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