, destroyed, obliterated or removed, shall be withheld from the market.

3. In § 112.4, the introductory paragraph is revised to read as follows:

§ 112.4 Subsidiaries, divisions, distributors, and permittees.

Labels used by subsidiaries, divisions, distributors, and permittees shall be affixed by the licensee in a licensed establishment where the product is produced. Such labels shall comply with requirements for their review, approval, and filing as provided in this section.

* * * * *

4. In § 112.6, new paragraphs (e) and (f) are added to read as follows:

§ 112.6 Packaging biological products.

* * * * *

(e) Final containers of biological product packaged at a licensed establishment in cartons or other containers shall not be removed from such cartons or containers and repackaged for sale or distribution unless each final container bears or is accompanied by complete and approved labeling which is affixed to or included with each container by the licensed establishment producing the product.

(f) Labels which are affixed to or included with a biological product shall not be removed or altered in any manner.

Done in Washington, DC, this 21st day of April 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–9889 Filed 4–27–93; 8:45 am]

BILLING CODE 3410–04–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Methcathinone into Schedule I

AGENCY: Drug 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 methcathinone into Schedule I of the Controlled Substances Act (CSA). This proposed action by the DEA Administrator is based on data gathered and reviewed by the 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 methcathinone.

DATES: Comments must be submitted on or before May 28, 1993.

ADDRESSES: 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 and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537. Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: On May 1, 1992, the Administrator of the DEA published a final rule in the Federal Register (57 FR 18824) temporarily placing methcathinone into Schedule I of the CSA using the temporary scheduling provisions of the CSA (21 U.S.C. 811(h)). This final rule, which became effective on the date of publication, was based on a finding by the Administrator that the temporary scheduling of methcathinone 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 temporary 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 methcathinone which would expire on May 1, 1993, may be extended to November 1, 1993. This extension is being ordered by the DEA Administrator in a separate action.

The DEA has gathered and reviewed the available information regarding the actual base and relative potential for abuse for methcathinone. The DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of methcathinone. By letter, the Administrator has submitted data which the DEA has gathered regarding methcathinone 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

HeinOnline -- 58 Fed. Reg. 25788 1993

scientific and medical evaluation and a scheduling recommendation for methcathinone from the Assistant Secretary for Health.

Methcathinone has a chemical structure and pharmacological profile similar to that of methamphetamine and cathinone. All forms of methamphetamine have been controlled in Schedule II of the CSA since 1971. As a result of prior control of cathinone in Schedule I of the 1971 Convention on Psychotropic Substances and in response to a recommendation received by the Administrator from the Assistant Secretary for Health and Human Services, cathinone was placed into Schedule I of the CSA on February 14, 1993.

In preclinical studies, methcathinone hydrochloride produces pharmacological effects and appears to have an abuse potential similar to that of psychomotor stimulants such as the amphetamines. In a manner similar to that of other amphetamines, methcathinone hydrochloride increases spontaneous rodent locomotor activity, potentiates the release of radiolabelled dopamine from dopaminergic nerve terminals in the brain and causes appetite suppression. In drug discrimination studies, methcathinone hydrochloride evokes either (+)-amphetamine or cocaine induced appropriate responding. When examined in particular pharmacological assays for psychomotor stimulant-like activity, both the d and the l enantiomeric forms of methcathinone hydrochloride have been found to be pharmacologically active. In these assays, the l-form of methcathinone is more active than either d-methcathinone or (+)-amphetamine. Racemic methcathinone hydrochloride is intravenously self-addressed by baboons, thus indicating that methcathinone produces reinforcing effects in this laboratory animal and suggesting that this drug has a potential for abuse in the human population.

To date, the distribution and abuse of methcathinone has been documented in Michigan and Wisconsin. Abuse of methcathinone has been known since at least January 1991. Since that time, the abuse of methcathinone has increased substantially in the upper peninsula of Michigan and, more recently, in Wisconsin. The principal form of methcathinone distributed and abused is the hydrochloride salt of the 1-enantiomer, which exists as a white to off-white, chunky powdered material. It is usually sold as itself under such street names as "Cat" and "Goob". Less often it is passed off as methamphetamine under such names as "Crank" or "Speed". The most common route of administration is via nasal insufflation. Other routes of administration include oral ingestion, intravenous injection and smoking. Methcathinone is abused in binges lasting two to six days. During this time, methcathinone is repeatedly administered, resulting in the daily administration of amounts surpassing one or two grams. The methcathinone binge resembles amphetamine binges in that the abuser does not sleep or eat and takes in little in the way of liquids. The methcathinone binge is followed by a "crash" characterized by long periods of sleep, excess eating and possibly depression.

Methcathinone is abused for its psychomotor stimulant effects. It is reported by abusers to produce such effects as a "burst of energy", "headrush", "bodyrush", a "speeding of the mind", an "increased feeling of self-confidence" and "euphoria". Abusers have also reported that methcathinone produces unpleasant effects such as paranoia, hallucinations, anxiety, tremor, insomnia, malnutrition, weight loss, dehydration, sweating, stomach pains, nose bleeding and body aches. Following the crash, some individuals have experienced depression with or without thoughts of suicide.

