Dated: June 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2687]

Daylen Diaz: 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 Daylen Diaz 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 Daylen Diaz 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. Daylen Diaz was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of February 26, 2023 (30 days after receipt of the notice), Ms. Diaz had not responded. Ms. Diaz' failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable June 21, 2023.

ADDRESSES: Any application by Daylen Diaz 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 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–2022–N–2687. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' 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, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) 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 under the FD&C Act. On October 18, 2022, Ms. Diaz 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 accepted her plea of guilty and entered judgment against her for one count of conspiracy to commit mail fraud and wire fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: As contained in the Information, entered into the docket on March 16, 2021, and the Factual Proffer in support of Ms. Diaz' guilty plea, entered into the docket on August 8, 2022, both from her case, Ms. Diaz was a research assistant and assistant study coordinator employed at Tellus Clinical Research, Inc. (Tellus). Tellus was a medical research clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. Sponsor 1 was a drug manufacturer that developed drugs for commercial distribution in the United States. Contract Research Organization 1 (CRO 1) was an organization that hired clinical investigators and managed clinical trials for sponsors. On or about December 23, 2013, CRO 1 entered into a contract with Tellus and one of Ms.

Diaz' co-conspirators in which Tellus and Ms. Diaz' co-conspirator agreed to serve as study site and clinical investigator, respectively, for a clinical trial initiated by sponsor 1 (IBS study 1) designed to evaluate a drug intended to treat irritable bowel syndrome in female patients. On or about September 5, 2014, CRO 1 entered into a contract to conduct a second clinical trial initiated by sponsor 1 (IBS study 2), which evaluated the same drug in the same population over the course of 52 weeks. Sponsor 2 was a drug manufacturer that developed drugs for commercial distribution in the United States. On or about January 5, 2015, sponsor 2 entered into a contract with Tellus and one of Ms. Diaz' co-conspirators in which they agreed to serve as study site and clinical investigator, respectively, for a clinical trial initiated by sponsor 2 (the diabetes study). The diabetes study was designed to evaluate the safety and efficacy of an experimental injectable drug intended to treat subjects with kidney damage from diabetes.

Ms. Diaz served as an assistant study coordinator for IBS study 1, IBS study 2, and the diabetes study (collectively, the ''Studies''). As an assistant study coordinator for the Studies, Ms. Diaz was responsible for administering procedures to subjects in the Studies and preparing honest and accurate written records, including records known as ''case histories,'' describing the participation of subjects in the Studies. Ms. Diaz along with her co-conspirators caused false information to be entered in subject case histories to make it appear that subjects had, among other things, satisfied the eligibility criteria to participate in the Studies, provided informed consent to participate in the Studies, received physical examinations, received or been administered the investigational drug for the Studies, and received payments for visits to Tellus when, in truth and in fact, and as Ms. Diaz well knew, such events had not occurred. For example, on or about April 6, 2015, Ms. Diaz initialed case history documentation for a study subject, K.L., falsely representing that K.L. was a study subject participating in IBS study 2, that K.L. visited Tellus, that Ms. Diaz obtained K.L.'s urine and blood for analysis as required by the protocol governing IBS study 2, that Ms. Diaz had performed an electrocardiogram on K.L., and that Ms. Diaz dispensed IBS study 2 medication to K.L. In truth and in fact, Ms. Diaz knew that K.L. was not participating in IBS study 2 and these representations were false. In addition, Ms. Diaz knew that IBS study 2 subjects were required to make daily phone calls to an ''e-diary'' (a toll-free number maintained by a third party) and report their personal experience with the IBS study 2 drug. In furtherance of the conspiracy, Ms. Diaz along with her co-conspirators knowingly placed telephone calls to the e-diary system, using the subjects' individual PIN numbers, for purposes of reporting fabricated data on behalf of IBS study 2 subjects. Ms. Diaz along with her co-conspirators placed these fraudulent telephone calls on behalf of more than 10 subjects in IBS study 2.

Ms. Diaz also participated in falsifying and fabricating data in connection with the diabetes study. For example, on May 13, 2015, Ms. Diaz initialed case history documentation for subject S.D., falsely representing that S.D. has visited Tellus, that Ms. Diaz trained S.D. on the appropriate handling of the investigational drug, and that S.D. self-administered the study drug by injection. In truth and in fact, Ms. Diaz knew that S.D. had not visited Tellus or received the study drug, and these representations were false. Ms. Diaz, along with her co-conspirators, also enrolled subjects in the diabetes study who did not meet the eligibility criteria or participate in the trial. Further, Ms. Diaz observed her co-conspirator dispense diabetes study medication into the garbage, but falsely represent in case history documentation that the medication had been administered to study subject S.D.

As a result of this conviction, FDA sent Ms. Diaz by certified mail on January 20, 2023, a notice proposing to permanently debar her 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 Ms. Diaz 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 under the FD&C Act. The proposal also offered Ms. Diaz an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her 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. Ms. Diaz received the proposal on January 27, 2023. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her 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 Ms. Diaz 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, Ms. Diaz 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 306(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 Ms. Diaz in any capacity during her 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 Ms. Diaz provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Diaz during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))). Note that, for purposes of sections 306 and 307 of the FD&C Act (21 U.S.C. 335a and 335b), a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act (21 U.S.C. 355, 360b, 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: June 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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