(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The bolt installation shall be done in accordance with Fokker Service Bulletin F27/57-25, Revision 1, dated August 1, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on March 12, 1993.

Issued in Renton, Washington, on January 28, 1993.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93-2705 Filed 2-4-93; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Zolpidem into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places zolpidem into Schedule IV of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of zolpidem.

EFFECTIVE DATE: February 5, 1993.

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: Zolpidem is a hypnotic drug pharmacologically similar to the benzodiazepines. It will be marketed under the trade name of Ambien for the treatment of transient, short-term and chronic insomnia. The Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, by letter dated September 4, 1992, recommended to the Administrator of the DEA that zolpidem be placed into Schedule IV of the CSA pending approval of a New Drug Application (NDA) for the drug. The Administrator of the DEA, in a November 24, 1992 **Federal Register** notice (57 FR 55201), proposed to place zolpidem into Schedule IV of the CSA if and when the Food and Drug Administration (FDA) approved an NDA for zolpidem. This notice provided an opportunity for all interested persons to submit their comments, objections or requests for a hearing in writing on the proposed scheduling of zolpidem until December 24, 1992. DEA received no comments regarding this proposal. The FDA notified the DEA that it has determined that zolpidem is safe and effective for use as recommended in the final labelling and accordingly approved the NDA for zolpidem on December 16, 1992.

Based on the information gathered and reviewed by the DEA, the scientific and medical evaluation and scheduling recommendation of the Assistant Secretary for Health, and the FDA's approval of the NDA for zolpidem, the Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811 (a) and (b), finds that:

(1) Zolpidem has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III;

(2) Zolpidem has a currently accepted medical use in treatment in the United States; and

(3) Abuse of zolpidem may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

The above findings are consistent with the placement of zolpidem into Schedule IV of the CSA. In order to avoid delays in the marketing of zolpidem, the Schedule IV control of zolpidem will be effective upon publication of this final notice in the **Federal Register**. In the event that the regulations impose special hardships on any registrant, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding zolpidem. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports zolpidem, or who engages in research or conducts instructional activities with zolpidem, 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.* Zolpidem must be manfactured, 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 zolpidem shall comply with the requirements of §§ 1302.03-1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Every registrant required to keep records and who possesses any quantity of zolpidem shall maintain an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding zolpidem.

6. *Prescriptions.* All prescriptions for products containing zolpidem shall comply with §§ 1306.01-1306.06 and §§ 1306.21-1306.26 of Title 21 of the Code of Federal Regulations.

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

8. *Criminal Liability.* Any activity with respect to zolpidem not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of zolpidem into Schedule IV of the CSA 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 will allow the initial marketing of a drug product which has been approved by the FDA.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 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 order to place zolpidem into Schedule IV of the CSA is a formal rulemaking "on the record after opportunity for a hearing." Such formal 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). Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon

review by OMB. Nevertheless, the Administrator has determined that this is not a "major rule," as that term is used in E.O. 12291, and that it would otherwise meet the applicable standards of Sections 2(a) and 2(b)(2) of E.O. 12778.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Pursuant to the authority vested in the Attorney General by 21 U.S.C. 811(a) and delegated to the Administrator of DEA by the regulations of the Department of Justice (28 CFR part 0.100), and based on the information gathered and reviewed by the DEA, the scientific and medical evaluation and scheduling recommendation of the Assistant Secretary for Health, and the FDA's approval of the NDA for zolpidem, the Administrator of the DEA hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.14 is amended by adding paragraph (c)(48) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(48) Zolpidem 2783

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Dated: January 27, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93-2753 Filed 2-4-93; 8:45 am]

BILLING CODE 4410-09-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[FRL-4560-7]

Disclosure of Confidential Data to Persons Working Under the Senior Environmental Employment Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim rule with request for comments.

