

congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for “Monsanto Co.” by removing “059945” and by adding in its place “000911”; and in the table in paragraph (c)(2) by removing the entry for “059945” and by numerically adding an entry for “000911” to read “Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Section 522.2112 is amended in paragraph (b) by removing “059945” and by adding in its place “000911”; in paragraph (c)(1) by removing “beginning” and by adding in its place “starting”; and by revising paragraphs (c)(2) and (c)(3) to read as follows:

§ 522.2112 Sometribove zinc suspension.

* * * * *

(c) * * *

(2) *Indications for use.* To increase production of marketable milk in healthy lactating dairy cows.

(3) *Limitations.* Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass.

There is no milk discard or preslaughter withdrawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

Dated: October 10, 2003.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

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 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 October 31, 2003.

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