

Rules and Regulations

Federal Register

Vol. 75, No. 43

Friday, March 5, 2010

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 524, and 526

[Docket No. FDA-2009-N-0665]

New Animal Drugs; Change of Sponsor

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 18 new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., to Boehringer Ingelheim Vetmedica, Inc. (Boehringer). In addition, FDA is amending the animal drug regulations to reflect a change of sponsor for 15 NADAs from Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, Inc., to Boehringer.

DATES: This rule is effective March 5, 2010.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017 (Pfizer) has informed FDA that it has transferred ownership of, and all rights and interest in, the following 18 approved NADAs and 1 approved ANADA to Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002

(Boehringer): NADA 15-030, 32-702, 34-879, 45-290, 55-021, 55-022, 55-030, 55-048, 55-054, 55-058, 97-222, 108-114, 119-688, 140-684, 140-806, 140-854, 141-096, and 141-274; and ANADA 200-088. In addition, Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of Pfizer, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 15 approved NADAs to Boehringer: NADA 6-084, 8-774, 12-198, 13-624, 33-127, 33-318, 33-319, 33-373, 40-181, 46-146, 65-269, 99-388, 122-271, 122-272, and 141-108. Accordingly, the agency is amending the regulations in 21 CFR parts 520, 522, 524, and 526 to reflect the transfer of ownership. In addition, several sections are being revised to reflect the current format.

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 Parts 520, 522, 524, and 526

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 parts 520, 522, 524, and 526 are 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 § 520.23 to read as follows:

§ 520.23 Acepromazine.

(a) *Specifications.* Each tablet contains 5, 10, or 25 milligrams (mg) acepromazine maleate.

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

(c) *Conditions of use—(1) Dogs—(i) Amount.* 0.25 to 1.0 mg per pound (lb) body weight orally.

(ii) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

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

(2) *Cats—(i) Amount.* 0.5 to 1.0 mg/lb body weight orally.

(ii) *Indications for use.* As a tranquilizer.

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

■ 3. Revise § 520.314 to read as follows:

§ 520.314 Cefadroxil.

(a) *Specifications.—(1) Each tablet contains 50, 100, or 200 milligrams (mg) or 1 gram of cefadroxil.*

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

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

(c) *Conditions of use in dogs and cats—(1) Amount—(i) Dogs.* Administer 10 mg per pound (lb) body weight twice daily orally.

(ii) *Cats.* Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use—(i) Dogs.* For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus*.

(ii) *Cats.* For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *S. aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

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

§ 520.315 [Removed]

■ 4. Remove § 520.315.

■ 5. In § 520.645, in paragraph (b), remove "000856" and in its place add "000010"; and revise paragraphs (d)(1)(i) and (d)(1)(iii) to read as follows:

§ 520.645 Difloxacin.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Administer 5 to 10 mg per kilogram (2.3 to 4.6 mg per pound) of body weight orally once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

* * * * *

(iii) *Limitations.* Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 6. In § 520.870, in paragraph (b), remove “053501” and in its place add “No. 000010”; revise paragraphs (d)(1)(i) and (d)(1)(iii) to read as follows:

§ 520.870 Etodolac.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Administer 10 to 15 mg per kilogram (4.5 to 6.8 mg per pound) of body weight per day orally.

* * * * *

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

* * * * *

■ 7. Revise § 520.1130 to read as follows:

§ 520.1130 Hetacillin.

(a) *Specifications.*—(1) Each capsule or tablet contains hetacillin potassium equivalent to 50, 100, or 200 milligrams (mg) of ampicillin.

(2) Each milliliter of suspension contains hetacillin potassium equivalent to 50 mg of ampicillin.

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

(c) *Conditions of use in dogs and cats.*—(1) *Amount.*—(i) *Dogs.* Administer 5 mg per pound (lb) of body weight orally, twice daily. In severe infections, administer 5 mg/lb three times daily, or up to 10 mg/lb twice daily. For stubborn urinary tract infections, administer up to 20 mg/lb twice daily.

(ii) *Cats.* Administer 50 mg twice daily.

(2) *Indications for use.* For the treatment of respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections associated with strains of organisms susceptible to hetacillin potassium.

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

§ 520.1130a [Removed]

■ 8. Remove § 520.1130a.

§ 520.1130b [Removed]

■ 9. Remove § 520.1130b.

§ 520.1130c [Removed]

■ 10. Remove § 520.1130c.

§ 520.1630 [Amended]

■ 11. In paragraph (b) of § 520.1630, remove “000856” and in its place add “No. 000010”.

■ 12. Revise § 520.2200 to read as follows:

§ 520.2200 Sulfachlorpyridazine.

(a) *Specifications.*—(1) Sodium sulfachlorpyridazine powder.

(2) Each bolus contains 2 grams sulfachlorpyridazine.

(3) Each tablet contains 250 milligrams (mg) sulfachlorpyridazine.

