



BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jun Yang/45596-424
FCI Texarkana
Federal Correctional Institution
Satellite Camp
Texarkana, TX 75505

10-01-2014

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2014-N-0964

Dear Mr. Yang:

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 four 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 FD&C Act) (21 U.S.C. § 335a(l)(1)(B)), 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 November 14, 2013, you were convicted, as defined in section 306(l)(1)(B), of the FD&C Act, in the United States District Court for the Northern District of Illinois, when the court accepted your plea of guilty and entered judgment against you for the offense of smuggling goods into the United States, in violation of 18 U.S.C. § 545. The underlying facts supporting this conviction are as follows:

On or about February 10, 2012, you facilitated the sale of imported honey with a declared value of \$92,800, knowing that the honey was of Chinese origin and was imported and brought into the United States contrary to law. As part of your fraudulent practice, you brokered the sale of two container loads of purported "100% pure Indian honey," knowing that the honey was falsely and fraudulently imported and brought into the United States as a product of India in avoidance of U.S.-imposed antidumping duties, thereby causing losses to the United States of approximately \$97,625. This conduct was in violation of 18 U.S.C. § 545.

In your plea agreement, you also admit that you operated and controlled National Honey, Inc., which did business as National Commodities Company, and served as the principal point of

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contact for brokering the sale of honey between overseas honey suppliers and U.S. customers. As further admitted in your plea agreement, between about 2009 and 2012, you sold 778 container loads of honey valued at approximately \$22,864,153 to Honey Holding and Honey Packer 1 (U.S. customers). This was part of a fraudulent practice to enter and introduce and cause others to enter and introduce transshipped Chinese-origin honey into the commerce of the United States in avoidance of U.S.-imposed antidumping duties. You did this even though you knew that the honey was falsely and fraudulently imported, entered, marketed, and sold as purely non-Chinese honey, including as honey from Malaysia and India. This fraudulent practice caused losses to the United States of as much as \$37,991,375.

In your plea agreement, you also admit that you ordered honey from Chinese honey suppliers, knowing that the Chinese honey suppliers would send the Chinese origin honey to countries including Malaysia and India, where the honey was mislabeled as to country of origin before it passed through a United States customhouse as non-Chinese-origin honey. You and National Commodities caused the formation of at least three companies and used at least one other company to import and enter honey from a Chinese honey supplier knowing that some of the honey was Chinese in origin. You and National Commodities benefitted from the companies filing custom entry forms that falsely and fraudulently declared all the honey as originating from Malaysia and India. You and National Commodities purchased honey imported by the companies despite knowing that some or all of the honey was Chinese in origin, but declared at the time of importation and entry as entirely originating from Malaysia and India.

Your plea agreement further specifies that you obtained and circulated and caused others to obtain and circulate false and fraudulent bills of lading, invoices, packing lists, country of origin certificates, and other papers, which you knew to be false and fraudulent. These records were used to declare Chinese-origin honey as having originated from Malaysia and India. As further specified in your plea agreement, you instructed an undercover law enforcement agent to destroy unfavorable test results that showed that purported Vietnamese honey that you sold tested positive for the presence of Chloramphenicol, an antibiotic. Residues of Chloramphenicol in honey cause the honey to be adulterated under the FD&C Act. In anticipation of an investigation by U.S. Customs and Border Protection and the U.S. Food and Drug Administration, you knowingly concealed and covered up three laboratory reports showing the presence of Chloramphenicol.

FDA's Findings

Section 306(b)(1)(C) of the FD&C 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 FD&C Act (21 U.S.C. § 335a(b)(3)(A)). FDA finds that your felony conviction for smuggling goods into the United States, in violation of 18 U.S.C. § 545 was for conduct relating to the importation of an article of food because you committed an offense related to the importation of honey into the United States. Because your felony conviction occurred less than five years before the initiation of this action, this action is timely under section 306(l)(2) of the FD&C 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 FD&C Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years. Section 306(c)(3) of the FD&C 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 FD&C 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 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 facilitated the sale of imported honey with a declared value of \$92,800, knowing that the honey was of Chinese-origin and was imported and brought into the United States contrary to law. As part of your fraudulent practice, you brokered the sale of two container loads of purported "100% pure Indian honey," knowing that the honey was falsely and fraudulently imported and brought into the U.S. as a product of India in avoidance of U.S.-imposed antidumping duties, thereby causing losses to the United States of approximately \$97,625. Accordingly, FDA considers the nature and seriousness of the offense as an unfavorable factor.

2. Nature and extent of management participation in any offense involved.

You operated and controlled National Commodities and served as their principal point of contact for brokering the sale of honey between overseas honey suppliers and the United States customers. You facilitated the sale imported honey, knowing that the honey was of Chinese origin and brought into the United States contrary to law. Accordingly, FDA considers the nature and extent of your participation as a person who operated and controlled National Commodities 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 goods into the United States. As part of your fraudulent practice to which you pled guilty, you brokered the sale of two container loads of purported "100% pure Indian honey," knowing that the honey was falsely and fraudulently imported and brought into the United States as a product of India in avoidance of U.S.-imposed antidumping duties.

However, you took some steps to cooperate with the government's investigation, as set forth in the transcript of your sentencing hearing and the government's position paper as to sentencing factors. Under section 306(c)(3)(C) of the FD&C Act, cooperation with an investigation is one type of action that can mitigate the impact on the public of an offense. FDA considers your cooperation with the investigation to be a favorable factor, though FDA considers your failure to take other 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 FDA. FDA considers this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA concludes that the facts supporting the unfavorable factors outweigh those in support of the favorable factor, and therefore warrant the imposition of a four-year period of debarment. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. § 335a(b)(1)(C)) debarring you from importing an article of food or offering such an article for import into the United States for a period of four years. You were convicted of smuggling goods into the United States, in violation of 18 U.S.C. § 545. FDA finds that this conviction was for conduct relating to the importation into the United States of food. Based on the analysis above, FDA concludes that the unfavorable factors outweigh the favorable factors. However, your efforts to cooperate with the government's investigation, in conjunction with your lack of prior criminal convictions involving matters within the jurisdiction of FDA, justify the imposition of less than the maximum period of debarment. FDA proposes that you be debarred for a period of four years.

In accordance with section 306 of the FD&C 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 FD&C Act (21 U.S.C. § 335a(i)).

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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 FD&C 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-2014-N-0964 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 FD&C Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the FD&C Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement & Import Operations, Office of Regulatory Affairs.

Sincerely,



Douglas Stearn
Director,
Office of Enforcement & Import Operations