DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5308]

Carlton Reico Mallard Jr.: 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 Carlton Reico Mallard Jr. for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Mallard was convicted of one felony count under Federal law for introduction into interstate commerce a misbranded drug, with the intent to defraud and mislead, and one felony count of illegal importation of merchandise. The factual bases supporting Mr. Mallard's convictions, as described below, are for conduct relating to the importation into the United States of a drug or controlled substance. Mr. Mallard 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 February 23, 2025 (30 days after receipt of the notice), Mr. Mallard had not responded. Mr. Mallard'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 29, 2025.

ADDRESSES: Any application by Mr. Mallard 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–5308. 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 Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, 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 (21 U.S.C. 335a(b)(1)(D)) 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 July 23, 2024, Mr. Mallard was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Middle District of Florida when the court accepted his plea of guilty and entered judgment against him for the offenses of Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud and 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) and of Illegal Importation of Merchandise in violation of 18 U.S.C. 545. The underlying facts supporting the conviction are as follows: As contained in the Information, and in the Plea Agreement from his case, Mr. Mallard was the president and director of Inspiring Estates, Inc., and an owner of Golden Royal Honey USA (GRH). Mr. Mallard also operated the website *www.goldenroyalhoneyusa.com* on behalf of GRH to market and offer for sale misbranded drugs, specifically male enhancement products. Mr. Mallard was a client of Fulfillment Company 1 (FC–1), a marketing and online order fulfillment service, and used FC–1 to receive shipments of these misbranded drug products unlawfully imported into the United States from foreign nations. Between May 2020 and February 2021, several packages addressed to GRH were seized by the United States Customs and Border Protection (CBP). Mr. Mallard also received notices from the FDA and/or CBP about the violative nature of the

products he was importing from China and other foreign countries.

On or about August 5, 2020, a Special Agent from the FDA's Office of Criminal Investigations (OCI), while undercover, purchased items through the GRH website. The three products were called ''Leopard Miracle Honey,'' ''Vitamax Double Shot Honey,'' and ''Golden Royal Honey VIP.'' After receiving the products, OCI sent them for laboratory analyses at the FDA Forensic Chemistry Center (FCC). The FCC testing and analyses confirmed that sildenafil was present in the ''Leopard Miracle Honey'' while tadalafil was present in both the ''Vitamax Double Shot Honey'' and ''Golden Royal Honey VIP.''

On or about February 27, 2021, Mr. Mallard was interviewed by CBP officers. He confirmed that he operated an online business that distributed honey products. CBP officers discovered Mr. Mallard received text messages from DHL about incoming foreign parcels between February 24, 2021, and February 26, 2021. On or about April 16, 2021, a search and seizure warrant for GRH inventory was executed at FC–1. During the execution of the warrant agents discovered hundreds of products violative of the FDCA that were imported into the United States from foreign countries. Thirty-eight (38) items were submitted to the FCC for testing. Approximately thirty (30) tested positive for sildenafil and/or tadalafil, all of which were violative of the FD&C Act. Fulfillment and shipping records provided by FC–1 revealed that in 2020, FC–1 received 13,000 shipments on behalf of GRH and it processed and shipped out over 12,000 orders. During 2020, Mr. Mallard received approximately $764,749.64 for the sale of misbranded drugs that lacked the required FDA approval.

FDA sent Mr. Mallard, by certified mail, on January 2, 2025, a notice proposing to debar him for a 10-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. Mallard's felony convictions under Federal law for Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud and 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) and of Illegal Importation of Merchandise in violation of 18 U.S.C. 545, were for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Mallard illegally imported and introduced misbranded drug products into 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. Mallard's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Mallard 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. Mallard received the proposal and notice of opportunity for a hearing on January 24, 2025. Mr. Mallard 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Carlton Reico Mallard Jr. has been convicted of multiple felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years, with the maximum possible period of debarment as provided by section 306(c)(2)(A)(iii) of the FD&C Act for each felony count to run consecutively.

As a result of the foregoing finding, Mr. Mallard is debarred for a period of 10 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 (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Mallard is a prohibited act.

Dated: May 22, 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–2018–D–1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff; 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 a final guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' This guidance document provides an overview of the mechanisms available to submitters through which they can request interactions with FDA related to medical device submissions. This guidance supersedes the document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' issued on June 2, 2023, and provides clarification and additional information on the scope of Q-Submission (Q-Sub) types, better delineation of how to obtain feedback for different types of questions (*i.e.,* informal communication vs. Pre-Submission or other Q-Sub types), and improved examples.

DATES: The announcement of the guidance is published in the **Federal Register** on May 29, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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