The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Veterinary Medicine Advisory Committee. This meeting was announced in the **Federal Register** of September 18, 2003 (68 FR 54734). The amendment is being made to reflect changes in the *Date and Time*, and the *Agenda*, portions of the document. Specifically, due to withdrawal of permission by a sponsor to discuss a specific fourth generation cephalosporin on November 3, 2003, the topic has been indefinitely postponed. Discussions on November 5, 2003, regarding genetic engineering research with food animals have also been postponed.

FOR FURTHER INFORMATION CONTACT: Aleta Sindelar, Center for Veterinary Medicine (CVM) (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4515, e-mail: *asindela@cvm.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 18, 2003, FDA announced that a meeting of the Veterinary Medicine Advisory Committee will be held on November 3, 4, and 5, 2003. On page 54734, in the second column, the *Date and Time* portion of the meeting is amended to read as follows:

Date and Time: The meeting will be held on November 4, 2003, from 9 a.m. to 5 p.m.

On page 54734, in the second column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On November 4, 2003, the committee will hear a preview of a draft risk assessment on animal cloning using somatic cell nuclear transfer. The risk assessment addresses both animal health and consumption of food derived from animal clones and their progeny. Background information that includes a draft executive summary of the risk assessment will be made available to committee members and the public in advance of the meeting and posted on CVM's home page at *http://www.fda.gov/cvm*. A limited number of paper copies of the background information will be available at the registration table. The complete draft risk assessment document will be made available for public comment at a later date.

Dated: October 28, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–27558 Filed 10–29–03; 1:11 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0221]

Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Endotoxin Assay; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Endotoxin Assay.'' This guidance document describes a means by which an endotoxin assay may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the endotoxin assay into class II (special controls). This guidance document is effective immediately as the special control for the endotoxin assay, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Class II Special Control Guidance Document: Endotoxin Assay'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the docket number found in brackets in the heading of this document.

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

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the endotoxin assay into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the endotoxin assay. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) 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) of the act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the act. 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 the issuance of an order classifying the device, FDA will publish a notice in the **Federal Register** announcing such classification.

Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under 21 CFR 10.115(g)(2), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on endotoxin assays. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Endotoxin Assay''

by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1222) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh.* A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control No. 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 17, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27393 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0476]

Guidance for Industry on Product Recalls, Including Removals and Corrections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry entitled ''Product Recalls, Including Removals and Corrections.'' This document provides members of industry regulated by FDA with guidance for handling all aspects of product recalls, including removals and corrections. The guidance applies to the recalls of all FDA-regulated products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of ''Product Recalls, Including Removals and Corrections'' to the Food and Drug Administration, Office of Enforcement, Division of Compliance Management and Operations (HFC–210), 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. For documents without a docket number, include the title of the guidance document. Send one self-addressed adhesive label to assist that office in processing your requests. You may fax your request to 301–827–0342. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Comments may be submitted at any time. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Willie R. Bryant, Jr., Senior Recall Officer, Division of Compliance Management and Operations (HFC–210), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–0391.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document that provides the agency's recommendations to members of FDA-regulated industry for the handling of product recalls. This document sets forth the agency's existing practices in recommending procedures for addressing all aspects of product recalls, including removals and corrections. The cooperation of manufacturers and distributors in expediting recall activities is vital. The recalling firm's notification of the local FDA District Recall Coordinator and submission of recall information outlined in the guidance allows FDA the opportunity to review, comment, offer assistance, and monitor the recall process.

II. Significance of Guidance

This is a level 2 guidance issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The agency is implementing this guidance document immediately in accordance with § 10.115(g)(4)(i)(B) and inviting public comment in accordance with § 10.115(g)(4)(i)(C). This guidance represents the agency's current thinking on product recalls, including removals and corrections. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining an electronic copy of the guidance may do so using the Internet. ORA maintains an entry on the Internet for easy access to information, including recent publications, consumer information references, compliance and inspection references, and recall information (model recall letters and press releases) that may be downloaded to a personal computer with Internet access. The ORA home page may be accessed at *http://www.fda.gov/ora/.* A search capability for all ORA guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available at *http://www.fda.gov/ohrms/dockets.*