List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 and 556 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. Section 520.955 is added to read as follows:

§ 520.955 Florfenicol.

(a) *Specifications*. Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.283 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount*. Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis* Type 2.

(3) *Limitations*. Do not slaughter within 16 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.283 is amended by revising paragraph (b) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm).

(ii) *Muscle*. The tolerance for florfenicol amine (the marker residue) is 0.3 ppm.

(2) *Swine*—(i) *Liver (the target tissue)*. The tolerance for parent florfenicol (the marker residue) is 2.5 ppm.

(ii) *Muscle*. The tolerance for parent florfenicol (the marker residue) is 0.2 ppm.

Dated: December 13, 2002.

Stephen F. Sundolf,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32341 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplemental ANADA provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

DATES: This rule is effective December 24, 2002.

FOR FURTHER INFORMATION CONTACT: Julia W. Punderson, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570, e-mail: *jpunder1@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, filed a supplement to approved ANADA 200–008 that provides for the use of BIO–MYCIN 200 (oxytetracycline injection) and OXY–TET 200 (oxytetracycline injection) as treatments for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of these oxytetracycline injectable solutions to lactating dairy cattle. The supplemental application is approved as of September 3, 2002, and the regulations are amended in 21 CFR 522.1660 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, 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 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) by removing in the eighth sentence ''000010, 059130, and 061623'' and adding in its place''059130 and 061623'', and by removing in the ninth sentence ''For sponsors'' and adding in its place ''For sponsors 000010,''.

Dated: December 4, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32276 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for subcutaneous use of an implant containing trenbolone acetate and estradiol for increased rate of weight gain and improved feed efficiency in feedlot heifers.

DATES: This rule is effective December 24, 2002.

FOR FURTHER INFORMATION CONTACT: Harlan J. Howard, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0231, hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–346 for COMPONENT TE–H (140 milligrams (mg) trenbolone acetate and 14 mg estradiol, in seven pellets, each pellet containing 20 mg of trenbolone acetate and 2 mg of estradiol) for increased rate of weight gain and improved feed efficiency in heifers fed in confinement for slaughter. Ivy Laboratories' COMPONENT TE–H is approved as a generic copy of Intervet's REVALOR–H, approved under NADA 140–992. The application is approved as of September 27, 2002, and the regulations are amended in 21 CFR 522.2477 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, 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 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.

§ 522.2477 [Amended]

2. Section 522.2477 *Trenbolone acetate and estradiol* is amended in paragraph (b)(1) by adding ''(d)(2)(i)(A), (d)(2)(ii)(A), (d)(2)(iii),'' after ''(d)(1)(iii),''.

Dated: December 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32342 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9030]

RIN 1545–AX28

Exclusion of Gain From Sale or Exchange of a Principal Residence

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the exclusion of gain from the sale or exchange of a taxpayer's principal residence. These regulations reflect changes to the law made by the Taxpayer Relief Act of 1997, as amended by the Internal Revenue Service Restructuring and Reform Act of 1998.

DATES: *Effective Date:* These regulations are effective December 24, 2002.

Applicability Date: For dates of applicability, *see* §§ 1.121–1(f), 1.121–2(c), 1.121–3(l), 1.121–4(l), and 1.1398–3(d).

FOR FURTHER INFORMATION CONTACT: Sara Paige Shepherd, (202) 622–4960 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On October 10, 2000, the IRS and the Treasury Department published in the **Federal Register** (65 FR 60136) a notice of proposed rulemaking (REG–105235–99) under section 121 of the Internal Revenue Code. Comments were specifically requested regarding what circumstances should qualify as unforeseen for purposes of the reduced maximum exclusion under section 121(c). Written and electronic comments responding to the notice of proposed rulemaking were received. A public hearing was held on January 26, 2001.

After considering all of the comments, the proposed regulations are adopted as amended by this Treasury decision. Proposed and temporary regulations regarding the reduced maximum exclusion are also published in this issue of the **Federal Register**.

On September 9, 2002, the IRS published Notice 2002–60 (2002–36 I.R.B. 482), which provides that certain taxpayers affected by the September 11, 2001, terrorist attacks may claim a reduced maximum exclusion for a sale or exchange of the taxpayer's principal residence by reason of unforeseen circumstances.

Explanation and Summary of Comments

1. Exclusion of Gain From the Sale or Exchange of a Principal Residence

Under section 121 and the proposed regulations, a taxpayer may exclude up to $250,000 ($500,000 for certain joint returns) of gain realized on the sale or exchange of the taxpayer's principal residence if the taxpayer owned and used the property as the taxpayer's principal residence for at least two years during the five-year period ending on the date of the sale or exchange.

a. Principal Residence

The proposed regulations provide that whether property is used by the taxpayer as the taxpayer's residence, and whether the property is used as the taxpayer's principal residence, depends upon all the facts and circumstances. The proposed regulations further provide that if a taxpayer alternates between two properties, the property that the taxpayer uses a majority of the time during the year will ordinarily be considered the taxpayer's principal residence.

Commentators requested a bright line test or a list of factors to identify a property as the taxpayer's principal residence in the case of a taxpayer with multiple residences. Other commentators questioned whether the property that a taxpayer uses a majority of the time during the year should generally be considered the taxpayer's