DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anneri Izurieta/83480-004
FDC Miami
Federal Detention Center
P.O. Box 019120
Miami, FL 33101

09-28-2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2011-N-0589

Dear Mrs. Izurieta:

This letter is to inform you that the U.S. Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of thirty 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 six 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 11, 2011, you were convicted in the United States District Court for the Southern District of Florida of one count of conspiracy to smuggle goods into the United States, in violation of 18 U.S.C. § 371, and five counts of smuggling goods into the United States, in violation of 18 U.S.C. § 545. The United States District Court for the Southern District of Florida entered judgment against you on July 29, 2011. The underlying facts supporting these convictions are as follows.

As alleged in the indictment that was filed against you, in or about April 2007, and continuing through about December 2010, you were a resident of Miami-Dade County and served as the President and Director of Naver Trading, Corp., a registered Florida corporation engaged in the business of importing and distributing food, including dairy products, in local and interstate commerce.

Beginning on or about April 18, 2007, and continuing through on or about December 23, 2010, in violation of 18 U.S.C. § 371, you knowingly, and with intent to further the object of the conspiracy, conspired with others to commit an offense against the United States - to fraudulently and knowingly import and bring into the United States merchandise contrary to law in violation of 18 U.S.C. § 545. Specifically, you conspired to distribute and sell imported dairy products that

FDA had detained after receiving notice from FDA that the dairy products were suspected to be adulterated.

While serving as President and Director of Naver Trading, you caused dairy products and other food to be imported from Honduras and Nicaragua. Despite requests from FDA to disclose the location of shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *E. coli, Staphylococcus aureus,* and *Salmonella*, you failed to do so. You also distributed shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *E. coli, Staphylococcus aureus,* and *Salmonella*. These shipments were not authorized for entry into the United States. You failed to redeliver for destruction and exportation shipments of dairy products that FDA had determined to be adulterated with *E. coli, Staphylococcus aureus,* and *Salmonella* and that were not authorized for entry into the United States. You then distributed dairy products that FDA had determined to be adulterated with *E. coli, Staphylococcus aureus,* and *Salmonella* and that were not authorized for entry into the United States. This conduct was in violation of 18 U.S.C. § 545.

Specifically, from approximately April 18, 2007, and continuing to approximately December 7, 2010, you fraudulently and knowingly imported and brought into the United States merchandise contrary to law, in particular, entry numbers BFV-0143458-8, WIG-2045735-2, BFV-0153541-8, WIG-2045978-8 and BYV-0004364-2. Further you failed to redeliver, export, and destroy with FDA supervision the dairy products and other food products contained in these shipments after receiving notice from FDA regarding concerns about the adulteration of these products with *E. coli, Staphylococcus aureus,* and/or *Salmonella*.

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 your felony convictions for conspiracy to smuggle goods into the United States, in violation of 18 U.S.C. § 371, and for smuggling goods into the United States, in violation of 18 U.S.C. § 545, were for conduct relating to the importation of an article of food because your offenses related to the importation of dairy products and other products into the United States. Because your 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 offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. § 371 and for smuggling goods into the United States in violation of 18 U.S.C. § 545.

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 knowingly and fraudulently imported and distributed merchandise that was adulterated and posed a risk to the public health into the United States contrary to law. 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.

As President and Director of Naver Trading, Corp., you were responsible for actions taken on behalf of the company, and you and other company employees fraudulently and knowingly imported food products into the United States contrary to law. To further enrich yourself and the company, you distributed adulterated dairy products despite determination by FDA that the products were adulterated with *E. coli, Staphylococcus aureus,* and *Salmonella* and were not authorized for entry into the United States. Accordingly, FDA concludes that the nature and extent of your participation in the relevant offenses as the president and director of the 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 were convicted of conspiring to smuggle goods into the United States and smuggling goods into the United States without declaring them on entry paperwork and making them available for an FDA examination. You distributed adulterated products in interstate commerce rather than redeliver, export, and destroy them after receiving notice from FDA that the dairy products tested positive for *Staphylococcus aureus* and *Salmonella*. You took no steps to mitigate the impact on the public of your actions. 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.

On October 4, 2010, you were convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), of breaking a customs seal, fastening, or mark, in violation of 18 U.S.C. § 549. Specifically, you removed red Customs and Border Protection (CBP) detention/seizure warning labels, which stated, "This property is under detention and/or seizure . . . . This seal must not be removed, broken, injured or defaced, or the property tampered with or removed except with the written authorization of a CBP/ICE officer," from pallets containing cheese products that you had imported into the United States and that had been detained by CBP. You also removed cheese products from the detained pallets and refilled the detained pallets with substitute cheese products. This conviction involved matters within the jurisdiction of FDA, because it involved food that was being imported into the United States and intended for introduction into interstate commerce. Accordingly, FDA has determined that your prior conviction involving matters within the jurisdiction of FDA supports the maximum possible period of debarment.

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 thirty years. You were convicted of conspiracy, in violation of 18 U.S.C. § 371, for conspiring to smuggle goods into the United States and for smuggling goods into the United States, in violation of 18 U.S.C. § 545 . FDA therefore finds that these 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 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-2011-N-0589 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 Affairs

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-615/Amy Barringer
HFS-600/Michael Roosevelt
HFC-2/ Melissa Pickworth
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