system. This approach has successfully led to several FDA approved and marketed mAbs. Typically, cancer cells are less susceptible to acquiring resistance to antibodies; however, as seen for trastuzumab, resistance can occur. Another limitation of mAbs is that they activate only part of the immune system and do not produce future immunity against the cancer. Currently, monoclonal antibodies are the only immunotherapy available for treating cancer. More recently, cancer vaccines are being developed as an improvement on the immunotherapy approach. It is expected that activating the cells of the immune system should be greatly more effective in killing cancer cells with the added benefit that it would lead to a sustained surveillance by the patient's own body that prevents the tumor from reemerging in the future.

Vaccines have been very successful in the prevention of infectious diseases, and are now being evaluated for the treatment of cancer. The development of a cancer vaccine could result in a paradigm shift in the treatment and clinical management of cancer. Currently, there are no cancer vaccines approved for the U.S. market but this could change with the development of the TRICOM-based technology of costimulatory vaccines that is designed to magnify the immune response against cancer cells and lead to prolonged cancer immunity.

PANVAC, using TRICOM, has much potential for becoming a therapeutically effective cancer vaccine. It has been successful in Phase I and II clinical studies demonstrating a high safety profile and that it is a good candidate for initiating pivotal efficacy studies. Recently, very encouraging results were announced for prostate cancer therapy using PROSTVAC™ which is a vaccine based on the same technology platform as PANVAC, which further validates this technology platform. PANVAC is a decidedly mature technology that holds promise to transform the treatment of cancer.

Patent Estate

The portfolio includes the following issued patents and pending patent applications:

1. U.S. Patent No. 6,969,609 issued 29 Nov. 2005 as well as issued and pending foreign counterparts [HHS Ref. No. E–256–1998/0];
2. U.S. Patent Application No. 11/321,868 filed 30 Dec. 2005 [HHS Ref. No. E–256–1998/1]; and
3. U.S. Patent No. 6,756,038 issued 29 Jun. 2004 as well as issued and pending foreign counterparts [HHS Ref. No. E–099–1996/0];
4. U.S. Patent No. 6,001,349 issued 14 Dec. 1999 as well as issued and pending foreign counterparts [HHS Ref. No. E–200–1990/3–US–01];
5. U.S. Patent No. 6,165,460 issued 26 Dec. 2000 as well as issued and pending foreign counterparts [HHS Ref. No. E–200–1990/4–US–01];
6. U.S. Patent No. 7,118,738 issued 10 Oct. 2006 as well as issued and pending foreign counterparts [HHS Ref. No. E–154–1998/0–US–07];
7. PCT Application No. PCT/US97/12203 filed 15 Jul. 1997 [HHS Ref. No. E–259–1994/3–PCT–02];
8. U.S. Patent Nos. 7,410,644 issued 12 Aug. 2008 and U.S. Patent Application No. 08/686,280 filed 25 Jul. 1996 [HHS Ref. No. E–259–1994/3–US–08 and/4–US–01];
9. U.S. Patent No. 6,946,133 issued 20 Sep. 2005 as well as issued and pending foreign counterparts [HHS Ref. No. E–062–1996/0–US–01];
10. U.S. Patent Application No. 11/606,929 filed 1 Dec. 2006 [HHS Ref. No. E–062–1996/0–US–11];
11. U.S. Patent Nos. 6,893,869, 6,548,068 and 6,045,802 issued 17 May 2005, 15 Apr. 2003 and 4 Apr. 2000 respectively, as well as issued and pending foreign counterparts [HHS Ref. Nos. E–260–1994/1–US–03, US–02, US–01]; and
12. U.S. Patent No. 7,368,116 issued 6 May 2008 [HHS Ref. No. E–260–1994/1–US–04];
13. U.S. Patent Application No. 12/280,534 filed 21 Feb. 2007, which published as US–2009–0035266 on 5 Feb. 2009, as well as pending foreign counterparts [HHS Ref. No. E–104–2006/0–US–06];
14. PCT Application No. PCT/US2008/055185 filed 27 Feb. 2008, which published as WO 2008/106551 on 4 Sep. 2008 [HHS Ref. No. E–074–2007/0–PCT–02].

Note that some of the patent estate above is available for non-exclusive licensing only.

Cooperative Research and Development Agreement (CRADA) Opportunities

A CRADA partner for the further codevelopment of this technology in all cancers with the exception of prostate, melanoma and colorectal cancer is currently being sought by the Laboratory of Tumor Immunology and Biology, Center for Cancer Research, NCI. The CRADA partner will (a) generate recombinant poxviruses expressing specific tumor-associated antigens, cytokines, and/or T-cell costimulatory factors, (b) cooperate to analyze the recombinant poxviruses containing these genes with respect to appropriate expression of the encoded gene product(s), (c) supply adequate amounts of recombinant virus stocks for preclinical testing, (d) manufacture selected recombinant vaccines for use in human clinical trials (with the exception of trials for prostatic diseases, melanoma, and colorectal cancer), (e) submit Drug Master Files detailing the development, manufacture, and testing of live recombinant vaccines to support the NCI-sponsored IND and/or company-sponsored IND, (f) supply adequate amounts of clinical grade recombinant poxvirus vaccines for clinical trials conducted at the NCI Center for Cancer Research (CCR), and (g) provide adequate amounts of vaccines for extramural clinical trials, if agreed upon by the parties, and conduct clinical trials under company-sponsored or NCI-sponsored INDs. NCI will (a) provide genes of tumor-associated antigens, cytokines and other immunostimulatory molecules for incorporation into poxvirus vectors, (b) evaluate recombinant vectors in preclinical models alone and in combination therapies, and (c) conduct clinical trials (with the exception of trials for prostatic diseases, melanoma, and colorectal cancer) of recombinant vaccines alone and in combination therapies.

Next Step: Teleconference

There will be a teleconference where the principal investigator, Dr. Jeffrey Schlom, will discuss this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference, please call or e-mail Sabarni Chatterjee; 301–435–5587; *chatterjeesa@mail.nih.gov*. OTT will then e-mail you the date, time, and number for the teleconference.

Dated: April 29, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–10479 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: July 14–15, 2009.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza—Tyson Corner, 1960 Chain Bridge Road, McLean, VA 22102.

Contact Person: Lorraine Gunzerath, PhD, MBA Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 2121, Bethesda, MD 20892–9304, 301–443–2369, *lgunzera@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10409 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Neuroscience Review Subcommittee.

Date: July 13–14, 2009.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Beata Buzas, PhD, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 2081, Rockville, MD 20852, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10408 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Coordinating Center for Infectious Diseases (CCID)

Notice of Cancellation: This notice was published in the **Federal Register** on April 13, 2009, Volume 74, Number 69, page 16877. The meeting previously scheduled to convene on May 14, 2009 has been cancelled due to the public health emergency.

Contact Person for More Information: Harriette Lynch, Office of the Director, CCID, CDC, Mailstop E–77, 1600 Clifton Road, NE., Atlanta, Georgia 30333, e-mail *hlynch@cdc.gov,* telephone (404) 498–2726.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 1, 2009.

Andre Tyler,

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

[FR Doc. E9–10554 Filed 5–4–09; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

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 June 12, 2009, from 8 a.m. to 5:45 p.m.

Location: Holiday Inn Gaithersburg, Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2392. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On June 12, 2009, the Committee will review and discuss a recent report from the UK Health Protection Agency attributing a case of variant Creutzfeldt-Jakob (vCJD) disease infection to treatment 11 years earlier