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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; Change of Sponsor; Chlortetracycline; Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for five new animal drug applications (NADAs) from Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., to Boehringer Ingelheim Vetmedica, Inc.

DATES: This rule is effective August 11, 2011.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, e-mail: *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017 has informed FDA that it has transferred ownership of, and all rights and interest in, five approved NADAs (NADAs 055–012, 055–018, 055–039, 065–071, and 065–440) to Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002. Accordingly, the Agency is amending the regulations in 21 CFR part 520 to reflect the transfer of ownership.

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 § 520.445 to read as follows:

§ 520.445 Chlortetracycline and sulfamethazine powder.

(a) *Specifications.* Each pound of soluble powder contains chlortetracycline bisulfate equivalent to 102.4 grams (g) of chlortetracycline hydrochloride and sulfamethazine bisulfate equivalent to 102.4 g of sulfamethazine.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use in swine.* Administer in drinking water as follows:

(1) *Amount.* 250 milligrams (mg) of chlortetracycline and 250 mg of sulfamethazine per gallon.

(2) *Indications for use.* For the prevention and treatment of bacterial enteritis; as an aid in the reduction of the incidence of cervical abscesses; and as an aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations.* Use as the sole source of chlortetracycline and sulfonamide. Not to be used for more than 28 consecutive days. Withdraw 15 days before slaughter.

§ 520.445a [Removed]

■ 3. Remove § 520.445a.

§ 520.445b [Redesignated as § 520.441]

■ 4. Redesignate § 520.445b as § 520.441.

■ 5. Amend newly redesignated § 520.441 by revising paragraphs (b)(2), (b)(3), and the last sentence of paragraph (d)(4)(iii)(C) to read as follows:

§ 520.441 Chlortetracycline powder.

* * * * *

(b) * * *

(2) Nos. 046573 and 000010 for use as in paragraph (d) of this section.

(3) No. 000010 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

* * * * *

(d) * * *

(4) * * *

(iii) * * *

(C) * * * For Nos. 000010 and 021930, do not slaughter animals for food within 5 days of treatment. For No. 000010, do not slaughter animals for food within 24 hours of treatment.

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§ 520.445c [Redesignated as § 520.443]

■ 6. Redesignate § 520.445c as § 520.443.

■ 7. Amend newly redesignated § 520.443 as follows:

■ a. Revise paragraphs (a) and (b);

■ b. Remove paragraph (d);

■ c. Redesignate paragraph (e) as paragraph (d); and

■ d. Revise the heading for newly redesignated paragraph (d) introductory text.

The revisions read as follows:

§ 520.443 Chlortetracycline tablets and boluses.

(a) *Specifications.* Each tablet/bolus contains 25, 250, or 500 milligrams (mg) chlortetracycline hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

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(d) *Conditions of use in calves*—* * * * * * * * *

Dated: August 4, 2011.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2011–20404 Filed 8–10–11; 8:45 am]

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