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.

[FR Doc. 2025–09651 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

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

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 No. FDA–2018–D–1774 for ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.'' Received comments 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 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 comments 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; 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

As part of the Medical Device User Fee Amendments of 2022, the Agency committed to issuing a final guidance to provide additional information to assist in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. This final guidance reflects such additional information and further clarifies other elements of the Q-Sub Program.

This guidance provides an overview of the mechanisms available to submitters through which they can request interactions with FDA, including written feedback and/or a meeting regarding medical device Investigational Device Exemption applications, Premarket Approval applications, Humanitarian Device Exemption applications, De Novo requests, 510(k) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications, Dual 510(k) and CLIA Waiver by Application submissions, Accessory Classification Requests, and certain Investigational New Drug applications and Biologics License Applications submitted to the Center for Biologics Evaluation and Research. FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

A notice of availability of the draft guidance appeared in the **Federal Register** of March 15, 2024 (89 FR 18947). FDA considered comments received and revised the guidance as appropriate in response to the comments, including expanded examples of Pre-Submission topics and questions, and minor clarifications.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive

an electronic copy of the document. Please use the document number GUI00001677 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form or collection instrument	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
Form FDA 3601 ''Medical Device User Fee Cover Sheet''; form FDA 3601(a), the ''Device Facility User Fee Cover Sheet''; ''FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act''.	Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet—Form FDA 3601 and Form 3601(a); 513(g) Request for Information.	0910–0511
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
''Medical Device Accessories—Describing Accessories and Classification Pathways''.	Accessories	0910–0823
''Center for Devices and Radiological Health Appeals Processes''.	Appeals Process	0910–0738
''Authorization of Medical Products for Use Emergencies''	Emergency Use Authorization	0910–0595
312	Investigational New Drug Application	0910–0014
601	Biologics License Application	0910–0338
FDA's web page: Total Product Life Cycle Advisory Program (TAP) (*https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap*).	TAP Pilot	0910–0930

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09618 Filed 5–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2602]

Second Annual Animal Drug User Fee Educational Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following educational conference (public meeting) entitled ''Second Annual Animal Drug User Fee Educational Conference.'' This is the second of five annual educational conferences FDA will host as described in the ''Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028.'' The purpose of this series of conferences is to provide educational sessions for stakeholders who are interested in the new animal drug approval process.

DATES: The second educational conference will be held on July 15, 2025, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. You may submit comments at any time for this series of educational conferences. We request that you submit either electronic or written comments by 90 days after each annual educational conference to ensure that the Agency considers your comment on a topic discussed at that conference.

ADDRESSES: The second educational conference will be available in person and virtually. The in-person conference will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Great Room Conference Center, Silver Spring, MD 20993–0002. Entrance for conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.* For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.* Persons interested in attending this educational conference must register at: *https://www.surveymonkey.com/r/ADUFAV_2025.*

You may submit comments 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