DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2010–N–0002]

Oral Dosage Form New Animal Drugs; Praziquantel and Pyrantel

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 Bayer HealthCare LLC. The supplement provides for two new sizes of praziquantel and pyrantel pamoate tablets used in cats and kittens for the removal of various internal parasites and for a revised kitten age and weight restriction.

DATES: This rule is effective September 3, 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, email: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141–008 for DRONTAL (praziquantel and pyrantel pamoate) Tablets used in cats and kittens for the removal of various internal parasites. The supplement provides for two new tablet sizes and for a revised kitten age and weight restriction. The supplemental NADA is approved as of June 15, 2010, and 21 CFR 520.1871 is amended to reflect the approval.

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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.1871, in paragraph (b)(1), remove "tablet" and in its place add "tablets"; and revise paragraphs (a)(1), (d)(1)(i), and (d)(1)(iii) to read as follows:

§ 520.1871 Praziquantel and pyrantel.

(a) * * *

(1) Each tablet contains 13.6 milligrams (mg) praziquantel and 54.3 mg pyrantel base (as pyrantel pamoate), 18.2 mg praziquantel and 72.6 mg pyrantel base (as pyrantel pamoate), or 27.2 mg praziquantel and 108.6 mg pyrantel base (as pyrantel pamoate).

* * * * *

(d) * * *

(1) * * *

(i) *Dosage.* Administer a minimum dose of 2.27 mg praziquantel and 9.2 mg pyrantel pamoate per pound of body weight according to the dosing tables on labeling. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated.

* * * * *

(iii) *Limitations.* Not for use in kittens less than 2 months of age or weighing less than 2.0 pounds. Consult your veterinarian before giving to sick or pregnant animals.

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Dated: August 31, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–22043 Filed 9–2–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2010–N–0002]

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol 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 a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA adds *Mycoplasma bovis* to the bovine respiratory disease (BRD) pathogens for which use of an injectable solution containing florfenicol and flunixin meglumine is an approved treatment.

DATES: This rule is effective September 3, 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*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed a supplement to NADA 141–299 that provides for use of RESFLOR GOLD (florfenicol and flunixin meglumine), a combination drug injectable solution. The supplement adds *M. bovis* to the BRD pathogens for which the use of this product is approved. The supplemental NADA is approved as of June 7, 2010, and the regulations in 21 CFR 522.956 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.

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.

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. In § 522.956, revise paragraph (d)(2) to read as follows:

§ 522.956 Florfenicol and flunixin.

* * * * *

(d) * * *

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

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Dated: August 31, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–22039 Filed 9–2–10; 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–2010–N–0002]

New Animal Drugs for Use in Animal Feed; 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 two supplemental new animal drug applications (NADAs) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADAs provide for administering a Type C medicated feed containing ractopamine hydrochloride as a top dress on Type C medicated feeds containing monensin, USP, or monensin, USP, and tylosin phosphate to cattle fed in confinement for slaughter.

DATES: This rule is effective September 3, 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.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–225 that provides for use of OPTAFLEXX (ractopamine hydrochloride) and RUMENSIN (monensin, USP) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter. Elanco Animal Health also filed a supplement to NADA 141–224 that provides for use of OPTAFLEXX (ractopamine hydrochloride), RUMENSIN (monensin, USP), and TYLAN (tylosin phosphate) Type A medicated articles to formulate three-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter.

The supplemental NADAs provide for administering ractopamine hydrochloride Type C medicated feeds as a top dress on Type C medicated feeds containing monensin, USP, or monensin, USP, and tylosin phosphate to cattle fed in confinement for slaughter as the means by which the two-way or three-way combinations will be created. Supplemental NADA 141–224 is approved as of June 7, 2010; supplemental NADA 141–225 is approved as of June 17, 2010; and the regulations in 21 CFR 558.500 are amended to reflect the approvals.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summaries of safety and effectiveness data and information submitted to support approval of these applications 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 these actions are of a type that do 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 the 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 § 558.500, add paragraphs (e)(2)(xii) and (e)(2)(xiii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d).	000986