Indeed, to avoid any costs, regulated entities need only comply with the law.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires an assessment of the impacts of proposed and final rule on small entities. An agency must prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601–612), unless the agency can certify that a regulation will not have a significant economic impact on a substantial number of small entities. This rule imposes no substantive burden and merely amends the existing penalties for those who engage in prohibited conduct to reflect statutory changes. The civil penalties will affect only those who engage in conduct prohibited by statute or related regulations. Those who comply with the law will not be affected by the civil penalties. Accordingly, the Office of the Secretary certifies that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule imposes no new reporting or record keeping requirements necessitating clearance by OMB.

List of Subjects in 14 CFR Part 383

Administrative practice and procedure, Penalties.

Accordingly, the Department of Transportation revises Part 383 of Title 14, as set forth below:

PART 383—CIVIL PENALTIES

Sec.
§ 383.1 Basis and purpose.
§ 383.2 Amount of penalty.

Authority: Secs. 222, 706, 707(b), Pub. L. 106–181, 114 Stat. 61; Pub. L. 101–410, 104 Stat. 890, as amended by sec. 31001, Pub. L. 104–134, 110 Stat. 1321.

§ 383.1 Basis and purpose.

(a) *Basis.* This part implements the civil penalty provisions of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21, Pub. L. 106–181; 114 Stat. 61; April 5, 2000, sections 222, 706, 707(b)), and the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, section 31001). The Debt Collection Improvement Act requires each agency head to adjust by regulation each civil monetary penalty provided by law by the inflation adjustment described under section 5 of the Federal Civil Penalties Inflation Adjustment Act. We have applied these guidelines to the civil penalty amounts that were not affected by AIR 21 and, taking into account the inflation that has occurred since the most recent adjustment, have found that no further adjustment is warranted as of June 2000.

(b) *Purpose.* This part states the civil penalty amounts with respect to violations of 49 U.S.C. 40127, 41705 and 41712 and other civil penalties provided in 49 U.S.C. 46301 (a)(1) for violations covered by this chapter.

§ 383.2 Amount of penalty.

A person is liable to the United States Government for a civil penalty of not more than $10,000 for each violation of 49 U.S.C. 41705 and a civil penalty of not more than $2,500 for each violation of 49 U.S.C. 40127 or 41712. For other violations of this chapter within the scope of 49 U.S.C. 46301, the civil penalty amount is $1,100.

* * * * *

Issued this 20th day of September, 2000, at Washington, D.C.

Rodney E. Slater,

Secretary of Transportation.

[FR Doc. 00–26197 Filed 10–13–00; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Levamisole Phosphate 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 an abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for use of levamisole phosphate solution by subcutaneous injection for the treatment of various species of gastrointestinal parasites in cattle.

DATES: This rule is effective October 16, 2000.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–271 for LEVAMISOLE PHOSPHATE Injectable Solution, 13.65%. The ANADA provides for use of levamisole phosphate solution by subcutaneous injection for the treatment of various species of gastrointestinal parasites in cattle. The ANADA is approved as a generic copy of Schering-Plough Animal Health's NADA 126–742 for LEVASOLE® Injection. ANADA 200–271 is approved as of September 7, 2000, and the regulations are amended in 21 CFR 522.1244 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.

§ 522.1244 [Amended]

2. Section 522.1244 *Levamisole phosphate injection* is amended in paragraph (b) by removing ''No. 000061'' and by adding in its place ''Nos. 000061 and 057561''.

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.