

permissible generic form of BOTOX does not create a genuine and substantial issue of fact.

In her request for a hearing, Panagotacos further emphasizes that she not only stopped using TRI-toxin upon learning that TRI was being prosecuted for conduct related to its marketing of the drug product, she also took “the extraordinary step” of coming “forward proactively to assist the investigation by providing information” before she was contacted by investigators. Indeed, the criminal record discloses that she sent a letter to the prosecutor in which she stated that TRI had convinced her to purchase and use TRI-toxin on her patients but that she had stopped using the drug and was returning the product to TRI. She also offered in the letter to provide information to the prosecutor. In the Agency’s proposal to debar, however, FDA took into account the circumstances Panagotacos now cites and considered her cooperation with government investigators as a favorable factor under section 306(c)(3)(C) of the FD&C Act. Therefore, her arguments affirming the circumstances and extent of her cooperation do not create a genuine and substantial issue of fact suitable for a hearing.

Panagotacos next challenges the manner in which FDA weighed the four factors that the Agency considered in the proposal to debar. She notes that, although FDA counted two of the four factors in her favor, it appears that the Agency did not take them into account because the proposal to debar found that she should be debarred for the maximum period of 5 years. Consistent with the proposal to debar, however, Panagotacos pled guilty to a misdemeanor under the FD&C Act for conduct related to her knowing purchase and use of an unapproved drug on her patients. She did so as a licensed physician with her own medical practice and thus held a position of authority relative to the offense of which she was convicted. The considerations in sections 306(c)(3)(A) and (B) of the FD&C Act weigh in favor of debaring Panagotacos for a maximum period of 5 years. Although the record establishes that Panagotacos took voluntary steps to mitigate the effect on the public health once she learned that there was a criminal investigation involving the company from which she purchased the unapproved drug (see section 306(c)(3)(C)), and although she appears to have no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F)), these considerations do not counter to a sufficient degree the

conduct underlying her misdemeanor conviction to warrant decreasing the period of debarment from 5 years.

III. Findings and Order

Therefore, the Chief Scientist and Deputy Commissioner for Science and Public Health, under section 306(b)(2)(B)(i) of the FD&C Act and under authority delegated to him, finds that Panagotacos has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the regulation of drugs. The Chief Scientist has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Panagotacos is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective May 9, 2012 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved, or pending, drug product application who knowingly uses the services of Panagotacos, in any capacity during her period of debarment, will be subject to civil money penalties. If Panagotacos, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Panagotacos during her period of debarment.

Any application by Panagotacos for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0475 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: April 16, 2012.

Jesse L. Goodman,
Chief Scientist and Deputy Commissioner for
Science and Public Health.

[FR Doc. 2012-11112 Filed 5-8-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Pancreatic Beta Cell Function in women with PCOS.

Date: May 24, 2012.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Tracking Adolescents after Bariatric Surgery.

Date: May 25, 2012.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, rushingp@extra.nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases

Special Emphasis Panel, NIDDK DEM Fellowship Review.

Date: June 4–5, 2012.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791,

goterrobinsonc@extra.nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, The NIDDK–KUH Fellowship Review Committee.

Date: June 13, 2012.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.nidk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Fellowships in Digestive Diseases and Nutrition.

Date: June 14, 2012.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1000 29th Street NW., Washington, DC 20007.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, DDK–C Conflicts.

Date: June 14, 2012.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1000 29th Street NW., Washington, DC 20007.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 2, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11078 Filed 5–8–12; 8:45 am]

BILLING CODE 4140–01–P

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: Hemostasis, Thrombosis and Hematology.

Date: May 30, 2012.

Time: 1:30 p.m. to 3:30 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: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community Influences on Health Behavior.

Date: June 4–5, 2012.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Hotel on Capitol Hill, 400 New Jersey Avenue NW., Washington, DC 20001.

Contact Person: Wenchi 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; RFA Panel: Research Relevant to the Family Smoking Prevention and Tobacco Control.

Date: June 5, 2012.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Hotel on Capitol Hill, 400 New Jersey Avenue NW., Washington, DC 20001.

Contact Person: Wenchi 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular Aspects of Diabetes and Obesity Study Section.

Date: June 6, 2012.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Robert Garofalo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6156, MSC 7892, Bethesda, MD 20892, 301–435–1043, *garofalors@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology B Study Section.

Date: June 7–8, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Miami, 400 SE. 2nd Avenue, Miami, FL 20892.

Contact Person: Lee Rosen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, *rosenl@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: May 3, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11182 Filed 5–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 a meeting of the Board of Scientific Counselors, National