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Peter X. Lam  
[REDACTED]

SEP 11 2009

PROPOSAL TO DEBAR  
NOTICE OF OPPORTUNITY FOR HEARING  
Docket No. FDA-2009-N-0293

Dear Mr. Lam:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of 20 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 four 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 October 29, 2008, you were convicted in the United States District Court for the Central District of California of one count of conspiracy, in violation of 18 U.S.C. 371, for conspiring to violate 18 U.S.C. 545 (importation contrary to law) and 21 U.S.C. 331(a) and (c) and 333(a)(2) (felony delivery and receipt of misbranded food) and of three counts of violating 18 U.S.C. 545 and 2(b) (trafficking in fish contrary to 18 U.S.C. 541 and 21 U.S.C. 331(a)). Specifically, you were involved in trafficking in fish of the species *Pangasius hypophthalmus*, commonly referred to as "Vietnamese catfish" or "basa," in an effort to evade your obligation to pay anti-dumping duties to the United States. Judgment was entered against you on May 22, 2009.

You were found guilty of the offenses as set forth in the indictment, which included the following:

- Beginning in or about May 2004 and continuing thereafter to on or about October 2006, in the Central District of California and elsewhere, in violation of 18 U.S.C. 371, you did knowingly conspire and agree to commit the following offenses against the United States, namely:
  - a. to knowingly make and submit a false record, account, and label for, and a false identification of, fish, specifically Vietnamese catfish, with a market value greater than \$350, which was transported in foreign commerce, imported, and sold, and

- imported with intent to sell;
  - b. to knowingly make a false statement in a declaration, or procure the making of such a false statement, as to a matter material thereto without reasonable cause to believe the truth of such statement;
  - c. to knowingly import and bring into the United States merchandise that is Vietnamese catfish, contrary to law, and to knowingly receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of such merchandise after importation, knowing it to have been imported and brought into the United States contrary to law;
  - d. to knowingly effect an entry of goods that is Vietnamese catfish, by the payment of less than the amount of duty legally due, and;
  - e. to introduce and deliver for introduction into and to receive in interstate commerce food, specifically frozen Vietnamese catfish fillets, that is misbranded and adulterated, with the intent to defraud and mislead.
- You accomplished the objectives of the conspiracy through the following means:
  - a. you engaged in a scheme to falsely identify, mislabel, and fraudulently declare certain imports of frozen fillets of Vietnamese catfish in order to evade anti-dumping duties and to then market the relatively low-priced frozen fillets in the United States, still falsely labeled;
  - b. you sold the imported frozen Vietnamese catfish fillets in the United States mislabeled as "sole," "grouper," "flounder," "common carp," "carp," "conger pike," "mudfish," and "channa," as well as "basa," for a lower price than would have been necessary if the anti-dumping duties had been paid;
  - c. you told purchasers who had specifically ordered *Pangasius hypophthalmus* and/or Vietnamese catfish and/or basa, and who questioned the subsequently received boxes of fish labeled as other species, or invoices identifying the fish as other species, that, among other things, the other names used were alternative names for what the purchasers had ordered, or that the factory had made an error with the boxes but the contents of the box were in fact the Vietnamese catfish that the purchasers had ordered; and
  - d. on or about November 17, 2004, you filled an order for 800 cases of "catfish Fillet (Basa)" with 800 cases of "conger pike Fillet," and then represented to the purchaser that "Conger pike Fillet" was the scientific name for basa and that the product sold to the purchaser was basa.
- On or about November 7, 2004, December 7, 2004, February 3, 2005 and February 27, 2005, in the Central District of California and elsewhere, in violation of 18 U.S.C. 545 and 2(b), you did knowingly make and submit a false record, account, and label for and a false identification of fish with a market value greater than \$350, in that you made and submitted to a customs broker a commercial invoice and related shipping and sale documents, and made labels for the containers of said fish, that identified the fish as "common carp," "sole," and "conger pike," when in truth and in fact, as you then knew, said fish was Vietnamese catfish, said fish having been transported in foreign commerce and imported with intent to sell.

