V–537 [Revised]

From Palm Beach, FL; INT Palm Beach 356° and Vero Beach, FL, 143° radials; Vero Beach; INT Vero Beach 318° and Orlando. FL, 140° radials; INT Orlando 140° and Melbourne, FL 298° radials; INT Melbourne 298° and Ocala, FL 145° radials; Ocala; Gators, FL; Greenville, FL; Moultrie, GA; to Macon, GA.

* * * * *

Issued in Washington, DC, on July 6, 2005.

Edith V. Parish,

Acting Manager, Airspace and Rules.

[FR Doc. 05–13682 Filed 7–11–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle and in swine, by injection, for the management of respiratory disease. FDA is also amending the regulations to add the acceptable daily intake for total residues of tulathromycin and tolerances for residues of tulathromycin in edible tissues of cattle and swine.

DATES: This rule is effective July 12, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–244 for DRAXXIN (tulathromycin) Injectable Solution. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle, by subcutaneous injection, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*; and in swine, by intramuscular injection, for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*. The application is approved as of May 24, 2005, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.2630 and in part 556 (21 CFR part 556) by adding § 556.745 to reflect the approval. The basis of approval is discussed in the freedom of information (FOI) summary.

In accordance with the FOI provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 24, 2005.

The agency has determined under 21 CFR 25.33(d)(5) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 522

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 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.2630 is added to read as follows:

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobaccillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.745 is added to read as follows:

§ 556.745 Tulathromycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tulathromycin is 15 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for CP–60,300 (the marker residue) is 5.5 parts per million (ppm).

(ii) [Reserved]

(2) *Swine*—(i) *Kidney (the target tissue)*. The tolerance for CP–60,300 (the marker residue) is 15 ppm.

(ii) [Reserved]

(c) *Related conditions of use*. See § 522.2630 of this chapter.

Dated: June 20, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–13586 Filed 7–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice 5130]

RIN 1400–ZA17

Amendments to the International Traffic in Arms Regulations: Part 126

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending and/or clarifying the content of the International Traffic in Arms Regulations (ITAR). The affected part of the ITAR is: Part 126—Policies and Provisions. See Supplementary Information for a description of the changes and clarifications made.

EFFECTIVE DATE: July 12, 2005.

ADDRESSES: Interested parties are invited to submit written comments to the Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, 12th Floor, SA–1, Washington, DC 20522–0112. E-mail comments may be sent to *DDTCResponseTeam@state.gov* with an appropriate subject line. Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at: *http://www.regulations.gov*. Comments will be accepted at any time.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Tomchik, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2799 or FAX (202) 261–8199. ATTN: Regulatory Change, USML Sections 126.5 and 126.15.

SUPPLEMENTARY INFORMATION: Two changes are made to the International Traffic in Arms Regulations (ITAR) Part 126—General Policies and Provisions. The first change affects 22 CFR 126.5. This section describes *inter alia* the modalities by which exporters, without a license issued by the Directorate of Defense Trade Controls (DDTC), may conduct permanent and temporary exports of defense articles to Canada, and temporary imports from Canada. These changes to 22 CFR 126.5 are designed to clarify for exporters the range of defense articles, related technical data, and defense services that will continue to require a license issued by the Directorate of Defense Trade Controls for export to or temporary import from Canada.

The list of items excluded from the provisions of Section 126.5 is outlined in paragraph (b). That list is amended in the following ways: the text of 126.5(b)(12) is amended to reflect textual revisions to Category XIV of the U.S. Munitions List regarding chemical and biological agents. The body of chemical agents encompassed by 126.5(b)(12) and previously controlled in a single paragraph of the Category now has been grouped by type and distributed into several distinct paragraphs. The text also clarifies but does not change the scope of biological agents controlled. Other changes are made to reflect the redesignation of paragraphs in the Category.

The second change is a result of statutory direction. A new section of the ITAR implements Section 1225 of Public Law 108–375 regarding ''Bilateral Exchanges and Trade in Defense Articles and Defense Services Between the United States and the United Kingdom and Australia.'' This section, to be designated 126.15, calls for the expeditious processing of license applications for the export of defense articles and services to Australia or the United Kingdom, consistent with national security and the requirements of the Arms Export Control Act (22 U.S.C. 2751 et seq.

Regulatory Analysis and Notices: This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996. It will not have substantial direct effects on the States, the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this rule does not have sufficient federalism implications to warrant application of the consultation provisions of Executive Orders 12372 and 13132. This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for Part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; Sec. 1225, Pub. L. 108–375.

■ 2. Section 126.5 is amended by revising paragraph (b)(12) to read as follows:

§ 126.5 Canadian exemptions.

* * * * *

(b) * * *

(12) Chemical agents listed in Category XIV (a), (d), and (e), biological agents and biologically derived substances in Category XIV (b), and equipment listed in Category XIV (f) for dissemination of the chemical agents and biological agents listed in Category XIV (a), (b), (d), and (e).

* * * * *

■ 3. Section 126.15 is added to read as follows:

§ 126.15 Expedited processing of license applications for the export of defense articles and defense services to Australia or the United Kingdom.

(a) Any application submitted for authorization of the export of defense articles or services to Australia or the United Kingdom will be expeditiously processed by the Department of State, in consultation with the Department of Defense. Such license applications will not be referred to any other Federal department or agency, except when the defense articles or defense services are classified or exceptional circumstances apply. (See section 1225, Pub. L. 108–375).

(b) To be eligible for the expedited processing in paragraph (a) of this section, the destination of the prospective export must be limited to Australia or the United Kingdom. No