Aspects of West Nile Virus in the United States, PA #04052.

Times and Dates: 8:30 a.m.–9 a.m., August 2, 2004 (Open). 9:15 a.m.–6 p.m., August 2, 2004 (Closed). 8:30 a.m.–9 a.m., August 3, 2004 (Open). 9:15 a.m.–6 p.m., August 3, 2004 (Closed).

Place: Renaissance Concourse Hotel, One Hartsfield Centre Parkway, Atlanta, GA 30354, Telephone (404) 209–9999.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Research into the Public Health Aspects of West Nile Virus in the United States, PA #04052.

For Further Information Contact: Trudy Messmer, Ph.D., Scientific Review Administrator, Centers for Disease Control, National Center for Infectious Diseases, 1600 Clifton Road NE., Mailstop C19, Atlanta, GA 30333, Telephone (404) 639–2176.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 1, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15800 Filed 7–12–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Initial Discussions for Concepts of Total Inward Leakage (TIL) Requirements and Test Methods for Halfmask Respirators Including Elastomeric and Filtering Facepiece Styles.

Date and Time: 9 a.m.–5 p.m., August 25, 2004.

Place: Marriott Key Bridge Hotel located at 1401 Lee Highway, Arlington, Virginia.

Status: This meeting is hosted by NIOSH and will be open to the public, limited only by the space available. The meeting room will accommodate approximately 50 people. Sleeping Rooms are reserved under a NIOSH/National Personal Protective Technology Laboratory (NPPTL) Public Meeting room block for the evening of Tuesday, August 24, 2004, at the government rate of $150 per night. The NIOSH/NPPTL public meeting must be referenced to receive this special rate. Interested parties should make hotel reservations directly with the Marriott at 1–800–228–9290 or 703/524–6400 before the cut-off date of August 4, 2004. Interested parties should confirm their attendance to this meeting by completing a registration form and forwarding it by e-mail (*npptlevents@cdc.gov*) or fax (304–285–4459) to the NPPTL Event Management Office. A registration form may be obtained from the NIOSH Homepage (*www.cdc.gov/niosh*) by selecting conferences and then the event.

An opportunity to make presentations regarding the discussions of concepts for standards and testing processes for TIL requirements and test methods suitable for halfmask respirators will be given. Requests to make such presentations at the public meeting should be made by e-mail or the NPPTL Event Management Office (*npptlevents@cdc.gov*). All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes.

After reviewing the requests for presentations, NPPTL Event Management will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meeting should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513–533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov*. E-mail attachments should be formatted in Microsoft Word. Comments should be submitted to Niosh no later than September 25, 2004, and should reference Docket Number NIOSH\036 in the subject heading.

Purpose: NIOSH will initiate discussions of conceptual standards and testing processes for TIL requirements and test methods suitable for halfmask respirators. NIOSH also wishes to obtain comments from individuals regarding the tentative schedules and priorities for future TIL respirator and other personal protective equipment standards development efforts. NIOSH will present information to attendees concerning the concept development for the overall TIL program and the initial concept for TIL testing for halfmask respirator testing and certification requirements. Participants will be given an opportunity to ask questions on these topics and to present individual comments for consideration. Interested participants may obtain a copy of the TIL concept paper from the NIOSH NPPTL web site, address: *www.cdc.gov/niosh/npptl*. The April 20, 2004, concept paper will be used as the basis for discussion at the public meeting. NIOSH wishes to obtain comments from individuals regarding the priorities for future standards efforts following the completion of the halfmask TIL standard.

For Further Information Contact: NPPTL Event Management, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, West Virginia 26507–0880, Telephone 304–285–4750, Fax 304–285–4459, E-mail *npptlevents@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15799 Filed 7–12–04; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0247]

Determination of Regulatory Review Period for Purposes of Patent Extension; CAMPATH

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CAMPATH and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product CAMPATH (alemtuzumab). CAMPATH is indicated 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. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CAMPATH (U.S. Patent No. 5,545,403) from Millenium and Ilex Partners, L.P., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of CAMPATH represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CAMPATH is 3,423 days. Of this time, 2,921 days occurred during the testing phase of the regulatory review period, while 502 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: December 25, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 25, 1991.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 23, 1999. The applicant claims December 22, 1999, as the date the product license application (BLA) for CAMPATH (BLA 103948/0) was initially submitted. However, FDA records indicate that BLA 103948/0 was submitted on December 23, 1999.

3. The date the application was approved: May 7, 2001. FDA has verified the applicant's claim that BLA 103948/0 was approved on May 7, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 632 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 13, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 10, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management (see **ADDRESSES**). Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–15802 Filed 7–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0279]

Developing Drug Information Association/Food and Drug Administration Workshop: Pharmacogenomic Combination Product Co-Development; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Drug Information Association (DIA), is announcing a public meeting to solicit views and to provide an interactive forum for discussion of industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. The input received at the meeting, comments received during the meeting, and comments made to the docket after the meeting, may be considered in developing a draft guidance on this topic.

DATES: The public meeting will be held on July 29, 2004, from 8 a.m. to 5:30 p.m. Attendees must register to attend. Submit written or electronic requests to speak at the public meeting by July 26, 2004. Submit written or electronic comments before or after the meeting by August 30, 2004.

ADDRESSES: The public meeting will be held at the Marriott Crystal Gateway Hotel, 1700 Jefferson Davis Hwy., Arlington, VA. A copy of the meeting's program is available on the Internet at *http://www.diahome.org/Content/Events/04040.pdf.*

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: