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