(1–888–472–6874). You will be asked to leave your name and address, and will be instructed to identify the Announcement number of interest (Announcement 01025).

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Edna Green, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01025, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone (404) 488–2743, E-mail address *ecg4@cdc.gov*.

For program technical assistance, contact: Sheila Isoke, Supervisory Public Health Advisor, Training and Technical Support Systems Branch, Division of HIV/AIDS Prevention—Intervention Research and Support, National Center for HIV, STD and TB Prevention, 1600 Clifton Road, NE., M/S E40, Atlanta, GA 30333, Telephone: (404) 639–0962, E-mail address: *shc1@cdc.gov*.

Dated: January 19, 2001.

Sandra R. Manning,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–2268 Filed 1–30–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Committee for Injury Prevention and Control, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the charter for the Advisory Committee for Injury Prevention and Control of the Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period, through October 31, 2002.

FOR FURTHER INFORMATION CONTACT: Thomas Blakeney, 1600 Clifton Road, NE, M/S K58, Atlanta, Georgia 30333, telephone 770/488–1481.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 25, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–2625 Filed 1–30–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Current Status of the Vessel Sanitation Program (VSP) and Experience to Date with Program Operations—Public meeting between CDC and the cruise ship industry, private sanitation consultants, and other interested parties.

Time and Date: 9 a.m.–4 p.m., March 13, 2001.

Place: Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316. Telephone (954) 356–6650; Fax (954) 356–6671.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

Purpose: During the past 15 years, as part of the revised VSP, CDC has conducted a series of public meetings with members of the cruise ship industry, private sanitation consultants, and other interested parties.

This meeting is a continuation of that series of public meetings to discuss current status of the VSP and experience to date with program operations.

Matters To Be Discussed: Agenda items will include a VSP Program Director Update; 2000 Program Review; Update on the implementation of the VSP Program Operations Manual 2000; Revision of the Final Recommended Shipbuilding Construction Guidelines for Cruise Vessels Destined to Call on U.S. Ports; Update on Disease Surveillance and Outbreak Investigations; and VSP Training Seminars.

For a period of 15 days following the meeting, through March 28, 2001, the official record of the meeting will remain open so that additional materials or comments may be submitted to be made part of the record of the meeting. Advanced registration is encouraged. Please provide the following information: Name, title, company name, mailing address, telephone number, facsimile number and E-mail address to Dorothy Johnson, facsimile (770)488–4127 or E-mail: DJJohnson@cdc.gov.

Contact Person for More Information: Dave Forney, Chief, VSP, NCEH, CDC, 4770 Buford Highway, NE, M/S F–16, Atlanta, Georgia 30341–3724, telephone (770)488–7333, E-mail: DForney@cdc.gov.

The Director, Management Analysis and Services office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 25, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–2627 Filed 1–30–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0037]

Draft ''Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion;'' 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: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion.'' The draft guidance document provides recommendations on manufacturing and quality assurance applicable to pre-storage leukocyte reduction of blood components intended for transfusion. This draft guidance document describes manufacturing procedures and controls that should be in place and would supersede the FDA memorandum issued on May 29, 1996, entitled ''Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products.''

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by May 1, 2001, to ensure their adequate consideration in preparation of the final guidance document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion'' 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, suite 200N, 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 **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion.'' The draft guidance document provides FDA recommendations regarding leukocyte reduction and provides information to assist licensed facilities in filing supplements to their biologics licenses to include leukocyte reduced products.

This draft guidance document describes the manufacturing procedures and controls applicable to pre-storage leukocyte reduced blood components for transfusion. Additionally, the agency would streamline the licensing procedure for leukocyte reduced products in order to assist blood establishments in making pre-storage leukocyte reduced products more widely available.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the leukocyte reduction of blood components intended for transfusion. 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 requirement of the applicable statute and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

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 (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by May 1, 2001, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/guidelines.htm.

Dated: January 22, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–2584 Filed 1–30–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0033]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling.'' The draft guidance discusses how to submit promotional materials in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This draft guidance is one of a series of guidances being developed by the agency to assist applicants who wish to make regulatory submissions in electronic format. Although submissions in electronic format are voluntary, the agency encourages them as a way to improve the efficiency of handling and reviewing documents and data.

DATES: Submit written comments on the draft guidance by April 2, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Written requests for copies of the draft guidance should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Fax: 1–888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Warren F. Rumble, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831, Rumblew@cder.fda.gov. or

Michael B. Fauntleroy, Center for Biologic Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5101, esubprep@cber.fda.gov

SUPPLEMENTARY INFORMATION:

Traditionally, regulations have required that submissions, such as investigational new drug application (IND's) and new drug applications (NDA's), be submitted as paper documents. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures regulation, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public Docket No. 92S–0251 to provide a list of