other key stakeholders in the medical device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled, ''Pediatric Medical Device Development.'' As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L. 115–52) the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Phone Survey	17	1	17	0.5 (30 minutes)	9
Online Survey	56	1	56	1	56
Total					65

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest hour.

The targeted groups for this collection of information include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110–85; 42 U.S.C. 282 note), and trade organizations, medical provider organizations, organizations and individuals involved with financing and reimbursement associated with medical devices, pediatric healthcare leaders, clinicians who regularly use medical devices in caring for children, and organizations and individuals representing patients and consumers.

Phone survey: Respondents participating in the phone survey will be executives from companies either producing products in pediatrics or from companies that produce products that could be used in pediatrics. Executives will be invited to engage in the 30-minute phone survey.

Online survey: The 1-hour online survey will be administered to leaders within pediatric companies and key decision makers in the pediatric medical device industry (*e.g.,* venture capitalists, banking investors, leaders in children's hospitals and research networks, and pediatric patient advocates).

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20626 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0317]

Roy Tuccillo, 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 (the FD&C Act) debarring Roy Tuccillo, Jr. 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. Tuccillo was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Tuccillo was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 15, 2022 (30 days after receipt of the notice), Mr. Tuccillo has not responded. His failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable September 23, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *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, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On November 9, 2021, Mr. Tuccillo was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Eastern District of New York, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to commit wire fraud in violation of 18 U.S.C. 371 and 1343.

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 stated in the indictment, filed September 26, 2018, transcript of guilty pleas, filed December 26, 2019, and Magistrate Judge Steven Locke's report and recommendation, filed May

10, 2020, all from Mr. Tuccillo's case, Mr. Tuccillo was the manager of Anchor Foods, Inc. and Advanced Frozen Foods, Inc. (collectively, ''Anchor Foods''), responsible for the purchase, sale, shipment, and storage of food products, including octopus and squid, by both businesses. Both Anchor Foods companies were located in Westbury, New York.

From on or about February 2011 and continuing through January 2014, Mr. Tuccillo knowingly and willfully conspired with Anchor Foods, Roy Tuccillo, Sr., and others to import giant squid from Peru to Mr. Tuccillo's companies' location in Westbury, New York, and repackage and sell that squid falsely labeled and identified as ''octopus.'' Mr. Tuccillo sold the falsely labeled squid in interstate commerce to grocery stores in New Jersey, Texas, and Massachusetts. Mr. Tuccillo used email and fax to sell and receive payments for the squid falsely labeled as octopus. In total, Anchor Foods made $1,128,388.50 worth of fraudulent sales of squid.

As a result of this conviction, FDA sent Mr. Tuccillo, by certified mail on June 6, 2022, a notice proposing to debar him for 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 that Mr. Tuccillo's felony conviction of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 371 and 1343, constitutes conduct relating to the importation into the United States of an article of food because Mr. Tuccillo knowingly and willfully conspired with Anchor Foods, Roy Tuccillo, Sr., and others to import giant squid from Peru to his companies' location in Westbury, New York, and repackage and sell that squid falsely labeled and identified as ''octopus'' in interstate commerce, using email and fax to sell and receive payments for the falsely labeled squid. 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. Tuccillo should be subject to a 5-year period of debarment. The proposal also offered Mr. Tuccillo 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. Tuccillo 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. Tuccillo 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. Tuccillo 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 Roy Tuccillo, Jr., is a prohibited act.

Any application by Mr. Tuccillo for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2022–N–0317 and sent to the Dockets Management Staff (**ADDRESSES**). 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 *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20709 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0316]

Roy Tuccillo, Sr.: 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 Roy Tuccillo, Sr. 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. Tuccillo was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Tuccillo was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 17, 2022 (30 days after receipt of the notice), Mr. Tuccillo has not responded. Mr. Tuccillo'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 September 23, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *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, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On November 9, 2021, Mr. Tuccillo was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Eastern District of New York, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to commit wire fraud in violation of 18 U.S.C. 371 and 1343.

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 stated in the indictment, filed September 26, 2018, transcript of guilty pleas, filed December 26, 2019, and Magistrate Judge Steven Locke's report and recommendation, filed May 10, 2020, all from Mr. Tuccillo's case, Mr. Tuccillo was the owner, president, and chief operating officer of Anchor Foods, Inc. and Advanced Frozen Foods, Inc. (collectively, ''Anchor Foods''), and had overall responsibility