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 § 522.522, revise paragraphs (d)(1) and (d)(2) to read as follows:

§ 522.522 Danofloxacin.

* * * * *

(d) * * *

(1) *Amount:* Administer by subcutaneous injection either:

(i) 6 mg per kilogram (mg/kg) of body weight, repeated in 48 hours; or

(ii) 8 mg/kg of body weight, as a single dose.

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

* * * * *

Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2012–1743 Filed 1–26–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2011–N–0003]

Implantation or Injectable Dosage Form New Animal Drugs; Gonadotropin Releasing Factor Analog-Diphtheria Toxoid Conjugate

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 Pfizer, Inc. The supplemental NADA extends the slaughter interval for intact male swine injected with gonadotropin releasing factor analog-diphtheria toxoid conjugate injectable solution.

DATES: This rule is effective January 27, 2012.

FOR FURTHER INFORMATION CONTACT: Matthew Lucia, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8116, email: *matthew.lucia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–322 for IMPROVEST (gonadotropin releasing factor analog-diphtheria toxoid conjugate) Sterile Solution for Injection, administered as two doses 4 weeks apart to intact male pigs for the reduction of boar taint. The supplement extends the slaughter interval from 4 to 8 weeks after the second dose to 3 to 10 weeks. The supplemental NADA is approved as of November 30, 2011, and the regulations in 21 CFR 522.1083 are amended 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), 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 § 522.1083, revise paragraphs (c)(1) and (c)(3) to read as follows:

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

* * * * *

(c) * * *

(1) *Amount.* Administer 0.4 mg (2 milliliter (mL)) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg (2 mL) should be administered at least 4 weeks after the first dose.

* * * * *

(3) *Limitations.* Not approved for use in female pigs and barrows. Do not use in intact male pigs intended for breeding because of the disruption of reproductive function. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Pigs should be slaughtered no earlier than 3 weeks and no later than 10 weeks after the second dose.

Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2012–1754 Filed 1–26–12; 8:45 am]

BILLING CODE 4160–01–P