FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 22, 2019

James R. Casey
Register Number: 92642-083
FCI Petersburg Prison
1100 River Road
Hopewell, VA 23860

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-1537

Dear Mr. Casey:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order under section 306(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(b)(1)(C)) that would debar you for a period of five years from importing articles of food or offering such articles for import into the United States. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. This letter also offers you an opportunity to request a hearing on this proposal and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On January 9, 2019, you were convicted as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), in the United States District Court for the Eastern District of Virginia, when the court accepted your plea of guilty and entered judgment against you 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). The underlying facts supporting this conviction are as follows:

As contained in the Stipulation of Facts incorporated into your Plea Agreement, filed on September 26, 2018, from on or about 2010 to June 2015, while you were serving as the owner, operator, and President of Casey's Seafood, Inc. ("the company") you regularly purchased foreign crab meat from a variety of sources and from a number of different countries. You also purchased foreign crab meat that had been recalled, returned, or that was approaching or beyond its posted "best used by" dates. You 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, you 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.

FDA's Finding

Section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) permits FDA to debar a person from importing an article of food or offering such an article for import into the United States. An individual who has been convicted of a felony for conduct relating to the importation into the United States of any food may be subject to debarment, as set forth in section 306(b)(3)(A) of the Act (21 U.S.C. § 335a(b)(3)(A)). FDA finds that the felony count for which you were convicted was for conduct relating to the importation of an article of food into the United States because you falsely labeled crab meat that was imported from a number of foreign countries as "Product of USA" in violation of 16 U.S.C. § 3372(d).

The maximum period of debarment for each felony under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness of and period of permissive debarment for an individual. Those factors relevant to the debarment of an individual for a felony conviction for conduct relating to the importation into the United States of any food are as follows:

1. the nature and seriousness of any offense involved,

2. the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

3. the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including . . . full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) . . . and any other actions taken to substantially limit potential or actual adverse effects on the public health,

4. whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future, and

5. prior convictions under the Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA has determined that three of these factors are applicable for consideration:

1. Nature and seriousness of any offense involved.

As described in detail above, you were convicted of the following offense: 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). The Agency finds that your conduct seriously undermined FDA's regulation of the introduction of

food that has been imported into the United States into interstate commerce and the labeling of such food. The false labeling could mislead the American consumer, who relies on a product's

labeling to determine its country of origin. Accordingly, FDA concludes that the nature and seriousness of the offense involved supports the maximum possible period of debarment.

2. **Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved.**

In determining the period of a debarment, FDA is also to consider the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. The FDA is unaware of any steps you took to mitigate the impact on the public of your actions, which undermined the integrity FDA's regulation of the importation of food, in this case foreign crab meat, into the United States and the introduction of such food into interstate commerce.

FDA considers your failure to take any steps to mitigate the potential impact on the public supports a negative factor.

3. **Prior convictions under the Act or involving matters within the jurisdiction of FDA.**

FDA is unaware of any prior criminal convictions involving matters within the jurisdiction of FDA. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Weighing all factors, FDA concludes that the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a maximum five-year period of debarment. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) that would debar you from importing articles of food or offering such articles for import into the United States for a period of five years. You were convicted of conspiracy to violate the Lacey Act by engaging in false labeling in violation of 16 U.S.C. § 3372(d) because you imported foreign crab meat that you falsely labeled as "Product of USA." As such, the FDA finds that the felony conviction was for conduct related to the importation into the United States of any food. FDA proposes that the felony offense be accorded a debarment period of five years.

In accordance with section 306 of the Act (21 U.S.C. § 335a) and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or

denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction supports your debarment under section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2019-N-1537 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You also may notify FDA that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to FDA in accordance with section 306(c)(2)(B) of the Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Division of Enforcement, Office of Regulatory Affairs pursuant to FDA Staff Manual Guide 1410.35.

Sincerely,

/s/
Scott MacIntire
Director
Division of Enforcement
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U. S. Food and Drug Administration