Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 21, 1998, the committee will participate in a general scientific discussion of clinical trial design questions for products intended for the treatment of psoriasis. On the morning of October 22, 1998, the committee will participate in a scientific discussion of clinical trial design issues for systemic immunomodulatory biological products intended for the treatment of psoriasis. On the afternoon of October 22, 1998, the committee will participate in a scientific discussion of clinical trial design questions for products intended for the treatment of tinea capitis.

Procedure: On October 21, 1998, from 8 a.m. to 5 p.m., and on October 22, 1998, from 9:30 a.m. to 11:30 a.m. and from 12 m. to 5 p.m., the meeting will be open to the public. 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 October 13, 1998. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. on October 21, 1998, and between approximately 9:30 a.m. and 10 a.m. and between approximately 1 p.m. and 1:30 p.m. on October 22, 1998. Time allotted for each presentation may be limited. Those desiring to make oral presentations should notify the contact person before October 13, 1998, 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.

Closed Committee Deliberations: On October 22, 1998, from 8 a.m. to 9:30 a.m., and from 11:30 a.m. to 12 m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding pending investigational new drug applications issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–25906 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Good Manufacturing Practices for Dietary Supplements Working Group of the Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Good Manufacturing Practices for Dietary Supplements Working Group of the Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 16, 1998, 9 a.m. to 4 p.m.

Location: Ramada Plaza O'Hare, 6600 North Mannheim Rd., Rosemont, IL.

Contact Person: Karen F. Strauss, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5123, FAX 202–205–5295, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Working Group will meet to discuss and further develop a draft report on good manufacturing practices identity testing and recordkeeping. The draft report will be presented to the food advisory committee at a later date for public discussion and consideration as the committee's recommendations to FDA.

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 October 8, 1998. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 8, 1998, 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.

This meeting is open to the public, but space is limited. For the convenience of the public, a block of 20-sleeping rooms has been set aside at a special rate on a first-come first-served basis. Members of the public who wish to reserve one of these rooms should call the hotel at 847–827–5131 and make reservations before October 8, 1998. The block is reserved as general public of the U.S. FDA.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–25912 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0746]

Guidance for Industry: Donor Screening for Antibodies to HTLV–II; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II.'' The guidance document provides information regarding human T-lymphotrophic virus type II (HTLV–II) screening tests for Whole Blood and blood components. This guidance document is a further effort of FDA to help ensure a safe blood supply for the United States of America (U.S.).

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II'' 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 **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.