

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DDM  
Display Date 2-20-08  
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Certifier R. Hawkins

Oral Dosage Form New Animal Drugs; Altrenogest

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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**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 [*insert date of publication in the Federal Register*].

**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:** 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: 2/11/08  
February 11, 2008.



Bernadette Dunham,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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gd 2/15/08

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