Dated: October 6, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–26403 Filed 10–13–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 526 and 556

Intramammary Dosage Form New Animal Drugs; Pirlimycin Hydrochloride

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 new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provides for use of a sterile solution of pirlimycin hydrochloride for intramammary treatment of clinical and subclinical staphylococcal and streptococcal mastitis in lactating dairy cows, for reduction in the preslaughter withdrawal period, and for revision of the milk discard statement in labeling to state the milk discard time only (i.e., to remove reference to the number of milkings).

DATES: This rule is effective October 16, 2000.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplemental application to NADA 141–036 that provides for use of PIRSUE® (pirlimycin hydrochloride) Sterile Solution for intramammary treatment of clinical and subclinical mastitis in lactating dairy cattle caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae, Streptococcus dysgalactiae,* and *Streptococcus uberis;* for reduction in the preslaughter withdrawal period from 28 days to 9 days; and for revision of the milk discard statement in labeling to state the 36-hour milk discard time only (i.e., to remove reference to the number of milkings). The supplemental NADA is approved as of September 7, 2000, and the regulations are amended in 21 CFR 526.1810 to reflect the approval.

In addition, the regulations are amended in (21 CFR 556.515) to add the previously established acceptable daily intake for total residues of pirlimycin, to add a tolerance for residues of pirlimycin in cattle muscle and, editorially, to reflect current format.

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 7, 2000, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new formulation for which the supplemental application was approved.

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 526

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 526 and 556 are amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORM

1. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.1810 [Amended]

2. Section 526.1810 *Pirlimycin hydrochloride aqueous gel* is amended by removing ''aqueous gel'' from the section heading, by removing ''(three milkings)'' from the first sentence in paragraph (d)(3), by removing ''28'' from the second sentence in paragraph (d)(3) and by adding in its place ''9'', and by removing the third sentence of paragraph (d)(3).

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

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

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

2. Section 556.515 is revised to read as follows:

§ 556.515 Pirlimycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of pirlimycin is 0.01 milligrams per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent pirlimycin (the marker residue) is 0.5 part per million (ppm).

(ii) *Muscle.* The tolerance for parent pirlimycin (the marker residue) is 0.3 ppm.

(iii) *Milk.* The tolerance for parent pirlimycin (the marker residue in cattle milk) is 0.4 ppm.

(2) [Reserved]

Dated: October 6, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–26404 Filed 10–13–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8897]

RIN 1545–AQ91

Rules for Property Produced in a Farming Business; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction of final regulations.

SUMMARY: This document contains corrections to final regulations relating to the application of section 263A of the Internal Revenue Code to property produced in the trade or business of farming. This document was published in the **Federal Register** on August 21, 2000 (65 FR 50638).

EFFECTIVE DATE: August 21, 2000.

FOR FURTHER INFORMATION CONTACT: Grant D. Anderson (202) 622–4970 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Need for Correction

As published, the final regulations (TD 8897) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 8897), which were the subject of FR Doc. 00–21103, is corrected as follows:

1. On page 50638, column 3, in the preamble under the paragraph heading, ''Background'', line 3, the language ''proposed rulemaking (REG–208151–91)'' is corrected to read ''proposed rulemaking (REG–209316–86)''.

2. On page 50640, column 3, paragraph 1, line 14, the language ''I.R.B. (Sept. 5, 2000)) issued'' is corrected to read ''I.R.B. 256 (Sept. 5, 2000)) issued''.

PART 1—[CORRECTED]

§ 1.263A–1 [Corrected]

3. On page 50644, column 2, in amendatory instruction Par. 5., remove item designations for items ''1.'' and ''2.'' and correctly designate the items ''2.'' and ''3.'', respectively. Add new item ''1.'' to read as follows:

1. The last sentence of paragraph (a)(3)(v) is revised.

4. On page 50644, column 2, § 1.263A–1, remove the five asterisks following the section heading and add the following language for the last sentence of paragraph (a)(3)(v) to read as follows:

§ 1.263A–1 Uniform capitalization of costs.

(a) * * *

(3) * * *

(v) * * * See sections 263A(d) and 263A(e) and § 1.263A–4 for rules relating to taxpayers engaged in a farming business.

* * * * *

§ 1.263A–4 [Corrected]

5. On page 50644, column 3, § 1.263A–4, paragraph (a)(2)(i)(B), line 3, the language ''disbursements method under section'' is corrected to read ''disbursements method of accounting (cash method) under section''.

6. On page 50648, column 3, § 1.263A–4, paragraph (d)(2), line 5 from the top of the column, the language ''required to use the accrual method'' is corrected to read ''required to use an accrual method''.

Cynthia E. Grigsby,

Chief, Regulations Unit, Office of Special Counsel (Modernization & Strategic Planning).

[FR Doc. 00–25998 Filed 10–13–00; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General of the Navy (Admiralty and Maritime Law) has determined that USS *Zephyr* (PC 8) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: June 5, 2000.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Gregg A. Cervi, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), Office of the Judge Advocate General, Washington Navy Yard, DC 20374–5066, Telephone number: (202) 685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General of the Navy (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS *Zephyr* (PC 8) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Rule 21(c) pertaining to the placement of the stern light as nearly as practicable at the stern. The Deputy Assistant Judge Advocate General of the Navy (Admiralty and Maritime Law) has also certified that the light involved is located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

Accordingly, 32 CFR part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

2. Table 3 of § 706.2 is amended by revising the entry for USS *Zephyr* to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *