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 **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II.'' This guidance document gives recommendations to manufacturers of Whole Blood and blood components regarding screening tests for HTLV–II. Issues discussed in the guidance document include but are not limited to: (1) Implementation of screening for antibodies to HTLV–II; (2) handling of donations with repeatedly reactive enzyme immunoassay test results; (3) quarantine and disposition of units from prior collections from donors who subsequently test repeatedly reactive for anti-HTLV–I or anti-HTLV–II; (4) donor deferral; (5) donor notification and counseling and; (6) blood product labeling. The guidance document is intended to supplement previous information provided in letters to registered blood establishments dated November 29, 1988, and July 19, 1996, regarding HTLV–I and HTLV–II.

On August 15, 1997, FDA approved a test kit to detect antibodies to HTLV–I and HTLV–II in human blood. FDA made this guidance document available via the CBER Internet World Wide Web (WWW) site on August 15, 1997, as outlined in the agency's good guidance practices (see the **Federal Register** of February 27, 1997 (62 FR 8961)). This guidance document was released for immediate implementation so that blood establishments would have guidance at the time of licensure of the previous mentioned test kit. FDA believes that making this guidance document available as soon as possible after licensure of the test kit was necessary to help ensure the safety of the U.S. blood supply and therefore FDA did not circulate the document for comment before releasing it for use. However, FDA accepts comments on guidance documents at any time and will consider comments in future revisions of the document.

This guidance document represents the agency's current thinking with regard to donor screening for antibodies to HTLV–II. 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, regulations, or both. 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

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance 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 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.

III. Electronic Access

Persons with access to the Internet may obtain the document using the WWW. For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: September 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25907 Filed 9–28–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following national advisory body scheduled to meet during the month of October 1998.

Name: Advisory Committee on Infant Mortality

Date and Time: October 26, 1998, 9:00 a.m.–5:00 p.m. October 27, 1998, 8:30 a.m.–4:00 p.m.

Place: Holiday Inn at Georgetown 2101 Wisconsin Avenue, N.W. Washington, D.C., 20007, (202) 338–4600.

The meeting is open to the public.

Agenda: Topics that will be discussed include: Early Postpartum Discharge; Low-Birth Weight; Discrepancies in Infant Mortality; and the Healthy Start Program and Evaluation.

Anyone requiring information regarding the Committee should contact Dr. Peter C. van Dyck, Executive Secretary, Advisory Committee on Infant Mortality, Health Resources and Services Administration, Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2170.

Persons interested in attending any portion of the meeting or having questions regarding the meeting should contact Ms. Kerry P. Nesseler, Health Resources and Services Administration, Maternal and Child Health Bureau, Telephone (301) 443–2170.

Agenda items are subject to change as priorities dictate.

Dated: September 23, 1998.

Jane M. Harrison,

Director, Division of Policy, Review and Coordination.

[FR Doc. 98–25990 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following national advisory body scheduled to meet during the month of November 1998.

Name: Maternal and Child Health Research Grants Review Committee.

Date and Time: November 18–20, 1998; 8:00 a.m.–5:00 p.m.

Place: Parklawn Building, The Chesapeake Room, 5600 Fishers Lane, Rockville, Maryland 20857.