



BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Karen L. Blyth/10871-003  
FCI Phoenix  
Federal Correctional Institution  
37910 N. 45<sup>th</sup> Ave.  
Phoenix, AZ 85086

**02-17-2012**

PROPOSAL TO DEBAR  
NOTICE OF OPPORTUNITY FOR HEARING  
Docket No. FDA-2011-N-0880

Dear Ms. Blyth:

This letter is to inform you that the U.S. Food and Drug Administration ("FDA" or "the Agency") is proposing to issue an order debaring you for a period of twenty 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 ten 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 May 4, 2011 you were convicted, as defined in section 306(l)(1)(B) of the Act, when the United States District Court for the Southern District of Alabama accepted your plea of guilty and entered judgment against you for the following offenses: one count of conspiracy to commit offenses against the laws of the United States, in violation of 18 U.S.C. § 371; nine counts of false labeling under the Lacey Act, in violation of 16 U.S.C. §§ 3372(d)(2) and 3373(d)(3)(A); two counts of receipt of merchandise imported contrary to law, in violation of 18 U.S.C. § 545; and one count of misbranding, in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 343(a)(1) and (b). The underlying facts supporting these convictions are as follows.

As stated in the factual resume accompanying the plea agreement referenced above and alleged in the indictment filed against you, you were a co-owner, President and Treasurer of CSE Inc., which was used to buy and sell seafood. You were also a co-owner, President and Chief Executive Officer of RF Inc. from on or about October 1, 2004 through on or about March 2007. RF Inc. also sold seafood, including but not limited to shrimp, oysters, Lake Victoria perch, and types of catfish, commonly called basa, swai, and sutchi.

Beginning on or about January 1, 2004 and continuing through on or about November 8, 2006, you knowingly, willingly, and unlawfully combined, conspired, confederated and agreed with your co-conspirators to commit offenses against the laws of the United States related to the importation of food. This conduct was in violation of 18 U.S.C. § 371. Specifically, you received and bought 81,000 pounds of fish of the genus *Pangasius* (a type of catfish commonly called basa, swai, or sutchi) that you knew had been unlawfully imported from Vietnam. You knew that the fish was falsely labeled as sole when it was imported, and that it was imported without the required anti-dumping duty having been paid. You created or caused others to create false invoices and labeling for this fish, and other fish of the genus *Pangasius* bought and sold to customers, totaling approximately 101,078 pounds. You sold and invoiced the fish as grouper or sole, allowing you to sell the fish in interstate commerce at higher profit margins and more readily than if the fish had been accurately labeled and described.

From on or about February 9, 2005 through on or about June 27, 2005, you knowingly made and caused to be made a false record, account, and label for, and false identification of fish, that had been and was intended to be transported in interstate and foreign commerce, having a market value greater than \$350, and that involved the sale and purchase, the offer of sale and purchase, and the intent to sell and purchase fish, and the importation of fish, in that you created and caused to be created invoices, boxes, and other documents that falsely identified the fish. Specifically, you falsely identified fish as sole and *Cynoglossus bilineatus*, when in fact it was fish of the genus *Pangasius*, a type of catfish. This conduct was in violation of Title 16 U.S.C. §§ 3372(d)(2) and 3373(d)(3)(A).

From about March 30, 2005 through about April 4, 2005 you knowingly received, concealed, bought, sold, and facilitated the transportation, concealment, and sale of merchandise after importation, specifically frozen fish fillets of the genus *Pangasius*, knowing it to have been imported and brought into the United States contrary to law, that is falsely declared and without applicable duties having been paid. This conduct was in violation of 18 U.S.C. § 545.

From approximately March 30, 2005 through approximately June 22, 2005, with intent to defraud and mislead, you introduced and delivered and caused to be introduced and delivered into interstate commerce food, specifically frozen fish fillets, that was misbranded in that it had been falsely and misleadingly labeled and described as sole and *Cynoglossus bilineatus*. In fact, the fish was of the genus *Pangasius*. This conduct was in violation of 21 U.S.C. §§ 331(a), 333(a)(2) & 343(a)(1) and (b).

