Authority: 21 U.S.C. 360b.

■ 13. Section 522.1696b is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations*. Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 053501 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 010515, 055529, and 059130: Treatment should not exceed 4 consecutive days. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.2200 [Amended]

■ 14. Section 522.2200 is amended in paragraph (e)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2220 [Amended]

■ 15. Section 522.2220 is amended in paragraph (a)(3)(iii)(*c*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2640a [Amended]

■ 16. Section 522.2640a is amended in paragraph (e)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

■ 18. Section 558.55 is amended in paragraphs (d)(1)(i)(*b*) and (d)(1)(ii)(*b*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

Dated: March 25, 2005.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 05–6518 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–262F]

Schedules of Controlled Substances: Placement of Zopiclone Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, zopiclone, including its salts, isomers and salts of isomers into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of zopiclone and products containing zopiclone.

DATES: *Effective Date:* April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION: Zopiclone is a central nervous system depressant drug. On December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta TM. Eszopiclone will be marketed as a prescription drug product for the treatment of insomnia.

On January 18, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a letter recommending that zopiclone and its isomers be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the January 18, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Zopiclone and its Optical Isomers in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

The correspondence from the Acting Assistant Secretary for Health to DEA dated January 18, 2005, confirmed that FDA approved the New Drug Application (NDA) for eszopiclone and issued an approval letter to the NDA sponsor on December 15, 2004. After a review of the available data, including the DHHS recommendation, the Deputy Administrator of the DEA, in a February 14, 2005, **Federal Register** notice of proposed rulemaking (70 FR 7449), proposed placement of zopiclone into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before March 16, 2005.

Comments Received

DEA received one comment in response to this notice of proposed rulemaking. The commenter stated that the current federal regulations governing the process of drug control and approval are excessive and are interfering with the practice of medicine.

DEA disagrees. The Controlled Substances Act contains specific mandates pertaining to the scheduling of controlled substances. DEA has followed all of those mandates regarding the scheduling of zopiclone, including receiving from the Secretary of DHHS a scientific and medical evaluation, and recommendation, regarding control (21 U.S.C. 811(b)); considering the factors enumerated in 21 U.S.C. 811(c); determining, based on the above, appropriate scheduling for zopiclone (21 U.S.C. 812(b)); and conducting a formal rulemaking to schedule zopiclone (21 U.S.C. 811(a)). In no way does this scheduling action interfere with the practice of medicine.

Scheduling of Zopiclone

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in

response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

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

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

(3) Abuse of zopiclone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. (21 U.S.C. 812(b)(4)).

Based on these findings, the Deputy Administrator of DEA concludes that zopiclone, including its salts, isomers, and salts of isomers, warrants control in Schedule IV of the CSA.

In order to make zopiclone pharmaceutical products available for medical use as soon as possible, the Schedule IV controls of zopiclone will be effective April 4, 2005. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding zopiclone. The applicable regulations are as follows:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with zopiclone, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with zopiclone, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before April 4, 2005, and may continue their activities until DEA has approved or denied that application.

Security. Zopiclone is subject to Schedule III-V security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Labeling and Packaging. All labels and labeling for commercial containers of zopiclone shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of zopiclone must keep an inventory of all stocks of zopiclone on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations after April 4, 2005. Every registrant who desires registration in Schedule IV for zopiclone is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Prescriptions. All prescriptions for zopiclone or prescriptions for products containing zopiclone are to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for zopiclone or products containing zopiclone issued after April 4, 2005, if authorized for refilling, shall, as of that date, be limited to five refills and shall not be refilled after October 3, 2005.

Importation and Exportation. All importation and exportation of zopiclone must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Criminal Liability. Any activity with zopiclone not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after April 4, 2005.

Regulatory Certifications

Administrative Procedure Act

The Administrative Procedure Act permits an agency to make a rule effective upon the date of publication where the agency finds good cause exists and publishes its findings with the rule (5 U.S.C. 553(d)(3)). As noted previously, on December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta™. Further, on January 18, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services, sent the Deputy Administrator of DEA a letter recommending that zopiclone and its isomers be placed into Schedule IV of the Controlled Substances Act. Since this is a new drug not previously available in the United States, in order to prevent harm to the public health and safety by delaying the availability of this new drug, the Drug Enforcement Administration finds good cause exists to make this Final Rule effective immediately upon publication.

Executive Order 12866

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 exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Eszopiclone products will be prescription drugs used for the treatment of insomnia. Handlers of eszopiclone also handle other controlled substances used to treat insomnia which are already subject to the regulatory requirements of the CSA.

