DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clenbuterol

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 new animal drug application (NADA) filed by Boehringer Ingelheim Animal Health, Inc. The NADA provides for veterinary prescription use of clenbuterol syrup (clenbuterol hydrochloride) indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

EFFECTIVE DATE: August 4, 1998.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, has filed NADA 140–973 that provides for veterinary prescription use of VENTIPULMIN® Syrup (clenbuterol hydrochloride) indicated for the management of horses affected with airway obstruction, such as occurs in COPD. The NADA is approved as of May 11, 1998, and the regulations are amended by adding 21 CFR 520.452 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 11, 1998, because no active ingredient of the drug, including any ester or salt of the active ingredient, has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(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.

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. Section 520.452 is added to read as follows:

§ 520.452 Clenbuterol syrup.

(a) *Specifications.* Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use.* Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations.* Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: June 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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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; Ampicillin Trihydrate For Sterile Suspension

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 abbreviated new animal drug application (ANADA) filed by G. C. Hanford Manufacturing Co. The ANADA provides for subcutaneous and/or intramuscular use of ampicillin trihydrate sterile powder when reconstituted as a sterile suspension, for treatment of dogs, cats, cattle, and calves including nonruminating (veal) calves.

EFFECTIVE DATE: August 4, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: G. C. Hanford Manufacturing Co., 304 Oneida St., P.O. Box 1017, Syracuse, NY 13201, is sponsor of ANADA 200–180 that provides for the subcutaneous or intramuscular use of ampicillin trihydrate sterile powder for reconstitution as a sterile suspension for treatment of respiratory, urinary tract, gastrointestinal, skin, soft-tissue, and post-surgical infections of dogs and cats, and intramuscular use for the treatment of respiratory infections in cattle and calves including nonruminating (veal) calves. The drug is limited to use by or on the order of a licensed veterinarian. G. C. Hanford Manufacturing Co.'s ANADA 200–180 is approved as a generic copy of Fort Dodge Animal Health's NADA 55–030 for Polyflex®.