redacted/blacked out, will be available for public viewing and posted on *http://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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product QUTENZA (capsaicin). QUTENZA is indicated for management of neuropathic pain associated with postherpetic neuralgia. Subsequent to this approval, the USPTO received a patent term restoration application for QUTENZA (U.S. Patent No. 6,239,180) from NeurogesX, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration and also requested that FDA determine the product's regulatory review period. In a letter dated June 23, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of QUTENZA represented the first permitted commercial marketing or use of the product. Thereafter, FDA also determined the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for QUTENZA is 2,944 days. Of this time, 2,547 days occurred during the testing phase of the regulatory review period, while 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 27, 2001. The applicant claims September 27, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 27, 2001, which 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:* October 16, 2008. The applicant claims October 13, 2008, as the date the new drug application (NDA) for QUTENZA was initially submitted. However, FDA records indicate that NDA 22–395 was submitted on October 16, 2008.

3. *The date the application was approved:* November 16, 2009. FDA has verified the applicant's claim that NDA 22–395 was approved on November 16, 2009.

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 1,687 days 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 ask for a redetermination (see **DATES**). Furthermore, 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 be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17187 Filed 7–20–16; 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 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: Center for Scientific Review Special Emphasis Panel; Harnessing Big Data to Halt HIV/AIDS.

Date: July 22, 2016.

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: Jose H. Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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 14, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–17175 Filed 7–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, August 03, 2016, 12:30 p.m. to August 03, 2016, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on July 14, 2016, 81 FR 45512.

The Meeting will begin at 11:00 a.m. The meeting date and location remain the same. The meeting is closed to the public.

Dated: July 15, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–17176 Filed 7–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0656]

Great Lakes Pilotage Advisory Committee; Vacancies

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Great Lakes Pilotage Advisory Committee. The Great Lakes Pilotage Advisory Committee provides advice and makes recommendations to the Secretary of Homeland Security through the Coast Guard Commandant on matters relating to Great Lakes pilotage, including review of proposed Great Lakes pilotage regulations and policies.

DATES: Completed applications should reach the Coast Guard on or before August 22, 2016.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the Great Lakes Pilotage Advisory Committee that also identifies which membership category the applicant is applying under, along with a resume detailing the applicant's experience via one of the following methods:

- *By Email: Michelle.R.Birchfield@uscg.mil.*
- *By Fax:* (202) 372–8387, ATTN: Ms. Michelle Birchfield.
- *By Mail:* Commandant (CG–WWM–2), U.S. Coast Guard, Attention: Ms. Michelle Birchfield, Alternate Designated Federal Officer, Great Lakes Pilotage Advisory Committee, 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Birchfield, Great Lakes Pilotage Advisory Committee Alternate Designated Federal Officer, 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509; telephone 202–372–1537, fax 202–372–8387, or email at *Michelle.R.Birchfield@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Great Lakes Pilotage Advisory Committee is a federal advisory committee established in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C., Appendix). The Great Lakes Pilotage Advisory Committee operates under the authority of 46 U.S.C. 9307, and makes recommendations to the Secretary and the Coast Guard on matters relating to the Great Lakes.

Meetings of the Great Lakes Pilotage Advisory Committee will be held with the approval of the Designated Federal Officer. The Committee is required to meet at least once per year. Additional meetings may be held at the request of a majority of the Committee or at the discretion of the Designated Federal Officer. Further information about the Great Lakes Pilotage Advisory Committee is available by going to the Web site: *https://www.facadatabase.gov.* Click on the search tab and type ''Great Lakes'' into the search form. Then select ''Great Lakes Pilotage Advisory Committee'' from the list.

Individuals shall serve terms of office of three years and may be reappointed to one additional term, serving not more than six consecutive years. All members serve at their own expense but may receive reimbursement for travel and per diem from the Federal Government.

We will consider applicants for two positions that expire or become vacant on September 30, 2016.

- One member representing the interests of Great Lakes ports, and
- One member representing the interests of shippers whose cargoes are transported through Great Lakes ports.

To be eligible, applicants shall have at least five years of practical experience in maritime operations.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability and genetic information, age, membership in an employee organization, or other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Ms. Michelle Birchfield, Alternate Designated Federal Officer of the Great Lakes Pilotage Advisory Committee via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice. Email submittals will receive email receipt confirmation.

Dated: July 14, 2016.

J.G. Lantz,

U.S. Coast Guard, Director of Regulations and Standards.

[FR Doc. 2016–17239 Filed 7–20–16; 8:45 am]

BILLING CODE 9110–04–P