Eszopiclone is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule IV of the CSA. This final rule will allow these entities to have access to a new pharmaceutical product.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $115,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement

Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices: or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

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 Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES [AMENDED]

■ 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 1308.14 is amended by adding a new paragraph (c)(51) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(51) Zopiclone—2784

* * * * *

Dated: March 30, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–6703 Filed 3–31–05; 12:24 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 10

[Public Notice 5036]

RIN 1400–AC09

Removal of Regulations on Employee Responsibilities and Conduct

AGENCY: State Department and United States Agency for International Development.

ACTION: Direct final rule.

SUMMARY: The Department of State and the United States Agency for International Development (USAID) are removing regulations on employee responsibilities and conduct (22 CFR part 10). Most of these regulations have been superseded or otherwise made unnecessary by Office of Government Ethics or Office of Personnel Management regulations of executive branch-wide applicability. Certain sections of the regulations are based on Foreign Service Act provisions that have been repealed. Some provisions have continuing application and are published, as modified, in the Foreign Affairs Manual and other provisions simply reference other statutory or regulatory provisions. The Department of State and USAID are using direct final rulemaking for this action because it is expected that there will be no significant adverse comment on the rule.

DATES: This direct final rule is effective on June 3, 2005, without further notice, unless the Department of State and USAID receive adverse comment by May 4, 2005. If adverse comment is received, then the Department of State and USAID will publish a timely withdrawal of the direct final rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by any of the following methods:

- E-mail: *eirinbergjl@state.gov*. You must include the RIN in the subject line of your message.
- Mail (paper, disk, or CD–ROM submissions): Julia L. Eirinberg, Attorney-Adviser, Department of State, Office of the Assistant Legal Adviser for Employment Law, 2201 C Street NW, Suite 5425, Washington, DC 20520.
- Fax: 202–647–6794.

Persons with access to the internet may also view this notice and provide comments by going to the regulations.gov Web site at: *http://www.regulations.gov/index.cfm*.

FOR FURTHER INFORMATION CONTACT: Julia L. Eirinberg, Attorney-Adviser, Department of State, Office of the Assistant Legal Adviser for Employment Law, 2201 C Street NW., Suite 5425, Washington DC 20520; e-mail address: *eirinbergjl@state.gov*.

SUPPLEMENTARY INFORMATION: The Department of State and USAID are removing part 10, ''Employee Responsibilities and Conduct,'' from 22 CFR as a result of developments in the executive branch ethics program and in other areas of law that have occurred since the promulgation of part 10 on May 2, 1978. While the regulations in 22 CFR part 10 also applied to the International Communication Agency (ICA), that agency no longer exists and its functions have been assumed by the Department of State.

Pursuant to the Ethics in Government Act of 1978 (5 U.S.C. App.), as amended, the U.S. Office of Government Ethics (OGE) now provides overall direction and leadership in relation to the executive branch ethics program. In 1989, E.O. 12674 (as modified by E.O. 12731) directed OGE to establish ''a single, comprehensive, and clear set of executive-branch standards of conduct'' and ''a system of nonpublic (confidential) financial disclosure.'' On August 7, 1992, OGE published the Standards of Ethical Conduct for Employees of the Executive Branch (Standards), now codified at 5 CFR part 2635. On April 7, 1992, OGE modified its existing financial disclosure regulation, at 5 CFR part 2634, to incorporate a revised system of confidential financial disclosure reporting.

Part 10 of 22 CFR was published in 1978 largely on the basis of a model standards of conduct regulation at old 5 CFR part 735 that had been promulgated by the Office of Personnel Management (OPM) pursuant to Executive Order 11222. The new OGE Standards became effective February 3, 1993. The Standards superseded individual executive agency conduct provisions—like those in 22 CFR part 10—that had been issued on the basis of the model OPM regulation, and superseded much of the model regulation itself. (As discussed below in relation to section 10.735–205 of part 10, certain agency conduct provisions were ''grandfathered'' or preserved for a few years after the February 3, 1993, effective date.) Provisions in the OGE regulation at 5 CFR part 2634 concerning the revised system of confidential financial disclosure became effective on October 5, 1992, and superseded those portions of individual executive agency regulations pertaining to confidential reporting that had been issued on the basis of the model OPM regulation. Taken together and as discussed more fully below, 5 CFR part 2635 and 5 CFR part 2634 superseded subpart C, subpart D, and much of subparts A and B of part 10. As also discussed below, the remaining sections of subparts A and B have been superseded or supplanted by other OGE regulations, are obsolete, or are unnecessary.

In subpart A of part 10, the statement of purpose in section 10.735–101 has been superseded by corollary sections in 5 CFR part 2635 and 5 CFR part 2634