

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)-propiofenone, alpha (methylamino)-propiofenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylaminopropiofenone, 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 4410-08-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

person believes that one or more issues warrant a hearing, the reasons for such belief should be stated and summarized. If the Administrator finds that the written responses to this proposal warrant a hearing, the Administrator will order a public hearing. A notice of the hearing will be published in the Federal Register summarizing the issues to be heard and setting a time for the hearing that will be at least 30 days after the publication of the notice. If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing. DEA's final decision concerning the relative abuse potential of LAAM will take into account the Acting Assistant Secretary's recommendation and any information received in response to this proposal.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the transfer of LAAM, as proposed herein, will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). Many of the regulatory requirements imposed on Schedule II substances are similar to those imposed on Schedule I substances. Additionally, substances in Schedule II may be used in medical treatment in the United States.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to transfer LAAM from Schedule I to Schedule II is a formal rulemaking "on the record after opportunity for hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements for Executive Order 12291 (46 FR 13193).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs, Reporting and Record keeping requirements.

Based on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for

Health, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on all available information, LAAM has a high potential for abuse.

(2) LAAM, upon final approval of a NDA by the FDA, will meet the criteria for currently accepted medical use in treatment in the United States.

(3) Abuse of this substance may lead to severe psychological or physical dependence.

Therefore, under the authority vested in the Attorney General (21 U.S.C. 811(a)) and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR Part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.11 is proposed to be amended by revising paragraph (b)(4) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(4) Alphacetylmethadol (except Levo-alphacetylmethadol (LAAM))—9603

* * * * *

3. Section 1308.12 is proposed to be amended by redesignating the existing paragraphs (c)(11) through (c)(25) as (c)(12) through (c)(26) respectively and adding a new paragraph (c)(11) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(11) Levo-alphacetylmethadol (LAAM)—9648

* * * * *

Dated: April 22, 1993.

Robert C. Bonner,
Administrator of Drug Enforcement.
[FR Doc. 93-9046 Filed 4-27-93; 8:45 am]

BILLING CODE 4410-99-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 52

[PS-89-91]

RIN 1545-AQ28

Exports of Chemicals That Deplete the Ozone Layer; Special Rules for Certain Medical Uses of Chemicals That Deplete the Ozone Layer; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to taxes imposed on exports of chemicals that deplete the ozone layer, taxes imposed on ozone-depleting chemicals used as medical sterilants or propellants in metered-dose inhalers, and floor stocks taxes on ozone-depleting chemicals.

DATES: The public hearing originally scheduled for Thursday, May 27, 1993, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Carol Savage of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622-8452 or (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under sections 4681 and 4682 of the Internal Revenue Code. A notice of proposed rulemaking and public hearing appearing in the Federal Register for Friday, January 15, 1993, (58 FR 4625), announced that the public hearing on the proposed regulations would be held on Thursday, May 27, 1993, beginning at 10 a.m., in the Commissioner's Conference Room, room 3313, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

The public hearing scheduled for Thursday, May 27, 1993, has been cancelled.

Dale D. Goode,
Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).
[FR Doc. 93-9854 Filed 4-27-93; 8:45 am]

BILLING CODE 4820-01-J