Dated: April 28, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–10451 Filed 5–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Notice of Extension for Public Comment Period for the Consideration of a Proposed Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines); Notice

A notice of consideration of a proposed action under the *NIH Guidelines* with an opportunity for public comment was published by the Department of Health and Human Services, National Institutes of Health, in the **Federal Register** (74 FR 9411) on March 4, 2009 for the Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the *NIH Guidelines for Research Involving Recombinant DNA Molecules.* The public comment period ends on May 4, 2009. This notice announces an extension of the public comment period until June 1, 2009.

If you have questions, or require additional information about these proposed changes, please contact OBA by e-mail at *oba@od.nih.gov,* or by telephone at 301–496–9838. Comments may be submitted to the same e-mail address or submitted by fax to 301–496–9839, or sent by mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892–7985. Background information may be obtained by contacting NIH OBA by e-mail at *oba@od.nih.gov.*

Dated: April 30, 2009.

Jacqueline Corrigan-Curay,

Acting Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. E9–10432 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Therapeutics for Use in Humans To Induce Tolerance for Transplantation and To Treat T cell Lymphoma and Leukemia, Autoimmune Diseases Such as Lupus, and Graft-Versus-Host Disease

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent No. 5,167,956 and PCT Application Serial No. PCT/US92/00813 and foreign equivalents thereof, entitled ''Immunotoxin with in vivo T cell suppressant activity and methods of use'' (HHS Ref. No. E–012–1991/0); U.S. Patent No. 5,725,857 and foreign equivalents thereof, entitled ''Immunotoxin with in vivo T cell suppressant activity and methods of use'' (HHS Ref. No. E–012–1991/2); U.S. Patent No. 5,762,927 and foreign equivalents thereof, entitled ''Immunotoxin with in vivo T cell suppressant activity and methods of use'' (HHS Ref. No. E–012–1991/4); Australian Patent No. 762197 and PCT Application Serial No. PCT/US96/05087 and other foreign equivalents thereof, entitled ''Methods of inducing immune tolerance using immunotoxins'' (HHS Ref. No. E–012–1991/5); U.S. Patent No. 6,103,235 and foreign equivalents thereof and U.S. Patent No. 7,125,553 and foreign equivalents thereof, entitled ''Methods of inducing immune tolerance using immunotoxins'' (HHS Ref. No. E–012–1991/7); Australian Patent No. 766692 entitled ''Novel vectors and expression methods for producing mutant proteins'' (HHS Ref. No. E–043–1997/0); U.S. Patent Application No. 10/566,886 and PCT Application No. PCT/US2004/24786 and foreign equivalents thereof entitled ''Methods for expression and purification of immunotoxins'' (E–043–1997/2); U.S. Patent No. 6,632,928 and PCT Application Serial No. PCT/US98/04303 and foreign equivalents thereof, entitled ''Novel immunotoxins and methods of inducing immune tolerance'' (HHS Ref. No. E–044–1997/0); U.S. Patent Application No. 10/296,085 and PCT Application Serial No. PCT/US01/16125 and foreign equivalents thereof entitled ''Immunotoxin Fusion Proteins and Means for Expression Thereof'' (HHS Ref. No. E–044–1997/1); U.S. Patent No. 7,288,254 and PCT Application Serial No. PCT/US99/08606 and foreign equivalents thereof entitled ''Use of immunotoxins to induce immune tolerance to pancreatic islet transplantation'' (HHS Ref. No. E–059–1998/0); Australian Patent No. 781547 and PCT Application No. PCT/US00/10253 and other foreign equivalents thereof, entitled ''Methods related to combined use of immunotoxins and agents that inhibit dendritic cell maturation'' (HHS Ref. No. E–168–1999/0), to Angimmune LLC which is located in Bethesda, Maryland. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be United States, Europe, Canada, Australia, Japan, India, Hong Kong, and Brazil and the field of use may be limited to the treatment of T cell lymphoma and leukemia, autoimmune diseases such as lupus, and complications of transplantation, including graft-versus-host disease, and induction of tolerance for organ, pancreatic islet, and cell transplantation as claimed in the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 6, 2009 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Samuel E. Bish, PhD, Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5282; Facsimile: (301) 402–0220; E-mail: *bishse@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The technology describes compositions of anti-human, anti-T cell bivalent immunotoxins, methods of producing immunotoxins using a genetically-engineered Pichia (yeast) expression system, and methods of using the immunotoxin moieties to treat various indications, including T cell lymphoma/leukemia, graft-versus-host disease (GVHD), and autoimmune diseases such as lupus, and methods to use the immunotoxins in combination with immunosuppressants to induce tolerance for organ, cell, and pancreatic islet transplants and to inhibit dendritic