FDA's Finding

Section 306(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(b)(1)(C)) permits the 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 Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any food. FDA finds that your three felony convictions for trafficking in illegally imported merchandise in violation of 18 U.S.C. 545 and 2(b) and your felony conviction for conspiracy in violation of 18 U.S.C. 371 were for conduct relating to the importation of an article of food. 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 offense 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 the 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 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 provided 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 the offense involved.**

As described in detail above, you were convicted of one count of conspiracy under 18 U.S.C. 371, for conspiring to violate 18 U.S.C. 545 and 21 U.S.C. 331(a) and (c) and 333(a)(2). You were also convicted of three counts of violating 18 U.S.C. 545 and 2(b) (trafficking in fish imported

contrary to 18 U.S.C. 541 and 21 U.S.C. 331(a)). Specifically, you were involved in a scheme to traffic in Vietnamese catfish to evade anti-dumping duties and market the Vietnamese catfish in the United States at less than fair market value. To accomplish this objective, you knowingly made and submitted a false record, account, and label for, and a false identification of, Vietnamese catfish which was transported in foreign commerce, imported, and sold, and imported with intent to sell. You also made and submitted to a customs broker a commercial invoice and related shipping and sale documents, and made labels for the containers of the fish that identified the fish as "common carp," "sole," and "conger pike," when in fact, as you then knew, the fish was Vietnamese catfish. To knowingly make and submit a false record, account, and label for, and a false identification of, Vietnamese catfish, which was transported in foreign commerce, imported and sold, and imported with the intent to sell is importation contrary to law.

FDA finds that your conduct seriously undermined the integrity of the United States customs process and of FDA's regulation of the importation of food into the United States and the introduction of food into interstate commerce. You knowingly created and submitted false information to a customs broker to facilitate the importation and sale of approximately 11.6 million pounds of Vietnamese catfish, you knowingly misbranded Vietnamese catfish imported into and offered for sale in the United States, and you personally sold a total of \$3,041,398.97 (black market wholesale value) of Vietnamese catfish that was falsely labeled as "sole," "conger pike," "common carp," "channa," or "grouper." Given the nature and scope of this conduct, FDA concludes that the nature and seriousness of the conduct underlying your conviction 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 participated in the planning of, directed, and initiated the conduct underlying your convictions. Starting in late summer or early fall of 2004, you became President and a Director of Virginia Star Seafood Corporation (Virginia Star), one of the corporations that imported and resold the Vietnamese catfish in which you trafficked. In addition to being President of Virginia Star, you were Virginia Star's primary salesperson. You were also the owner of all of the stock of International Sea Products Corporation (ISP), another corporation that imported and resold the Vietnamese catfish in which you trafficked. Between approximately May 2004 and March 2005, U.S. Customs records show that Virginia Star and ISP imported some 11.6 million pounds (\$15.6 million) of frozen fish fillets labeled and declared as "sole," "pike," "flounder," or "freshwater fish." You personally sold, between September 2004 and June of 2005, a total of \$3,041,398.97 (black market wholesale value) of Vietnamese catfish labeled as "sole," "conger pike," "common carp," "channa," or "grouper." You had direct contact with customers who had ordered Vietnamese catfish or basa, and when these customers would call to ask why the product was labeled as different than what they had ordered, you explained that there had been a factory error, or that the name used was just another name, or the scientific name, for Vietnamese catfish or basa. Therefore, FDA considers that the nature and extent of your management participation supports the maximum possible period of debarment.

Peter X. Lam  
Docket No. FDA-2009-N-0293

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

In determining the period of a debarment, FDA is also to consider the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigation (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. You were convicted of engaging in a scheme to falsely identify, mislabel, and fraudulently declare certain imports of frozen fillets of Vietnamese catfish in order to evade anti-dumping duties, and to then market the frozen fillets in the United States, still falsely labeled. You failed to take any action necessary to mitigate the public's potential reliance on this false information, you had direct contact with the public and knowingly provided your customers with false information when you were asked about the false labels, and you received financial gain as a result of the conduct underlying your conviction. Therefore, FDA considers 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 the FDA.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA 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 20 years. You were convicted of three counts of trafficking in illegally imported merchandise, causing an act to be done in violation of 18 U.S.C. 545, and one count of conspiracy, in violation of 18 U.S.C. 371. FDA finds that your three felony convictions for trafficking in illegally imported merchandise in violation of 18 U.S.C. 545 and 2(b) and your felony conviction for conspiracy in violation of 18 U.S.C. 371 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

Peter X. Lam  
Docket No. FDA-2009-N-0293

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.

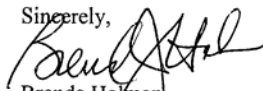
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the 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-2009-N-0293 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 Hoffman  
Acting Director  
Office of Enforcement  
Office of Regulatory Affairs