

ensure that the parties to proceedings are known to each other and to the Commission and that service of pleadings and orders is provided to all parties.

17. Moreover, to permit the easy identification of related filings for compliance filings receiving new root docket, <sup>19</sup> pipelines and utilities are urged to include as part of their eFiling description an indication that they are making a compliance filing and the docket number to which they are complying. This filing description will appear in the Commission's notice and will aid in the identification of the relationship between the compliance filing and the original proceeding.

#### *The Commission Orders*

(A) The procedures described in the body of this order will apply to tariff filings that are submitted in electronic format.

(B) The Secretary shall publish a copy of this order in the **Federal Register**.

By the Commission, Commissioner Norris voting present.

**Kimberly D. Bose**,  
Secretary.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA-2010-N-0002]

#### Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid

**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 supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment of lower respiratory tract infections in horses.

**DATES:** This rule is effective January 29, 2010.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary

Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-209 for EXCEDE (ceftiofur crystalline free acid) Sterile Suspension. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*. The application is approved as of December 16, 2009, and the regulations are amended in 21 CFR 522.313a to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 that this action is of a type that does 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 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. In § 522.313a, add paragraph (e)(3) to read as follows:

**§ 522.313a Ceftiofur crystalline free acid.**  
\* \* \* \* \*

(e) \* \* \*

(3) *Horses*—(i) *Amount*. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use*. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations*. Do not use in horses intended for human consumption.

Dated: January 22, 2010.

**Bernadette Dunham**,

Director, Center for Veterinary Medicine.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 524

[Docket No. FDA-2010-N-0002]

#### Ophthalmic and Topical Dosage Form New Animal Drugs; Miconazole, Polymixin B, and Prednisolone Suspension

**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 Janssen Pharmaceutica NV. The NADA provides for use of miconazole nitrate, polymixin B sulfate, and prednisolone acetate for the treatment of otitis externa in dogs.

**DATES:** This rule is effective January 29, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium, filed NADA 141-298 that provides for veterinary prescription use of SUROLAN (miconazole nitrate, polymixin B sulfate, and prednisolone acetate) Otic Suspension in dogs for the treatment of otitis externa associated with

<sup>19</sup> These will be filings without the Filing Identifier of a related filing.