

Having considered the conduct that forms the basis of his conviction and the fact that this conduct occurred in the course of his profession and showed a disregard for the obligations of his profession, FDA finds that Mr. Santos has demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if he were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. Therefore, FDA has reason to believe that, if Mr. Santos were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products.

The proposal offered Mr. Santos 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. The proposal was received on April 16, 2014. Mr. Santos failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Armando Santos has been convicted of seven counts of felonies under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters, and, on the basis of these convictions and other information, finds that Mr. Santos has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products.

As a result of the foregoing finding, Armando Santos is debarred for 12 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), 306(c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 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. Santos, in any capacity during his 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. Santos 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 from Mr. Santos during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Santos for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2013-N-1106 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.

Any application by Mr. Santos for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2013-N-1106 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: November 4, 2014.

Armando Zamora,
Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of an advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 2014, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: BRUDAC@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 <http://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.

Agenda: The meeting will be closed to permit discussion of whether FDA should permit further clinical development of an existing investigational drug product, which will include the review of trade secret and/or confidential information.

Procedure: On December 18, 2014, from 8:30 a.m. to 9:45 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before December 4, 2014. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.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 24, 2014. 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 25, 2014.

Closed Committee Deliberations: On December 18, 2014, from 9:45 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will review data from an investigational new drug (IND) application. Information regarding pending applications, including active INDs, is generally not publicly available under applicable laws and regulations, including 21 CFR 312.120 and 314.430.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt 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 <http://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: November 4, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-26582 Filed 11-7-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 contract proposals 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 and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI T32 Institutional Training Grants.

Date: December 2, 2014.

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, Room 7189, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301-443-8784, constantsl@nhlbi.nih.gov.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 5, 2014.

Time: 8:00 a.m. to 3:00 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: Jeffrey H. Hurst, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301-435-0303, hurstj@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Multi-Ethnic Study of Atherosclerosis.

Date: December 5, 2014.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, 6701 Rockledge Drive, Room 7178, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and

Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725, johnsonwj@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 4, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID SEP for Career Development Grant Applications.

Date: December 2, 2014.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 5601 Fishers Lane, Rockville, MD 20892982 (Telephone Conference Call).

Contact Person: Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer Scientific Review Program Division of Extramural Activities, National Institutes of Health/ NIAID 6700B Rockledge Drive, MSC 7616 Bethesda, MD 20892-7616, 301-402-9523, zhuqing.li@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: December 3-4, 2014.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: