registration information and requests to make a presentation by June 16, 2008.

**ADDRESSES:** The meeting will be held at 5600 Fishers Lane, 3rd fl., Chesapeake Conference Room, Rockville, MD 20857. For security reasons, all attendees must preregister 3 days prior to the meeting and are asked to arrive no later than 2:50 p.m. because attendees will be escorted from the front entrance of 5600 Fishers Lane to the Chesapeake Conference Room.

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

**FOR FURTHER INFORMATION CONTACT:** Tammie Bell, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX: 301–827–0003, e-mail: *Tammie.Bell2@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining the highest level of global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics' industry trade associations. Currently, the ICCR members are Health Canada; the European Commission Directorate General for Enterprise and Industry; the Ministry of Health, Labor, and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by the members of ICCR will be made by consensus and will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will require input from stakeholders.

## II. Registration and Requests for Oral Presentations

Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person (*Tammie.Bell2@fda.hhs.gov*) (see **DATES**).

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

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 4 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person (*Tammie.Bell2@fda.hhs.gov*) (see **DATES**) and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

## III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

## IV. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

## V. Electronic Access

The agenda for the public meeting will be made available via the internet at *http://www.cfsan.fda.gov/~lrd/vidtel.html*

Dated: May 28, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–12338 Filed 6–2–08; 8:45 am]

**BILLING CODE 4160–01–S**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Immunotoxins With Deletions in Domain II That Remove Immunogenic Epitopes With Minimal Loss of Cytotoxic Activity**

*Description of Technology:* Anti-CD22 immunotoxins consist of a disulfide-linked FV ($V_H/V_L$) antibody fragment recombinantly linked to a toxic moiety capable of killing cells. In particular, a 38-kDa active fragment of Pseudomonas exotoxin A (PE38) containing three specific domains (domain Ib, domain II and domain III) has been used successfully in these immunotoxins. These immunotoxins have been shown to have activity against various forms of cancer, such as hairy cell leukemia and chronic lymphocytic leukemia, and are

currently being evaluated in clinical trials.

This technology involves the development of a less immunogenic form of anti-CD22 immunotoxins. Specifically, the inventors have removed all of domain Ib and the majority of domain II from the PE38 portion of the immunotoxin. The resulting construct maintains a similar cytotoxicity to the larger immunotoxin, but with lowered immunogenicity.

*Application:* Treatment of cancers associated with the increased expression of CD22, such as leukemia and lymphoma.

*Advantages:* Less immunogenic immunotoxin results in improved cytotoxicity; Targeted therapy decreases non-specific killing of non-cancerous cells.

*Inventors:* Ira Pastan (NCI) *et al.*

*Patent Status:* U.S. Provisional Application No. 60/969,929 filed 09 Sep 2007 (HHS Reference No. E–292–2007/0–US–01).

*Licensing Contact:* David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov*.

**The Combination of Anti-CD22 Immunotoxins With Standard Chemotherapeutic Agents on a Human Burkitt Lymphoma Cell Line**

*Description of Technology:* The treatment of hematological malignancies has been a major public health challenge because patients frequently do not respond to conventional therapies with long-term complete remission. However, current therapies are associated with multiple toxicities, suggesting that new therapies are needed.

In the past several years immunotoxins have been developed as an alternative approach to treat different malignancies. Since hematological malignancies are readily accessible via the blood stream, immunotoxins represent a viable therapeutic approach. Furthermore, immunotoxins have the potential for decreased nonspecific toxicity, suggesting these agents could lead to improved cancer therapies.

This technology relates to new combination therapies using an immunotoxin and chemotherapeutic agent. Specifically, the anti-CD22 immunotoxin HA22 has been used in combination with 4 different chemotherapeutic agents: Taxol, cisplatin, etopside and doxorubicin. The combinations were shown to have a synergistic effect when examined in both *in vitro* cell models and *in vivo* animal models. As a result, it may be possible for this combination therapy to overcome previous shortcomings seen with chemotherapy treatment alone.

*Application:* Treatment of cancers associated with the increased expression of CD22, such as leukemia and lymphoma.

*Advantages:* Uses a combination of agents previously shown to be effective in killing cancer cells; Combination of immunotoxins and chemotherapeutics showed a synergistic effect, suggesting the combination offers distinct advantages of the use of either agent alone.

*Inventors:* Ira Pastan (NCI) *et al.*

*Patent Status:* PCT Application No. PCT/US2008/002747 filed 28 Feb 2008 (HHS Reference No. E–132–2007/2–PCT–01).

*Licensing Contact:* David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov*.

Dated: May 23, 2008.

**Steven M. Ferguson,**

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

[FR Doc. E8–12291 Filed 6–2–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Urologic Research Development.

*Date:* June 24, 2008.

*Time:* 8:30 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Thomas A. Tatham, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov*.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Hepatitis C Ancillary Study.

*Date:* June 26, 2008.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* D. G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov*.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK Hepatitis B Clinical Research Network.

*Date:* July 10–11, 2008.

*Time:* 6 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Xiaodu Guo, MD, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov*.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Molecular Therapy Core Centers.

*Date:* July 22, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Atul Sahai, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–2242, *sahaia@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 27, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–12284 Filed 6–2–08; 8:45 am]

**BILLING CODE 4140–01–P**