

and redesignating (g)(5) and (g)(6) as (g)(3) and (g)(4).

John C. Lawn,
Administrator.

Date: April 10, 1989.

[FR Doc. 89-8755 Filed 4-12-89; 8:45 am]

BILLING CODE 4410-09-M

21 CFR Part 1308

Schedules of Controlled Substances; Placement of (±)cis-4-methylaminorex into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place (±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine ((±)cis-4-methylaminorex), a stimulant, into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is taken following a review and evaluation of the relevant data by both DEA and the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS). Based on these reviews, the DEA Administrator finds that (±)cis-4-methylaminorex meets the statutory criteria for placement into Schedule I of the CSA. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I will be applicable to the manufacture, distribution, importation, exportation and possession of (±)cis-4-methylaminorex.

EFFECTIVE DATE: April 13, 1989.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537. Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: (±)cis-4-methylaminorex is a potent central nervous system stimulant that is similar in its pharmacological action to amphetamine, a Schedule II substance. This substance has been produced in clandestine laboratories, identified in drug evidence submissions and associated with at least two overdose deaths.

On October 15, 1987, the Administrator of DEA issued a final rule in the Federal Register temporarily placing 4-methylaminorex into Schedule I of the CSA for one year pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h). This action was based on a finding by the Administrator of DEA that the emergency scheduling of 4-

methylaminorex was necessary to avoid an imminent hazard to the public safety. Emergency control was extended until April 15, 1989 through issuance of an additional final rule (53 FR 40061).

On October 14, 1988, in a notice of proposed rulemaking published in the Federal Register (53 FR 40391), the DEA Administrator proposed to place 4-methylaminorex (4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) in Schedule I of the CSA. This proposal followed a review of the relevant data by DEA pursuant to 21 U.S.C. 811(a). The proposed rule provided the opportunity for interested parties to submit comments, objections or requests for a hearing regarding the proposed scheduling of 4-methylaminorex. There was one comment submitted on October 18, 1988 by an individual who expressed an interest in the use of 4-methylaminorex as a nasal decongestant. Since receipt of that comment, two requests for a hearing were received from the same individual on January 30 and February 3, 1989. Since the requests for a hearing were not filed in a timely manner and did not follow the procedures set forth in 21 CFR 1303.44 and 1303.45, they have been denied.

During the period of temporary control of 4-methylaminorex in Schedule I, DEA gathered information regarding the abuse and abuse potential, the clandestine manufacture and the illicit distribution and trafficking of 4-methylaminorex. The Administrator of DEA submitted this information by letter to the Assistant Secretary for Health (DHHS) and recommended that 4-methylaminorex be placed into Schedule I of the CSA. Enclosed with the letter was a document prepared by the DEA entitled "Scheduling Recommendation for 4-methylaminorex." The document contained a review of the factors which the CSA requires the Attorney General (delegated to the Administrator of DEA) to consider (21 U.S.C. 811(b)) and the summarized recommendations regarding the scheduling of 4-methylaminorex.

As stated in the proposed rulemaking, DEA's final decision concerning the scheduling of 4-methylaminorex took into account the recommendation of the Acting Assistant Secretary for Health (DHHS), its own review, and any information received in response to this proposal. By letter dated April 5, 1989, the DEA Administrator received the scientific and medical evaluation and scheduling recommendation for 4-methylaminorex from the Acting Assistant Secretary for Health (DHHS). The recommendation stated that (±)cis-4-methylaminorex has actions that are consistent with central nervous system

stimulation of the amphetamine type and that it should be placed into Schedule I of the CSA.

Based on the information gathered and reviewed by DEA and the recommendation of the Acting Assistant Secretary for Health (DHHS), the Administrator of DEA, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

- (1) (±)cis-4-methylaminorex has a high potential for abuse;
- (2) (±)cis-4-methylaminorex has no currently accepted medical use in treatment in the United States; and
- (3) There is a lack of accepted safety for use of (±)cis-4-methylaminorex under medical supervision.

The above findings are consistent with the placement of (±)cis-4-methylaminorex into Schedule I of the CSA. In accordance with 21 U.S.C. 811(h)(5), the emergency scheduling order for (±)cis-4-methylaminorex shall be vacated on the effective date of this final rule, with the placement of (±)cis-4-methylaminorex into Schedule I of the CSA pursuant to 21 U.S.C. 811(a).

Since (±)cis-4-methylaminorex is already under temporary control in Schedule I, all regulations applicable to Schedule I substances continue to be effective as of April 13, 1989.

The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports (±)cis-4-methylaminorex 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.* (±)cis-4-methylaminorex must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels and labeling for commercial containers of (±)cis-4-methylaminorex must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for (±)cis-4-methylaminorex 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 (±)cis-4-methylaminorex shall take an inventory pursuant to §§ 1304.11-1304.19 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 §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall maintain such records on (±)cis-4-methylaminorex.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34-1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding (±)cis-4-methylaminorex.

