

warning letter additionally noted that none of the products described had an approved application and that their introduction or delivery for introduction into interstate commerce violated section 301(d) of the FD&C Act. Mr. Yanikian was advised to immediately correct the violations.

In response, on April 11, 2005, Mr. Yanikian wrote a reply letter to FDA in which he stated that the products were mailed for sale outside the United States to hospitals that deal with natural health products. He further noted that his products were not intended for sale as over-the-counter or for single individuals in the United States until they were approved by FDA.

Despite knowing that he was not allowed to sell these unapproved new drugs in the United States without FDA approval, and despite his repeated representations to FDA that he was not selling his products to customers in the United States, Mr. Yanikian subsequently sold his unapproved new drug products to an undercover agent in November 2005, and again in November 2006, in violation of sections 301(d), 505(a), and 303(a)(1) of the FD&C Act and 18 U.S.C. 2(b).

As a result of his conviction, on April 3, 2012, FDA sent Mr. Yanikian a notice by certified mail proposing to debar him for 10 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA subsequently confirmed that Mr. Yanikian personally received the notice on April 11, 2012. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act that Mr. Yanikian was convicted of two counts of a misdemeanor under Federal law. In the notice, FDA found that the conduct underlying these Federal misdemeanor convictions relates to the development or approval, including the process for development or approval, of drug products and relates to the regulation of drug products under the FD&C Act and undermines the process for the regulation of drugs because the introduction and causing the introduction of unapproved new drugs into interstate commerce are prohibited by the FD&C Act. The proposal also offered Mr. Yanikian an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Yanikian failed to respond within the timeframe prescribed by regulation, and has therefore waived his opportunity for a

hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Sami Arshak Yanikian has been convicted of two counts of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Yanikian is debarred for 10 years from providing services in any capacity to a person with an approved or pending drug product application under sections 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 (see **DATES**), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Yanikian, in any capacity during Mr. Yanikian's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Yanikian provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Yanikian during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Yanikian for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0063 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.

Dated: June 15, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012-16156 Filed 6-29-12; 8:45 am]

BILLING CODE 4160-01-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; Review of Behavioral and Social HIV/AIDS Applications.

Date: July 20, 2012.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, rubertm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 12-010: NIH Competitive Revision Applications for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (R01).

Date: July 20, 2012.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, rubertm@csr.nih.gov.

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

Date: July 23, 2012.

Time: 1 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: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301-496-8551, ingrahamrh@mail.nih.gov.

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

Date: July 26–27, 2012.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

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

Date: July 30–31, 2012.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: National Computational Resource Center Review.

Date: July 30–August 1, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites At The Chevy Chase Pavilion, 4300 Military Rd. NW., Washington, DC 20015.

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301-435-1042, capraramg@mail.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: June 26, 2012.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-16049 Filed 6-29-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2012 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to the current grantee of the Suicide Prevention Resource Center (SPRC) program.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award a programmatic supplement of approximately \$800,000 (total costs) for up to one year to the current grantee of the Suicide Prevention Resource Center program. The current grantee is the Education Development Center, Inc. in Newton, Massachusetts. This is not a formal request for applications. Assistance will be provided only to the Education Development Center, Inc. based on receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM-12-011.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520C and 520A of the Public Health Service Act, as amended.

Justification: The purpose of this one-year supplement to the SPRC is twofold. The first goal is to expand and enhance the level of support provided to the National Action Alliance for Suicide Prevention. This supplement will expand future organizational development, partnerships, and collaborations to support the implementation of the *National Strategy for Suicide Prevention* (NSSP).

A second goal is to build on existing SPRC activities to support the Garrett Lee Smith (GLS) Suicide Prevention grantees in youth suicide prevention on campuses and in States and Tribes, to include:

- Providing technical assistance in youth suicide prevention to a new cohort of GLS Suicide Prevention State, Tribal, and Campus grantees;
- Developing and implementing a strategic framework to embed sustainable and coordinated, comprehensive youth suicide prevention activities in States, Tribes and colleges across the country. This should include a review of effective suicide prevention practices and programs utilized by GLS grantees that

are most likely to be sustained in States, Tribes, and colleges; and

- Developing a plan to improve inclusion of youth substance abuse treatment and prevention programming in GLS grant activities.

This cooperative agreement is financed in part with FY 2012 Prevention and Public Health Funds (PPHF-2012). SAMHSA funds only one Suicide Prevention Resource Center, SAMHSA's primary vehicle for providing technical assistance to GLS Suicide Prevention grantees and to the field. Therefore, this program supplement will be awarded to the grantee that manages the SPRC, specifically to the Education Development Center, Inc. in Newton, Massachusetts. There are no other sources with the available resources and expertise to successfully complete the tasks of this proposal. Further, it would be both inefficient and wasteful to fund a second technical assistance provider for the same group of grantees.

FOR FURTHER INFORMATION CONTACT:

Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8-1097, Rockville, MD 20857; Telephone: (240) 276-2316; Email:

cathy.friedman@samhsa.hhs.gov.

Cathy Friedman,

Public Health Analyst, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0027]

National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of an open Federal Advisory Committee Meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet on Tuesday, July 17, 2012, at the Department of Transportation's National Highway Institute, 1310 North Courthouse Road, Suite 300, Virginia Room, Arlington, VA 22201. The meeting will be open to the public.

DATES: The NIAC will meet Tuesday, July 17, 2012, from 1:30 p.m. to 4:30 p.m. The meeting may close early if the committee has completed its business. For additional information, please consult the NIAC Web site, www.dhs.gov/NIAC, or contact the NIAC Secretariat by phone at (703) 235-2888 or by email at NIAC@dhs.gov.