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Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Andrew LeBoeuf, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-0503.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Self-Identification of Generic Drug Facilities, Sites, and Organizations." The guidance announced in this notice finalizes the draft guidance of the same name announced in the **Federal Register** of August 27, 2012 (77 FR 51811). Compared to the draft guidance, the final guidance clarifies various matters, including that the self-identification requirements have been implemented, and simplifies the instructions for electronic submission of self-identification information. FDA received one comment on the draft guidance, which was considered as the guidance was finalized.

On July 9, 2012, GDUFA (Pub. L. 112-144, Title III) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program. GDUFA will also significantly improve global supply chain transparency by requiring owners of facilities producing generic drug products, active pharmaceutical ingredients (API), and certain other sites and organizations that support the manufacture or approval of these

products to electronically self-identify with FDA and update that information annually.

Self-identification is required for two purposes. First, it is necessary to determine the universe of facilities required to pay user fees. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification enables quick, accurate, and reliable surveillance of generic drugs and facilitates inspections and compliance.

Most facilities that self-identify are required to pay an annual facility user fee. These include facilities manufacturing, or intending to manufacture, API of human generic drugs and/or finished dosage form (FDF) human generic drugs. Other facilities, sites, and organizations must self-identify, but are not required to pay the annual facility user fee. These include facilities that solely manufacture positron emission tomography drugs, or sites and organizations that only perform testing, repackaging, or relabeling operations. Please note that while re-packagers are not required to pay user fees, packagers are, in most cases, FDF manufacturers and subject to facility fees.

A separate system for the electronic self-identification of generic industry facilities, sites, and organizations was established for GDUFA. Entities required to register and list (under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) or section 351 of the Public Health Service Act (42 U.S.C. 262)), and those required to self-identify under GDUFA, submit information separately to the respective systems. Each system populates its own database to meet unique requirements and deadlines. The new GDUFA system uses the same platform and technical standards already familiar to manufacturers required to register and list.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Self-Identification of Generic Drug Facilities, Sites, and Organizations." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceCompliance>

[RegulatoryInformation/Guidances/default.htm](http://www.regulations.gov/RegulatoryInformation/Guidances/default.htm) or <http://www.regulations.gov>.

Dated: September 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-22944 Filed 9-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service; Extension of Comment Period

AGENCY: Indian Health Service, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: This document extends the comment period in the Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service announcement that was published in the **Federal Register** on June 3, 2016.

DATES: The comment period has been extended to November 30, 2016.

FOR FURTHER INFORMATION CONTACT: Roselyn Tso, Acting Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443-1104. (This is not a toll-free number.)

Dated: September 16, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016-22922 Filed 9-22-16; 8:45 am]

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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; Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: October 18–19, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Raymond R. Schleef, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3E61, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5019, schleefrr@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 19, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22899 Filed 9–22–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Clinical and Epidemiological grant applications (Cooperative Agreements and RPGs).

Date: October 19, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, jeanetteh@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: September 19, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22898 Filed 9–22–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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: National Institute of General Medical Sciences Special Emphasis Panel; Review of SCORE Applications.

Date: October 27–28, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis, Washington DC, 923 16th and K Street NW., Washington, DC 20006.

Contact Person: John J. Laffan, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, Bethesda, MD 20892, 301–594–2773, laffanjo@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of MIRA Applications.

Date: November 3–4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Saraswathy Seetharam, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301–594–2763, seetharams@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research; Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 19, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22900 Filed 9–22–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive License: Therapeutics for Frontotemporal Dementia, Alzheimer's Disease Excluding Intranasal Delivery, Neuronal Injury (Stroke, Traumatic Brain Injury (TBI) and Epilepsy), and Progressive Supranuclear Palsy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive license to Cogentis Therapeutics, Inc. which is located in Maryland, to practice the inventions embodied in the following patents: U.S. Patent 8,597,660, issued December 3, 2013 (HHS reference E–144–2010/0–US–02).

The patent rights in these inventions have been assigned to the United States of America. The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to Frontotemporal dementia, Alzheimer's disease excluding intranasal delivery, Neuronal injury (stroke, traumatic brain injury (TBI) and epilepsy), and Progressive Supranuclear Palsy.

DATES: Only written comments and/or applications for a license which are received by NINDS Technology Transfer on or before October 11, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive license