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.

[FR Doc. 03–27395 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

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

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.

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: October 10, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–27390 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003D–0221]

Medical Devices; Immunology and Microbiology Devices; Classification of the Endotoxin Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the endotoxin assay into class II (special controls). The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for the device.

DATES: This rule is effective December 1, 2003.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after issuing an order classifying the device, FDA will publish a notice in the **Federal Register** announcing the classification.

On April 14, 2003, FDA received a petition submitted under section 513(f)(2) of the act by the Devices and Diagnostics Consulting Group, Inc., seeking an evaluation of the automatic class III designation of its ''endotoxin activity assay.'' In accordance with section 513(f)(1) of the act, FDA issued an order classifying the device in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or II. After reviewing information submitted in the petition, FDA determined that the endotoxin activity assay could be classified in class II under the generic name, endotoxin assay, with the establishment of special controls. This device is intended to measure endotoxin activity as an aid in the risk assessment on the first day of the patient's admission to the intensive care unit (ICU). FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the risk to health associated specifically with this type of device as improper patient management. Therefore, in addition to the general controls of the act, the device is subject to a special controls guidance document entitled ''Class II Special Controls Guidance Document: Endotoxin Assay.'' FDA believes this special controls guidance document will reasonably assure the safety and effectiveness of this type of device.

The class II special controls guidance provides information on how to meet