SUMMARY: EPA is issuing interim regulations modifying certain of EPA's regulations at 40 CFR part 2, subpart B governing confidential business information. This rule authorizes disclosure of confidential data, submitted pursuant to certain environmental statutes administered by the Agency, to persons working under the Senior Environmental Employment Program.

EFFECTIVE DATE: This rule is effective February 5, 1993.

ADDRESSES: Send or deliver written comments to Donald A. Sadowsky, Contracts, Information and General Law Division (LE-132K), Office of General Counsel, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Donald A. Sadowsky, Office of General Counsel. Telephone 202/260-5469.

SUPPLEMENTARY INFORMATION: On May 20, 1975 EPA published in the **Federal Register** (40 FR 21987) a proposed rule concerning procedures for the treatment of confidential business information (CBI) submitted under various environmental statutes. This rule was made final on September 1, 1976 (41 FR 36902), codified as 40 CFR part 2, subpart B. Rules governing treatment of CBI submitted under additional environmental statutes were promulgated on September 8, 1978 (43 FR 40003), December 18, 1985 (50 FR 51663), and July 29, 1988 (53 FR 28772).

A. The SEE Program

The Senior Environmental Employment (SEE) program is authorized by the Environmental Programs Assistance Act of 1984 (Pub. L. 98-313), which provides that the Administrator may "make grants or enter into cooperative agreements" for the purpose of "providing technical assistance to Federal, State, and local environmental agencies for projects of pollution prevention, abatement, and control."

EPA currently has cooperative agreements under the SEE program with organizations such as the American Association for Retired Persons and the National Urban League. Persons working under the SEE program perform a multitude of functions for the Agency, including opening mail, filing documents, clerical support, answering telephones, staffing hot lines, providing support to Agency enforcement activities, and compiling data.

B. Disclosure of Confidential Data to SEE Enrollees

Under sections 114, 208, and 307(a) of the Clean Air Act (42 U.S.C. 7414, 7542, and 7607), sections 308 and 509(a) of the Clean Water Act (33 U.S.C. 1318 and 1369(a)), section 1445(d) of the Safe Drinking Water Act (42 U.S.C. 300j-4), sections 3001(b)(3)(B), 3007(b), and 9005(b) of the Solid Waste Disposal Act (42 U.S.C. 6921(b)(3)(B), 6927(b), and 6995(b)), and section 104(e)(7) of the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(e)(7)) EPA may disclose CBI to authorized representatives of the United States. Similarly, under section 10(e) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136h(e)) EPA may disclose CBI to contractors with the United States. And under section 408(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a(f)) EPA may disclose CBI to persons authorized by the Administrator or by an advisory committee.

Although Congress did not require that authorized representatives have a contractual relationship with EPA, the Agency chose to confine the definition of authorized representatives to contractors (and state or local governmental bodies where allowed by statute) when it first proposed and promulgated regulations governing disclosure of CBI to authorized representatives. See 40 FR 21990, 40 CFR 2.301(h)(2)(i). At the time there was no SEE program, and it was therefore not contemplated that there would be a need to disclose CBI to persons assisting EPA who were not contractors. EPA's regulations at 40 CFR 350.23(b)(1), implementing section 322(f) of the Emergency Planning and Community Right-to-Know Act (EPCRA) (42 U.S.C. 11042(f)) and promulgated after the inception of the SEE program, specifically allow a grantee who performs work for EPA in connection with EPCRA or regulations which implement EPCRA to be an authorized representative. See the **Federal Register** notice of July 29, 1988 (53 FR 28772).

The nature of EPA's work requires that the Agency collect significant amounts of CBI. In order for SEE enrollees to perform their duties, they must be authorized for access to this information. Many Agency offices have been providing SEE enrollees with access to CBI, under the impression that EPA regulations allowed such access. The Agency is hereby rectifying this error by amending its regulations to provide for access to SEE enrollees.

Although section 10(e) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for access to CBI by "contractors", rather than the broader term "authorized representatives" employed in other environmental statutes, EPA's Office of Pesticide Programs has a long-standing