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Dated: March 29, 2007.

By the Commission.

Eileen A. Donovan,

Acting Secretary of the Commission.

[FR Doc. E7-6190 Filed 4-3-07; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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 an original new animal drug application (NADA) filed by Virbac AH, Inc. The NADA provides for use of chewable tablets containing praziquantel and pyrantel pamoate in dogs and puppies for the treatment and control of various internal parasites.

DATES: This rule is effective April 4, 2007.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed NADA 141-261 for WORMXPLUS (praziquantel and pyrantel pamoate) Flavored Chewables and VIRBANTEL (praziquantel and pyrantel pamoate) Flavored Chewables that provides for their use in dogs and puppies for the treatment and control of

various internal parasites. The NADA is approved as of March 13, 2007, and 21 CFR 520.1871 is 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)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 13, 2007.

FDA has determined under 21 CFR 25.33(d)(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 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. Amend § 520.1871 as follows:

■ a. Revise the section heading and paragraphs (a) and (b);

■ b. Redesignate paragraph (c) as paragraph (d) and add new paragraph (c); and

■ c. Revise newly redesignated paragraphs (d)(1)(i), (d)(1)(iii), and (d)(2).

The revisions, redesignation, and addition read as follows:

§ 520.1871 Praziquantel and pyrantel.

(a) *Specifications*—(1) Each tablet contains 18.2 milligrams (mg) praziquantel and 72.6 mg pyrantel (as pyrantel pamoate).

(2) Each chewable tablet contains 30 mg praziquantel and 30 mg pyrantel pamoate or 114 mg praziquantel and 114 mg pyrantel pamoate.

(b) *Sponsors*. See sponsors in § 510.600(c) for use as in paragraph (d) of this chapter.

(1) See No. 000859 for use of tablet described in paragraph (a)(1) of this section for use as in paragraph (d)(1) of this section.

(2) See No. 051311 for use of tablets described in paragraph (a)(2) of this section for use as in paragraph (d)(2) of this section.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) * * *

(1) * * *

(i) *Dosage*. 1.5 to 1.9 pounds, 1/4 tablet; 2 to 3 pounds, 1/2 tablet; 4 to 8 pounds, 1 tablet; 9 to 12 pounds, 1 1/2 tablets; 13 to 16 pounds, 2 tablets. If reinfection occurs, treatment may be repeated.

* * * * *

(iii) *Limitations*. Not for use in kittens less than 1 month of age or weighing less than 1.5 pounds. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. Consult your veterinarian before giving to sick or pregnant animals.

(2) *Dogs*—(i) *Amount*. Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) *Indications for use*. For the treatment and control of roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) in dogs and puppies.

Dated: March 26, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7-6181 Filed 4-3-07; 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 Feeds; Melengestrol and Lasalocid

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 Ivy Laboratories, Div. of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol and lasalocid to make two-way combination drug Type B or Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective April 4, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200-451 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix and BOVATEC (lasalocid sodium) single-ingredient Type A medicated articles to make dry and liquid, two-way combination drug Type B or Type C medicated feeds for heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200-451 is approved as a generic copy of NADA 140-288, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., for combination use of MGA 500 and BOVATEC. The application is approved as of March 12, 2007, and the regulations are amended in 21 CFR 558.342 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(a)(2) 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.

§ 558.342 [Amended]

■ 2. In § 558.342, amend the table in paragraph (e)(1)(iii) in the "Sponsor" column by adding in numerical sequence "021641".

Dated: March 26, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7-6180 Filed 4-3-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 500 and 501

[BOP-1116; AG Order No. 2878-2007]

RIN 1120-AB08

National Security; Prevention of Acts of Violence and Terrorism

AGENCY: Bureau of Prisons, Department of Justice.

ACTION: Final rule.

SUMMARY: This rule finalizes the interim rules on Special Administrative Measures that were published on October 31, 2001 (66 FR 55062). The previously existing regulations authorized the Bureau of Prisons (Bureau), at the direction of the Attorney General, to impose special administrative measures with respect to specified inmates, based on information provided by senior intelligence or law enforcement officials, if determined necessary to prevent the dissemination of either classified information that could endanger the national security, or of other information that could lead to acts of violence and/or terrorism. The interim rule extended the period of time for which such special administrative measures may be imposed from 120 days to up to one year, and modified the standards for approving extensions of such special administrative measures. In addition, where the Attorney General

has certified that reasonable suspicion exists to believe that an inmate may use communications with attorneys (or agents traditionally covered by the attorney-client privilege) to further or facilitate acts of violence and/or terrorism, the interim rule amended the previously existing regulations to provide that the Bureau must provide appropriate procedures to monitor or review such communications to deter such acts, subject to specific procedural safeguards, to the extent permitted under the Constitution and laws of the United States. The interim rule also requires the Director of the Bureau of Prisons to give written notice to the inmate and attorneys and/or agents before monitoring or reviewing any communications as described in this rule. The interim rule also provided that the head of each component of the Department of Justice that has custody of persons for whom special administrative measures are determined to be necessary may exercise the same authority to impose such measures as the Director of the Bureau of Prisons.

DATES: Effective date: June 4, 2007.

ADDRESSES: Rules Unit, Office of the General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT:

Sarah Qureshi, Office of the General Counsel, Bureau of Prisons, (202) 307-2105.

SUPPLEMENTARY INFORMATION: This rule finalizes interim rules on Special Administrative Measures that were published on October 31, 2001 (66 FR 55062). These rules are codified at 28 CFR 501.2 (national security) and 501.3 (violence and terrorism). We received approximately 5000 comments in opposition to the rule, which we discuss below.

Section 501.2

Section 501.2 authorizes the Director of the Bureau, at the direction of the Attorney General, to impose special administrative measures with respect to a particular inmate that are reasonably necessary to prevent disclosure of classified information. These procedures may be implemented after written certification by the head of a United States intelligence agency that the unauthorized disclosure of such information would pose a threat to the national security and that there is a danger that the inmate will disclose such information. These special administrative measures ordinarily may include housing the inmate in special housing units and/or limiting certain privileges, including, but not limited to,