

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 OPSUMIT (macitentan). OPSUMIT is indicated for the treatment of pulmonary arterial hypertension to delay disease progression. Subsequent to this approval, the USPTO received a patent term restoration application for OPSUMIT (U.S. Patent No. 7,094,781) from Actelion Pharmaceuticals Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OPSUMIT represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OPSUMIT is 1,935 days. Of this time, 1,570 days occurred during the testing phase of the regulatory review period, while 365 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:* July 3, 2008. The applicant claims July 2, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 3, 2008, 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 19, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for OPSUMIT (NDA 204410) was initially submitted on October 19, 2012.

3. *The date the application was approved:* October 18, 2013. FDA has verified the applicant's claim that NDA 204410 was approved on October 18, 2013.

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 1,151 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. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–05389 Filed 3–9–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Meetings

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 Neurological Disorders and Stroke 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.

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 materials, 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 Neurological Disorders and Stroke Council.

*Date:* May 26–27, 2016.

*Open:* May 26, 2016, 8:00 a.m. to 2:30 p.m.

*Agenda:* Report by the Director, NINDS; Report by the Associate Director for Extramural Research; Administrative and Program Developments; and an Overview of the NINDS Intramural Program.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Closed:* May 26, 2016, 2:30 p.m. to 4:45 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Closed:* May 26, 2016, 4:45 p.m. to 5:15 p.m.

*Agenda:* To review and evaluate the Division of Intramural Research Board of Scientific Counselors' Reports.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Closed:* May 27, 2016, 8:00 a.m. to 11:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Robert Finkelstein, Ph.D., Director of Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Bethesda, MD 20892, (301) 496-9248.

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: <http://www.ninds.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: March 3, 2016.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-05335 Filed 3-9-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be open to the public, 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 Cancer Institute Council of Research Advocates.

*Date:* April 11, 2016.

*Time:* 8:30 a.m. to 4:30 p.m.

*Agenda:* Advocacy Community Engagement in Future National Cancer Research Initiatives.

*Place:* National Institutes of Health, 50 South Drive, Building 50, Conference Rooms 1328/1334, Bethesda, MD 20892.

*Contact Person:* Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 301-594-3194, [williaam@mail.nih.gov](mailto:williaam@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 4, 2016.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-05334 Filed 3-9-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 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 Cancer Institute Special Emphasis Panel; Cognitive Assessment of Cancer.

*Date:* March 16-17, 2016.

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

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute, 9609 Medical Center Drive, Room 7W266, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Gerald G. Lovinger, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center

Drive, Room 7W266, Rockville, MD 20850, 240-276-6385, [lovingeg@mail.nih.gov](mailto:lovingeg@mail.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. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 4, 2016.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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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; PAR-15-356: Major Opportunities for Research in Epidemiology of Alzheimer's Disease and Cognitive Resilience (R01).

*Date:* March 23, 2016.

*Time:* 11:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* George Vogler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, MSC 7770, Bethesda, MD 20892, (301) 237-2693, [voglergp@csr.nih.gov](mailto:voglergp@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.