cell maturation. The immunotoxins are fusion proteins consisting of a truncated diphtheria toxin joined to an anti-CD3 antibody, which binds to the CD3 antigen found on the T cell receptor (TCR) of mature T lymphocytes (T cells). The toxin moiety acts to kill cells, the anti-CD3 antibody portion performs cell targeting to direct the toxin to specifically kill T cells, and the bivalency allows the immunotoxin to bind to target cells with greater efficiency than monovalent constructs. Thus, bivalent, anti-CD3 immunotoxins that specifically deplete T cells, such as those constructs created by the inventors, could yield innovative therapeutics for T cell lymphoma and other disorders caused by T cell-related abnormalities.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 28, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–10480 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0049]

Homeland Security Advisory Council

AGENCY: The Office of Policy, DHS.

ACTION: Committee Management; Notice of Partially Closed Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet on June 5, 2009, in Albuquerque, New Mexico. The meeting will be partially closed to the public.

DATES: The HSAC will meet June 5, 2009, from 10 a.m. to 3 p.m. The meeting will be closed from 12:20 p.m. to 3 p.m.

ADDRESSES: The open portion of the meeting will be held at the University of New Mexico Student Union, Ballroom B—main campus, in Albuquerque, New Mexico. Requests to have written material distributed to each member of the committee prior to the meeting should reach the contact person at the address below by May 29, 2009. Comments must be identified by Docket number DHS–2009–0049 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: HSAC@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* 202–282–9207.
- *Mail:* Homeland Security Advisory Council, 245 Murray Drive, SW., Building 410, Mailstop 0850, Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the HSAC, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Homeland Security Advisory Council, (202) 447–3135, *HSAC@dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. The HSAC provides independent advice to the Secretary of the Department of Homeland Security to aide in the creation and implementation of critical and actionable policies and capabilities across the spectrum of homeland security operations. The HSAC periodically reports, as requested, to the Secretary, on such matters. The HSAC serves as the Secretary's primary advisory body with the goal of providing strategic, timely and actionable advice.

The HSAC will meet for the purpose of receiving briefings and updates from DHS principals on the current status of the HSAC, a threat assessment and intelligence briefing focused on border security, internal DHS management directives and the successes and challenges of the DHS transition. The meeting will also include information briefings of the Department's sensitive processes including law enforcement and transportation security procedures. HSAC members will receive a classified intelligence briefing during the closed session.

Basis for Closure: This meeting will include updates on operational challenges, intelligence briefings, and pre-decisional policies from various DHS Components, including: various State and local senior officials including the office of International Affairs, Immigration and Customs Enforcement as well as Customs and Border Protection. The briefings will include information on sensitive homeland security procedures and the capabilities of the Department of Homeland Security Components.

In accordance with section 10(d) of the Federal Advisory Committee Act, it has been determined that this HSAC meeting concerns matters that ''disclose investigative techniques and procedures'' under 5 U.S.C. 552b(c)(7)(E) and are ''likely to significantly frustrate implementation of a proposed agency action'' within the meaning of 5 U.S.C. 552b(c)(9)(B). Discussion of ongoing investigations with Department of Homeland Security enforcement Components and outside law enforcement partners fall within the meaning of 5 U.S.C 552b(7)(E) insofar as they will ''disclose investigative techniques and procedures.'' Additionally, release of information presented during the briefings and the nature of the discussion could lead to premature disclosure of information on Department of Homeland Security actions that would be ''likely to significantly frustrate implementation of a proposed agency action.'' Therefore, the portion of the meeting of the HSAC from 12:20 p.m. to 3 p.m. will be closed to the public.

Public Attendance: Members of the public may register to attend the public session on a first-come, first-served basis per the procedures that follow. For security reasons, we request that any member of the public wishing to attend the public session provide his or her full legal name, date of birth and contact information no later than 5 p.m. EST on May 31, 2009, to the HSAC via e-mail at *HSAC@dhs.gov* or via phone at (202) 447–3135. Photo identification may be required for entry into the public session. Registration begins at 9 a.m. Those attending the public session of the meeting must be present and seated by 10 a.m. From 10:15 a.m. to 12 noon, the HSAC will meet to be sworn in and receive their initial briefing from the Secretary on their role within her administration and receive updates on