

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.*

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**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