period prior to filing for bankruptcy from high unexpected outflows of deposits and increased liquidity requirements from counterparties. Though the immediate failure event may be liquidity-related and associated with a lack of market confidence in the financial condition of the covered company or its material legal entity subsidiaries prior to the final recognition of losses, the demonstration and description of material financial distress may also include depletion of capital. Therefore, the Plan should also consider the likelihood of the depletion of capital.

8. The firm should not assume any waivers of section 23A or 23B of the Federal Reserve Act in connection with the actions proposed to be taken prior to or in resolution.

9. The Plan should support any assumptions that the firm will have access to the Discount Window and/or other borrowings during the period immediately prior to entering bankruptcy. To the extent the firm assumes use of the Discount Window, Federal Home Loan Banks, and/or other borrowings, the Plan should support that assumption with a discussion of the operational testing conducted to facilitate access in a stress environment, placement of collateral, and the amount of funding accessible to the firm. The firm may assume that its depository institutions will have access to the Discount Window only for a few days after the point of failure to facilitate orderly resolution. However, the firm should not assume its subsidiary depository institutions will have access to the Discount Window while critically undercapitalized, in FDIC receivership, or operating as a bridge bank, nor should it assume any lending from a Federal Reserve credit facility to a non-bank affiliate.

Financial Statements and Projections. The Plan should include the actual balance sheet for each material entity and the consolidating balance sheet adjustments between material entities as well as pro forma balance sheets for each material entity at the point of failure and at key junctures in the execution of the resolution strategy. It should also include statements of projected sources and uses of funds for the interim periods. The pro forma financial statements and accompanying notes in the Plan should clearly evidence the failure trigger event; the Plan's assumptions; and any transactions that are critical to the execution of the Plan's preferred strategy, such as recapitalizations, the creation of new legal entities, transfers of assets, and asset sales and unwinds.

Material Entities. Material entities should encompass those entities, including foreign offices and branches, which are significant to the maintenance of an identified critical operation or core business line. If the abrupt disruption or cessation of a core business line might have systemic consequences to U.S. financial stability, the entities essential to the continuation of such core business line should be considered for material entity designation. Material entities should include the following types of entities:

1. Any U.S.-based or non-U.S. affiliates, including any branches, that are significant to the activities of an identified critical operation.

2. Subsidiaries or foreign offices whose provision or support of global treasury operations, funding, or liquidity activities (inclusive of intercompany transactions) is significant to the activities of an identified critical operation.

3. Subsidiaries or foreign offices that provide material operational support in resolution (key personnel, information technology, data centers, real estate or other shared services) to the activities of an identified critical operation.

4. Subsidiaries or foreign offices that are engaged in derivatives booking activity that is significant to the activities of an identified critical operation, including those that conduct either the internal hedge side or the client-facing side of a transaction.

5. Subsidiaries or foreign offices engaged in asset custody or asset management that are significant to the activities of an identified critical operation.

6. Subsidiaries or foreign offices holding licenses or memberships in clearinghouses, exchanges, or other FMUs that are significant to the activities of an identified critical operation.

For each material entity (including a branch), the Plan should enumerate, on a jurisdiction-by-jurisdiction basis, the specific mandatory and discretionary actions or forbearances that regulatory and resolution authorities would take during resolution, including any regulatory filings and notifications that would be required as part of the preferred strategy, and explain how the Plan addresses the actions and forbearances. The Plan should describe the consequences for the covered company's resolution strategy if specific actions in a non-U.S. jurisdiction were not taken, delayed, or forgone, as relevant.

IX. Public Section

SPOE & MPOE

The purpose of the public section is to inform the public's understanding of the firm's resolution strategy and how it works.

The public section should discuss the steps that the firm is taking to improve resolvability under the U.S. Bankruptcy Code. The public section should provide background information on each material entity and should be enhanced by including the firm's rationale for designating material entities. The public section should also discuss, at a high level, the firm's intra-group financial and operational interconnectedness (including the types of guarantees or support obligations in place that could impact the execution of the firm's strategy).

The discussion of strategy in the public section should broadly explain how the firm has addressed any deficiencies, shortcomings, and other key vulnerabilities that the agencies have identified in prior plan submissions. For each material entity, it should be clear how the strategy provides for continuity, transfer, or orderly wind-down of the entity and its operations. There should also be a description of the resulting organization upon completion of the resolution process.

The public section may note that the Plan is not binding on a bankruptcy court or other resolution authority and that the proposed failure scenario and associated assumptions are hypothetical and do not necessarily reflect an event or events to which the firm is or may become subject.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on August 9, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–18191 Filed 8–14–24; 8:45 am]

BILLING CODE 6210–01–P; 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank

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]

BILLING CODE P

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