completing the elements must be somewhat broad to account for differences in the goals, objectives, and activities across the programs.

Comment Two: Request confirmation that the grantee will be responsible for submitting a comprehensive PPR each reporting period to ACL (as opposed to having grantees' subcontractors *each* submit individual reports to ACL).

ACL response: Although grantees could work with their subcontractors to gather information to complete their PPR, grantees would be responsible for submitting a comprehensive PPR to ACL for the specified reporting period.

Estimated Program Burden

ACL estimated total annual burden for this generic IC is 50,223.60 hours. This estimate is based on the current number of grantees for the OAA and EJA programs below, consideration of the program performance information necessary to ensure adequate progress toward program goals, and previous experience with program performance reporting.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Formula Grantees	112	1	70.3	7,873.60
Tribal Formula Grantees	282	1	60	16,920
Competitive Grantees	1,189	2	10	23,780
Veteran Organization Competitive Grantees	275	12	0.5	1,650
Total Annual Hours				50,223.60

Dated: March 19, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–06208 Filed 3–22–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3615]

Martin Valdes: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Martin Valdes, M.D., 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. Valdes was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Dr. Valdes was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of January 7, 2023 (30 days after receipt of the notice), Dr. Valdes had not responded. Dr. Valdes's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 25, 2024.

ADDRESSES: Any application by Dr. Valdes for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–3615. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*

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]

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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.* 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/*