these petitions had been received and providing an opportunity for interested persons to submit comments on the petitions by August 20, 1998. FDA received no comments. FDA has reviewed these petitions and, for the following reasons, has determined that these devices do not meet the criteria for exemption described previously and is, therefore, issuing this order denying the petitions to exempt these devices from the requirements of premarket notification.

1. *Gastrointestinal motility monitoring system*. Gastrointestinal motility monitoring systems could include a wide variety of devices to measure and assess the functioning of the gastrointestinal tract. The gastrointestinal monitoring systems including such components as electronic instruments, recorders, displays, and software are viewed as integral components of the system and must be evaluated together with the monitoring probes or catheters. FDA believes that review of all components of the system is necessary to provide adequate labeling and to ensure the safety and effectiveness of these products in comparison to legally marketed devices of this type.

The submission has not provided sufficient information that demonstrates that the characteristics and labeling, which are necessary to determine acceptable device performance, are well established. Further, it is neither apparent, nor has it been established, that changes in the device that could affect safety and effectiveness, and lead to device errors, would either: (a) Be readily detectable by users by visual examination or other means, such as routine testing, before causing harm; or (b) not materially increase the risk of incorrect output potentially leading to incorrect diagnosis.

2. *Ophthalmoscope*. The petition, as presented, does not meet the criteria for exemption, because changes in the device that could affect safety and effectiveness would not be readily detectable by users by visual examination or routine testing. Specifically, hazards causing retinal phototoxicity have long been recognized to be associated with the retinal exposure of the light (including, especially, invisible infrared and ultraviolet wavelengths). In addition, FDA requires testing to determine the amount of light emitted and has established maximum exposure levels to mitigate this risk. The potential sight-threatening hazard from retinal phototoxicity due to exposure to the light from the ophthalmoscope cannot be determined without appropriate measurements of the exposure level. The need for special controls has been recognized nationally (American National Standards Institute) and internationally (International Standards Organization). In the near future, FDA intends to propose special controls for the ophthalmoscope and, at the same time, intends to propose to exempt them from the premarket notification requirements. Until the establishment of such controls, however, the characteristics of the device necessary for its safe and effective performance are not well established and changes in the use of the device may result in materially increasing the risk of injury. Accordingly, the device will not presently be exempt from premarket review.

3. *Radiation Oncologist Data Entry Workstation*. Radiation therapy and radiation therapy dose calculation is an exacting procedure. The goal is to maintain the actual dose to within 5 percent of that prescribed. The data entry workstation provides data input to the radiation treatment planning system (RTP) on patient contours and tumor volumes and boundaries. It, therefore, is providing measurement information to the computer that is specific to a particular patient and fundamental to the accuracy of any subsequent treatment planning. As such, the workstation must be regarded as an integral component of the RTP system.

Radiation therapy systems and RTP systems are high-risk devices. Providing an incorrect treatment dose that is too low can result in tumor regrowth. Providing an incorrect treatment dose that is too high can lead to unacceptable complications. Malfunctions of these device types have resulted in patient deaths.

The submission has not provided sufficient information to establish that the characteristics of the device necessary for its safe and effective performance are well established. Further, since that workstation operates by direct connection to the RTP system, it is neither apparent, nor has it been established, that changes in the device that could affect safety and effectiveness or device errors would either: (a) Be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

4. *Cytomegalovirus serological reagents*. Cytomegalovirus infection is the most common identified cause of congenital infection. It has been reported that fewer than 5 percent of these infants develop symptoms during the newborn period. Cytomegalovirus infections are frequent and occasionally severe in children and adults with congenital and acquired cellular immunity defects, such as those with acquired immunodeficiency syndrome (AIDS), in cancer patients (especially those with leukemia), and in those who have received organ transplants. FDA believes that errors caused by these devices could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

5. *Varicella-zoster virus serological reagents*. Varicella-zoster infection may cause severe or fatal disease in individuals who are receiving immunosuppressive therapy or who have an immune response defect. A specific diagnosis of this infection in immunosuppressed individuals may guide the clinician in appropriate therapy. This device would also be useful to evaluate the effect of vaccine in patients. FDA believes that errors caused by these devices could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

Dated: September 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–25916 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs 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 21 and 22, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tracy K. Riley or Angie Whitacre, Center for Drug

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