#### 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 ten of the thirteen felony counts for which you were convicted were for conduct relating to the importation of an article of food into the United States because the ten offenses related to the importation into the United States of fish in the genus *Pangasius*. These convictions were for: conspiracy against the laws of the United States, in violation of 18 U.S.C. § 371; false labeling under the Lacey Act, in violation of 16 U.S.C. §§ 3372(d)(2) and 3373(d)(3)(A); receipt of merchandise imported contrary to law, in violation of

18 U.S.C. § 545; and misbranding, in violation of 21 U.S.C. §§ 331(a), 333(a)(2) & 343(a)(1) and (b). 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(1)(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 against the laws of the United States, in violation of 18 U.S.C. § 371; false labeling under the Lacey Act, in violation of 16 U.S.C. §§ 3372(d)(2) and 3373(d)(3)(A); receipt of merchandise imported contrary to law, in violation of 18 U.S.C. § 545; and misbranding in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 343(a)(1) and (b).

The Agency finds that your conduct seriously undermined FDA's regulation of the importation of food into the United States and the introduction of food into interstate commerce. You pleaded guilty to numerous felonies for your role in receiving, purchasing, and selling falsely labeled seafood. You received and bought illegally imported fish in the genus *Pangasius* from Vietnam into the United States, and you knew that the fish had been imported without any anti-dumping duties having been paid. Accordingly, FDA concludes that the nature and seriousness of the offenses involved support the maximum possible period of debarment.

**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 Co-Owner, President and Treasurer of CSE Inc., as well as Co-Owner President and Chief Executive Officer of RF Inc. As a principal for these two companies, you violated federal laws in a misguided scheme to defraud the American consumer and the United States. You knowingly and willfully, with the intent to defraud the United States, bought and sold seafood you knew had been illegally imported into the United States. You knew that the seafood had been imported without the required anti-dumping duties having been paid, and that it had been falsely described as sole when it was imported. You also conspired to sell falsely labeled seafood that you knew had been unlawfully imported and substituted cheaper seafood for more expensive products. Accordingly, FDA concludes that the nature and extent of your participation in the relevant offenses---as the Co-Owner, President and Treasurer of CSE Inc., and Co-Owner, President and Chief Executive Officer of RF Inc.---support the maximum possible period of debarment.

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

You were convicted of conspiring to commit an offense against the laws of the United States, false labeling, receipt of merchandise imported contrary to law, and misbranding. You knowingly received, concealed, bought, sold, and facilitated the transportation, concealment, and sale of frozen fish fillets of the genus *Pangasius*, knowing them to have been imported and brought into the United States contrary to law. Additionally, you acted with the intent to defraud and mislead when you introduced into interstate commerce imported fish that had been misbranded, in that the fish had been falsely and misleadingly labeled and described as sole and *Cynoglossus bilineatus*, when you knew it was fish of the genus *Pangasius*. You took no steps to mitigate the impact on the public of your actions.

The facts support the belief that you displayed a wanton disregard for the food importation regulatory process. Accordingly, FDA has determined that your failure to take any steps to mitigate the impact on the public supports the maximum possible period of debarment.

**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 conspiracy count, nine violations of false labeling under the Lacey Act, two counts of receiving smuggled goods and one misbranding count, all Federal felony offenses. FDA finds that ten of these thirteen convictions were for conduct relating to the

importation of an article of food.

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 ten 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 50 years. FDA has concluded that the purposes of the debarment provision of the Act will be served if: (1) the five-year period of debarment for count 1 runs consecutively with the other periods of debarment, (2) the five-year periods of debarment for counts 2-7 run concurrently, (3) the five-year periods of debarment for counts 8-9 run concurrently, and (4) the five-year period of debarment for count 10 runs consecutively with the other periods of debarment. The four periods of debarment described in the preceding sentence shall run consecutively to each other, resulting in a total debarment period of twenty years. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) debaring you from importing articles of food or offering such articles for import into the United States for a period of twenty 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

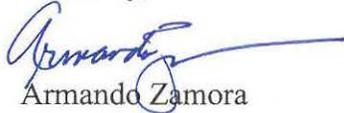
Karen L. Blyth  
Docket No. FDA-2011-N-0880

hearing, must be identified with Docket No. FDA-2011-N-0880 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 and under authority delegated to the Director, Office of Enforcement, Office of Regulatory Affairs.

Sincerely,

A handwritten signature in blue ink, appearing to read "Armando Zamora", with a long horizontal flourish extending to the right.

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

Karen L. Blyth  
Docket No. FDA-2011-N-0880

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