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.

[FR Doc. 98–20699 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

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®.

The ANADA is approved as of April 24, 1998, and the regulations in 21 CFR 522.90b(b) are amended to reflect the approval. The basis of 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.

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.

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. Section 522.90b is amended by revising paragraph (b) to read as follows:

§ 522.90b Ampicillin trihydrate for sterile suspension.

* * * * *

(b) *Sponsor.* (1) See 000856 in § 510.600(c) of this chapter for use of 50, 100, and 250 milligrams per milliliter ampicillin suspension.

(2) See 010515 in § 510.600(c) of this chapter for use of 100 and 250 milligrams per milliliter ampicillin suspension.

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Dated: June 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–20698 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8777]

RIN 1545–AV17

Qualified Nonrecourse Financing Under Section 465(b)(6)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on certain issues regarding qualified nonrecourse financing under section 465(b)(6). These final regulations affect individuals and C corporations for which the stock ownership requirement of section 542(a)(2) is satisfied. These regulations provide guidance on certain issues relating to section 465(b)(6).

DATES: Effective date: These regulations are effective August 4, 1998.

Applicability dates: See Effective Dates under Supplementary Information of the preamble.

FOR FURTHER INFORMATION CONTACT: Jeff Erickson at (202) 622–3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends 26 CFR part 1 to provide rules regarding qualified nonrecourse financing under section 465(b)(6). Section 465 limits a taxpayer's loss deduction for an activity to the taxpayer's amount at risk in the activity at the close of the taxable year. A taxpayer's amount at risk generally includes the amount of any cash and the adjusted tax basis of any property contributed by the taxpayer to the activity plus any amounts borrowed for use in the activity to the extent the taxpayer is personally liable for repayment. For the activity of holding real property, section 465(b)(6) provides that a taxpayer may include as an amount at risk the taxpayer's share of any qualified nonrecourse financing that is secured by real property used in the activity of holding real property, even though the taxpayer is not personally liable for repayment of the financing.

On August 13, 1997, the IRS published in the **Federal Register** (62 FR 43295) a notice of proposed rulemaking regarding section 465(b)(6). A number of comments were received on the proposed regulations. The public hearing scheduled for December 10, 1997, was canceled because no one requested to speak. After considering the written comments, the proposed regulations are adopted as revised by this Treasury decision.

Explanation of Provisions

I. Secured by Real Property

A. Proposed Rule

Section 465(b)(6)(A) provides that qualified nonrecourse financing must be secured by real property used in the activity of holding real property. The proposed regulations provided that a financing can be a qualified nonrecourse financing if, in addition to the real property used in the activity of holding real property, the financing is secured by other property that is incidental to the activity of holding real property (incidental property).

B. Discussion of Comments

A commentator recommended that the final regulations clarify the term *incidental property.* Another commentator asked that the IRS and Treasury define incidental property as any property with a value of not more than 15 percent of the value of the real property held by the borrowing partnership. A third commentator explained that real estate partnerships often hold assets in addition to real property and incidental property. This commentator was concerned that only financings held by partnerships that own only real estate assets could satisfy the proposed regulations. Under the final regulations, if the total gross fair market value of property that is neither real property used in the activity of holding real property nor incidental property is less than 10 percent of the total gross fair market value of all the property securing the financing, such other property is ignored in determining whether the financing satisfies the secured-by-real-property requirement.

Another commentator asked for a look-through rule for partnerships that own an interest in another partnership to determine the character of the assets securing a qualified nonrecourse financing. The final regulations adopt this suggestion by requiring a borrower (whether or not a partnership) to determine the character of its assets by treating itself as owning directly its proportional share of the assets in any partnership in which it owns (directly or indirectly through a chain of partnerships) an equity interest. If a borrower pledges a partnership interest as security for a financing, the partnership assets attributable to the borrower's proportional share of the partnership's assets will be treated as security for the financing.