

issue. Is there consumer benefit in having OTC fluoride-containing drug products labeled to state their fluoride levels? If the answer is yes, what is the best way(s) to provide this information to consumers. The agency particularly invites comments on the fluoride labeling options discussed above, as well as any other possible labeling options that might be used. Would a combination of labeling options (e.g., percent w/v and mg/in) provide consumers with the most useful information?

The agency is currently developing the final rule for OTC anticaries drug products. The agency believes that it would be appropriate to reopen the administrative record to consider comments on these fluoride labeling issues. The agency also needs to respond to the Subcommittee's request for recommendations on the labeling of OTC fluoride-containing drug products. The agency therefore finds that good cause exists to reopen the administrative record. The agency plans to discuss identification of fluoride levels in the labeling of OTC drug products containing fluoride in the final rule.

Interested persons may on or before January 25, 1993, submit to the Dockets Management Branch (address above) written comments regarding the labeling of OTC fluoride-containing drug products to identify their fluoride levels. Three copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### References

(1) Department of Health and Human Services, "Review of Fluoride Benefits and Risks: Report of the Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs," February, 1991, in OTC Vol. No. 08FLTFM, Docket No. 80N-0042, Dockets Management Branch.

(2) Department of Health and Human Services, "Executive Summary of the Review of Fluoride Benefits and Risks," February, 1991, in OTC Vol. No. 08FLTFM, Docket No. 80N-0042, Dockets Management Branch.

(3) Letter from W. E. Gilbertson, FDA, to C. Whall, Council on Dental Therapeutics of the American Dental Association, coded LET15, Docket No. 80N-0042, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA, to J. D. Cope, Nonprescription Drug Manufacturers Association, coded LET16, Docket No. 80N-0042, Dockets Management Branch.

(5) Letter from W. E. Gilbertson, FDA, to E. E. Kavanaugh, The Cosmetic, Toiletry and

Fragrance Association, coded LET17, Docket No. 80N-0042, Dockets Management Branch.

(6) Comment No. C0086, Docket No. 80N-0042, Dockets Management Branch.

(7) Comment No. C0087, Docket No. 80N-0042, Dockets Management Branch.

(8) Comment No. C0085, Docket No. 80N-0042, Dockets Management Branch.

(9) Letter from W. E. Gilbertson, FDA, to K. H. Burrell, Council on Dental Therapeutics of the American Dental Association, coded LET19, Docket No. 80N-0042, Dockets Management Branch.

(10) Comment No. C0088, Docket No. 80N-0042, Dockets Management Branch.

Dated: November 3, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

#### Schedules of Controlled Substances; Proposed Placement of Zolpidem Into Schedule IV

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule places the drug, zolpidem, into Schedule IV of the Controlled Substances Act (CSA). The Administrator of the Drug Enforcement Administration (DEA) has received a recommendation from the Department of Health and Human Services (DHHS) that zolpidem be controlled in Schedule IV.

**DATES:** Comments must be submitted on or before December 24, 1992.

**ADDRESSES:** Comments and objections should be submitted to: 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 September 15, 1992, the Administrator of the DEA received a letter from the Assistant Secretary for Health, acting on behalf of the Secretary of the DHHS, recommending that zolpidem be placed in Schedule IV of the CSA (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-996)). Enclosed with this letter from the Assistant Secretary was a document which listed the factors which the Act

requires the Secretary to consider and the summarized considerations of the Secretary in recommending control for zolpidem. In his letter, the Assistant Secretary recommended, further, that this scheduling action become effective if and when the zolpidem New Drug Application (NDA) receives final approval by the Food and Drug Administration (FDA).

The factors considered by the Assistant Secretary for zolpidem were:

(1) Its actual or relative potential for abuse;

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

(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.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary of Health, received in accordance with section 201(f) of the Act (21 U.S.C. 811(f)), the Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, zolpidem has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III;

(2) Zolpidem will, upon issuance of a NDA by the FDA, have 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.

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 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 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 exempted from the consultation requirements of Executive Order 12291 (46 FR 13193) and are outside the scope of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612 (52 FR 41685), 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 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 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 to add a new paragraph (c)(48) to read as follows:

#### § 1308.14 Schedule IV.

(c) \* \* \*  
(48) Zolpidem

Dated: November 13, 1992.