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

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Calves.*—(i) *Amount.* Administer 30 to 45 mg sulfachlorpyridazine powder per pound (lb) of body weight per day in milk or milk replacer, or in a bolus, in divided doses twice daily for 1 to 5 days.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(iii) *Limitations.* Treated ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine.*—(i) *Amount.* Administer 20 to 35 mg/lb body weight per day, in divided doses twice daily for 1 to 5 days:

(A) In drinking water or

(B) For individual treatment, in an oral suspension containing 50 mg per milliliter.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

(3) *Dogs.*—(i) *Amount.* Administer tablets orally at 500 mg per 10 to 15 lb of body weight daily, in two or three divided doses.

(ii) *Indications for use.* As an aid in the treatment of infectious tracheobronchitis and infections caused by *E. coli*, and in the treatment of infections caused by other Gram-positive and Gram-negative organisms that are susceptible to sulfonamide therapy.

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

§ 520.2200a [Removed]

■ 13. Remove § 520.2200a.

§ 520.2200b [Removed]

■ 14. Remove § 520.2200b.

§ 520.2200c [Removed]

■ 15. Remove § 520.2200c.

§ 520.2260a [Amended]

■ 16. In paragraph (a)(1) of § 520.2260a, remove “053501” and in its place add “000010”.

§ 520.2261a [Amended]

■ 17. In § 520.2261a, in the first sentence of paragraph (a), remove “053501” and in its place add “000010”; and remove paragraph (d).

§ 520.2261b [Amended]

■ 18. In paragraph (b) of § 520.2261b, remove “053501” and in its place add “000010”.

§ 520.2345d [Amended]

■ 19. In paragraphs (b)(3), (d)(1)(iii), and (d)(2)(iii) of § 520.2345d, remove “053501” and in its place add “000010”.

§ 520.2481 [Removed]

■ 20. Remove § 520.2481.

§ 520.2482 [Removed]

■ 21. Remove § 520.2482.

■ 22. Add § 520.2483 to read as follows:

§ 520.2483 Triamcinolone.

(a) *Specifications.*—(1) Each tablet contains 0.5 milligram (mg) or 1.5 mg triamcinolone acetonide.

(2) Each 15 grams of powder contains 10 mg triamcinolone acetonide.

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

(c) *Special considerations.* See § 510.410 of this chapter.

(d) *Conditions of use.*—(1) *Dogs and cats.* Use tablets described in paragraph (a)(1) of this section as follows:

(i) *Amount.* Administer 0.05 mg per pound (lb) of body weight daily by mouth; up to 0.1 mg per pound (lb) of body weight daily, if response to the smaller dose is inadequate. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide tablets should be administered beginning 5 to 7 days after the injection.

(ii) *Indications for use.* As an anti-inflammatory agent.

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

(2) *Horses.* Use oral powder described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Administer 0.005 to 0.01 mg/lb of body weight twice daily, sprinkled (top-dressed) on a small portion of feed. Therapy may be initiated with a single injection of triamcinolone acetonide suspension as in § 522.2483 of this chapter, in which case triamcinolone acetonide oral powder should be administered beginning 3 or 4 days after the injection.

(ii) *Indications for use.* As an anti-inflammatory agent.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 23. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 24. Revise § 522.23 to read as follows:

§ 522.23 Acepromazine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000010 for use as in paragraphs (d) and (e) of this section.

(2) No. 059130 for use as in paragraph (d) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use.* It is used in dogs, cats, and horses as follows:

(1) *Amount.* *Dogs:* 0.25 to 0.5 mg per pound (lb) of body weight; *Cats:* 0.5 to 1.0 mg/lb of body weight; *Horses:* 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* As a tranquilizer.

(e) *Conditions of use.* It is used in dogs as follows:

(1) *Amount.* *Dogs:* 0.25 to 0.5 mg/lb of body weight.

(2) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

§ 522.90b [Amended]

■ 25. In § 522.90b, in the section heading, remove “sterile”; and in paragraph (b)(1), remove “000856” and in its place add “No. 000010”.

§ 522.775 [Amended]

■ 26. In paragraph (b) of § 522.775, remove “000856” and in its place add “000010”.

§ 522.870 [Amended]

■ 27. In paragraph (b) of § 522.870, remove “000856” and in its place add “000010”.

§ 522.1145 [Amended]

■ 28. In paragraph (c)(2) of § 522.1145, remove “000856” and in its place add “No. 000010”.

§ 522.1222a [Amended]

■ 29. In paragraph (b) of § 522.1222a, remove “000856,”.

■ 30. Revise § 522.2200 to read as follows:

§ 522.2200 Sulfachlorpyridazine.

(a) *Specifications.* Each milliliter of solution contains sodium sulfachlorpyridazine equivalent to 200 milligrams (mg) sulfachlorpyridazine.

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

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use in calves.* It is used as follows:

(1) *Amount.* Administer 30 to 45 mg per pound (lb) of body weight in divided doses by twice daily injection for 1 to 5 days.

(2) *Indications for use.* For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(3) *Limitations.* Treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 31. Amend § 522.2260 as follows:

■ a. Revise the section heading;

■ b. Revise paragraphs (a) and (b);

■ c. Remove paragraph (d);

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

■ e. Revise newly redesignated paragraph (d) introductory text and paragraph (d)(1).

■ The revisions read as follows:

§ 522.2260 Sulfamethazine.

(a) *Specifications.* Each milliliter of solution contains 250 milligrams sulfamethazine sodium.

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

* * * * *

(d) *Conditions of use in cattle—*(1) *Amount.* 20 milliliters for each 50 pounds of body weight (100 milligrams per pound) initially; 20 milliliters per 100 pounds of body weight (50 milligrams per pound) daily, thereafter.

* * * * *

■ 32. Revise § 522.2483 to read as follows:

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

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

(c) *Conditions of use—*(1) *Dogs and cats—*(i) *Amount—*(A) *Intramuscular or subcutaneous.* For inflammatory, arthritic, or allergic disorders, administer 0.05 to 0.1 mg per pound (lb) of body weight as a single injection. For dermatologic disorders, administer 0.1 mg per pound (lb) of body weight as a single injection. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.

(B) *Intralesional.* Administer 1.2 to 1.8 mg, divided in several injections around the lesion, spaced 0.5 to 2.5 centimeters apart, depending on lesion size. At any one site, the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(C) *Intra-articular and intrasynovial.* Administer 1 to 3 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders, and the management and treatment of acute arthritis and allergic and dermatologic disorders.

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

(2) *Horses—*(i) *Amount—*(A) *Intramuscular or subcutaneous.* Administer 0.01 to 0.02 mg/lb of body weight as a single injection. Usual dose is 12 to 20 mg.

(B) *Intra-articular and intrasynovial.* Administer 6 to 18 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2662 [Amended]

■ 33. In paragraph (b)(2) of § 522.2662, remove “000856” and in its place add “000010”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.2481 [Redesignated as § 524.2483]

■ 35. Redesignate § 524.2481 as § 524.2483.

§ 524.2483 [Amended]

■ 36. In paragraph (b) of newly redesignated § 524.2483, remove “015914, 053501, and 054925” and in its place add “000010, 015914, and 054925”.

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 37. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.363 [Amended]

■ 38. In paragraph (b) of § 526.363, remove “000856” and in its place add “000010”.

§ 526.365 [Amended]

■ 39. In paragraph (b) of § 526.365, remove “000856” and in its place add “000010”.

■ 40. In § 526.464a, revise the section heading and paragraph (c) to read as follows:

§ 526.464a Cloxacillin benzathine.

* * * * *

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use in dairy cows.

* * * * *

§ 526.1130 [Amended]

■ 41. In § 526.1130, in paragraph (b), remove “000856” and in its place add “000010”; and in paragraph (c)(3), remove the first sentence.

Dated: February 26, 2010.

Steven D. Vaughn,

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

[FR Doc. 2010-4560 Filed 3-4-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1313

[Docket No. DEA-295F]

RIN 1117-AB07

Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing, without change, the Notice of Proposed Rulemaking published in the **Federal Register** on March 31, 2008 (73 FR 16793). The Combat Methamphetamine Epidemic Act of 2005 (CMEA) requires DEA to collect from importers of ephedrine, pseudoephedrine, and phenylpropanolamine all information known to the importer on the foreign chain of distribution of the chemical from the manufacturer to the importer. This rule amends DEA regulations to incorporate the requirement for this information.

DATES: Effective Dates: This Final Rule is effective May 4, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with

controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture, distribution, import, and export of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109-177). The changes made by this rule are needed to implement the statutory provisions. This Final Rule amends the language of the regulations to be consistent with that of the statute.

Import/Export Declaration Requirements

Under existing DEA regulations (21 CFR part 1313), importers of listed chemicals are required to provide DEA with advance notification of imports unless the importer has met the requirements as a regular importer of the listed chemical; for regular importers, the notification must be filed by the date of importation. In the importation declaration (DEA Form 486), the importer must provide information on the chemical (name, size and weight of the container, number of containers, total weight of chemical), importation (date, foreign port of shipment, United States port of entry) and the foreign supplier (name, address, contact information).

CMEA imposes several new requirements on imports of listed chemicals. CMEA amended 21 U.S.C. 971, “Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals,” to require DEA to collect information regarding persons to whom the U.S. importer, exporter, broker, or trader transfers the listed chemical, actual quantities shipped, and the date the shipment occurred. If the person to whom the listed chemical is to be transferred is not a regular customer of the U.S. importer or exporter, then the importer or exporter must notify DEA no later than 15 days before the transaction is to take place. Further, if the person to whom the chemical is to be transferred changes subsequent to initial notification of DEA, or if the amount of the chemical to be transferred increases, the importer or exporter shall