application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.813 is added to read as follows:

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications.* Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.228 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount.* 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications.* Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations.* Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.228 is added to subpart B to read as follows:

§ 556.228 Enrofloxacin.

A tolerance of 0.3 part per million is established for residues of enrofloxacin (marker residue) in muscle (target tissue) of chickens and turkeys.

Dated: October 28, 1996.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 96–28291 Filed 11–4–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–152P]

Schedules of Controlled Substances: Placement of Remifentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the narcotic drug, remifentanil and salts thereof, into Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This rule imposes the regulatory controls and criminal sanctions of a Schedule II narcotic substance under the CSA on the manufacture, distribution, dispensing, importation, and exportation of remifentanil and salts thereof. Remifentanil hydrochloride was recently approved by the Food and Drug Administration (FDA) for marketing as an intravenous analgesic agent.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: 202–307–7183.

SUPPLEMENTARY INFORMATION:

Remifentanil is a narcotic drug pharmacologically similar to, but shorter acting than, fentanyl, alfentanil and sufentanil. Remifentanil hydrochloride will be marketed under the trade name of ULTIVA as an intravenous analgesic agent for use during the induction and maintenance of general anesthesia and monitored anesthesia care. The Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services (DHHS), by letter dated August 23, 1996, recommended to the Deputy Administrator of the DEA that remifentanil, and its salts, be placed into Schedule II of the CSA. The Deputy Administrator of the DEA, in a September 16, 1996, Federal Register notice (61 FR 48655) proposed placing remifentanil, and salts thereof, into Schedule II of the CSA. Interested parties were given until October 16, 1996, to submit comments, objections or requests for a hearing regarding the proposal. None were received.

Based on the scientific and medical evaluation and scheduling recommendation contained in the August 23, 1996, letter from the Assistant Secretary for Health, DHHS, the Acting Deputy Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811 (a) and (b) and 812(b), finds that:

(1) Remifentanil has a high potential for abuse;

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

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

The above findings are consistent with the placement of remifentanil into Schedule II of the CSA. The Acting Deputy Administrator further finds that remifentanil is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to morphine. Consequently, remifentanil is a narcotic since the definition of narcotics, as stated in 21 U.S.C. 802(17)(A), includes; ''Opium, opiates, derivatives of opium and opiates.''

In order to make a remifentanil pharmaceutical product available for medical use as soon as possible, the Schedule II control of remifentanil will be effective November 5, 1996. In the event that this poses special hardships on any registrant, the DEA will entertain any justified request of an extension of

time. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes dispenses, imports or exports remifentanil or who engages in research or conducts instructional activities with remifentanil, 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.* Remifentanil must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (a), (c), and (d), 1301.73, 1301.74, 1301.75 (b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, remifentanil which is distributed on and after November 5, 1996 shall comply with the requirements of §§ 1302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for remifentanil are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing remifentanil are required to take inventories pursuant to §§ 1304.04 and 1304.11–1304.19 of Title 21 of the Code of Federal Regulations.

6. *Records.* All registrants must keep records pursuant to §§ 1304.04 and 1304.21–1304.29 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants are required to file reports pursuant to §§ 1304.34–1304.37 of Title 21 of the Code of Federal Regulations.

8. *Order Forms.* Each distribution of remifentanil requires the use of an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* As remifentanil has been approved by the FDA for use in medical treatment, the drug may be dispensed by prescription. Prescriptions for remifentanil are to be issued pursuant to §§ 1306.01–1306.07 and 1306.11–1306.15 of Title 21 of the Code of Federal Regulations.

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

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

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this order to place remifentanil into Schedule II of the CSA 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 (E.O.) 12866, Section 3(d)(1).

The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Remifentanil 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 II of the CSA. Remifentanil, a potent opioid drug, can produce drug dependence of the morphine type. This drug is likely to be diverted and abused if access to it is not closely monitored. The labeled indication for use of remifentanil is to provide analgesia during the induction and maintenance of general anesthesia. It is to be administered by trained professionals in monitored anesthesia care settings. Schedule II narcotic control will provide the necessary drug monitoring. Small-business entities which are likely to handle this drug maintain a Schedule II narcotic registration with the DEA. This rule will allow these entities to have access to a new pharmaceutical product.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule 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 the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy 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) unless otherwise noted.

2. Section 1308.12 is amended by redesignating the existing paragraph (c)(26) as (c)(27) and adding a new paragraph (c)(26) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(26) Remifentanil 9739

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Dated: October 26, 1996.

James S. Milford, Jr.,

Acting Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96–28294 Filed 11–4–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 2465]

Removal of Commercial Communications Satellites and Hot Section Technology From State's USML for Transfer to Commerce's CCL

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) by removing from the U.S. Munitions List (USML), for transfer to the Department of Commerce's Commerce Control List, hot-section technologies associated with commercial aircraft engines and commercial communications satellites.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: William Lowell, Director, Office of Defense Trade Controls, Department of State, Telephone (703) 812–2567 or FAX (703) 875–6647 ATTN: Regulatory Change, Commercial Communications Satellites and Commercial Hot Section Technologies.

SUPPLEMENTARY INFORMATION: On March 14, 1996, the Administration announced a decision concerning commercial aircraft engine hot section technologies and commercial communications satellites. The decision has several key features. First, commercial aircraft engine hot section technologies will be controlled on the Commerce Control List (CCL) of dual-use items that are licensed by Commerce. Commercial