Agenda: The committee will be asked to discuss new drug application (NDA) 209128, sufentanil sublingual tablets, submitted by AcelRx Pharmaceuticals, Inc., for the management of moderate-to-severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adult patients in a medically supervised setting. The committee will also be asked to discuss risk-benefit considerations and whether this product should be approved.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 4, 2018, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 26, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 27, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19668 Filed 9–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Photoactivatable Liposomal Nanoparticle for the Delivery of an Immunotherapeutic or Immunotherapeutic-Enabling Agent

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Nano Red LLC (''Nano Red'') located in Milwaukee, Wisconsin.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 26, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jasmine Yang, Sr. Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240) 276–5530; Facsimile: (240) 276–5504 Email: *jasmine.yang@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application (Application No. 61/845,861) filed July 12, 2013, HHS Reference No.: E–482–2013/0–US–01
2. PCT Application (Application No. PCT/US2014/045922) filed July 09, 2014, HHS Reference No.: E–482–2013/0–PCT–02
3. Canada Patent Application (Application No. 2917545) filed 09 July 2014, HHS Reference No.: E–482–2013/0–CA–03
4. European Patent Application (Application No. 14745037.3) filed 09 July 2014, HHS Reference No.: E–482–2013/0–EP–04
5. U.S. Patent Application (Allowed Application No. 14/904,385) filed January 11, 2016, HHS Reference No.: E–482–2013/0–US–05

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be where patent applications are filed and the field of use may be limited to ''Photoactivatable liposomal nanoparticle for the delivery of an immunotherapeutic or immunotherapeutic-enabling agent''. Additional licensable fields of use are available (*e.g.* encapsulating imaging agent).

This technology discloses a photoactivatable, lipid-based nanoparticles containing at least one hydrophilic agent, wherein the agent could be an anti-cancer agent, an imaging agent, or an anti-inflammatory agent and the lipid bilayer wall of the nanoparticle is comprised of (i) a lipid bilayer comprising (a) 1,2-bis(tricosa-10,12-diynoyl)-sn-glycero-3-phosphocholine (DC8,9PC), (b) 1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-methoxy(polyethylene glycol) (DSPE–PEG) and (c) dipalmitoylphosphatidylcholine (DPPC), and (ii) a tetrapyrollic photosensitizer, 2-[1-hexyloxyethyl]-2-devinyl pyropheophorbide-a (HPPH), and wherein the encapsulated agent is released by exposure to near-infrared light.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 31, 2018.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018–19604 Filed 9–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 Advisory Eye 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 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 Advisory Eye Council.

Date: October 12, 2018.

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

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: NIH, National Eye Institute, 6700B Rockledge Drive, First Floor Conference Rooms, Bethesda, MD 20817.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, National Eye Institute, 6700B Rockledge Drive, First Floor Conference Rooms, Bethesda, MD 20817.

Contact Person: Paul A. Sheehy, Ph.D., Director, Division of Extramural Affairs, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 12300, Bethesda, MD 20892, 301–451–2020, *ps32h@nih.gov*.

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

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

Dated: *September 5, 2018.*

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–19606 Filed 9–10–18; 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 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: October 10, 2018.

Time: 10:30 a.m. to 6:00 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: Chelsea D. Boyd, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852–9834, 240–669–2081, *chelsea.boyd@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required) and NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44 Clinical Trial Required).

Date: October 10, 2018.

Time: 11:00 a.m. to 3:00 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: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program,5601 Fishers Lane, Room 3G13, Rockville, MD 20852, 240–669–5047, *bgustafson@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 5, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–19607 Filed 9–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, September 25, 2018, 10:00 a.m. to September 25, 2018, 12:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on August 15, 2018, 83 159 FR 2018–17674.

The meeting date was changed to October 9, 2018. The meeting time did not change. The meeting is closed to the public.

Dated: September 5, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–19608 Filed 9–10–18; 8:45 am]

BILLING CODE 4140–01–P