

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

New Animal Drugs; Altrenogest

TMB
Display Date 10-30-03
Publication Date 10-31-03
Certifier R LEDESMA

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 new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for use of an altrenogest oral solution in gilts for synchronization of estrus.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV 128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301 827-1600, *e-mail: candres@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed NADA 141-222 for the oral use of MATRIX (altrenogest) 0.22% Solution for synchronization of estrus in sexually mature gilts that have had at least one estrous cycle. The NADA is approved as of September 30, 2003, and the regulations are amended in 21 CFR 520.48 and in part 556 (21 CFR part 556) by adding § 556.36 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) 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 September 30, 2003.

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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 520 and 556 are 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. Section 520.48 is amended by revising paragraphs (c) and (d) to read as follows:

§ 520.48 Altrenogest solution.

* * * * *

(c) *Tolerances.* See § 556.36 of this chapter.

(d) Conditions of use ⁽¹⁾~~Horses~~—(i) *Amount.* 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use.* For suppression of estrus in mares.

(iii) *Limitations.* For oral use in horses only; avoid contact with the skin.

Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days by top-dressing on a portion of each gilt's daily feed.

(ii) *Indications for use.* For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

(iii) *Limitations.* Do not use in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis). Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

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10-28-03
per
D. Battie
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PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

- 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

- 4. Section 556.36 is added to read as follows:

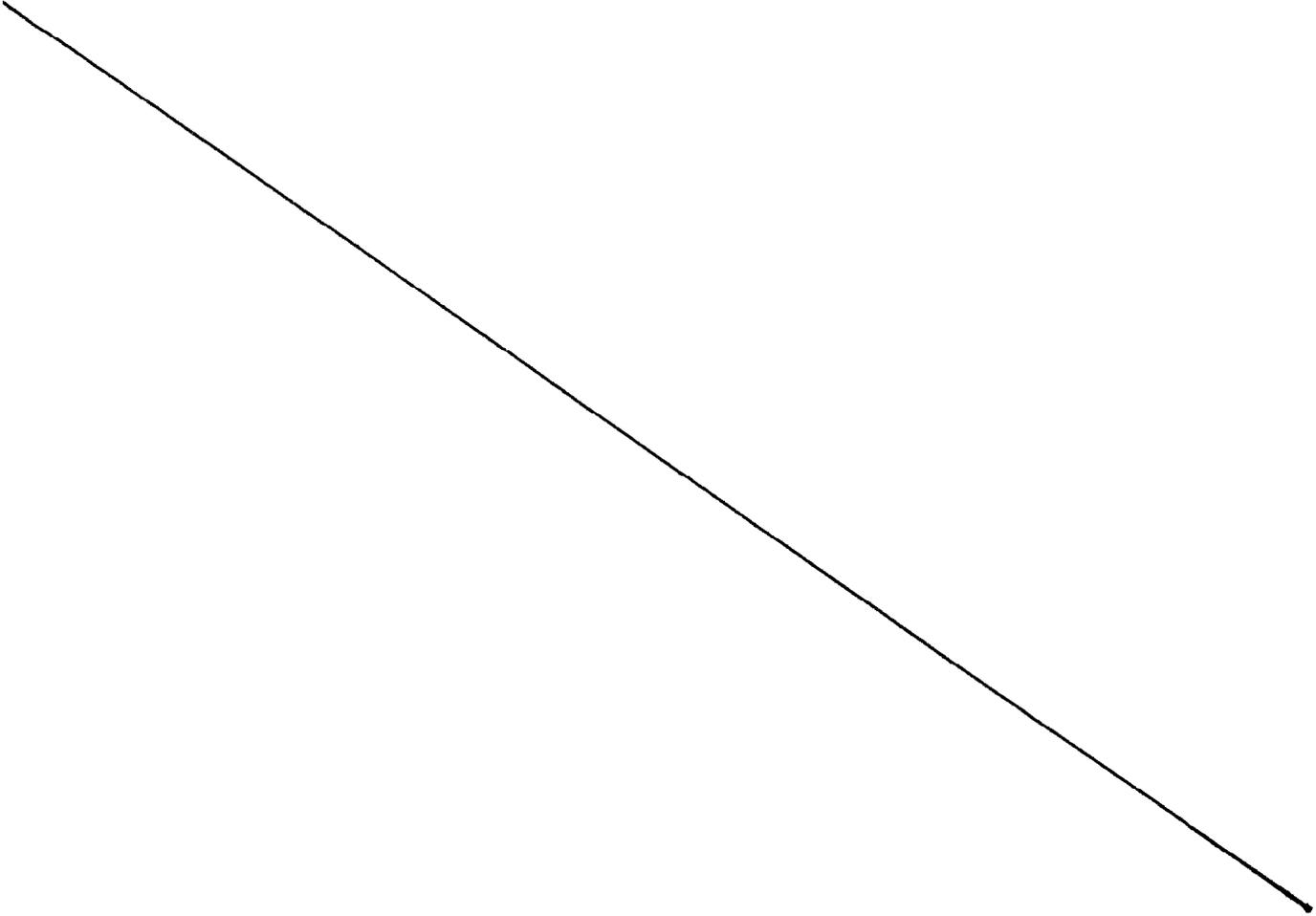
§ 556.36 Altrenogest.

(a) *Acceptable Daily Intake (ADI)*. The ADI for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*—(i) *Liver (the target tissue)*. The tolerance for altrenogest (the marker residue) is 4 parts per billion (ppb).

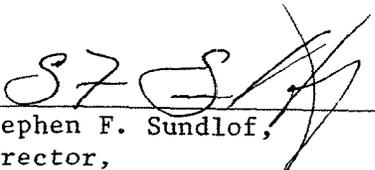
(ii) *Muscle*. The tolerance for altrenogest (the marker residue) is 1 ppb.

(2) [Reserved].



Dated: 10/10/03
October 10, 2003.

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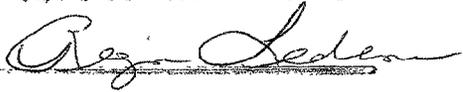


Stephen F. Sundlof,
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