

Dated: October 23, 2007.

Christopher A. Padilla,
Assistant Secretary for Export
Administration.

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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; Ivermectin

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 Norbrook Laboratories, Ltd. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a one percent ivermectin solution by subcutaneous injection.

DATES: This rule is effective November 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: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed a supplement to ANADA 200-437 that provides for use of NOROMECTIN (ivermectin) Injection for Cattle and Swine. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites of cattle. The supplemental ANADA is approved as of October 5, 2007, and the regulations are amended in 21 CFR 522.1192 to reflect the approval.

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 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. In § 522.1192, revise paragraph (b)(2) and add paragraph (b)(3) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(b) * * *

(2) No. 055529 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(C), (e)(2)(iii), (e)(3), (e)(4) and (e)(5) of this section.

(3) No. 059130 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(B), (e)(2)(iii), (e)(3), (e)(4), and (e)(5) of this section.

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Dated: October 26, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary
Medicine.

[FR Doc. E7-21839 Filed 11-6-07; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9362]

RIN 1545-BG23

Foreign Tax Credit: Notification of Foreign Tax Redeterminations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary Income Tax Regulations relating to a United States taxpayer's obligation under section 905(c) of the Internal Revenue Code (Code) to notify the IRS of a foreign tax redetermination, which is a change in the taxpayer's foreign tax liability that may affect the taxpayer's foreign tax credit. This document also contains temporary Procedure and Administration Regulations under section 6689 relating to the civil penalty for failure to notify the IRS of a foreign tax redetermination as required under section 905(c). These temporary regulations affect taxpayers that have paid foreign taxes which have been redetermined and provide guidance needed to comply with statutory changes made to the applicable law by the Taxpayer Relief Act of 1997 and the American Jobs Creation Act of 2004. The text of the temporary regulations also serves as the text of the proposed regulations (REG-209020-86) set forth in the notice of proposed rulemaking on this subject published elsewhere in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on November 7, 2007.

Applicability Dates: For dates of applicability, see §§ 1.905-3T(a), 1.905-4T(f), and 301.6689-1T(e). These regulations generally apply to foreign tax redeterminations occurring in taxable years of United States taxpayers beginning on or after November 7, 2007, where the foreign tax redetermination affects the amount of foreign taxes paid or accrued by a United States taxpayer. Where the redetermination of foreign tax paid or accrued by a foreign corporation affects the amount of foreign taxes deemed paid under section 902 or 960, this section applies to foreign tax redeterminations occurring in a taxable year of a foreign corporation which ends with or within the taxable year of the domestic corporate shareholder beginning on or after November 7, 2007. Section 1.905-3T(b) generally applies to taxes paid or