DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen C. Delaney, Jr.
(b) (6)

7-09-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-0405

Dear Mr. Delaney:

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 of one 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 April 8, 2011, you were convicted in the United States District Court for the District of Massachusetts of one count of false labeling under the Lacey Act in violation of 16 U.S.C. § 3372(d). The United States District Court for the District of Massachusetts entered judgment against you on September 21, 2011. The underlying facts supporting this conviction are as follows.

As alleged in the indictment that was filed against you, you were the president and owner of a seafood packing and re-packing company. On or about April 15, 2009, in violation of 16 U.S.C. § 3372(d), you did knowingly make and submit a false record, account and label for, and a false identification of fish that had been and was intended to be, imported, purchased, and received from a foreign country and transported in interstate commerce, and involved the sale and purchase, the offer of sale and purchase, and the intent to sell and purchase, fish with a market value of approximately $8,000. Specifically, you falsely labeled imported frozen fillets of pollock, product of China, as cod loins, product of Canada.

FDA's Finding

Section 306(b)(1)(C) of the Federal Food, Drug, and Cosmetic 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 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 frozen fish fillets that were imported from China as cod loins from Canada, 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 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 offense: false labeling under the Lacey Act in violation of 16 U.S.C. § 3372(d).

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 an imported product's labeling to determine its country of origin. A jury found you guilty after a plea of not guilty for your role in receiving, purchasing, and selling falsely labeled imported seafood. Accordingly, FDA concludes that the nature and seriousness of the offense involved supports 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 owner of a seafood packing and re-packing company. In that role, you falsely labeled imported seafood - this false labeling could mislead the United States and the American consumer. As the owner, you were directly involved in the false labeling of approximately $8,000 worth of frozen fillets of pollock, a product of China, as cod loins, from Canada. Accordingly, FDA concludes that the nature and extent of your participation in the relevant offense as the owner of a seafood packing company 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 knowingly falsely labeled fish that had been imported, purchased, and received from a foreign country and was intended to be transported in interstate commerce. You took no steps to mitigate the impact on the public of your actions. 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 imposition of a 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)) debarring 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 false labeling in violation of 16 U.S.C. § 3372(d). FDA finds that this conviction was for conduct relating to the importation of an article of food.

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-2012-N-0405 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
GCF-1/Rebecca Goldberg
HFC-230/Debarment File
HFC-230/CF
HFC-200/CF