DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard Stowell
(b) (6)

9-24-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-0714

Dear Mr. Stowell:

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 three 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 FD&C 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 July 27, 2011, you were convicted, as defined in section 306(*l*)(1)(B) of the FD&C Act, when the United States District Court for the 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 seafood, 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 3373(d)(3)(A)(ii)[1]; and one count of misbranding food, in violation of 21 U.S.C. §§ 331(a), 343(a)(1), and 333(a)(2).[2] The underlying facts supporting these convictions are as follows:

You were the president and sole shareholder of United Seafood Imports, Inc. (United), a Florida based seafood wholesaler engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products, including shrimp.

[1] The District Court's judgment references 16 U.S.C. § 373(d)(3)(A)(ii). This appears to be an error. The relevant provision of the Lacey Act that is cited in Count Two of the Information, to which you pled guilty, is 16 U.S.C. § 3373(d)(3)(A)(ii).

[2] The District Court's judgment references "21 USC 331(a), 331(a), 333(a)(2)." It seems that the repetition of "331(a)" is an error. Count 22 of the Information, to which you pled guilty, encompasses violations of 21 U.S.C. §§ 331(a), 343(a)(1), and 333(a)(2).

Beginning in or around January 25, 2007, and continuing through on or about August 7, 2009, you did knowingly and with the intent to further the objects of a conspiracy combine, conspire, confederate, and agree with others to commit an offense against the United States. Specifically, your company United purchased approximately one million pounds of shrimp in boxes labeled "Shrimp, Product of Thailand," "Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia." Your company United then sent the shrimp to another company, Shifco, and instructed them to repackage and re-label the shrimp as "Shrimp, Product of Panama," "Shrimp, Product of Ecuador," and "Shrimp, Product of Honduras." United, and employees under your direction and control, managed and directed the labeling operations of Shifco by providing instructions and other directives to them. Your company United then sold the shrimp that was relabeled to a company who in turn subsequently sold the shrimp to a supermarket chain. This was in violation of 18 U.S.C. § 371.

On or about January 26, 2007, you purchased 180 cases of shrimp valued at approximately $24,912.00 and knowingly created and caused to be created individual labels, pre-printed bags, and other documents falsely identifying the shrimp as being "Shrimp, Product of Ecuador," when in truth and in fact you knew the shrimp was a product of Malaysia. This was in violation of 16 U.S.C. §§ 3372(d)(2) and 3373(d)(3)(A)(ii).

On or about July 2, 2009, you knowingly engaged in an offense that involved the introduction and delivery for introduction into interstate commerce of a food that was misbranded, that is, approximately 52 cases of shrimp, 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 a product of Panama when in truth and in fact, you knew the shrimp was a product of Indonesia. This was in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 343(a)(1).

FDA's Finding

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. FDA finds that all 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. These convictions were for: conspiracy to falsely label and misbrand seafood, 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 3373(d)(3)(A)(ii); and misbranding food, in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 343(a)(1). 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 FD&C Act (21 U.S.C. § 335a(*l*)(2)).

The maximum period of debarment for each offense under section 306(c)(2)(A)(iii) of the FD&C 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 FD&C 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 FD&C 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 here:

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 seafood, 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 3373(d)(3)(A)(ii); and misbranding food in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 343(a)(1).

The Agency finds that your conduct undermined FDA's regulation of the importation of food into the United States and the introduction of food into interstate commerce. You pled guilty to three felonies for your role in selling falsely labeled seafood. You received and bought shrimp imported from Thailand, Malaysia and Indonesia. You then directed that these shrimp be falsely relabeled as products of Panama, Ecuador, and Honduras. You and your co-conspirators unlawfully enriched yourselves by introducing a less marketable seafood product into interstate commerce that you misrepresented as a more marketable product. Accordingly, the Agency will consider the nature and seriousness of the offenses involved 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 president and sole shareholder of United. As a principal for this company, you violated federal laws in a scheme to defraud consumers in the United States. You knowingly, with the intent to defraud or mislead, engaged in an offense that involved the introduction and delivery for introduction into interstate commerce of seafood that had been misbranded. You conspired to falsely label and sell less marketable seafood that you misrepresented as more expensive products. Accordingly, FDA will consider the nature and extent of your participation in the relevant offenses as the president and sole shareholder of United 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 seafood; false labeling; and misbranding. You knowingly, with the intent to defraud or mislead, engaged in an offense that involved the introduction and delivery for introduction into interstate commerce of seafood that had been misbranded. The facts support the belief that you displayed a wanton disregard for the food importation regulatory process. However, you cooperated with the government's investigation, as set forth in the government's motion in aid of sentencing. Under section 306(c)(3)(C) of the FD&C Act, cooperation with an investigation is one type of action that can mitigate the impact on the public of an offense. FDA considers your cooperation with the investigation to be a favorable factor, though FDA considers your failure to take other steps to mitigate the impact on the public to be an unfavorable factor.

4. Prior convictions under the FD&C 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 unfavorable factors outweigh the favorable factors and warrant a three-year period of debarment for each offense. You pled guilty to one conspiracy count, one count of false labeling under the Lacey Act, and one misbranding count, all Federal felony offenses. FDA finds that these convictions were for conduct relating to the importation of an article of food. Nevertheless, your substantial cooperation with the government's investigation, in conjunction with your lack of prior criminal convictions involving matters within the jurisdiction of FDA, justifies the imposition of less than the maximum period of debarment.

In the case of a person debarred for multiple offenses, under section 306(c)(2)(A) of the FD&C Act (21 U.S.C. 335a(c)(2)(A)) FDA may determine whether the periods of debarment shall run concurrently or consecutively. In light of your cooperation with the government, as set forth in the government's motion in aid of sentencing, FDA has concluded that the purposes of the debarment provision of the FD&C Act will be served if the periods of debarment for the three offenses described in the preceding paragraph run concurrently, resulting in a total debarment period of three years. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. § 335a(b)(1)(C)) debarring you from importing articles of food or offering such articles for import into the United States for a period of three years.

In accordance with section 306 of the FD&C 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 FD&C 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 FD&C 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-2012-N-0714 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 FD&C Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the FD&C 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
GCF-1/Rebecca Goldberg
HFC-230/Debarment File
HFC-230/CF
HFC-200/CF