

tenth month following their receipt are countable as resources at that time.

(c) *Exception:* For any payments described in paragraph (a) of this section received before March 2, 2004, we will exclude for the month following the month of receipt the unspent portion of any such payment.

■ 8. Amend § 416.1236 by revising paragraph (a)(24) and adding a new paragraph (a)(25) to read as follows:

**§ 416.1236 Exclusions from resources; provided by other statutes.**

(a) \* \* \*

(24) Assistance provided for flood mitigation activities under section 1324 of the National Flood Insurance Act of 1968, pursuant to section 1 of Public Law 109–64 (119 Stat. 1997, 42 U.S.C. 4031).

(25) Payments made to individuals under the Energy Employees Occupational Illness Compensation Program Act of 2000, pursuant to section 1, app. [Div. C. Title XXXVI section 3646] of Public Law 106–398 (114 Stat. 1654A–510, 42 U.S.C. 7385e).

\* \* \* \* \*

■ 9. Revise § 416.1240 to read as follows:

**§ 416.1240 Disposition of Resources.**

(a) Where the resources of an individual (and spouse, if any) are determined to exceed the limitations prescribed in § 416.1205, such individual (and spouse, if any) shall not be eligible for payment except under the conditions provided in this section. Payment will be made to an individual (and spouse, if any) if the individual agrees in writing to:

(1) Dispose of, at current market value, the nonliquid resources (as defined in § 416.1201(c)) in excess of the limitations prescribed in § 416.1205 within the time period specified in § 416.1242; and

(2) Repay any overpayments (as defined in § 416.1244) with the proceeds of such disposition.

(b) Payment made for the period during which the resources are being disposed of will be conditioned upon the disposition of those resources as prescribed in paragraphs (a)(1) and (a)(2) of this section. Any payments so made are (at the time of disposition) considered overpayments to the extent they would not have been paid had the disposition occurred at the beginning of the period for which such payments were made.

(c) If an individual fails to dispose of the resources as prescribed in paragraphs (a)(1) and (a)(2) of this section, regardless of the efforts he or

she makes to dispose of them, the resources will be counted at their current market value and the individual will be ineligible due to excess resources. We will use the original estimate of current market value unless the individual submits evidence establishing a lower value (e.g., an estimate from a disinterested knowledgeable source).

[FR Doc. 2010–241 Filed 1–8–10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA–2009–N–0665]

#### Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate 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 a supplemental new animal drug application (NADA) filed by Anika Therapeutics, Inc. The supplemental NADA provides for a revised human food safety warning for use of hyaluronate sodium injectable solution in horses.

**DATES:** This rule is effective January 11, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Anika Therapeutics, Inc., 236 W. Cummings Park, Woburn, MA 01801, filed a supplement to NADA 122–578 that provides for the veterinary prescription use of HYVISC (hyaluronate sodium) Sterile Injection in horses. The supplemental NADA provides for a revised human food safety warning on product labeling. The supplemental NADA is approved as of December 11, 2009, and the regulations are amended in 21 CFR 522.1145 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA has determined under 21 CFR 25.33 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 the 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.

#### § 522.1145 [Amended]

■ 2. In paragraph (f)(3)(iii) of § 522.1145, remove the third sentence and in its place add “Do not use in horses intended for human consumption.”

Dated: December 31, 2009.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2010–207 Filed 1–8–10; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA–2009–N–0665]

#### Implantation or Injectable Dosage Form New Animal Drugs; Flornfenicol and Flunixin

**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 original new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for veterinary prescription use of a combination injectable solution containing

florfenicol and flunixin meglumine in cattle.

**DATES:** This rule is effective January 11, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: [cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed NADA 141-299 that provides for use RESFLOR GOLD (florfenicol and flunixin meglumine), a combination injectable solution, for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle. The NADA is approved as of November 23, 2009, and the regulations in 21 CFR part 522 are amended by adding § 522.956 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.

The agency has determined under 21 CFR 25.33 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.

■ 2. Add § 522.956 to read as follows:

**§ 522.956 Florfenicol and flunixin.**

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) florfenicol and 16.5 mg flunixin (27.37 mg flunixin meglumine).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Tolerances.* See §§ 556.283 and 556.286 of this chapter.

(d) *Conditions for use in cattle*—(1) *Amount.* 40 mg florfenicol/kg body weight (BW) and 2.2 mg flunixin/kg BW (equivalent to 2 mL/15 kg BW or 6 mL/100 lbs) once, by subcutaneous injection.

(2) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals intended for human consumption must not be slaughtered within 38 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

Dated: December 31, 2009.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2010-209 Filed 1-8-10; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

[Docket No. FDA-2009-N-0665]

**New Animal Drugs; Ractopamine**

**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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for administering ractopamine hydrochloride Type C medicated feeds as a top dress to cattle fed in confinement for slaughter.

**DATES:** This rule is effective January 11, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141-221 that provides for use of OPTAFLEXX 45 (ractopamine hydrochloride) Type A medicated articles to formulate Type B and Type C medicated feeds administered to cattle fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed. The supplement provides for feeding ractopamine hydrochloride Type C medicated feed as a top dress. The supplemental NADA is approved as of December 11, 2009, and the regulations in 21 CFR 558.500 are amended 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.

The agency has determined under 21 CFR 25.33 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.

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.

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.