

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-P-0101]

Determination That COREG CR (Carvedilol Phosphate) Extended-Release Capsules, 10 Milligrams, 20 Milligrams, 40 Milligrams, and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that COREG CR (carvedilol phosphate) extended-release capsules, 10 milligrams (mg), 20 mg, 40 mg, and 80 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 mg, are the subject of NDA 022012, held by Waylis Therapeutics LLC, and initially approved on October 20, 2006. COREG CR is an alpha-/beta-adrenergic blocking agent indicated for the treatment of mild to severe chronic heart failure, left ventricular dysfunction following myocardial infarction in clinically stable patients, and hypertension.

COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Amata Labs Ltd. submitted a citizen petition dated January 9, 2025 (Docket No. FDA-2025-P-0101), under 21 CFR 10.30, requesting that the Agency determine whether COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 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 COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 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 these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list COREG CR (carvedilol phosphate) extended-release capsules, 10 mg, 20 mg, 40 mg, and 80 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0128]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments." Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct

is on FDA's website entitled "Postmarketing Requirements and Commitments: Reports" (<https://www.fda.gov/drugs/postmarketing-requirements-and-commitments-introduction/postmarketing-requirements-and-commitments-reports>).

FOR FURTHER INFORMATION CONTACT:

Lauren Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6424, Silver Spring, MD 20993-0002, 301-796-0700; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants are required to, or have committed to, conduct and for which annual status reports have been submitted. Under the regulations governing postmarketing studies at 21 CFR 314.81(b)(2)(vii) and 601.70, applicants of approved drug products and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application, as applicable. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial "otherwise undertaken . . . to investigate a safety issue . . ."

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval¹ until the PMR/PMC is

¹ An applicant must submit an annual status report on the progress of each open PMR/PMC

completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2023 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments" for fiscal year 2023. Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year 2023 (*i.e.*, as of September 30, 2023). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) the number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year (FY) of establishment² (FY2017 to FY2023) for PMRs and PMCs open at the end of FY2023, or those closed within FY2023. Additional information about PMRs/PMCs is provided on FDA's website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarketing-requirements-and-commitments-introduction>.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

² The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5281]

Evan Asher Field: 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 (FD&C Act) debarring Evan Asher Field for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Field was convicted of one felony count under Federal law. The factual basis supporting Mr. Field's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Field 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 April 25, 2024 (30 days after receipt of the notice), Mr. Field had not responded. Mr. Field'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 May 30, 2025.

ADDRESSES: Any application by Mr. Field 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