

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on December 12, 2017, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

FOR FURTHER INFORMATION CONTACT: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993-0002, 301-796-7047, Sara.Anderson@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On December 12, 2017, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Barricaid Anular Closure Device by Intrinsic Therapeutics. The proposed Indication for Use, as stated in the PMA, is as follows: The Barricaid is intended to be implanted following a limited discectomy, to prevent reherniation and the recurrence of pain or dysfunction. The Barricaid is indicated for patients with radiculopathy (with or without back pain), a posterior or posterolateral herniation, characterized by radiographic confirmation of neural compression using magnetic resonance imaging, and a large anular defect (e.g., between 4–6 mm tall and between 6–12 mm wide) post discectomy, at one level between L4 and S1.

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 Web site 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 Web site 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. Written submissions may be made to the contact person on or before December 1, 2017. 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 November 3, 2017. 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 November 9, 2017.

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

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 AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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: October 6, 2017.

Anna K. Abram,

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

[FR Doc. 2017-22174 Filed 10-12-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Derivatives of Docosahexaenoyl ethanolamide (DEA) for Neurogenesis

The invention pertains to derivatives of docosahexaenoyl ethanolamide (synaptamide or DEA) and their use in inducing neurogenesis, neurite growth, and/or synaptogenesis. As such, these DEA derivatives can be used as therapeutics for neurodegenerative diseases such as traumatic brain injury, spinal cord injury, peripheral nerve injury, stroke, multiple sclerosis, autism, Alzheimer's disease, Huntington's disease, Parkinson's disease, amyotrophic lateral sclerosis. The DEA derivatives of the invention have increased potency and hydrolysis resistance as compared to native DEA. Docosahexaenoic acid (DHA), an n-3

polyunsaturated fatty acid accumulates in the brain during development, and has been implicated in learning and memory development. DEA, a metabolite derived from DHA, also has been shown to accelerate neuronal growth and development. In vitro studies in which neural progenitor cells were treated with DEA derivatives showed an increase in the number of somatic neurons produced after differentiation.

Potential Commercial Applications

- Neurogenesis,
- Neurite growth,
- Synaptogenesis,
- Therapeutics for traumatic brain injury, spinal cord injury, peripheral nerve injury, stroke, multiple sclerosis, autism, Alzheimer's disease, Huntington's disease, Parkinson's disease, and amyotrophic lateral sclerosis.

Inventors: Erika Englund (NCATS), Juan Marugan (NCATS), Samarjit Patnaik (NCATS), Hee-Yong Kim (NIAAA).

Intellectual Property: HHS Reference No. E-070-2012/0, U.S. Provisional Patent Application 61/624,741 filed April 16, 2012 (expired), International Patent Application PCT/US2013/032333 filed March 15, 2013 (expired), U.S. Patent 9,422,308; German Patent 602013016154.2, French Patent 2847178, and UK Patent 2847178.

Licensing Contact: Michael Shmilovich, Esq. CLP; 301-435-5019; shmilovm@nih.gov.

Dated: October 5, 2017.

Michael Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2017-22146 Filed 10-12-17; 8:45 am]

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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, 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; Immune System Plasticity in Dental, Oral, and Craniofacial Diseases.

Date: November 1, 2017.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-17-263: Innovation for HIV Vaccine Discovery.

Date: November 3, 2017.

Time: 10:00 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: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Epidemiology, Ethical and Population Sciences.

Date: November 3, 2017.

Time: 2:30 p.m. to 4:30 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: Gniesha Yvonne Dinwiddie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20892, dinwiddiegy@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Systems Science and Health in the Behavioral and Social Science.

Date: November 7, 2017.

Time: 1:00 p.m. to 5:00 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: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301-451-8428, wup4@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel:

Improving Smoking Cessation in Socioeconomically Disadvantaged Populations via Scalable Interventions.

Date: November 7, 2017.

Time: 1:00 p.m. to 5:00 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: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301-496-0726, prenticekj@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: November 8-9, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301-435-1243, garciamc@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Computational, Modeling, and Biodata Management.

Date: November 8, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301-379-9351, allen.richon@nih.hhs.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pathophysiology of Neurodevelopmental Disorders.

Date: November 8, 2017.

Time: 11:00 a.m. to 2:00 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: Boris P Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301-408-9115, bsokolov@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-17-171: Cancer Tissue Engineering Collaborative Research.

Date: November 8, 2017.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

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