

# Rules and Regulations

Federal Register

Vol. 73, No. 3

Friday, January 4, 2008

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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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](mailto: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.gothardt@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 <sup>1</sup> Type A | Type B maximum (200x)                  | Assay limits percent <sup>1</sup> Type B/C <sup>2</sup> |
|--|--|--|---|
| * * * * *  | * * * * *                                | * * * * *                              | * * * * *   |
| Semduramicin (as semduramicin sodium)<br>Semduramicin (as semduramicin sodium biomass) | 90-110<br>90-110                         | 2.27 g/lb (0.50%)<br>2.27 g/lb (0.50%) | 80-110<br>80-120  |
| * * * * *  | * * * * *                                | * * * * *                              | * * * * *   |

<sup>1</sup>Percent of labeled amount.

<sup>2</sup>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 <i>Eimeria tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. necatrix</i> , and <i>E. mitis</i> . | 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            |