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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Form New Animal Drugs; Pirlimycin

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., a Division of Pfizer, Inc. The supplemental NADA extends the dosage regimen for pirlimycin hydrochloride intramammary infusion in lactating dairy cattle to daily treatment for up to 8 days.

DATES: This rule is effective January 4, 2008.

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: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–036 that provides for veterinary prescription use of PIRSUE (pirlimycin hydrochloride) Sterile Solution in lactating dairy cattle for the treatment of mastitis. The supplement extends the dosage regimen to daily treatment for up to 8 days. The supplemental NADA is approved as of December 12, 2007, and the regulations are amended in 21 CFR 526.1810 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.

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 supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33(d)(5) 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 526

Animal drugs.

■ 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 part 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 526.1810, revise the section heading and paragraphs (a), (b), and (d) to read as follows:

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

* * * * *

(d) *Conditions of use in cattle*—(1) *Amount.* Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use.* For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–25606 Filed 1–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Semduramicin

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 new animal drug application (NADA) filed by Phibro Animal Health. The NADA provides for use of a Type A medicated article containing semduramicin (as semduramicin sodium biomass) to manufacture Type C medicated broiler chicken feed for the prevention of coccidiosis.

DATES: This rule is effective January 4, 2008.

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: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed NADA 141–281 that provides for the use of AVIAX II (semduramicin) Type A medicated article containing semduramicin (as semduramicin sodium biomass) to manufacture Type C medicated broiler chicken feed for the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix*, and *E. mitis*. The NADA is approved as of December 3, 2007, and the regulations are amended in 21 CFR 558.4 and 21 CFR 558.555 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33(a)(3) 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. In paragraph (d) of § 558.4, in the ''Category I'' table, revise the entry for ''Semduramicin'' and alphabetically add an entry for ''Semduramicin (as semduramicin sodium biomass)'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent[1] Type A	Type B maximum (200x)	Assay limits percent[1] Type B/C[2]
* *	* *	*	* *
Semduramicin (as semduramicin sodium) Semduramicin (as semduramicin sodium biomass)	90–110 90–110	2.27 g/lb (0.50%) 2.27 g/lb (0.50%)	80–110 80–120
* *	* *	*	* *

[1]Percent of labeled amount.

[2]Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

* * * * *

■ 3. In § 558.555, revise paragraphs (a) and (b); and add paragraph (e) to read as follows:

§ 558.555 Semduramicin.

(a) *Specifications*. Type A medicated article containing:

(1) 22.7 grams (g) per pound (lb) (50 g/kilogram (kg)) semduramicin (as semduramicin sodium).

(2) 22.7 g/lb (50 g/kg) semduramicin (as semduramicin sodium biomass).

(b) *Approvals*. See No. 066104 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d) of this section; for use of product described in paragraph (a)(2) as in paragraph (e) of this section.

* * * * *

(e) *Conditions of use in chickens*. It is used in chicken feed as follows:

Semduramicin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix, and E. mitis*.	Do not feed to laying hens.	066104
(2) [Reserved]				

Dated: December 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–25605 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[DA 07–4354]

List of Office of Management and Budget Approved Information Collection Requirements

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document revises the Commission's list of Office of Management and Budget (OMB) approved public information collection requirements with their associated OMB expiration dates. This list will provide the public with a current list of public information collection requirements approved by OMB and their associated control numbers and expiration dates as of September 28, 2007.

DATES: Effective January 4, 2008.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of the Managing Director, (202) 418–0214 or by e-mail to *Judith-B.Herman@fcc.gov*.

SUPPLEMENTARY INFORMATION: This document adopted on December 10, 2007 and released on December 10, 2007 by the Managing Director in DA 07–4354 revised 47 CFR 0.408 in its entirety.

1. Section 3507(a)(3) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(3), requires agencies to display a current control number assigned by the Director, Office of Management and Budget (''OMB'') for each agency information collection requirement.

2. Section 0.408 of the Commission's rules displays the OMB control numbers assigned to the Commission's public information collection requirements that have been reviewed and approved by OMB.

3. Authority for this action is contained in section 4(i) of the Communications Act of 1934 (47 U.S.C. 154(i)), as amended, and § 0.231(b) of the Commission's rules. Since this amendment is a matter of agency organization procedure or practice, the notice and comment and effective date provisions of the Administrative Procedure Act do not apply. See 5 U.S.C. 553(b)(A)(d). For this reason, this rulemaking is not subject to the Congressional Review Act and will not be reported to Congress and the Government Accountability Office. See 5 U.S.C. 801.

4. Accordingly, *it is ordered, that* section 0.408 of the rules is *revised* as set forth in the revised text effective on January 4, 2008.

5. Persons having questions on this matter should contact Judith B.Herman at (202) 418–0214 or e-mail to *Judith-B.Herman@fcc.gov*.

List of Subjects in 47 CFR Part 0

Reporting, recordkeeping and third party disclosure requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 0 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read:

Authority: Secs. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Section 0.408 is revised to read as follows:

§ 0.408 OMB control numbers and expiration dates assigned pursuant to the Paperwork Reduction Act of 1995.

(a) *Purpose.* This section displays the control numbers and expiration dates for the Commission information collection requirements assigned by the Office of Management and Budget (''OMB'') pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. The Commission intends that this section comply with the requirement that agencies ''display'' current control numbers and expiration dates assigned by the Director, OMB, for each approved information collection requirement. Not withstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number. Questions concerning the OMB control numbers and expiration dates should be directed to the Associate Managing Director—Performance Evaluation and Records Management, (''AMD–PERM''), Office of Managing Director, Federal Communications Commission, Washington, DC 20554 by sending an e-mail to *Judith-B.Herman@fcc.gov*.

(b) *Display*

OMB Control No.	FCC form number or 47 CFR section or part, docket number or title identifying the collection	OMB expiration date
3060–0004	Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, ET Docket No. 93–62	03/31/08
3060–0009	FCC 316	08/31/08
3060–0010	FCC 323	01/31/09
3060–0016	FCC 346	05/31/08
3060–0017	FCC 347	05/31/09
3060–0027	FCC 301	09/30/08
3060–0029	FCC 340	02/28/10
3060–0031	FCC 314, FCC 315	08/31/08
3060–0053	FCC 703	08/31/08
3060–0055	FCC 327	10/31/09
3060–0056	Part 68	04/30/08
3060–0057	FCC 731	12/31/08
3060–0059	FCC 740	02/28/10
3060–0061	FCC 325	12/31/08
3060–0065	FCC 442	06/30/08
3060–0068	FCC 702	08/31/08
3060–0075	FCC 345	09/30/08
3060–0076	FCC 395	12/31/07
3060–0084	FCC 323–E	06/30/08
3060–0093	FCC 405	01/31/09