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; Member Conflict: Neurobiology of Addictions.

Date: March 11, 2015.

Time: 11:30 a.m. to 12:30 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: 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.*

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.

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

Date: March 11, 2015.

Time: 12:30 p.m. to 3:00 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.*

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts and Continuous Submissions.

Date: March 25, 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: Olga A. Tjurmina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 451–1375, *ot3d@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–13–009: Secondary Dataset Analyses in Heart, Lung, and Blood Diseases and Sleep Disorders.

Date: March 26, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Georgetown Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

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.*

(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 25, 2015.

Carolyn Baum,

Program Analyst. Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05005 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–0302]

Jeffrey L. Rockmore; 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. Jeffrey L. Rockmore, and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Rockmore 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. Rockmore 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. Rockmore's debarment, FDA has considered the relevant factors listed in the FD&C Act. Dr. Rockmore 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. Rockmore, 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. Rockmore'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. Rockmore then proceeded to inject approximately 26 patients, who believed they were being injected with BOTOX, with TRI-toxin as a substitute.

Dr. Rockmore 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 was convicted of a misdemeanor under Federal law relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. By notice to Dr. Rockmore dated November 30, 2010,