List of Subjects in 21 CFR Part 522

Animal drugs.

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 part 522 is 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 522.2478 is revised to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications*. Each implant dose consists of:

(1) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(2) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*. (i) For an implant as described in paragraph (a)(1) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(C) *Limitations*. Implant subcutaneously in ear only.

(ii) For an implant as described in paragraph (a)(2) of this section:

(A) *Amount*. 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain.

(C) *Limitations*. Implant subcutaneously in ear only.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate (as described in paragraph (a)(1) of this section).

(ii) *Indications for use*. For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Not for dairy or beef replacement heifers.

Dated: December 17, 2002.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–32750 Filed 12–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Danofloxacin

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 danofloxacin solution in cattle, by subcutaneous injection, for treatment of bovine respiratory disease associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*. FDA is also amending the regulations to add the acceptable daily intake for total residues of danofloxacin and tolerances for residues of danofloxacin in edible tissues of cattle.

DATES: This rule is effective December 27, 2002.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301–827–7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed NADA 141–207 for A180 (danofloxacin mesylate) Injectable Solution. The NADA provides for the veterinary prescription use of danofloxacin solution in cattle, by subcutaneous injection, for treatment of bovine respiratory disease associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*. The application is approved as of September 20, 2002, and the regulations are amended in 21 CFR part 522 by adding new § 522.522 and in 21 CFR part 556 by adding new § 556.169 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning September 20, 2002.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA'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 (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

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 522.522 is added to read as follows:

§ 522.522 Danofloxacin.

(a) *Specifications*. Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

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

(c) *Related tolerances*. See § 556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia*

(Pasteurella) haemolytica and *Pasteurella multocida*.

(3) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating 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. Federal law prohibits the extra-label use of this drug in food-producing animals.

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 556.169 is added to read as follows:

§ 556.169 Danofloxacin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of danofloxacin is 2.4 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent danofloxacin (the marker residue) is 0.2 part per million (ppm).

(ii) *Muscle.* The tolerance for parent danofloxacin (the marker residue) is 0.2 ppm.

(2) [Reserved].

Dated: December 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32747 Filed 12–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 585 and 586

Unblocking of Assets; Federal Republic of Yugoslavia (Serbia & Montenegro) and Bosnian Serb-Controlled Areas of the Republic of Bosnia and Herzegovina Sanctions Regulations; Federal Republic of Yugoslavia (Serbia & Montenegro) Kosovo Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control (''OFAC'') of the U.S. Department of Treasury is issuing general licenses, to be effective February 25, 2003, unblocking certain property and interests in property presently blocked pursuant to the Federal Republic of Yugoslavia (Serbia & Montenegro) and Bosnian Serb-controlled areas of the Republic of Bosnia and Herzegovina Sanctions Regulations set forth at 31 CFR part 585 and the Federal Republic of Yugoslavia (Serbia & Montenegro) Kosovo Sanctions Regulations set forth at 31 CFR part 586. The general licenses effecting the unblocking under both of the above sets of regulations will not apply to property or interests in property of those persons who are presently subject to sanctions under either the Federal Republic of Yugoslavia (Serbia & Montenegro) Milosevic Regulations set forth at 31 CFR part 587 or the Western Balkans Transactions Regulations set forth at 31 CFR part 588, or who are otherwise subject to sanctions under other parts of 31 CFR chapter V. In addition, the general license effecting the unblocking under 31 CFR part 585 will not apply to property or interests in property of diplomatic and/or consular missions of the former Socialist Federal Republic of Yugoslavia or to the blocked property or interests in property of the National Bank of Yugoslavia subject to part 585. In order to allow for claims and encumbrances associated with the property and interests in property being unblocked to be addressed, OFAC is also issuing general licenses, effective December 27, 2002, authorizing any person or government to seek judicial or other legal protection of any rights they may have with respect to the property and interests in property being unblocked.

DATES: Effective Date: December 27, 2002.

Applicable Dates: The general licenses set forth in 31 CFR §§ 585.529(a) and 586.520(a) shall become applicable February 25, 2003. The general licenses set forth in 31 CFR 585.529(b) and 586.520(b) shall become applicable December 27, 2002.

FOR FURTHER INFORMATION CONTACT: Chief of Compliance Programs, tel.: 202/622–2490, Chief of Licensing, tel.: 202/622–2480, Chief of Policy Planning and Program Management, tel.: 202/622–2500, or Chief Counsel, tel.: 202/622–2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

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Background

Pursuant to Presidential Determination No. 96–7 of December 27, 1995 (61 FR 2887, January 29, 1996), and Executive Order 13192 of January 17, 2001 (66 FR 7379, Jan. 23, 2001), most Treasury-administered sanctions imposed upon the Federal Republic of Yugoslavia (Serbia & Montenegro) (the ''FRY(S&M)'') in response to the actions of the FRY(S&M) in Bosnia and Herzegovina from 1992 through 1995 and with respect to Kosovo from 1998 through 2000 have been suspended or lifted. Nevertheless, most property and interests in property blocked under either the Bosnia-related sanctions regulations (31 CFR part 585) or the Kosovo-related sanctions regulations (31 CFR part 586) have remained blocked, primarily to provide for the address of claims and encumbrances that may be associated with such property or interests in property, including potential claims of the successor states of the former Socialist Federal Republic of Yugoslavia.

As part of the U.S. Government's efforts to assist the FRY(S&M) in recovering from the effects of the Milosevic regime, certain steps are being taken to unblock much of the remaining property and interests in property blocked under either 31 CFR part 585 or 31 CFR part 586. On October 3, 2001 (66 FR 50506), OFAC issued an interim final rule amending 31 CFR part 586, which included authorization for the unblocking of certain Yugoslav debt and authorization for the release of certain blocked financial transfers. At present, OFAC is issuing general licenses, effective February 25, 2003, authorizing the unblocking of all remaining blocked property and interests in property, except (i) property or interests in property of diplomatic and/or consular missions of the former Socialist Federal