8. *Order Forms.* All registrants involved in the distribution of (±)cis-4-methylaminorex must comply with the order form requirements of §§ 1305.01-1305.16 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of (±)cis-4-methylaminorex shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with respect to (±)cis-4-methylaminorex not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the scheduling of (±)cis-4-methylaminorex will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This drug control action relates to the control of a substance that has no legitimate use or manufacturer in the United States. In accordance with the provisions of 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 the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193). 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 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 DEA by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator

hereby orders 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).

§ 1308.11 [Amended]

2. Paragraph (f) of § 1308.11 is amended by redesignating the existing paragraph (f)(2) as (f)(3) and adding a new paragraph (f)(2):

§ 1308.11 Schedule I.

* * * * *
 (f) * * *
 (2) (±)cis-4-methylaminorex
 ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine).....1590
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3. Paragraph (g) of § 1308.11 is amended by removing paragraph (g)(3) and redesignating existing paragraph (g)(4) as (g)(3).

Date: April 10, 1989.

John C. Lawn,
 Administrator.
 [FR Doc. 89-8756 Filed 4-12-89; 8:45 am]
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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6717

[WY-930-09-4214-10; WYW 101818]

Withdrawal of Public Land and Mineral Estate for the Spanish Point Cave System; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 11,415.86 acres of public land and mineral estate from surface entry and mining for a period of 15 years for the Bureau of Land Management to protect the Spanish Point Caves and associated subsurface karstic waterways. The lands have been and remain open to mineral leasing.

EFFECTIVE DATE: April 13, 1989.

FOR FURTHER INFORMATION CONTACT: Tamara Gertsch, Wyoming State Office, P.O. Box 1828, Cheyenne, Wyoming 82003, 307-772-2072.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, the following described public lands and mineral estate are hereby withdrawn from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C., Ch. 2), but not from leasing under the mineral leasing laws, to protect the Spanish Point Caves and associated subsurface karstic waterways:

Sixth Principal Meridian

Federal surface and subsurface estates, managed by the Bureau of Land Management:

- T. 50 N., R. 88 W.,
 Sec. 5, lots 6 and 7.
- T. 50 N., R. 89 W.,
 Sec. 1, lots 12-20, N½NW¼SW¼;
 Sec. 2, lots 17-20, N½S½;
 Sec. 3, lots 8, 9, 19, 20, SE¼;
 Sec. 4, lots 5, 6, 11-14, 19, and 20.
- T. 51 N., R. 88 W.,
 Sec. 4, SW¼NW¼, W½SW¼;
 Sec. 5, lots 6-10, SW¼NE¼, S½SE¼NE¼, SE¼;
 Sec. 8, lot 1, NW¼NE¼;
 Sec. 28, W½SW¼;
 Sec. 32, lots 2-4, NE¼, N½SE¼, SW¼ SE¼;
 Sec. 33, W½NW¼.
- T. 51 N., R. 89 W.,
 Sec. 1, lot 11;
 Sec. 11, E½E½;
 Sec. 12, lots 1-4, SW¼NE¼, S½NW¼, SW¼, W½SE¼;
 Sec. 13, lots 1-3, N½NW¼.
 Sec. 14, lots 1 and 2, NE¼, S½NW¼, NE¼ SW¼, S½SW¼, W½SE¼;
 Sec. 22, E½E½;
 Sec. 23, W½;
 Sec. 26, W½NW¼;
 Sec. 27, E½;
 Sec. 33, E½SE¼;
 Sec. 34, N½, N½NE¼SW¼; W½SW¼.
- T. 52 N., R. 88 W.,
 Sec. 16, SW¼SW¼;
 Sec. 17, E½SE¼SE¼;
 Sec. 32, lot 4, SW¼SE¼.
- T. 52 N., R. 89 W.,
 Sec. 21, S½;
 Sec. 22, S½N½, S½;
 Sec. 23, SW¼NE¼, SE¼NW¼, N½S½, SW¼SW¼.

The areas described aggregate 6,439.30 acres in Bighorn County.

Federal surface and subsurface estates, managed by the U.S. Forest Service, Bighorn National Forest:

- T. 51 N., R. 88 W.,
 Sec. 4, lots 5-7, S½NE¼, SE¼NW¼, E½ SW¼, SE¼;
 Sec. 9, NE¼, E½NW¼, N½NE¼SW¼, N½NW¼SE¼;
 Sec. 28, E½, E½W½;
 Sec. 33, E½, E½W½.
- T. 52 N., R. 88 W.,
 Sec. 15, W½ Unsurveyed;
 Sec. 16, E½, E½W½;
 Sec. 21, NE¼, E½NW¼, N½NE¼SW¼, N½SE¼;
 Sec. 22, NW¼, N½SW¼ Unsurveyed;
 Sec. 33, SE¼SW¼, S½SE¼.

The areas described aggregate 3,220.04 acres in Bighorn County.