

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 520
Oral Dosage Form New Animal Drugs; Lincomycin and Spectinomycin Powder

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 Agri Laboratories, Ltd. The ANADA provides for the oral use of lincomycin and spectinomycin soluble powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis.

DATES: This rule is effective December 8, 2006.

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: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200-407 that provides for use of Lincomycin-Spectinomycin (lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate) Water Soluble Powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Agri Laboratories, Ltd.'s Lincomycin-Spectinomycin Water Soluble Powder is approved as a generic copy of L-S 50 Water Soluble Powder, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 046-109. The ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1265 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 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.

FDA 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 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. In § 520.1265, revise the section heading and paragraph (b)(2) to read as follows:

§ 520.1265 Lincomycin and spectinomycin powder.

* * * * *

(b) * * *

(2) Nos. 057561, 059130, and 061623 for use of product described in paragraph (a)(2) of this section.

* * * * *

Dated: November 28, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6-20929 Filed 12-7-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 520
Oral Dosage Form New Animal Drugs; Oxytetracycline Powder

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 IVX Animal Health, Inc. The supplemental ANADA revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of fowlbrood of honeybees.

DATES: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200-247 that provides for the use of Oxytetracycline HCl Soluble Powder-343 in several species. The supplement revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of fowlbrood of honeybees. The supplemental ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1660d to reflect the approval and a current format.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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 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. In § 520.1660d, revise paragraph (d)(2)(ii) to read as follows:

§ 520.1660d Oxytetracycline powder.

(d) * * *
(2) * * *
(ii) *Indications for use.* For control of American fowlbrood caused by *Paenibacillus larvae* and European fowlbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

Dated: November 22, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. E6-20928 Filed 12-7-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9286]

RIN 1545-BE91

Railroad Track Maintenance Credit; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document corrects temporary regulations (TD 9286) that were published in the **Federal Register** on Friday, September 8, 2006 (71 FR 53009) providing rules for claiming the railroad track maintenance credit under section 45G of the Internal Revenue Code for qualified railroad track maintenance expenditures paid or incurred by a Class II railroad or Class III railroad and other eligible taxpayers during the taxable year.

DATES: This correction is effective September 8, 2006.

FOR FURTHER INFORMATION CONTACT: Winston H. Douglas, (202) 622-3110 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9286) that is the subject of this document is under section 45G of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (TD 9286) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR parts 1 and 602 are corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.45G-0T is amended by removing the entry for § 1.45G-1T(e) and (e)(2) and redesignating the entries for § 1.45G-1T(e)(1) and § 1.45G-1T(e)(1)(i), (ii) and (iii) as the entries for (e), (e)(1), (e)(2) and (e)(3) respectively.

■ **Par. 3.** Section 1.45G-1T is amended by:

- 1. Removing paragraph (e)(2);
- 2. Redesignating paragraphs (e)(1)(i), (e)(1)(ii), and (e)(1)(iii) as paragraphs (e)(1), (e)(2), and (e)(3), respectively;
- 3. Revising paragraph (a), sixth sentence, paragraph (b)(9), paragraph (d)(6) *Example 2* (ii), last sentence, paragraph headings (e), (e)(1), (e)(2) and (e)(3), paragraph (e)(2), second and fifth sentences, paragraph (e)(3), first sentence, *Example 1* (i), third sentence, *Example 1* (iii), second sentence, *Example 2* (iii), fourth sentence, and paragraph (g)(3). The revisions read as follows:

§ 1.45G-1T Railroad track maintenance credit (temporary).

(a) * * * Paragraph (e) of this section contains rules for adjusting basis for the amount of the RTMC claimed by an eligible taxpayer. * * *

(b) * * *

(9) Except as provided in paragraph (e)(2) of this section, *railroad track* is property described in STB property accounts 8 (ties), 9 (rails and other track material), and 11 (ballast) in 49 CFR part 1201, subpart A.

* * * * *

(d) * * *

(6) * * *

Example 2. * * *

(ii) * * * Because O's tentative amount of RTMC does not exceed O's credit limitation amount for the taxable year ending March 31, 2007, O may claim a RTMC for the taxable year

ending March 31, 2007, in the amount of \$75,000.

* * * * *

(e) *Adjustments to basis*—* * *

(1) *In general.* * * *

(2) *Basis adjustment made to railroad track.* * * * For purposes of section 45G(e)(3) and this paragraph (e)(2), the adjusted basis of any railroad track with respect to which the eligible taxpayer claims the RTMC is limited to the amount of QRTME, if any, that is required to be capitalized into the qualifying railroad structure or an intangible asset. * * * If all or some of the QRTME paid or incurred by an eligible taxpayer during the taxable year is capitalized under section 263(a) to more than one asset, whether tangible or intangible (for example, railroad track and bridges), the reduction to the basis of these assets under this paragraph (e)(2) is allocated among each of the assets subject to the reduction in proportion to the unadjusted basis of each asset at the time the QRTME is paid or incurred during that taxable year.

(3) *Examples.* The application of this paragraph (e) is illustrated by the following examples. * * *

Example 1. * * *

(i) * * * X uses the track maintenance allowance method for track structure expenditures (for further guidance, see Rev. Proc. 2002-65 (2002-2 CB 700) and § 601.601(d)(2)(ii)(b) of this chapter). * * *

(iii) * * * In accordance with paragraph (e)(2) of this section, X reduces the capitalized amount of \$250,000 by the RTMC of \$500,000 claimed by X for 2006, but not below zero. * * *

Example 2. * * *

(iii) * * * In accordance with paragraph (e)(2) of this section, Z reduces the capitalized amount of \$1 million by the RTMC of \$500,000 claimed by Z for 2006. * * *

* * * * *

(g) * * *

(3) *Special rules for 2005 returns.* If a taxpayer's Federal income tax return for a taxable year beginning after December 31, 2004, and ending before September 7, 2006, is filed before October 10, 2006, and the taxpayer is not filing an amended Federal income tax return for that taxable year pursuant to paragraph (g)(2) of this section before the taxpayer's next filed original Federal income tax return, see paragraphs (d)(4)(iv) and (f)(7) of this section for the statements that must be attached to the taxpayer's next filed original Federal income tax return.