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]

BILLING CODE 4164–01–P

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

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–2024–N–2602 for ''Second Annual Animal Drug User Fee Educational Conference.'' 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.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–0885, *adufa_v_edu_conference@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act (Pub. L. 108–130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency's funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency's mission to protect and promote human and animal health.

The Animal Drug User Fee Amendments of 2023 (ADUFA V), the most recent reauthorization of the Act, authorizes FDA to collect user fees through fiscal year 2028. ''The Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028'' (Performance Goals Letter) sets forth the Agency's performance goals for the period covered by ADUFA V. Among other goals, the document commits the Agency to hosting triannual meetings (three meetings per calendar year) with Animal Health Institute (AHI) members, one of which will consist of an educational conference of up to 8 hours for the animal drug industry. This notice announces the second of these annual Animal Drug User Fee Educational Conferences. These conferences are open to the public.

II. Topics for Discussion at the Educational Conference

As described in the Performance Goals Letter, FDA will plan a series of topics for the educational conferences during the 5 years of ADUFA V. While the agenda for each educational conference is determined by the Agency with input from AHI, all stakeholders are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This second conference will focus on the following topics:

(1) Overview of User Fees and Waivers
(2) Foreign Data
(3) Real World Data/Evidence
(4) What Makes a High-Quality Submission?
(5) Adaptive Study Designs

The conference will also contain Q&A sessions during which FDA will address specific questions from the in-person and virtual audience as time allows. Questions and comments received during each annual conference and comments submitted to the docket will inform the conversation and topics considered in subsequent conferences.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, and email. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend in person. Registrants will receive confirmation when their registration has been received and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at *https://www.surveymonkey.com/r/ADUFAV_2025* no later than July 8, 2025. Onsite registration will be provided on the day of the conference on a first-come, first-served basis, until the room capacity is

reached. No overflow seating will be provided. Onsite registration will open at the conference site at 8 a.m. on July 15, 2025.

If you need special accommodations due to a disability, please contact Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**) no later than July 8, 2025.

Recording of Conference: Please be advised that as soon as a recording of this conference is available, it will be accessible at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09584 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–2025–N–0030]

Quality Poultry and Seafood, Incorporated: 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 Quality Poultry and Seafood, Incorporated (QPS) for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that QPS was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. QPS was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of March 15, 2025 (30 days after receipt of the notice), QPS has not responded. QPS' failure to respond and request a hearing constitutes a waiver of its right to a hearing concerning this matter.

DATES: This order is applicable May 29, 2025.

ADDRESSES: Any application by QPS 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–2025–N–0030. 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)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar a person, including a firm or corporation, from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the person has been convicted of a felony for conduct relating to the importation into the United States of any food.

On December 11, 2024, QPS was convicted as defined in section 306(l)(1)(A) of the FD&C Act in the U. S. District Court for the Southern District of Mississippi when the court accepted its plea of guilty and entered judgment against it for the offense of Conspiracy to Commit Misbranding and Wire Fraud in violation of 18 U.S.C. 371.The underlying facts supporting the conviction are as follows: As contained in the Information, whose facts alleged therein QPS admitted to in QPS' Plea Agreement, QPS is a Mississippi corporation operating in Biloxi as a wholesale supplier of poultry and seafood to restaurants, casinos, and retail markets. It also sold poultry and seafood to the general public from its