submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring MD, 20993, 301–796–4548, email: *Amanda.Roache@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation, was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In 2015 the ICH was reformed to make the ICH a true global initiative that expands beyond the previous ICH members. More involvement from regulators around the world is expected, as they will join their counterparts from Europe, Japan, USA, Canada, and Switzerland as ICH regulatory members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Webinar Attendance and Participation

A. Registration

If you wish to attend the meeting, please register at the following Web site: *https://ich_regional_consultation.eventbrite.com.* Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 1:30 p.m. and 2 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) by April 19, 2017, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public Webinar will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm536015.htm.*

Dated: March 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04839 Filed 3–10–17; 8:45 am]

BILLING CODE 4164–01–P

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; AREA: Immunology.

Date: March 9, 2017.

Time: 12:00 p.m. to 4:00 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: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr, Room 4203, Bethesda, MD 20817, (301) 435–3566, *alok.mulky@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuropharmacology.

Date: March 28, 2017.

Time: 2:00 p.m. to 5:30 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: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Neural Regulation of Cancer.

Date: March 29, 2017.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, *jakobir@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 16–218: Provocative Questions in Pediatric Cancer.

Date: April 4, 2017.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Charles Morrow, MD, Ph.D., 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*.

(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: March 7, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–04807 Filed 3–10–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing 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.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

N6, A Novel, Broad, Highly Potent HIV-Specific Antibody

Description of Technology

The N6 antibody has evolved a unique mode of binding that depends less on a variable area of the HIV envelope known as the V5 region and focuses more on conserved regions, which change relatively little among HIV strains. This allows N6 to tolerate changes in the HIV envelope, including the attachment of sugars in the V5 region, a major mechanism by which HIV develops resistance to other VRC01-class antibodies. N6 was shown in pre-clinical studies to neutralize approximately 98 percent of HIV isolates tested. The studies also demonstrate that N6 neutralizes approximately 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently. Its breadth and potency makes N6 a highly desirable candidate for development in therapeutic or prophylactic strategies.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- HIV therapeutic
- HIV prophylactic

Competitive Advantages

- Neutralized 98 percent of HIV isolates tested.
- Neutralized 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently.

Development Stage: Pre-Clinical.

Inventors: Mark Connors, Jinghe Huang, Byong Ha Kang, John Mascola, Elise Ishida, Tongqing Zhou, Peter Kwong, Anqi Zheng, all of NIAID.

Publications: Huang, Jinghe, et al. ''Identification of a CD4-binding-site antibody to HIV that evolved near-pan neutralization breadth.'' Immunity 45.5 (2016): 1108–1121.

Intellectual Property: HHS Reference No. E–131–2015 *et seq.*—US provisional application 62/136,228, US provisional application 62/250,378, and PCT application PCT/US2016/023145.

Licensing Contact: Chris Kornak, 240–627–3705, *chris.kornak@nih.gov.*

Collaborative Research Opportunity: The Technology Transfer and Intellectual Property Office (TTIPO) is seeking parties interested in collaborative research to further co-develop this technology. For collaboration opportunities, please contact Chris Kornak, 240–627–3705, *chris.kornak@nih.gov.*

Dated: March 3, 2017.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2017–04834 Filed 3–10–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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 Allergy and Infectious Diseases Special Emphasis Panel NIAID; Investigator Initiated Program Project Applications (P01).

Date: March 29, 2017.

Time: 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.