Methcathinone hydrochloride is produced for street distribution in clandestine laboratories. Between June, 1991 and February, 1993, 19 active or clandestine methcathinone laboratories were seized by Federal, state and local law enforcement officials in Michigan. In August 1991 a clandestine methcathinone laboratory was seized in Seattle, Washington. Since January, 1993, at least two clandestine methcathinone laboratories have been encountered in Wisconsin.

Methcathinone has been encountered by law enforcement officials in Michigan and Wisconsin. Michigan State Police obtained the first street sample of methcathinone in February 1991. Since that time there have been over 50 encounters of methcathinone by Federal, state and law enforcement officials in Michigan. Methcathinone was first encountered in Wisconsin in March 1992. Since October 1992, there have been more than twenty Federal, state or local law enforcement encounters of methcathinone in Wisconsin. With the exception of the seizure of a single clandestine methcathinone laboratory in Washington, the DEA is not aware of any other law enforcement encounters of methcathinone within the United States, other than those in Michigan and Wisconsin.

Health officials in Michigan and Wisconsin have encountered abusers of methcathinone. There have been a number of documented emergency room cases involving the purported abuse of methcathinone. Drug abuse treatment centers in Marquette and Iron Mountain, Michigan, as well as several psychiatric treatment centers in Wisconsin have reported encounters with methcathinone abusers.

Sigma Chemical Company is the only known commercial manufacturer and supplier of methcathinone in the United States. The Food and Drug Administration (FDA) has notified the DEA that there are no exemptions or approvals in effect under section 505 of the Federal Food, Drug and Cosmetic Act for methcathinone. A search of the scientific and medical literature revealed no indications of current medical use of methcathinone in the United States.

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 and to support that methcathinone 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 evaluation and scheduling recommendation 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

HeinOnline -- 58 Fed. Reg. 25789 1993

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 of the **Federal Register**, summarizing the issues to be heard and setting the time for hearing.

The Administrator of the DEA hereby certifies that the proposed placement of methcathinone into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the control of a substance with no currently approved medical use or manufacture in the United States.

This proposed rulemaking is not a major rule for the purposes of Executive Order 12291 (46 FR 13193) of February 17, 1981. It has been determined that drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. Accordingly, this drug scheduling action is not subject to the provisions of Executive Order 12778 which are contingent upon review by OMB.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this proposed rulemaking does 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 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:

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

2. Section 1308.11 is amended by adding paragraph (f)(6) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(6) Methcathinone (Some other names: 2-(methylamino)-propiophenone, alpha (methylamino)-propiophenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylaminopropiophenone, monomethylpropion, ephedrone, N-methylcathinone, methycathinone, AL-464, AL-422, AL-463 and UR1431) its salts, optical isomers and salts of optical isomers . . . 1237.

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

Dated: April 22, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93-9945 Filed 4-27-93; 8:45 am]

BILLING CODE 4410-09-M

---

21 CFR Part 1308

Schedules of Controlled Substances Proposed Transfer of Levo-alphacetylmethadol From Schedule I Into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of proposed rulemaking to transfer the Schedule I narcotic, levo-alphacetylmethadol (LAAM), to Schedule II of the Controlled Substances Act (CSA) in accordance with 21 U.S.C. 801 *et seq.* This action is initiated upon receipt of a letter from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), recommending that LAAM be transferred from Schedule I to Schedule II upon approval of a New Drug Application (NDA) for LAAM. As a result of this proposed rule, if finalized, the regulatory controls and criminal sanctions of Schedule II will be applicable to the manufacture, distribution, importation and exportation of LAAM. Additionally, the use of LAAM for the treatment of narcotic addiction will be subject to compliance with the requirements of the Narcotic Addict Treatment Act of 1974 and regulations concerning narcotic treatment programs.

DATES: Comments must be submitted on or before May 28, 1993.

ADDRESSES: Comments should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: On March 12, 1993, the Acting Assistant Secretary for Health, on behalf of the Secretary of the DHHS, sent the Administrator of the DEA a letter recommending that levo-alphacetylmethadol be transferred to Schedule II of the CSA once it is approved for marketing. Enclosed with the letter was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Transferring of Levo-alpha-acetylmethadol (LAAM) from Schedule I to II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b) and 811(c)) and the summarized recommendations regarding the transfer of LAAM. The factors considered by the Acting Assistant Secretary for Health with respect to LAAM are:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects, if known;

(3) The state of the 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 this title.

The FDA has received and reviewed substantial evidence on the effectiveness and safety of LAAM. The FDA's scientific and medical evaluation shows that LAAM has a potential for abuse and physical and psychological dependence liability similar to other μ-opioid agonists which are in Schedule II of the CSA. Upon approval of the NDA for treatment of narcotic addiction, LAAM will have met DEA's criteria for currently accepted medical use in treatment in the United States. These criteria were discussed at length in the matter of the Marijuana Rescheduling Petition, 57 FR 10499, 10503-10507 (1992). This transfer will apply to the *levo* isomer of alphacetylmethadol while all other isomers of alphacetylmethadol will remain in Schedule I.

Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a

HeinOnline -- 58 Fed. Reg. 25790 1993