DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Adrian Vela
(b) (6)

9-28-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-0777

Dear Mr. Vela:

This letter is to inform you that the U.S. Food and Drug Administration ("FDA" or "the Agency") is proposing to issue an order debarring 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 Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(l)(1)(B)), of three felony counts 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 November 21, 2011 you were convicted, as defined in section 306(1)(l)(B) of the Act, when the United States District Court Southern District of Florida accepted your plea of guilty and entered judgment against you for the following offenses: one count of conspiracy to falsely label and misbrand food, in violation of 18 U.S.C. § 371; one count of false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. § 3372(d)(2); and one count of misbranding food in violation of 21 U.S.C. § 331(a). The underlying facts supporting these convictions are as follows.

According to the criminal information that was filed against you, you were the operating manager and sole shareholder of Sea Food Center, a seafood wholesaler engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products.

As alleged in the portions of the criminal information filed against you to which you pleaded guilty, beginning on or about June 30, 2008, and continuing through on or about June 29, 2009, you knowingly combined, conspired, confederated, and agreed with your co-conspirators to commit an offense against the laws of the United States related to the importation of food. The purpose of the conspiracy was for you and your co-conspirators to unlawfully enrich yourselves by introducing what the criminal information describes as less marketable substituted seafood products into the United States seafood market. Those products---"Shrimp, Product of Thailand,"

"Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia"--- were misbranded, marketed, and intended to be marketed as "Shrimp, Product of Panama," a seafood product that the criminal information describes as more readily marketable. You instructed employees at Sea Food Center's Tampa facility to divide the shrimp received from Thailand, Malaysia, and Indonesia into smaller count portions, and mark them as "Shrimp, product of Panama," on the individual packages, and then place them in boxes, also marked "Shrimp, product of Panama." Employees under the direction of your co-conspirator managed and directed the labeling operations at Sea Food Center by providing instructions and other directives to you. The relabeled shrimp were subsequently sold to a food wholesaler based in Keene, New Hampshire, which in turn sold the shrimp to a supermarket chain headquartered in Landover, Maryland. This conduct was in violation of 18 U.S.C. § 371.

On or about July 8, 2008 you knowingly engaged in an offense that involved the sale and purchase of, the offer of sale and purchase of, and the intent to sell and purchase shrimp, with a market value greater than $350.00. You knowingly made and caused to be made individual labels, pre-printed bags, and other documents falsely identifying the shrimp as being "Shrimp, Product of Panama," when in truth and in fact you knew the shrimp were "Shrimp, Product of Thailand," "Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia." This conduct was in violation of 16 U.S.C. § 3372(d)(2).

On or about July 8, 2008 you engaged in an offense that involved the introduction or delivery for introduction into interstate commerce of a food that was misbranded, with the intent to defraud or mislead, in that you created and caused to be created individual labels, pre-printed bags, and other documents falsely identifying the shrimp as being "Shrimp, Product of Panama," when in fact the shrimp was "Shrimp, Product of Thailand," "Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia." This conduct was in violation of 21 U.S.C. § 331(a).

FDA's Finding

Section 306(b)(1)(C) of the 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. 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 all three of the felony counts for which you were convicted were for conduct relating to the importation of an article of food into the United States. FDA makes this finding because the three offenses related to the importation into the United States of the shrimp in that they conveyed false information about the shrimp's country of origin. That is, all three of the felony counts for which you were convicted involved conduct resulting in false information regarding the countries from which the shrimp was imported. These convictions were for: conspiracy to falsely label and misbrand food, in violation of 18 U.S.C. § 371; false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. § 3372(d)(2); and misbranding food, in violation of 21 U.S.C. § 331(a). Because these felony convictions occurred less than five years before the initiation of this action, this action is timely under section 306(l)(2) of the Act (21 U.S.C. § 335a(l)(2)).

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, and debarment periods may run concurrently or consecutively in the case of a person debarred for multiple offenses. 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 four 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 offenses: conspiracy to falsely label and misbrand food in violation of 18 U.S.C. § 371; false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. § 3372(d)(2); and misbranding of food, in violation of 21 U.S.C. § 331(a).

The Agency finds that your conduct reflected a disregard for FDA's authority to prohibit false or misleading labeling of imported food. You mislabeled and misbranded shrimp labeled as "Shrimp, Product of Thailand," "Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia." You mislabeled and misbranded this seafood as "Shrimp, Product of Panama," a product described in the criminal information as more readily marketable. You and your co-conspirators conspired to do this in order to unlawfully enrich yourselves. Your actions demonstrate that you were not concerned with the accuracy of seafood labeling. Accordingly, FDA considers the nature and seriousness of the offenses as an unfavorable factor.

2. 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.

You were the operating manager and sole shareholder of Sea Food Center. As a principal for this company, you violated federal laws in a scheme to defraud the American consumer. With the

intent to defraud and mislead, you introduced or delivered for introduction into interstate commerce misbranded seafood. You conspired to falsely label and misbrand the seafood in order to enrich yourself. Accordingly, FDA considers the nature and extent of your participation in the relevant offenses as the operating manager and sole shareholder of Sea Food Center as an unfavorable factor.

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

You were convicted of conspiring to falsely label and misbrand food, false labeling of seafood under the Lacey Act, and misbranding food. You introduced or delivered for introduction into interstate commerce misbranded seafood, in that the seafood had been falsely labeled as "Shrimp, Product of Panama." You took no steps to mitigate the impact on the public of your actions. Accordingly, FDA will consider your failure to take any steps to mitigate the impact on the public as an unfavorable factor.

4. 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. FDA 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 in support of the favorable factors and warrant the maximum five-year period of debarment for each offense. You pled guilty to one count of conspiracy to falsely label and misbrand food, one count of mislabeling seafood under the Lacey Act, and one count of misbranding food, all Federal felony offenses. FDA finds that all of these convictions were for conduct relating to the importation of an article of food into the United States.

In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. 335a(c)(2)(A)). FDA has concluded that you need not consecutively serve the five-year period of debarment for each of the three offenses relating to the importation of an article of food into the United States. Serving all of the debarment periods consecutively would result in a period of debarment of 15 years. FDA has concluded that the purposes of the debarment provision of the Act will be served if he three periods of debarment for each offense to which you pled guilty run concurrently to each other, resulting in a total debarment period of five years. FDA has reached this conclusion because, in your case, and in light of your age, a 15-year debarment period would be tantamount to permanent debarment. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the Act debarring you from importing articles of food or offering such articles for import into the United States for a 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 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-2012-N-0777 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, Office of Enforcement, Office of Regulatory Affairs.

Sincerely,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affair

cc:
HF-22/Matthew Warren
HFC-130/Michael Rogers
HFC-300/ Jeffrey Ebersole
HFM-100
HFC-180/Anthony Taube
HFC-170/Domenic Veneziano
HFS-605/Jennifer Thomas
HFS-600/Michael Roosevelt
HFC-1Michael Verdi
GCF-1/Joy Dawson
GCF-1/Ann Wion
GCF-1/Jessica O'Connell
HFC-230/Debarment File
HFC-230/CF
HFC-200/CF