DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2011–N–0003]

Oral Dosage Form New Animal Drugs; Gentamicin Sulfate

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 an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for use of gentamicin sulfate soluble powder used to make medicated drinking water for swine.

DATES: This rule is effective January 27, 2012.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8197, email: *john.harshman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–494 for use of GENTAMED (gentamicin sulfate) Soluble Powder used to make medicated drinking water for swine. Cross Vetpharm Group's Gentamicin Soluble Powder is approved as a generic copy of GARACIN (gentamicin sulfate) Soluble Powder, sponsored by Intervet Inc., under NADA 133–836. The abbreviated application is approved as of December 14, 2011, and the regulations are amended in 21 CFR 520.1044c 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.

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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Revise § 520.1044c to read as follows:

§ 520.1044c Gentamicin sulfate powder.

(a) *Specifications.* Each gram of powder contains gentamicin sulfate equivalent to:

(1) 16.7, 66.7, or 333.3 milligrams (mg) gentamicin.

(2) 333.3 mg gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) No. 000061 for products described in paragraph (a)(1) of this section.

(2) Nos. 057561 and 061623 for product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water for 3 consecutive days as follows:

(i) For colibacillosis: Gentamicin sulfate equivalent to 25 mg of gentamicin per gallon of drinking water to provide 0.5 mg per pound of body weight per day;

(ii) For swine dysentery: Gentamicin sulfate equivalent to 50 mg of gentamicin per gallon of drinking water to provide 1 mg per pound of body weight per day. Treatment may be repeated if dysentery recurs.

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water.

(4) *Withdrawal period.* 10 days.

Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2012–1753 Filed 1–26–12; 8:45 am]

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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; 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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for an additional dosage regimen for use of danofloxacin mesylate injectable solution for the treatment of bovine respiratory disease in beef cattle.

DATES: This rule is effective January 27, 2012.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8341, email: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–207 for ADVOCIN (danofloxacin mesylate) Injectable Solution. The supplemental NADA provides for an additional dosage regimen for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica,* and *Pasteurella multocida* in beef cattle. The supplemental NADA is approved as of December 16, 2011, and 21 CFR 522.522 is 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)(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*.

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Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

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

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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]

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