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

retail outlet and served meals to customers at its cafe. QPS, along with coconspirators, entered into a conspiracy to mislabel foreign seafood and sell it as local varieties of seafood. Through QPS' employees, QPS would purchase frozen seafood from foreign countries, with the intent to advertise and sell the seafood as local premium species of seafood, when in fact the fish was not local and not species they were advertised to be. On at least one occasion, while standing in QPS' large freezer, QPS' sales manager handed to a coconspirator, packages of three different fish suggesting that the coconspirator sample each and decide which would be best to substitute for the local premium species on the conspirator's menu. On a separate occasion QPS sold fish to a customer; QPS represented the fish to be local premium Red Snapper but which genetic analysis determined was not Red Snapper but was instead an imported species of lesser value. Later, one of QPS' seafood purchasing agents notified some of QPS' other employees that due to a shortage on snapper, QPS would be substituting triple tail for all snapper. Triple tail was not a local fish, and QPS had in fact imported it from South America. During a search of QPS facilities in September 2018, two of QPS' employees, its sales manager and business manager, made multiple false statement to FDA investigators, including, that any mislabeling of fish by QPS was inadvertent and that if anyone in QPS' retail market was mislabeling fish with other than its true name, it was happening without approval. Even after the September 2018 search of QPS facilities, QPS continued selling mislabeled seafood to customers in lieu of local varieties of seafood for at least another year.

As a result of this conviction, FDA sent QPS, by certified mail, on February 10, 2025, a notice proposing to debar it for a 5-year period from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that QPS' felony conviction under Federal law for Conspiracy to Commit Misbranding and Wire Fraud in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of an article of food because QPS entered into a scheme to purchase foreign seafood which it then would either mislabel itself and sell it directly to its retail customers or would sell it to its retail customers in order for the retail customers to mislabel it and sell it as local varieties of seafood to consumers. 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 QPS' offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed QPS of the proposed debarment and offered it an opportunity to request a hearing, providing QPS 30 days from the date of receipt of the letter in which to file the request, and advised it that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. QPS received the proposal and notice of opportunity for a hearing on February 13, 2025. QPS failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived its opportunity for a hearing and waived any contentions concerning its 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)(1)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that QPS has been convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food and that it is subject to a 5-year period of debarment.

FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, QPS is debarred for a period of 5 years from importing articles of food or offering such articles for import 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 an article of food by, with the assistance of, or at the direction of QPS is a prohibited act.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09652 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–D–1082]**

### Electronic Submission Template for Medical Device Q-Submissions; Draft 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 the draft guidance entitled ''Electronic Submission Template for Medical Device Q-Submissions.'' FDA is issuing this draft guidance to introduce submitters of certain Q-Submissions (Q-Subs), specifically Pre-Submissions (Pre-subs) to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), to the current resources and associated content developed and made publicly available to support Pre-Sub electronic submissions to FDA. This draft guidance, when finalized, is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by July 28, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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