

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 529

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 parts 510 and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add a new entry for “B.L. Mitchell, Inc.”; and in the table in paragraph (c)(2) numerically add a new entry for “067188” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * *				
(c) * * *				
(1) * * *				
Firm name and address			Drug labeler code	
* * *			* *	
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.			067188	
* * *			* *	

(2) * * *

Drug labeler code		Firm name and address		
* *		* * *		
067188		B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756		
* *		* * *		

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1030 [Amended]

■ 4. In paragraph (b)(1) of § 529.1030, remove “Nos. 049968 and 050378” and add in its place “Nos. 049968, 050378, and 067188”.

Dated: August 1, 2007.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. E7–15763 Filed 8–10–07; 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; Ampicillin Sodium

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 the use of ampicillin sodium powder in aqueous solution by injection in horses for the treatment of various bacterial infections.

DATES: This rule is effective August 13, 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: G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201, filed ANADA 200–335 that provides for use of ampicillin sodium as a constituted solution by injection in horses for the treatment of various bacterial infections.

G. C. Hanford Manufacturing Co.’s Ampicillin Sodium is approved as a generic copy of Pfizer, Inc.’s, AMP-EQUINE, approved under NADA 55–084. The ANADA is approved as of July 12, 2007, and the regulations are amended in 21 CFR 522.90c to reflect the approval and a current format. 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 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 AND 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. Revise § 522.90c to read as follows:

§ 522.90c Ampicillin sodium.

(a) Specifications. Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) Sponsors. See Nos. 000069 and 010515 in § 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount: 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) Indications for use. For the treatment of respiratory tract infections (pneumonia and strangles) due to

Staphylococcus spp., *Streptococcus* spp. (including *S. equi*), *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 1, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7-15761 Filed 8-10-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9332]

RIN 1545-BG00

Exclusions From Gross Income of Foreign Corporations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9332) that were published in the **Federal Register** on Monday, June 25, 2007 (72 FR 34600) relating to the exclusion from gross income of income derived by certain foreign corporations engaged in the international operation of ships or aircraft.

DATES: The correction is effective August 13, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia A. Bray, (202) 622-3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are under section 883 of the Internal Revenue Code.

Need for Correction

As published, final and temporary regulations (TD 9332) contain an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

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 1.883-1 is amended by revising paragraph (h)(3) to read as follows:

§ 1.883-1 Exclusion of income from the international operation of ships or aircraft.

* * * * *

(h) * * *

(3) For further guidance, see the entry for § 1.883-1T(h)(3).

* * * * *

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E7-15271 Filed 8-10-07; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9332]

RIN 1545-BG00

Exclusions From Gross Income of Foreign Corporations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9332) that were published in the **Federal Register** on Monday, June 25, 2007 (72 FR 34600) relating to the exclusion from gross income of income derived by certain foreign corporations engaged in the international operation of ships or aircraft.

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SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are

under section 883 of the Internal Revenue Code.

Need for Correction

As published, final and temporary regulations (TD 9332) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 9332), which was the subject of FR Doc. E7-12039, is corrected as follows:

1. On page 34601, column 3, in the preamble, under the paragraph heading “2. *Elimination of Foreign Base Company Shipping Income*”, line 3, the language “(118 Stat. 1418) (AJCA) repealed section” is corrected to read “(118 Stat. 1418) (AJCA) repealed section”.

2. On page 34602, column 3, in the preamble, under the paragraph heading “C. Reporting requirements related to *qualified shareholder stock ownership test*”, last line, the language “at the office of that such practitioner.” is corrected to read “at the office of that practitioner.”.

3. On page 34603, column 1, in the preamble, under the paragraph heading “2. *Activities Incidental to the International Operation of Ships or Aircraft*”, line 7 from the bottom of the paragraph, the language “to the international operation of a ship” is corrected to read “to the international operation of ships”.

4. On page 34603, column 3, in the preamble, under the paragraph heading “4. *Countries that Provide an Exemption Through an Income Tax Convention and by Other Means*”, lines 5 through 10, the language “exemption under section 883 through a diplomatic note, domestic statutory law, or by generally imposing no income tax on foreign corporations engaged in the international operation of ships or aircraft will continue to have the choice” is corrected to read “exemption under section 883 (through a diplomatic note, domestic statutory law, or because income tax is generally not imposed on foreign corporations engaged in the international operation of ships or aircraft) will continue to have the choice”.

5. On page 34604, column 1, in the preamble, under the paragraph heading “5. *Reporting Requirements Related to Qualified Shareholder Stock Ownership Test*”, first paragraph of the column, line 9, the language “addresses of shareholders in” is corrected to read “addresses of shareholders of”.

6. On page 34604, column 2, in the preamble, under the paragraph heading