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 numbers, pipelines and utilities are urged to include as part of their eFilings 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

[FR Doc. 2010–1538 Filed 1–28–10; 8:45 am]
BILLING CODE 6717–01–P

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 the 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 514.110(o)(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:


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.

[FR Doc. 2010–1790 Filed 1–28–10; 8:45 am]

BILLING CODE 4160–01–S

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 the 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.

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
susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius). The NADA is approved as of November 23, 2009, and the regulations are amended in 21 CFR part 524 by adding new 21 CFR 524.1445 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), 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.

FDA 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 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:


2. Add §524.1445 to read as follows:

§524.1445 Miconazole, polymixin B, and prednisolone suspension.

(a) Specifications. Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

(b) Sponsor. See No. 012578 in 510.600(c) of this chapter.

3. The authority citation for 21 CFR part 524 continues to read as follows:


(c) Conditions of use in dogs—

(1) Amount. Instill five drops in the ear canal twice daily for 7 consecutive days.

(2) Indications for use. For the treatment of canine otitis externa associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 22, 2010.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

[FR Doc. 2010–1794 Filed 1–28–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–1129]

Drawbridge Operation Regulation; Inner Harbor Navigational Canal, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Senator Ted Hickey (Leon C. Simon) Bascule Bridge across the Inner Harbor Navigational Canal, mile 4.6, at New Orleans, LA. The deviation is necessary to ensure the safety of pedestrians as they bike across the bridge for the Ochsner Ironman 70.3 New Orleans event. This deviation allows the bridge to remain closed during the event.

DATES: This deviation is effective from 5 a.m. to 2 p.m. on April 18, 2010, and the regulations are amended in 21 CFR by adding new 21 CFR 524.1445 to reflect the approval.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2009–1129 and are available online by going to http://www.regulations.gov, inserting USCG–2009–1129 in the “Keyword” box and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1220 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lindsey Middleton, Bridge Administration Branch; telephone 504–671–2128, e-mail Lindsey.R.Middleton@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The bridge owner approved the request for the closure of the Senator Ted Hickey (Leon C. Simon) Bascule Bridge on Seabrook Highway crossing the Inner Harbor Navigational Canal, mile 4.6, at New Orleans, LA. In the closed-to-navigation position, the vertical clearance of the bridge is 45 feet above mean sea level. Currently, according to 33 CFR 117.458 (c), the draw of the Leon C. Simon Blvd. (Seabrook) bridge, mile 4.6, shall open on signal; except that, from 7 a.m. to 8:30 a.m. and 5 p.m. to 6:30 p.m. Monday through Friday, the draw need not be opened. This deviation allows the draw span of the bridge to remain closed to navigation between 5 a.m. and 2 p.m. on April 18, 2010 while the Ironman contenders travel across the bridge as part of the 56 mile bike course.

Navigation on the waterway consists mainly of tugs with tows. As a result of coordination between the Coast Guard and the waterway users, it has been determined that this closure will not have a significant effect on these vessels. The Coast Guard will inform users through the Local and Broadcast Notice to Mariners of the closure period. There are alternate routes available to vessel traffic. Vessels that can pass under the bridge in the closed-to-navigation position can do so at any time. The bridge will not be able to open for emergencies.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.


David M. Frank,
Bridge Administrator.

[FR Doc. 2010–1801 Filed 1–28–10; 8:45 am]

BILLING CODE 9110–04–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2010–13 and CP2010–12; Order No. 365]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.


29JAR1 4693