or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 30, 2024.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Head of Bank Applications) 33 Liberty Street, New York, NY 10045–0001. Comments can also be sent electronically to *comments.applications@ny.frb.org:*

1. *The D'Angelo Family Trust, with George D'Angelo and Dahlia D'Angelo, as trustees, all of Old Greenwich, Connecticut;* to acquire voting shares of First Greenwich Financial, Inc., and thereby indirectly acquire voting shares of First Bank of Greenwich, both of Cos Cob, Connecticut.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–18309 Filed 8–14–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3028]

Cubist Pharmaceuticals LLC; Withdrawal of Approval of a New Drug Application for ENTEREG (Alvimopan) Capsules, 12 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for ENTEREG (alvimopan) Capsules, 12 milligrams (mg), held by Cubist Pharmaceuticals LLC, 126 East Lincoln Ave., Rahway, NJ 07065 (Cubist). Cubist notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of September 16, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Cubist has informed FDA that ENTEREG (alvimopan) Capsules, 12 mg is no longer marketed and has requested that FDA withdraw approval of NDA 021775 under the process in § 314.150(c) (21 CFR 314.150(c)). Cubist has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of NDA 021775, and all amendments and supplements thereto, is hereby withdrawn as of September 16, 2024. Approval of the entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of ENTEREG (alvimopan) Capsules, 12 mg without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any ENTEREG (alvimopan) Capsules, 12 mg, that is in inventory on September 16, 2024 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: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18269 Filed 8–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1090]

Ryan Stabile: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Ryan Stabile for a period of 15 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Stabile was convicted of three felony counts under Federal law: one count of conspiracy and two counts of introduction of misbranded drugs with intent to defraud/mislead. The factual basis supporting Mr. Stabile's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Stabile was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of June 7, 2024 (30 days after receipt of the notice), Mr. Stabile had not responded. Mr. Stabile's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable August 15, 2024.

ADDRESSES: Any application by Mr. Stabile for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) 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–2024–N–1090. 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, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On February 14, 2024, Mr. Stabile was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the District of Massachusetts when the court accepted his plea of guilty and entered judgment against him for the offenses of conspiracy in violation of 18 U.S.C. 371, and two counts of introduction of misbranded drugs with intent to defraud/mislead in violation of 21 U.S.C 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows: As contained in the indictment and plea agreement, Mr. Stabile owned the companies Ultra Vulgar Media, LLC and Supplements for Work (S4W). S4W sold nootropics, a class of drugs and supplements claiming to enhance mood and cognitive functioning. Tianeptine, when sold as a mood enhancer or as a nootropic, or when otherwise intended to treat or mitigate a disease or to affect the structure or any function of the human body, is a drug within the meaning of section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)), and a prescription drug within the meaning of section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). A drug is misbranded under section 503(b)(1) of the FD&C Act if it is a prescription drug dispensed without the prescription of a practitioner licensed by law to administer such drugs. A drug is also misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if its labeling does not bear adequate directions for use.

Mr. Stabile and S4W operated several websites where Mr. Stabile knowingly sold various forms of tianeptine, which were not approved by the FDA. Although Mr. Stabile's websites displayed statements that the tianeptine being sold was for research purposes only, and not intended for human consumption, Mr. Stabile sold it to customers for those customers' personal use. Mr. Stabile sold tianeptine without requiring the prescription of a practitioner licensed by law to administer prescription drugs. In addition, the tianeptine Mr. Stabile sold was not labeled with adequate directions for use. Mr. Stabile and his coconspirators smuggled the tianeptine into the United States from a supplier in China and had the supplier send shipments to Mr. Stabile or his coconspirators at several post office boxes Mr. Stabile controlled. Mr. Stabile and his coconspirators gave his supplier in China instructions on steps they could take to mislabel packages of tianeptine in order to evade U.S. Customs and Border Protection (CBP) detection. Through Mr. Stabile's illegal smuggling and distribution of tianeptine, he earned at least $1,833,922.13.

Beginning in December 2017, some of the packages of tianeptine Mr. Stabile and his coconspirators imported were intercepted and seized by CBP. In an effort to have CBP release the packages, Mr. Stabile and his coconspirators filed a petition to have a package of tianeptine released, which falsely represented that the package was mislabeled and that the tianeptine was for research and development only.

FDA sent Mr. Stabile, by certified mail, on May 3, 2024, a notice proposing to debar him for a 15-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Stabile's felony convictions under Federal law for conspiracy in violation of 18 U.S.C. 371, and two counts of introduction of misbranded drugs with intent to defraud/mislead in violation of sections 301(a) and 303(a)(2) of the FD&C Act, were for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Stabile illegally imported tianeptine from China and then distributed tianeptine in

interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Stabile's offense and concluded that the offense warranted the imposition of a 15-year period of debarment.

The proposal informed Mr. Stabile of the proposed debarment and offered him 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 a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Stabile received the proposal and notice of opportunity for a hearing on May 8, 2024. Mr. Stabile failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived 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(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Ryan Stabile has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 15 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Stabile is debarred for a period of 15 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Stabile is a prohibited act.

Dated: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18268 Filed 8–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0187, FDA–2024–E–0188, FDA–2024–E–0189, FDA–2024–E–0190, and FDA–2024–E–0191]

Determination of Regulatory Review Period for Purposes of Patent Extension; MIEBO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MIEBO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 15, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 11, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2024–E–0187, FDA–2024–E–0188, FDA–2024–E–0189, FDA–2024–E–0190, and FDA–2024–E–0191 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; MIEBO.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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