

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 522 and 556**

DMS

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Certifier G. Henry

**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 [*insert date of publication in the Federal Register*].

**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: 12/17/02  
December 17, 2002.



Stephen F. Syndlof,  
Director,  
Center for Veterinary Medicine.

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