agency has compiled these comments into a plan for further discussion by the committee.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 2, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 10, 2002, and between approximately 1 p.m. and 2 p.m. on July 11, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 2, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2000, through September 30, 2001:

Center for Biologics Evaluation and Research:
- Biological Response Modifiers Advisory Committee;
- Blood Products Advisory Committee;
- Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research:
- Anti-Infective Drugs Advisory Committee;
- Arthritis Advisory Committee;
- Cardiovascular and Renal Drugs Advisory Committee;
- Dermatologic and Ophthalmic Drugs Advisory Committee;
- Oncologic Drugs Advisory Committee.

Center for Devices and Radiological Health:
- Medical Devices Advisory Committee.

National Center for Toxicological Research:
- Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

- (2) The Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FURTHER INFORMATION CONTACT:
Linda Ann Sherman, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2000, through September 30, 2001:

Center for Biologics Evaluation and Research:
- Biological Response Modifiers Advisory Committee;
- Blood Products Advisory Committee;
- Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research:
- Anti-Infective Drugs Advisory Committee;
- Arthritis Advisory Committee;
- Cardiovascular and Renal Drugs Advisory Committee;
- Dermatologic and Ophthalmic Drugs Advisory Committee;
- Oncologic Drugs Advisory Committee.

Center for Devices and Radiological Health:
- Medical Devices Advisory Committee.

National Center for Toxicological Research:
- Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

- (2) The Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: June 14, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–15897 Filed 6–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees: Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings.

ADDRESSES: Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–6860. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0266]

Draft “Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated June 2002. The draft guidance document provides information that would assist manufacturers of human cellular and tissue-based products in minimizing the possible risk of transmission of CJD/ vCJD by HCT/Ps through deferral of donors with possible exposure to the agents of CJD and vCJD. Because there is no readily available demographic information about the HCT/P donor population, FDA encourages establishments to submit with their comments study data concerning the effect that implementation of these recommendations could have on the HCT/P supply.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 23, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the
I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated June 2002. The draft guidance document provides information that would help human cellular and tissue-based product manufacturers minimize the possible risk of transmission of CJD/vCJD by HCT/Ps through deferral of donors with possible exposure to the agents causing CJD and vCJD.

The draft guidance document represents the agency’s current thinking on this topic. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cannot ensure adequate consideration in preparation of the final document by December 23, 2002. Two copies of any written comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to http://www.fda.gov/dockets/ecomments.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.


Margaret M. Dotzel,
Associate Commissioner for Policy.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of May 21, 2002 (67 FR 35826). The document revokes the Compliance Policy Guide (CPG) entitled “Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13).”


SUPPLEMENTARY INFORMATION: In FR Doc. 02–12623, appearing on page 35826 in the Federal Register of Tuesday, May 21, 2002, the following correction is made:

1. On page 35827, in the first column, the DATES section is corrected to read “DATES: This revocation is effective June 20, 2002.”

Dated: June 18, 2002.

Deborah D. Ralston,
Acting Associate Commissioner for Regulatory Affairs.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two final guidances for industry (Nos. 113 and 114, respectively) entitled “Effectiveness of Anthelmintics: Specific Recommendations for Feline” (VICH GL20), and “Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus gallus” (VICH GL21). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

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

ADDRESSES: Submit written requests for single copies of the final guidances to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the final guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the SUPPLEMENTARY INFORMATION section for electronic access to the final guidance documents.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl.,