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

premarket notification submission (510(k)) requirements for the device, including recommendations for labeling and performance studies. FDA believes manufacturers of the device that adhere to the class II special controls guidance will address the potential risk to health identified in the previous paragraph.

Following the effective date of this final classification rule, any firm submitting a 510(k) for an endotoxin assay will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, the device is not exempt from the premarket notification requirements. The endotoxin assay is a device that uses serological techniques in whole blood. The device is intended for use in conjunction with other laboratory findings and clinical assessment of the patient to aid in the risk assessment of critically ill patients for progression to severe sepsis. FDA review of performance characteristics and labeling will ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a 510(k) containing information on the endotoxin assay before marketing the device.

On June 16, 2003, FDA issued an order classifying the endotoxin activity assay and substantially equivalent devices of this generic type into class II. FDA identifies this generic type of device as an endotoxin assay, which is intended for the use of serological techniques in whole blood. The device is intended for use in conjunction with other laboratory findings and clinical assessment of the patient to aid in the risk assessment of critically ill patients for progression to severe sepsis. The order also stated the endotoxin activity assay is intended for use only on the first day of admission to the ICU.

FDA is codifying the classification of this device by adding 21 CFR 866.3610. The order also identifies a special control applicable to this device, a guidance document entitled ''Class II Special Controls Guidance Document: Endotoxin Assay.'' 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.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer of this type of device. Classification of these devices in class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866–IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3610 is added to subpart D to read as follows:

866.3610 Endotoxin assay.

(a) *Identification.* An endotoxin assay is a device that uses serological techniques in whole blood. The device is intended for use in conjunction with other laboratory findings and clinical assessment of the patient to aid in the risk assessment of critically ill patients for progression to severe sepsis.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance entitled ''Class II Special Controls Guidance Document: Endotoxin Assay.'' See § 866.1(e) for the availability of this guidance document.

Dated: October 17, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27392 Filed 10–30–03; 8:45 am]

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