Robert C. Bonner,

Administrator of Drug Enforcement.

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## PEACE CORPS

### 22 CFR Part 309

#### Claims Collection

**AGENCY:** Peace Corps of the United States (Peace Corps).

#### **ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Peace Corps proposes to revise its regulations regarding the Collection of Claims by Administrative Offset. These changes are being made to enhance Peace Corps' ability to collect its debts by providing guidance to officers and employees charged with debt collection responsibilities. The proposed rules implement the collection procedures authorized by the Federal Claims Collection Act of 1966, as amended by the Debt Collection Act of 1982. In addition, these rules implement 31 U.S.C. 3720A, which authorizes Federal agencies to notify the Internal Revenue Service of a past-due legally enforceable debt for the purpose of offsetting the debtor's tax refund. These laws have been implemented by the Federal Claims Collection Standards issued jointly by the General Accounting Office and the Department of Justice, regulations issued by the Office of Personnel Management, the procedures prescribed by the Office of Management and Budget in Circular A-129, and by the Internal Revenue Service procedures.

**DATES:** To be assured consideration, comments must be in writing and must be received on or before December 24, 1992. Comments should refer to specific sections in the regulation.

**ADDRESSES:** Comments should be sent to Arnold Intrater, Acting General Counsel, Peace Corps, 1990 K Street, NW., room 8300, Washington, DC 20526. Comments will be available for public inspection from 9 a.m. to 5 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Arnold Intrater, Acting Peace Corps General Counsel, or Daniel Bosco, Assistant General Counsel at (202) 606-3114 (Voice) or (202) 606-1313 (TDD).

**SUPPLEMENTARY INFORMATION:** The Debt Collection Act of 1982 authorizes procedures for the collection of debts owed to the United States including: (1) Salary offset, (2) administrative offset, (3) contracting for collection services to recover debts. In addition, section 3720A of Title 31 U.S.C. authorizes agencies to notify the Internal Revenue Service of a past-due legally enforceable debt for the purpose of offsetting the debtor's tax refund. Although these are separate procedures, any procedure may be used by itself or in conjunction with other procedures.

Salary Offset. Section 5 of the Debt Collection Act (codified at 5 U.S.C. 5514) establishes the procedures to be used when an agency collects money owed it by offsetting the salary of a federal employee. Agencies of the Government

may cooperate with one another in order to effectuate recovery of the claim.

Salary offset procedures permit an employee to review the determination of indebtedness before offset is implemented, and an employee against whom an offset is sought is automatically entitled to a hearing on matters surrounding the determination of the debt, or the percentage of disposable pay to be deducted each pay period.

Administrative Offset. The procedures authorized for administrative offset are contained in section 10 of the Debt Collection Act (codified at 31 U.S.C. 3716). The Act requires that notice procedures be observed by the agency.

The debtor is also afforded an opportunity to inspect and copy government records pertaining to the claim, enter into an agreement for repayment, and to a review of the claim (if requested). Like salary offset, agencies may cooperate with one another in order to effectuate recovery of the claim.

Collection Services. Section 13 of the Debt Collection Act (codified at 31 U.S.C. 3718) authorizes agencies to enter into contracts for the collection services to recover debts owed the United States. The Act requires that certain provisions be contained in such contracts including:

(1) The agency retains the authority to resolve a dispute, including the authority to terminate a collection action or refer the matter to the Attorney General for civil remedies; and

(2) The contractor is subject to the Privacy Act of 1974, as it applies to private contractors, as well as subject to State and Federal laws governing debt collection practices.

Tax Refund Offset. Title 31 U.S.C. 3720A authorizes the Internal Revenue Service (IRS) to reduce a refund of a taxpayer's overpayment of tax by the amount of any legally enforceable debt which is owed to a Federal agency and is at least three months overdue. This section also requires the agency to give taxpayer-debtors at least 60 days notice of the agency's intention to use the provisions of this section. Under this authority, the Peace Corps may refer to the IRS for collection by tax refund offset from refunds otherwise payable, past-due legally enforceable debts owed to the Peace Corps if: (i) The debts are eligible for offset pursuant to 31 U.S.C. 3720A, section 6402(d) of the Internal Revenue Code, 26 CFR 301.6420T, and the agreement between the Peace Corps and the IRS, and (ii) the Peace Corps provides the information required by the agreement for each debt.