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JUN 10 2010 (Resent)

Su Van Ho  
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MAY 26 2010

PROPOSAL TO DEBAR  
NOTICE OF OPPORTUNITY FOR HEARING  
Docket No. FDA-2010-N-0213

Dear Mr. Ho:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debaring you for a period of 15 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 pled guilty to three felonies 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.

Conduct Related to Conviction

On August 4, 2009, the United States District Court for the Central District of California accepted your plea of guilty and entered judgment against you for the offenses of: Smuggling, Causing an Act to be Done in violation of 18 U.S.C. § 545, as charged in Count 1 of the Information; Concealing a Material Fact by Trick or Device in violation of 18 U.S.C. § 1001(a)(1), as charged in Count 2 of the Information; and Receipt of an Adulterated Food and Delivery Thereof for Pay in violation of 21 U.S.C. §§ 331(c), 333(a)(1), and 342(a)(3), as charged in Count 5 of the Information. The underlying facts supporting these convictions are as follows:

Between at least January 1, 2003, through September 16, 2004, you owned and operated Vincent Seafood and Trading, a frozen seafood import and distribution business. On or about August 20, 2004, in violation of 18 U.S.C. §§ 545 and 2(b), you knowingly and willfully, with the intent to defraud the United States, did pass and cause to be passed through the customhouse a fraudulent commercial invoice that falsely described 610 cartons of Frozen Silk Worm as "Frozen Dade" fish and 461 cartons of Pineapple Brand Betel Nut as "Frozen Palmnut."

On or about September 16, 2004, in violation of 18 U.S.C. § 1001(a)(1), you knowingly and willfully concealed and covered up by trick, scheme, or device a material fact. Specifically, you were ordered by the United States Food and Drug Administration (FDA) to export or destroy 118 cartons of frozen Featherback fish from import shipment N08-0026008-0 that contained *Salmonella* bacteria, with verification of such exportation or destruction by the FDA. You

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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 here:

**1. Nature and seriousness of any offense involved.**

As described in detail above, you were convicted of the offenses of smuggling, causing an act to be done in violation of 18 U.S.C. § 545; concealing a material fact by trick or device in violation of 18 U.S.C. § 1001(a)(1); and for receipt of an adulterated food and delivery thereof for pay in violation of 21 U.S.C. §§ 331(c), 333(a)(1), and 342(a)(3).

The Agency finds that your conduct seriously undermined the integrity of the United States customs process and the FDA's regulation of the importation of food into the United States and the introduction of goods into interstate commerce. 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.**

As the owner and operator of Vincent Seafood and Trading, you knowingly and willfully, with the intent to defraud the United States, did pass and cause to be passed through customs a fraudulent commercial invoice that falsely described 610 cartons of Frozen Silk Worm as "Frozen Dade" fish and 461 cartons of Pineapple Brand Betel Nut as "Frozen Palmnut." In addition, you were ordered by the United States Food and Drug Administration to export or destroy 118 cartons of frozen Featherback fish from an import shipment that contained *Salmonella* bacteria and you were told to verify the exportation or destruction. Instead of exporting or destroying the contaminated fish, you sold 103 cartons of the contaminated fish and concealed and covered up this fact. In furtherance of your cover up, you substituted 103 cartons of Featherback fish from other, unrelated import shipments and presented the substituted cartons of fish for verification of exportation or destruction. Accordingly, the Agency will consider the nature and extent of your participation as the owner and operator of the company 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 smuggling merchandise into the United States without properly declaring the merchandise as required by United States Customs law. You knew that the merchandise was of a type that should have been declared, and you acted willfully with the intent to defraud the United States.

You used trick, scheme, or device to conceal and cover up a matter within the jurisdiction of the executive branch of the United States government. You acted willfully, deliberately and with knowledge.

You received in interstate commerce and delivered in exchange for payment an adulterated food, namely, frozen Featherback fish contaminated with *Salmonella*.

The facts support the belief that you displayed a wanton disregard for the public health and the food importation regulatory process. The Agency considers your failure to take any steps to mitigate the impact on the public to be 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 the FDA.

Proposed Action and Notice of Opportunity for Hearing

FDA concludes that the findings discussed above support the maximum 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 15 years. You were convicted of smuggling, causing an act to be done in violation of 18 U.S.C. § 545; concealing a material fact by trick or device in violation of 18 U.S.C. § 1001(a)(1); and receipt of an adulterated food and delivery thereof for pay in violation of 21 U.S.C. §§ 331(c), 333(a)(1), and 342(a)(3). FDA finds that these three convictions were 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

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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-2010-N-0213 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.

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 (FDA Staff Manual Guide 1410.35).

Sincerely,



Brenda Holman  
RADM, United States Public Health Service  
Acting Director  
Office of Enforcement  
Office of Regulatory Affairs