

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. On August 18, 2023, Dr. Valdes was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Southern District of Florida-Miami Division, when the court entered judgment against him, after a jury trial, for one count of False Statements in violation of 18 U.S.C. 1001(a)(2).

The underlying facts supporting the conviction are as follows: As contained in the Indictment, entered into the docket on February 24, 2021, and as contained in the Acceptance of Responsibility signed by Dr. Valdes and entered into the docket on July 31, 2023, Dr. Valdes was a Florida licensed medical doctor. From in or about September 2013 and continuing through in or about May 2016, Dr. Valdes was the principal investigator responsible for conducting clinical research trials at Tellus Clinical Research, Inc. (Tellus). Tellus was a medical research clinic located in Miami, Florida, that conducted clinical trials on behalf of pharmaceutical company sponsors. Among the clinical research trials conducted by Tellus were two studies of an investigational drug intended to treat irritable bowel syndrome in subjects (collectively, IBS trials). On or about April 6, 2016, Dr. Valdes was interviewed by an FDA investigator. During that interview, Dr. Valdes

knowingly and willfully made a false statement and/or representation; namely, that Dr. Valdes personally performed a physical examination on each subject of the IBS trials for which his signature appeared on the subject's case history form, when in fact he had not conducted such a physical examination on each subject.

As a result of this conviction, FDA sent Dr. Valdes by certified mail on December 4, 2023, a notice proposing to debar him permanently from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Dr. Valdes was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. The proposal also offered Dr. Valdes 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Dr. Valdes received the proposal on December 8, 2023. Dr. Valdes did not request a hearing 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Dr. Valdes has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Valdes is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). 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 Dr. Valdes 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 Dr. Valdes

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 application from Dr. Valdes during his period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a "drug product" is defined as a drug subject to regulation 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) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-06242 Filed 3-22-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that an in-person meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public as well as streamed live on [hhs.gov/live](https://www.hhs.gov/live). A pre-registered public comment and innovation spotlight session will be held during the meeting. Pre-registration is required for members of the public who wish to present their comments or innovations live during the meeting. Individuals who wish to send in their written public comment should send an email to CARB@hhs.gov. Registration information is available on the website <http://www.hhs.gov/paccarb> and must be completed by May 16, 2024, to attend the May 21-22, 2024, public meeting or by May 14, 2024, to provide live comments at the meeting. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/>

paccarb on the Upcoming Meetings page.

DATES: The meeting is scheduled to be held on May 21–22, 2024, from 9 a.m. to 4 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at <http://www.hhs.gov/paccarb> when this information becomes available. Pre-registration for attending the meeting is strongly suggested and should be completed no later than May 16, 2024.

ADDRESSES: The meeting will be held in-person at the Westin Tyson's Corner, 7801 Leesburg Pike, Falls Church, VA, 22043. The meeting will also be live streamed and can be accessed through a live webcast on the day of the meeting. Additional instructions regarding attending this meeting virtually will be posted at least one week prior to the meeting at: <https://www.hhs.gov/paccarb>.

FOR FURTHER INFORMATION CONTACT:

Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Rockville, MD 20852. Phone: 202–746–1512; Email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for

combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The focus of the May 21–22, 2024, meeting will be to deliberate and vote on the Global Antimicrobial Resistance Working Group report to the Secretary of Health and Human Services. The remainder of the public meeting will include updates on AMR in conflict zones, the environment, and the voice of the patient. The meeting agenda will be posted on the PACCARB website at <http://www.hhs.gov/paccarb> when it has been finalized. All agenda items are tentative and subject to change.

Instructions regarding attending the meeting virtually will be posted at least one week prior to the meeting at: <http://www.hhs.gov/paccarb>. Members of the public will have the opportunity to provide comments during the May meeting by pre-registering online at <https://www.hhs.gov/paccarb>; pre-registration is required for participation in this session with limited spots available. Written public comments can also be emailed to CARB@hhs.gov by midnight May 14, 2024, and should be limited to no more than one page. All public comments received prior to May 14, 2024, will be provided to the PACCARB members. Additionally, companies or organizations working to combat antimicrobial resistance may share their innovation during the May meeting by pre-registering to speak during the meeting's Innovation Spotlight. Pre-registration online at <http://www.hhs.gov/paccarb> is required for participation in this session, and limited spots are available.

Dated: March 14, 2024.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2024–06157 Filed 3–22–24; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections; Correction

AGENCY: Office of the Assistant Secretary for Health, Office for Infectious Disease and HIV/AIDS Policy, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: HHS published a document in the *Federal Register* of March 12, 2024, announcing the Presidential Advisory Council on HIV/AIDS (PACHA) 80th full council meeting. Due to unforeseen circumstances, there has been an update in meeting location.

FOR FURTHER INFORMATION CONTACT: Caroline Talev, caroline.talev@hhs.gov, (202) 795–7622.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of March 12, 2024, in FR Doc. 2024–05183, on page 17859, third column, correct the **ADDRESSES** caption to read:

ADDRESSES: The public meeting will now be held at the UT School of Public Health, 1200 Pressler Street in Houston, Texas 77030. To attend the meeting virtually, please visit www.hhs.gov/live.

Dated: March 20, 2024.

Caroline Talev,

Senior Management Analyst, Office of Infectious Disease and HIV/AIDS Policy, Alternate Designated Federal Officer, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2024–06362 Filed 3–21–24; 4:15 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as