§ 983.147 Reports.

(a) *ACP–2, Failed Lot Notification.* Each handler shall notify the Administrative Committee for Pistachios (committee) of all lots that fail to meet the order's maximum aflatoxin requirements by completing section A of this form. Handlers shall furnish this report to the committee no later than 10 days after completion of the aflatoxin test. Each USDA-approved aflatoxin testing laboratory shall complete section C of this report, and forward this report and the failing aflatoxin test results to the committee and to the handler within 10 days of the test failure.

* * * * *

§ 983.147 [Amended]

■ 20. Paragraph (d) of § 983.147 is suspended indefinitely.

Dated: December 4, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 07–5989 Filed 12–5–07; 10:02 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Erythromycin

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 Cross Vetpharm Group Ltd. The supplemental NADA provides for use of a 100 milligram per milliliter (mg/mL) strength erythromycin injectable solution in cattle for the treatment of bovine respiratory disease.

DATES: This rule is effective December 7, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to NADA 12–123 for GALLIMYCIN–100 (erythromycin) Injection. The supplemental NADA provides for use of a 100 mg/mL strength erythromycin injectable solution in cattle for the treatment of bovine respiratory disease. The supplemental NADA is approved as of November 15, 2007, and the regulations in 21 CFR 522.820 are amended to reflect the approval and a current format.

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(a)(1) 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 Subject 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. Revise § 522.820 to read as follows:

§ 522.820 Erythromycin.

(a) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(b) *Specifications*—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.

(2) Each mL of solution contains 200 mg erythromycin base.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use*—(1) *Dog.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 3 to 5 mg per pound (/lb) body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

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

(2) *Cats.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 3 to 5 mg/lb body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

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

(3) *Cattle.* Administer products described in paragraph (b) of this section as follows:

(i) *Amount.* 4 mg/lb body weight by deep intramuscular injection once daily for up to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations.* Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To avoid excess trim, do not slaughter within 21 days of last injection.

Dated: November 30, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23763 Filed 12–6–07; 8:45 am]

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