*Contact Person:* Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will participate in a general scientific discussion of allogeneic transplantation with a focus on haplo-identical transplantation and other high risk transplantations.

*Procedure:* On November 13, 1998, from 8:30 a.m. to 5 p.m., the meeting is 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 November 6, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 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 November 13, 1998, from 8 a.m. to 8:30 a.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)). This portion of the meeting will be closed to discuss issues related to past and pending biologics license applications and investigational new drug applications.

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

Dated: October 22, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–28906 Filed 10–28–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Oncologic 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*: Oncologic 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 November 16, 1998, 8:30 a.m. to 5:30 p.m., and on November 17, 1998, 8 a.m. to 5 p.m.

*Location*: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Contact Person*: Karen M. Templeton-Somers, 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 12542. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On November 16, 1998, the committee will discuss: (1) New drug application (NDA) 20–886 Panretin® (alitretinoin) Gel 0.1 percent, Ligand Pharmaceuticals Inc., indicated for the first-line topical treatment of cutaneous lesions in patients with acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma; and (2) NDA 21–041 DepoCyt™ (cytarabine liposome injection), DepoTech Corp. indicated for the intrathecal treatment of lymphomatous meningitis. On November 17, 1998, the committee will discuss the labeling of NDA 17–970/S–040 Nolvadex® (tamoxifen citrate), Zeneca Pharmaceuticals, and whether the indication should be ''for reducing the short term incidence of breast cancer'' in women at high risk of developing the disease or ''as a preventative agent for the reduction of breast cancer in women at high risk for developing the disease. The term prevention indicates a reduction in the incidence (risk) of invasive breast cancer over the period of the NSABP P–1 trial, and does not necessarily imply that the initiation of breast cancer has been prevented or that the tumors have been permanently eliminated * * *.''

*Procedure*: On November 16, 1998, from 8:30 a.m. to 5:30 p.m., and on November 17, 1998, from 8 a.m. to 1:30 p.m., the meeting is 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 November 9, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9 a.m., and between approximately 1:45 p.m. and 2 p.m. on November 16, 1998, and between approximately 8:15 a.m. and 8:45 a.m. on November 17, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 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. After the scientific presentations, a 30-minute open public session will be conducted for interested persons who have submitted their request to speak by November 9, 1998, to address issues specific to the submission or topic before the committee.

*Closed Committee Deliberations*: On November 17, 1998, from 1:30 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss personal conflict of interest issues.

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

Dated: October 22, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–28905 Filed 10–28–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Product and Clinical Development of Tumor Vaccines; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Product and Clinical Development of Tumor Vaccines. This workshop, which is cosponsored by FDA and the National Institutes of Health, will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

*Date and Time*: The public workshop will be held on Thursday, December 10,

7:30 a.m. to 5 p.m., and Friday, December 11, 1998, 8 a.m. to 5:30 p.m.

*Location*: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact*: Abdur Razzaque, Center for Biologics Evaluation and Research (HFM–530), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0675.

*Registration and Requests for Oral Presentations*: Send registration information (including name, title, firm name, address, telephone, and fax number) to Karen Blackburn, Tascon, Inc., 1803 Research Blvd., suite 305, Rockville, MD 20850, 301–315–9000, ext. 514, FAX 301–738–9786, or e-mail kblackburn@tascon.com.

On December 10, 1998, beginning at 7:30 a.m., registration will be held at the public workshop location on a space available basis. However, because space is limited, interested parties are encouraged to register early. There is no registration fee for the public workshop.

If you need special accommodations due to a disability, please contact Karen Blackburn at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The goals of the workshop include discussing the following: (1) Regulatory considerations in the clinical development process for tumor vaccines; (2) morphological, immunophenotypic,and functional characteristics of dendritic cells; (3) current methods for physicochemical and functional characterization of autologous and allogeneic whole cell tumor vaccines, tumor cell lysates, polyvalent tumor antigen preparations, antigen presenting cells and other cell-derived vaccines; (4) novel preclinical strategies and biological/immunological assessments in early clinical trials; and (5) issues regarding the detection and monitoring of tumor cell contamination in cellular vaccines. The information obtained from these discussions will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

*Transcripts*: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: October 21, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–28908 Filed 10–28–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Vaccines and Related Biological Products 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*: Vaccines and Related Biological Products 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 November 19, 1998, 8 a.m. to 6:30 p.m., and on November 20, 1998, 8 a.m. to 3:30 p.m.

*Location*: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Persons*: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On November 19, 1998, the committee will discuss issues relating to the use of cell substrates. On November 20, 1998, the committee will discuss issues relating to the manufacture and safety of live attenuated influenza virus vaccines.

*Procedure*: On November 19, 1998, from 8 a.m. to 1:30 p.m., and on November 20, 1998, from 8 a.m. to 3:30 p.m., the meeting is 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 persons by November 12, 1998. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m. on November 19, 1998, and between approximately 8:15 a.m. and 8:30 a.m., and between approximately 10:20 a.m. and 10:50 a.m. on November 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 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 November 19, 1998, from 1:30 p.m. to 6:30 p.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)). These portions of the meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications.

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

Dated: October 22, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–28904 Filed 10–28–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0451]**

### Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guide entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (the guide). The guide is designed to provide voluntary guidance on good agricultural practices and good management practices and to minimize microbial food safety hazards common to the growing, harvesting, packing, and transport of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (i.e., raw) form. This action is in response to the Presidential initiative to ensure the safety of imported and domestic fresh