was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 30, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for KENGREAL (NDA 204958) was initially submitted on April 30, 2013.

3. *The date the application was approved:* June 22, 2015. FDA has verified the applicant's claim that NDA 204958 was approved on June 22, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in 21 CFR 60.30, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of 21 CFR 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with 21 CFR 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18380 Filed 8–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment. This meeting will be open to the public. Information about the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment and the agenda for this meeting can be obtained by contacting CDR Holly Berilla at (301) 443–9965 or *hberilla@hrsa.gov.*

DATES: October 25, 2017, 9:00 a.m. to 5:30 p.m. (Eastern) and October 26, 2017, 9:00 a.m. to 4:15 p.m. (Eastern).

ADDRESSES: This meeting will be held in person and offer virtual access through teleconference and Adobe Connect. The address for the meeting is 5600 Fishers Lane, Pavilion, Rockville, Maryland 20857. The conference call-in number is (888) 469–0566 and passcode is 6012320. The webinar link is *https://hrsa.connectsolutions.com/october_chac_meeting/.*

FOR FURTHER INFORMATION CONTACT: Those requesting information regarding the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment should contact CDR Holly Berilla, Senior Public Health Analyst, Division of Policy and Data (DPD), HIV/AIDS Bureau (HAB), HRSA, in one of three ways: (1) Mail a request to CDR Holly Berilla, Senior Public Health Analyst, HRSA/HAB/DPD, 5600 Fishers Lane, 9N164C, Rockville, Maryland 20857; (2) call (301) 443–9965; or (3) send an email to *hberilla@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment was established under Section 222 of the Public Health Service Act, [42 U.S.C. Section 217a], as amended.

The purpose of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment is to advise the Secretary of HHS, the Director of CDC, and the Administrator of HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, AIDS, viral hepatitis and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV/AIDS, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional education, patient healthcare delivery, and prevention services; HHS policies about prevention of HIV/AIDS, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to CDC and HRSA in their development of responses to emerging health needs related to HIV, viral hepatitis, and other STDs.

During the October 25 to 26, 2017, meeting, the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment will discuss strategies to link, retain, and re-engage people living with HIV into the Ryan White HIV/AIDS Program system of care; HAB's benchmarking and risk adjustment initiatives; HRSA and CDC initiatives regarding congenital syphilis; and committee workgroup reports. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment should be sent to CDR Holly Berilla, using the contact information listed above, by October 11, 2017.

The building at 5600 Fishers Lane, Rockville, MD 20857, requires a security screening on entry. To facilitate your access to the building please contact CDR Holly Berilla (contact information provided above). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify CDR Holly Berilla (contact information provided above) at least 10 days prior to the meeting.

Status: This advisory committee meeting will be open to the public.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–18426 Filed 8–29–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

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.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: September 12, 2017.

Closed: 8:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Open: 2:30 p.m. to 4:30 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 35A, Porter Building, Room 640, 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, 301–435–0260, *moenl@mail.nih.gov.*

This notice is being amended to reflect changes in open and closed sessions.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 24, 2017.

Jennifer S, Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–18340 Filed 8–29–17; 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, 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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 Peer Review Meeting,

Date: September 27, 2017.

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

Agenda: To review and evaluate contract proposals.

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

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Program, Division of Extramural Activities, Room 3F40B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5036,*poeky@mail.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: *August 24, 2017.*

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–18337 Filed 8–29–17; 8:45 am]

BILLING CODE 4140–01–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, 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; PAR17–033: Integrative Research to Understand the Impact of Sex Differences on the Molecular Determinants of AD Risk and Responsiveness to Treatment.

Date: September 25, 2017.

Time: 11:00 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: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

Name of Committee: Center for Scientific Review, Special Emphasis Panel; PAR15–357: Understanding Alzheimer's Disease in the Context of the Aging Brain.

Date: September 25, 2017.

Time: 11:00 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: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: September 28–29, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 East Wacker Drive, Chicago, IL 60601.

Contact Person: Boris P Sokolov, Ph.D., Scientific Review Officer, Center for