

Any application by Dr. Rockmore for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0302 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov>.

Dated: February 24, 2015.

Stephen Ostroff,

Director, Office of the Chief Scientist.

[FR Doc. 2015-05045 Filed 3-4-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: National Institute of Environmental Health Sciences Special Emphasis Panel, International Collaborations in Environmental Health.

Date: March 24–25, 2015.

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

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709, (Virtual Meeting).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Officer, National Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1446, eckertt1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk

Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: February 25, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05004 Filed 3-4-15; 8:45 am]

BILLING CODE 4140-01P

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-14-317 and 318: Role of the Microbiome in HIV Vaccine Responses.

Date: March 18, 2015.

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.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special R01 Review.

Date: March 25, 2015.

Time: 3:00 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: Wallace Ip, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301-435-1191, ipws@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA ES-14-010: Centers of Excellence on Environmental Health Disparities Research.

Date: March 30–April 1, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW., Washington, DC 20037.

Contact Person: Wenchu Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301-435-0681, liangw3@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: “Cloud based Data Sharing and Analysis with Privacy Protection”.

Date: March 30, 2015.

Time: 1:00 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, (Virtual Meeting).

Contact Person: Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301-996-7702, jacobsonrh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; TW-14-003: Limited Competition: Research Training for Career Development of Junior Faculty in Medical Education Partnership Initiative (MEPI) Institutions.

Date: March 31, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Hilary D. Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, (301) 594-6377, sigmonh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AIDS and AIDS Related Applications.

Date: March 31, 2015.

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

Agenda: To review and evaluate grant applications and/or proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301-451-8754, tuo@nei.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-14-280: Pilot Centers for Precision Disease Modeling.

Date: March 31, 2015.

Time: 8:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Residence Inn Washington DC, 1199 Vermont Avenue NW., Washington, DC 20005.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301-435-0229, kenneth.ryan@nih.hhs.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pregnancy/Neonatology Research.

Date: March 31, 2015.

Time: 9:00 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: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, gary.hunnicutt@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Innovative Molecular Analysis Technology.

Date: March 31, 2015.

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: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594-2414, huzhuang@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapeutics.

Date: March 31, 2015.

Time: 1:00 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: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435-3504, tothct@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Organelles' Dysfunction in Neurodegenerative Disorders.

Date: March 31, 2015.

Time: 4:00 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, (Telephone Conference Call).

Contact Person: Alessandra C. Rovescalli, Scientific Review Officer, National Institutes

of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC 7846, Bethesda, MD 20892, (301) 435-1021, rovescall@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; "Program Project: BTRC Center Review".

Date: March 31–April 2, 2015.

Time: 6:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301-435-2204, girouxcn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–14–015: Facile Methods and Technologies for Synthesis of Biomedically Relevant Carbohydrates.

Date: March 31, 2015.

Time: 12:00 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.

Contact Person: Kathryn M. Koeller, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301-435-2681, koellerk@csr.nih.gov.

(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: February 27, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05008 Filed 3–4–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0299]

Douglas M. Hargrave; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Dr. Douglas M. Hargrave (Dr. Hargrave), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Dr. Hargrave for 2 years from providing services in any capacity to a person that has an

approved or pending drug product application. FDA bases this order on a finding that Dr. Hargrave was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Hargrave's debarment, FDA has considered the relevant factors listed in the FD&C Act. Dr. Hargrave has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective March 5, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nathan Doty, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8556.

SUPPLEMENTARY INFORMATION:

I. Background

On August 11, 2009, in the U.S. District Court for the Northern District of New York, Dr. Hargrave, a physician, pled guilty to a misdemeanor under the FD&C Act, namely misbranding a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(k), 352(i)(3), 333(a)(1)) and 18 U.S.C. 2. The basis for this conviction was conduct surrounding his injection of patients seeking treatment with BOTOX/BOTOX Cosmetic (BOTOX) with a product, TRI-toxin, distributed by Toxin Research International, Inc. BOTOX is a biological product derived from Botulinum Toxin Type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans for the treatment of facial wrinkles in 1991. According to the records of the criminal proceedings, Dr. Hargrave's colleague in the same medical practice, The Plastic Surgery Group (TPSG), directed a nurse to obtain 31 vials of TRI-toxin, an unapproved drug product, which was represented by its distributor as "Botulinum Toxin Type A." Dr. Hargrave then proceeded to inject approximately 25 patients, who believed they were being injected with BOTOX, with TRI-toxin as a substitute. Dr. Hargrave is subject to debarment based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)): (1) That he