

radius of Williamsport-Lycoming County Airport extending clockwise from a 025° bearing to a 067° bearing from the airport and within a 12.6-mile radius of Williamsport-Lycoming County Airport extending clockwise from a 067° bearing to a 099° bearing from the airport and within a 6.7-mile radius of Williamsport-Lycoming County Airport extending clockwise from a 099° bearing to a 270° bearing from the airport and within a 17.9-mile radius of Williamsport-Lycoming County Airport extending clockwise from a 270° bearing to a 312° bearing from the airport and within a 19.6-mile radius of Williamsport-Lycoming County Airport extending clockwise from a 312° bearing to a 350° bearing from the airport and within a 6.7-mile radius of Williamsport-Lycoming County Airport extending clockwise from a 350° bearing to a 025° bearing from the airport and within 4.4 miles each side of the Williamsport-Lycoming County Airport ILS localizer east course extending from the Picture Rocks NDB to 11.3 miles east of the NDB; and that airspace within a 6-mile radius of the point in space (Lat. 41°14'43" N., long. 77°00'04" W.) serving the Williamsport Hospital.

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Issued in College Park, GA, on February 7, 2008.

Barry A. Knight,

*Acting Manager, System Support Group,
Eastern Service Center.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Altrenogest

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 provides for revised food safety labeling for altrenogest oral solution used in horses.

DATES: This rule is effective February 21, 2008.

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.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane,

Millsboro, DE 19966, filed a supplement to NADA 131-310 for REGU-MATE (altrenogest), an oral solution administered to mares for suppression of estrus. The supplemental application provides for a revised warning statement on product labeling. The supplemental NADA is approved as of January 18, 2008, and 21 CFR 520.48 is amended 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.

The agency has determined under 21 CFR 25.33(a)(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. In § 520.48, revise the section heading and paragraph (d)(1)(iii) to read as follows:

§ 520.48 Altrenogest.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: February 11, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-3265 Filed 2-20-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The supplemental ANADA provides revised labeling for ivermectin oral liquid used in horses.

DATES: This rule is effective February 21, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200-202 for PHOENECTIN (ivermectin) Liquid for Horses. The supplemental application provides for the addition of indications for use and minor revisions to product labeling that conform to the pioneer product labeling. The supplemental ANADA is approved as of January 24, 2008, and 21 CFR 520.1195 is amended to reflect the approval.

In addition, the regulation is being amended to add the drug labeler code for another approved generic product (69 FR 24958, May 5, 2004), which was removed in error in the **Federal Register** of September 24, 2004 (69 FR 57173). This action is being taken to improve the accuracy of the regulations.

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)(1) that this action is of a type that does not individually or cumulatively have a significant effect on