under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 040065	Prednisolone Sodium Phosphate solution/drops, Equivalent to (EQ) 0.11% phosphate.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 202031	Gemcitabine Hydrochloride (HCl) injectable, EQ 200 milligrams (mg) base/vial and EQ 1 gram (g) base/vial.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 202562	Dactinomycin injectable, 0.5 mg/vial	Do.
ANDA 213390	Vigabatrin for solution, 500 mg/packet	KubsTech Inc., U.S. Agent for Propel Pharma Corp, 22 Tanner Dr., Princeton, NJ 08540.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of April 14, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on April 14, 2025 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04107 Filed 3–13–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4938]

Bernardo Garmendia; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Bernardo Garmendia, also known as Bernardo Germendia, (Garmendia) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Garmendia 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 Garmendia 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. FDA provided notice to Garmendia of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Garmendia submitted a request for hearing but failed to file with the Agency information and analyses sufficient to create a basis for a hearing.

DATES: The order is applicable March 14, 2025.

ADDRESSES: Any application for termination of debarment by Garmendia under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) 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

Submit written/paper submissions as follows:

- *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–4938. An application will be placed in the docket and, unless 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: Karen Fikes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 1, Rm. 4232, Silver Spring, MD 20993, 301–796–9603.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act mandates permanent debarment 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 for development or approval, of any drug product. On June 20, 2023, following a guilty plea, the U.S. District Court for the Southern District of Florida-Miami Division entered a judgment against Garmendia for one count of conspiracy to commit wire fraud in violation of 18 U.S.C. 1349.

Garmendia's conviction is based upon conduct from on or about September 2015 through on or about March 2018, committed in his capacity at AMB Research Center, Inc. (AMB Research), a medical clinic that conducted clinical trials of new drugs for pharmaceutical companies and sponsors. Garmendia was co-owner of AMB Research and served as vice president and back-up study coordinator. Garmendia and his co-conspirators did willfully, that is, with the intent to further the object of the conspiracy, and knowingly combine, conspire, confederate, and agree with each other to commit wire fraud, that is: to knowingly, and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing the scheme and artifice, did transmit and cause to be transmitted by means of wire communication and interstate and foreign commerce, certain writings, signs, signals, pictures, and sounds, in violation of 18 U.S.C. 1349.

Specifically, AMB Research entered into a clinical trial agreement with a contract research organization to lead a pharmaceutical company's clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea (CDAD clinical trial). Garmendia and his co-conspirators conspired to unlawfully enrich themselves by, among other things, securing contracts to conduct the CDAD clinical trial; fabricating and falsifying documents, study data, and other items related to the CDAD clinical trial to obtain payments and inflate the payments due and owing to the conspirators under the clinical trial agreement; receiving payment for the CDAD clinical trial by making material false and fraudulent representations; and using the fraudulently obtained funds for personal use and benefit, the use and benefit of others, and to further the conspiracy. Garmendia's conduct included direct involvement in falsifying and fabricating study documents. In addition, Garmendia transported study documents to the principal investigator for purposes of obtaining a signature for the CDAD clinical trial at AMB Research. Garmendia received $80,027.44 in proceeds from payments made to AMB Research for the CDAD clinical trial.

Garmendia is subject to permanent debarment based on a finding by the Office of Regulatory Affairs (ORA), under section 306(a)(2)(A) of the FD&C Act, that he 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. By letter dated January 8, 2024, ORA informed Garmendia of the proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. The letter also offered Garmendia an opportunity to request a hearing, providing 30 days from the date of Garmendia's receipt of the letter in which to file the request and 60 days from the date of Garmendia's receipt of the letter to support any hearing request with information sufficient to justify a hearing. In a letter dated February 6, 2024, Garmendia requested a hearing. More than 60 days have passed from the date Garmendia received ORA's letter, and Garmendia has not filed any additional information to justify a hearing.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director, Office of Scientific Integrity (OSI Director), has considered Garmendia's request for a hearing. Hearings will be granted upon a showing of a genuine and substantial issue of fact; not on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged, even if accurate (see 21 CFR 12.24(b)). Garmendia has failed to present any arguments or evidence raising a genuine and substantial issue of fact to support his hearing request. Accordingly, the OSI Director denies Garmendia's request for a hearing.

II. Findings and Order

Therefore, the OSI Director, under section 306(a)(2)(A) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that Garmendia has been 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.

As a result of the foregoing findings, Garmendia is permanently debarred 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 March 14, 2025 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Garmendia, in any capacity during his period of 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 Garmendia, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, 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 Garmendia during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: March 7, 2025.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2025–04117 Filed 3–13–25; 8:45 am]

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