will provide a response within 2 business days.

Dated: June 5, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–12248 Filed 6–7–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2688]

Analay Rico: 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 Analay Rico 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 Ms. Rico 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. Analay Rico 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 March 3, 2023 (30 days after receipt of the notice), Ms. Rico had not responded. Ms. Rico's 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 8, 2023.

ADDRESSES: Any application by Analay Rico 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–2688. 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. Rico 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. Rico's guilty plea, entered into the docket on August 8, 2022, both from her case, Ms. Rico was a clinical research coordinator employed at Tellus Clinical Research, Inc. (Tellus). Tellus was a medical research clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. Among the clinical research trials conducted by Tellus were two different studies of an investigational drug intended to treat opioid dependency sponsored by

Sponsor 1 and managed by Contract Research Organization (CRO) 1 (the opioid dependency trials); two studies of an investigational drug intended to treat irritable bowel syndrome in female patients sponsored by Sponsor 2 and by CRO 2 (the IBS trials); and one study of an investigational injectable drug intended to treat diabetic nephropathy sponsored by Sponsor 3 and managed by CRO 3 (the diabetes trial). One of Ms. Rico's co-conspirators was the clinical investigator hired by the sponsors and/or the CROs for each of these five studies (the Studies). Ms. Rico served as a study coordinator for the Studies. In that role, she 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 the subjects in the Studies.

Ms. Rico and her co-conspirators caused false information to be entered in subject case histories to make it appear that subjects had, among other things, satisfied 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 for the Studies when, in truth and in fact, Ms. Rico knew that such events had not occurred.

For example, on or about March 12, 2014, Ms. Rico initialed case history documentation in the first Opioid dependency study for subject, N.F., the mother of one of Ms. Rico's co-conspirators, wherein Ms. Rico indicated falsely that N.F. was eligible to participate in the study, provided a urine sample that tested positive for opiates and buprenorphine, received study medication from one of Ms. Rico's co-conspirators, and that another co-conspirator witnessed N.F. receive the study medication. Ms. Rico knew that N.F. was not eligible to participate in the study, had not provided a urine sample that tested positive for opiates or buprenorphine, and had not received any study medication, and these representations were false. In addition, on or about June 9, 2015, Ms. Rico initialed case history documentation for subject G.C., falsely representing that G.C. was a study subject participating in the second IBS study, that G.C. had visited Tellus, that Ms. Rico had obtained G.C.'s urine and blood for analysis as required by the protocol governing IBS Study 2, that Ms. Rico had performed an electrocardiogram on G.C., and that Ms. Rico had dispensed IBS Study 2 medication to G.C. In truth, Ms. Rico knew that G.C. was not participating in the second IBS study and that these representations were false.

Furthermore, Ms. Rico knew that subjects in the IBS trials were required to make daily phone calls to an ''e-diary'' system (a toll-free number maintained by a third party) and report their personal experience with the study drug. In furtherance of the conspiracy, Ms. Rico and 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 subjects in the IBS studies. Ms. Rico and her co-conspirators placed these fraudulent telephone calls on behalf of more than 10 subjects in the IBS trials. Ms. Rico also participated in falsifying and fabricating data in connection with the diabetes trial. For example, on or about November 20, 2015, Ms. Rico initialed case history documentation for subject S.D. in the diabetes trial, falsely representing that she witnessed one of her co-conspirators dispense the study drug to subject S.D. at Tellus. In truth, Ms. Rico knew these representations were false. For her work as a clinical research coordinator at Tellus and for her participation in the conspiracy, Ms. Rico received approximately $240,000.

In 2016, FDA conducted a regulatory inspection of Tellus relating to allegations of fraudulent and fabricated data submitted in the IBS trials. For the purpose of preventing FDA investigators from learning the truth about fabricated data at Tellus, Ms. Rico contacted certain individuals enrolled as subjects in the IBS trials and instructed them to lie to FDA investigators regarding their participation in the IBS trials. Among other things, Ms. Rico instructed subjects to falsely represent to FDA investigators that they had participated in an IBS study at Tellus, received physical examinations and electrocardiograms, and met with a doctor who matched the physical description of one of Ms. Rico's co-conspirators.

As a result of this conviction, FDA sent Ms. Rico 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. Rico 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. Rico 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. Rico received the proposal on February 1, 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. Rico 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. Rico 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. Rico 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. Rico 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). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Rico during her 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, 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 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12249 Filed 6–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–0120]

Determination That BUSPAR (Buspirone Hydrochloride) Capsules, 5 Milligrams, 7.5 Milligrams, 10 Milligrams, and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that BUSPAR (buspirone hydrochloride) capsules, 5 milligrams (mg), 7.5 mg, 10 mg, and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA) for buspirone hydrochloride capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 240–402–4318, *Caitlin.Callahan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, are the subject of NDA 021190, held by Bristol Myers Squibb Co., and initially approved on December 20, 2000. BUSPAR is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety.

In correspondence dated December 28, 2012, Bristol Myers Squibb Co. requested withdrawal of NDA 021190 for BUSPAR (buspirone hydrochloride). In the **Federal Register** of December 5, 2014 (79 FR 72186), FDA announced that it was withdrawing approval of NDA 021190, effective January 5, 2015.

Epic Pharma, LLC submitted a citizen petition dated January 10, 2023 (Docket No. FDA–2023–P–0120), under 21 CFR 10.30, requesting that the Agency determine whether BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12247 Filed 6–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2136]

Advisory Committee; Antimicrobial Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2024, expiration date.

[1] FDA previously determined that BUSPAR (buspirone hydrochloride) tablets, 5 mg, 10 mg, 15 mg, and 30 mg, approved under NDA 018731 and held by Bristol Myers Squibb Co. Pharmaceutical Research Institute, were not withdrawn from sale for reasons of safety or effectiveness. See 75 FR 64310 (October 19, 2010), 81 FR 61220 (September 6, 2016).