

*Estimated Total Annual Burden Hours:* 627.

*Comments:* The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority for the IRG information collection activities is:* (1) 42 U.S.C. 652(a)(7), which requires the federal OCSE to provide technical assistance to state child support enforcement agencies to help them establish effective systems for collecting child and spousal support; (2) 42 U.S.C. 666(f), which requires states to enact the Uniform Interstate Family Support Act; (3) 45 CFR 301.1, which defines an intergovernmental case to include cases between states and tribes; (4) 45 CFR 303.7, which requires state CSE agencies to provide services in intergovernmental cases; and (5) 45 CFR 309.120, which requires a tribal child support program to include intergovernmental procedures in its tribal IV-D plan.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-1537]

#### James R. Casey: 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 James R. Casey 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 Mr. Casey was

convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Casey was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of June 30, 2019 (thirty days after receipt of the notice), Mr. Casey had not responded. Mr. Casey'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 November 29, 2019.

**ADDRESSES:** Submit applications for termination of debarment to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 or at [debarments@fda.hhs.gov](mailto: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 an individual 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 individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2019, Mr. Casey was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into Mr. Casey's Plea Agreement, filed on September 26, 2018, from on or about 2010 to June 2015, while serving as the owner, operator, and President of Casey's Seafood, Inc. ("the company"), Mr. Casey regularly purchased foreign crab meat from a variety of sources and from a number of different countries. Mr.

Casey also purchased foreign crab meat that had been recalled, returned, or that was approaching or beyond its posted "best used by" dates. Mr. Casey directed company employees to unpack the foreign crab meat from containers and re-pack the crab meat into company containers, all of which were labeled "Product of USA." During that time period, employees routinely emptied foreign crab meat onto tables, comingling crab meat from different sources, and then re-packaged the crab meat into company containers, all of which were labeled "Product of USA." From on or about July 1, 2012 and continuing until June 17, 2015, Mr. Casey caused to be sold at least 367,765 pounds of crab meat falsely labeled "Product of USA" with a total wholesale value of approximately \$4,324,916.

As a result of this conviction, FDA sent Mr. Casey by certified mail on May 22, 2019, a notice proposing to debar him a period of 5 years 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 (21 U.S.C. 335a(b)(1)(C)) that Mr. Casey's felony conviction of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii) constitutes conduct relating to the importation into the United States of an article of food because the offense he committed involved falsely labeling crab meat that was imported from a number of foreign countries as "Product of USA."

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Casey should be subject to a 5-year period of debarment. The proposal also offered Mr. Casey 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. Casey failed to respond 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Casey has

been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Casey 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 Mr. Casey is a prohibited act.

Any application by Mr. Casey for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-1537 and sent to the Dockets Management Staff (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at <http://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0879]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 30, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0354. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—21 CFR part 123

*OMB Control Number 0910-0354—Extension*

This information collection supports regulations in part 123 (21 CFR part 123), which mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (4)).

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the values for processing times, temperatures, acidity, etc., as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided.

HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and on the nature of the equipment or instruments required to monitor critical control points. The burden estimate in table 1 includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. The estimate also does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (§ 1240.60 (21 CFR 1240.60)) is a customary and usual practice among seafood processors. Consequently, the estimates in table 1 account only for information collection and recording requirements attributable to part 123.

*Description of Respondents:* Respondents to this collection of information include processors and importers of seafood.

In the **Federal Register** of September 4, 2019 (84 FR 46544), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows: