741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On November 3, 2005, in the morning, the committee will hear updates on the following topics: (1) West Nile Virus; (2) draft guidance on nucleic acid testing (NAT) for human immunodeficiency virus (HIV)–1 and hepatitis C virus (HCV): Testing, product disposition, and donor deferral and re-entry; (3) summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability held on September 19 and 20, 2005; and (4) re-entry of donors deferred based on hepatitis B core antigen (anti-HBc) test results. The committee will discuss approaches to over-the-counter (OTC) home-use HIV test kits the rest of the day. On November 4, 2005, in the morning, the committee will hear information on serious adverse events resulting from interference with measurement of blood glucose following infusion of maltose-containing immune globulin intravenous (human) and will discuss Alpha-1-Proteinase Inhibitor products. In the afternoon, the committee will hear an overview of the research programs of the Office of Blood Research and Review, Center for Biologics Evaluation and Research, as presented to a subcommittee of the Blood Products Advisory Committee during their site visit on July 22, 2005, and discuss a subcommittee report.

*Procedure*: On November 3, 2005, the entire meeting is open to the public. On November 4, 2005, from 8 a.m. to 2:15 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 October 25, 2005. Oral presentations from the public will be scheduled on November 3, 2005, between approximately 2 p.m. and 3:45 p.m. and on November 4, 2005, between 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2005, 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 4, 2005, from 2:15 p.m. to 3 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)), and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss a subcommittee's report of the internal research programs in the Office of Blood Research and Review, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

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

Dated: October 6, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. 05–20560 Filed 10–13–05; 8:45 am]

**BILLING CODE 4160–01–S**

## 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). The meeting is open 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 November 8, 2005, from 8 a.m. to 5 p.m.

*Location*: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person*: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Oncologic Drugs Advisory Committee (ODAC).'' (Click on the year 2005 and scroll down to ODAC meetings.)

*Agenda*: The committee will discuss new drug applications approved under 21 CFR 314.500 and 601.40 (subparts H and subpart E, respectively, accelerated approval regulations) in an open session to do the following: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. The committee will discuss phase IV commitments of: (1) new drug application (NDA) 50–718, DOXIL (doxorubicin hydrochloride liposome injection, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of acquired immune deficiency syndrome (AIDS) related Kaposi's sarcoma in patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) NDA 20–221/S–002, ETHYOL for injection (amifostine, MedImmune Oncology, Inc.) for reducing the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced nonsmall cell lung cancer; (3) biologics license application (BLA) 103767/0, ONTAK (denileukin diftitox, Seragen Incorporated) for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the interleukin-2 receptor; (4) NDA 21–041, DEPOCYT (cytarabine liposome injection, SkyePharma Inc.) for the intrathecal treatment of lymphomatous meningitis; and (5) NDA 21–156, CELEBREX (celecoxib capsules, Pfizer, Inc.) for reducing the number of adenomatous colorectal polyps in familial adenomatous polyposis, as an adjunct to usual care (e.g., endoscopic surveillance, surgery); (6) NDA 21–174, MYLOTARG (gemtuzumab ozogamicin for injection, Wyeth Pharmaceuticals, Inc.) for the treatment of patients with CD33 positive acute myeloid leukemia

in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy; and (7) BLA 103948/0, CAMPATH (alemtuzumab, ILEX Pharmaceuticals, L.P.) for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy.

*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 November 1, 2005. Oral presentations from the public will be scheduled between approximately 2 p.m. to 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Johanna Clifford at least 7 days in advance of the meeting.

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

Dated: October 6, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. 05–20559 Filed 10–13–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Transmissible Spongiform Encephalopathies 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*: Transmissible Spongiform Encephalopathies 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 31, 2005, from 8 a.m. to 5:30 p.m.

*Location*: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person*: William Freas or Sheila D. Langford, 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 3014512392. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On October 31, 2005, the committee will hear updates on the following topics: Current status of bovine spongiform encephalopathy (BSE) in the United States, incidence and prevalence worldwide of variant Creutzfeldt-Jakob Disease (vCJD), and a summary of FDA's device panel discussion on September 27, 2005, on criteria for considering label claims of effective decontamination for surgical instruments exposed to transmissible spongiform encephalopathy (TSE) agents. The committee will then discuss progress in development of a risk assessment model for vCJD in U.S.-licensed human plasma-derived Antihemophilic Factor (Factor VIII). The latter discussion will focus on selection of input parameters for the model. In the afternoon, the committee will discuss labeling claims for TSE clearance studies for blood component filters.

*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 21, 2005. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m., and 4:15 p.m. and 4:45 p.m. on October 31, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila Langford at least 7 days in advance of the meeting.

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

Dated: October 6, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. 05–20558 Filed 10–13–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[USCG–2005–22613]**

### National Maritime Security Advisory Committee

**AGENCY:** U.S. Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Maritime Security Advisory Committee (NMSAC) will hold a meeting to discuss various issues relating to national maritime security. This notice announces the date, time, and location for the meeting of the NMSAC.

**DATES:** NMSAC will meet on Tuesday, November 1, 2005, from 8:30 a.m. to 3:30 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before October 21, 2005. Any material requested to be distributed to each member of the Committee should reach the Coast Guard on or before October 24, 2005.

**ADDRESSES:** NMSAC will meet in Room 329 at the George Mason University School of Law, 3401 North Fairfax Drive, Arlington, VA 22201. Send written material and requests to make oral presentations to Mr. John Bastek, Commandant (G–MPS–2), U.S. Coast Guard Headquarters, 2100 Second St. SW., Washington, DC 20593–0001. This notice is available on the Internet at *http://dms.dot.gov*.

**FOR FURTHER INFORMATION CONTACT:** Mr. John Bastek, Executive Secretary,