and Research Support Awards, National Institutes of Health, HHS)

Dated: July 18, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18172 Filed 7–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 19–20, 2012.

Closed: September 19, 2012, 5:00 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Open: September 20, 2012, 8:30 a.m. to 2:00 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse & Alcoholism National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737, *bautista@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.niaaa.nih.gov/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 18, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID); Notice of Workshop

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health; the Food and Drug Administration (FDA); the Transformational Medical Technologies (TMT); and Biomedical Advanced Research and Development Authority (BARDA) are holding an Animal Model Development Workshop to explore the scientific and regulatory challenges of developing medical countermeasures (MCM) under the ''Animal Rule'' (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products). The goals of this workshop are to highlight the significant progress made in animal model development for MCMs, review recent case studies of products under development using animal models, and capture lessons learned to inform future animal model development efforts. In addition, the workshop will provide a forum to discuss current challenges and identify potential solutions or mitigation strategies.

DATES: The workshop will be held on September 17–18, 2012, at 8 a.m. EST. Participants must register by September 10, 2012.

ADDRESSES: The workshop will be held at the NIH Natcher Conference Center, Building 45, 45 Center Drive, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: During the past decade, much progress has been made in the development of candidate medical products to prevent, treat, or diagnose the health effects of exposure to chemical, biological, radiological, and nuclear (CBRN) agents. With the convergence of scientific progress in medical countermeasures (MCMs) development, improvements in containment laboratory infrastructure, technological advances, and additional regulatory guidance, the stage is set for tangible progress in our ability to advance MCMs for CBRN agents. The effects of these efforts were evident in several recent FDA Advisory Committee meetings: *anthrax vaccines (2010), smallpox therapeutics (2011),* and *plague antimicrobials (2012).* Especially promising is the recent emphasis on cooperation among government agencies to leverage resources (scientific, human, and fiscal) in an effort to advance the development of animal models.

A solid regulatory and policy framework for fostering development of well-characterized animal models now exists. The Animal Rule laid the foundation for current efforts. FDA's draft guidance on *Animal Models—Essential Elements to Address Efficacy Under the Animal Rule* (January 2009) built upon that foundation and is currently undergoing substantial revision. More recently, the draft guidance on *Qualification Process for Drug Development Tools* (October 2010) outlined a concrete process for qualifying animal models. However, multiple scientific and regulatory challenges remain in animal model development.

This workshop is designed to explore the unique challenges being faced with the development of animal models for the evaluation of medical countermeasures for CBRN agents, including, but not limited to, the following crosscutting issues:

- Missing or limited data on the pathophysiological mechanisms of disease development in humans, especially with:
  - No recent outbreaks in humans, or outbreaks occur only in remote locations with limited infrastructure and capabilities
  - Altered virulence or other properties of the natural agent
  - A difference between the normal route of exposure and the route likely to be used in a bioterrorism event
- Use of mortality as an endpoint, particularly when case fatality of naturally occurring disease in humans is less than 100 percent
- Incorporation and importance of biomarkers
- Correlates of disease progression
- Definition of supportive care and implementation given:
  - Adequate veterinary care
  - Intervention necessary for model development
  - Intervention to mimic human clinical care
- Acceptability of euthanasia criteria and early study endpoints
- Reproducibility of models

If you are interested in attending, please register at the following link: *https://respond.niaid.nih.gov/conferences/AMDW/Pages/default.aspx* by September 10, 2012. There is no registration fee for the workshop. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please contact Dr. Judy Hewitt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the workshop.

FOR FURTHER INFORMATION CONTACT: Dr. Judy Hewitt, Office of Biodefense Research Affairs, Division of Microbiology and Infectious Diseases, NIAID, at telephone 301–402–4197 or telefax 301–480–1263 or email *AMworkshopSep2012@mail.nih.gov* (Subject line: Animal Model Workshop).

Dated: July 18, 2012.

Lawrence A. Tabak,

Deputy Director, NIH.

[FR Doc. 2012–18168 Filed 7–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: August 14, 2012.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles Morrow, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–451–4467, *morrowcs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Healthcare Delivery and Methodologies.

Date: August 28, 2012.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301–437–7872, *jenkinsml2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 18, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18055 Filed 7–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Glucocerebrosidase Activators for the Treatment of Gaucher Disease and Central Nervous System Proteinopathies, Including Parkinson's 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 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to Lysosomal Therapeutics, Inc., a company having a place of business in Boston, Massachusetts, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/420,946, filed December 8, 2010 (HHS Ref. No. E–257–2010/0–US–01) and PCT Patent Application No. PCT/US2011/063928, filed December 8, 2011 (HHS Ref. No. E–257–2010/0–PCT–02), both entitled ''Substituted Pyrazolopyrimidines as Glucocerebrosidase Activators.'' The patent rights in these inventions have been assigned to the United States of America. The prospective exclusive evaluation option license territory may be ''worldwide'', and the field of use may be limited to ''Treatment of Gaucher disease and human central nervous system proteinopathies, including without limitation Parkinson's disease.'' Upon the expiration or termination of the exclusive evaluation option license, Lysosomal Therapeutics, Inc. will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the evaluation license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 9, 2012 will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, and comments relating to the contemplated exclusive license should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4426; Facsimile: (301) 402–0220; Email: *tarak@mail.nih.gov.* A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: Gaucher disease is a rare lysosomal storage disease caused by mutations in the glucocerebrosidase (GCase) gene; GCase is localized in the lysosome and is responsible for the breakdown of glucocerebroside, an intermediate in glycolipid metabolism. This technology provides small molecule activators of GCase that facilitate the proper folding of GCase and its transport to the lysosome, without inhibiting its activity in the lysosome. Thus, these compounds are extremely promising candidates for the development of a small molecule drug to treat Gaucher disease. Mutations in the GCase gene have also been associated with the development of Parkinson's disease, and therefore, these compounds may also be useful for the treatment of Parkinson's disease. It is also possible that these compounds could be utilized to treat other proteinopathy-based diseases.

The prospective exclusive evaluation option license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written