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]

BILLING CODE 4160–01–F

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.

The meeting is open to the public on Wednesday, November 18, from 9:00 a.m. to 10:00 a.m., and closed for the remainder of meeting.

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Systems, Education and Science, who will report on program issues, congressional activities, and other topics of interest to the field of maternal and child health. The meeting will be closed to the public on Wednesday, November 18, 1998 from 10:00 a.m., to the remainder of the meeting for the review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92–463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Gontran Lamberty, Dr. P.H., Executive Secretary, Maternal and Child Health Grants Review Committee, Room 18A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, or by telephone at (301) 443–2190.

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. 98–25991 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part M of the Substance Abuse and Mental Health Services Administration (SAMHSA) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (61 FR 39146–39151, July 26, 1996 as amended most recently at 63 FR 1112–1113, January 8, 1998) is amended to: (1) realign the equal employment opportunity function by establishing formally the Office of Equal Employment Opportunity and Civil Rights within the Office of the Administrator; and (2) revise the functional statement of the Office of Applied Studies (OAS) and establish a substructure organization within OAS.

Section M–20, Functions, is amended as follows:

Under the heading, *Immediate Office of the Administrator* (MA–1) delete item (2), ''carries out SAMHSA-wide functions relating to equal employment opportunity'' and renumber the items following this item as (2), (3), (4) and (5) respectively.

Under the heading, *Office of the Administrator (MA),* insert the following title and functional statement after the functional statement for the *Office of Minority Health (MAE):*

Office of Equal Employment Opportunity and Civil Rights (MAF)

(1) Processes both informal and formal complaints of employment discrimination under three primary statutes as amended: Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16); Section 15 of the Age Discrimination in Employment Act of 1967 (29 U.S.C. 633a); and Sections 501 and 505 of the Rehabilitation Act of 1973 (29 U.S.C. 791, 794a); (2) plans and administers a coordinated Agency special emphasis/affirmative employment program focusing on minorities, women, and persons with disabilities; (3) develops, implements, and monitors affirmative employment plans for minorities and women and for persons with disabilities required by the Equal Employment Opportunity Commission; (4) manages the agency disability reasonable accommodations process; (5) provides guidance and logistical support for an employee EEO advisory council reporting to the Administrator; (6) promotes the awarding of contracts under Section 8(a) of the Small Business Act (15 U.S.C. 637(a)) and Executive Orders 12432 and 12138 to disadvantaged businesses and women-owned small businesses; advocate for civil rights and related principles; (7) develops internal civil rights compliance policy for the Agency and serves as the internal advocate for civil rights and related principles; and (8) assesses the Agency's compliance with applicable civil rights statutes, executive orders, regulations, policies and programs.

Under the heading, *Office of Applied Studies (MC),* delete the functional statement and substitute the following functional statement:

(1) Collects information on the incidence, prevalence, trends, correlates, and consequences of substance abuse and mental health problems in the United States; (2) collects information on the number, characteristics, conduct, and performance of facilities and organizations providing prevention and treatment services for substance abuse at the national and local level; (3) plans, directs, and conducts studies based on data collected by the Office of Applied Studies and other organizations of issues associated with substance abuse and mental health problems; (4) designs and carries out special data collection and analytic projects to examine topical issues for SAMHSA and other Federal agencies; (5) conducts epidemiologic, statistical, and policy studies of existing or emerging issues; (6) coordinates planning for program evaluation activities of the Agency; (7) manages Agency activities associated with the Paperwork Reduction Act and Office of Management and Budget clearance of information collection activities; (8) prepares reports and disseminates findings through Agency publications, the press, scientific journals, and electronic systems.

After the functional Office for the *Office of Applied Studies (MC),* add the following titles and functional statements:

Office of the Director (MC–1)

(1) Provides overall leadership to the Office of Applied Studies; (2) determines that data collection and analytic activities are consistent with the mission and priorities of the Department and the Agency; (3) advises the Administrator and other Agency officials and staff on policy and technical issues associated with collecting information on substance abuse and mental health problems; (4) serves as Agency liaison to the Office of the Secretary, the Office of National Drug Control Policy, the Drug Enforcement Administration, and other Federal agencies; to State and Local Government agencies; and to non-governmental organizations and institutions on matters related to the collection and analysis of data on substance abuse and mental health problems.

Division of Population Surveys (MCA)

(1) Plans, develops, and manages the National Household Survey on Drug Abuse (NHSDA) and other surveys of the population to obtain information on substance abuse and mental health problems; (2) develops, implements, and evaluates new statistical and data collection methods, questionnaires, and sampling strategies for surveys; (3) analyzes information obtained from surveys conducted by the Office of Applied Studies to determine the incidence, prevalence, correlates, and consequences of substance abuse; (4) analyzes data from the NHSDA and related sources of information to examine program and policy issues and evaluate the impact of various Federal initiatives related to substance abuse; (5) prepares statistical publications, special reports, and analyses based on information derived from the NHSDA