Date: May 20, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608. 301–443–1225. *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10430 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0197]

Psychopharmacologic Drugs 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: Psychopharmacologic Drugs 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 9, 2009 from 8 a.m. to 6 p.m. and June 10, 2009, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to *http://www.regulations.gov*. Enter ''FDA–2009–N–0197 Use of Antipsychotics for Schizophrenia and Bipolar Disorder in Pediatric and Adolescent Patients'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Comments received on or before May 26, 2009, will be provided to the committee before the meeting.

Location: Marriott Conference Centers, UMUC Inn and Conference Center, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7385.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. 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 both days, the committee will discuss safety and efficacy issues for the following new drug applications (NDAs): (1) NDA 20–639/S–045 and S–046: SEROQUEL (quetiapine fumarate) Tablets, AstraZeneca Pharmaceuticals LP, for the acute treatment of schizophrenia in adolescents from 13 to 17 years of age, and the acute treatment of bipolar mania in children from 10 to 12 years of age and adolescents from 13 to 17 years of age; (2) NDA 20–825/S–032: GEODON (ziprasidone hydrochloride) Capsules, Pfizer Inc., for the acute treatment of manic or mixed episodes associated with bipolar disorder, with or without psychotic features in children and adolescents ages from 10 to 17 years of age; and (3) NDA 20–592/S–040 and S–041: ZYPREXA (olanzapine) Tablets, Eli Lilly and Co., for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the acute treatment of schizophrenia in adolescents. The committee will be asked to vote on whether or not these products have been shown to be effective and acceptably safe for these pediatric indications.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 26, 2009. Oral presentations from the public will be scheduled between approximately 4 p.m. and 6 p.m. on June 9, 2009. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 22, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 26, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

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