DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Hung Yi Lin/ 64368-112
FCI Victorville Medium II
Federal Correctional Institution
PO Box 3850
Adelanto, CA 92301

07-25-2014

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2013-N-1484

Dear Ms. Lin:

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 twelve 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 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, and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On September 30, 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 three counts of the offense of entry of goods into the United States by means of false statements, in violation of 18 U.S.C. § 542. The underlying facts supporting this conviction are as follows:

You owned and operated KBB Express Inc., a freight forwarding company located in South El Monte, California that provided nationwide transportation, delivery, and other logistical services for imported and entered merchandise, including Chinese-origin honey. You also served as the U.S. agent for at least twelve importers for which you handled the process of importing, and coordinating with customhouse brokers to enter and bring in, Chinese-origin honey into the United States.

On or about December 13, 2009, you entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and

false papers, including Bureau of Customs and Border Protection (CBP) forms that falsely declared that approximately four container loads of Chinese-origin honey with a declared value upon entry of approximately $92,822 was Chinese honey syrup. By so doing, you caused losses to the United States of approximately $205,141 in uncollected anti-dumping duties and honey assessment fees, when in fact you knew the product was Chinese honey. This was in violation of 18 U.S.C. § 542.

On or about December 13, 2009, you entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CBP forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately $69,617 was Chinese honey syrup. By so doing, you caused losses to the United States of approximately $153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact you knew the product was Chinese honey. This was in violation of 18 U.S.C. § 542.

On or about December 13, 2009, you entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CBP forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately $69,617 was Chinese honey syrup. By so doing, you caused losses to the United States of approximately $153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact you knew the product was Chinese honey. This was in violation of 18 U.S.C. § 542.

You admitted that between 2009 and 2012, you caused up to 764 shipping containers of Chinese-origin honey valued at approximately $11,489,306 to be fraudulently imported and entered into the United States, thereby causing losses to the United States of as much as $39,203,144 through your fraudulent practices.

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 convictions for entry of goods by means of false statements in violation of 18 U.S.C. § 542 constitute conduct relating to the importation of an article of food because you committed an offense related to the importation of Chinese honey 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 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, and debarment periods may run concurrently or consecutively in the case of a person debarred for multiple offenses. 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 entry of goods into the United States by means of false statements in violation of 18 U.S.C. § 542.

FDA 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 caused the submission of false information to CBP, which relied on this information, by declaring that Chinese-origin honey was instead honey syrup. By so doing, you caused losses to the United States of as much as $39,203,144 in uncollected antidumping duties and honey assessment fees. Accordingly, FDA considers 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 KBB Express Inc., a freight forwarding company that provided transportation and other logistical services for imported goods, you entered and introduced Chinese-origin honey into the United States that was falsely declared to be Chinese honey syrup. Accordingly, FDA considers the nature and extent of your participation as the owner and operator of KBB Express Inc. 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 entry of goods into the United States by means of false statements in violation of 18 U.S.C. § 542. Specifically, you entered and introduced Chinese-origin honey into the United States that was falsely declared to be Chinese honey syrup. You knew that the declarations made about the merchandise being imported were false, and you acted willfully with the intent to defraud the United States. However, you took some steps to cooperate with the government's investigation, as set forth in the transcript of your sentencing hearing. 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 has determined that debarment is appropriate, and 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 for a period of twelve years from importing an article of food or offering such an article for import into the United States. You pled guilty to three counts of entry of goods by means of false statements, in violation of 18 U.S.C. § 542. 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, justifies the imposition of less than the maximum period of debarment. FDA proposes that each felony offense be accorded a debarment period of four years.

In the case of a person debarred for multiple offenses, under section 306(c)(2)(A) of the FD&C Act (21 U.S.C. § 335a(c)(2)(A)), FDA may determine whether the periods of debarment shall run concurrently or consecutively. FDA determines that the four year period of debarment for each of the three offenses should be served consecutively, resulting in a total debarment period of twelve years. Accordingly, FDA 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 articles of food or offering such articles for import into the United States for a period of twelve 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)).

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-2012-N-1484 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 and Import Operations, Office of Regulatory Affairs.

Sincerely,

Douglas Stearn
Director
Office of Enforcement and Import Operations

cc:
HFC-200/Douglas Stearn
HF-22/Matthew Warren
HFC-130/Michael Rogers
HFC-300/ Thomas South
HFM-100
HFC-180/Anthony Taube
HFC-170/Domenic Veneziano
HFS-605/Jennifer Thomas
HFS-600/Michael Roosevelt
HFC-1Michael Verdi
GCF-1/Ann Wion
GCF-1/Jessica O'Connell
HFC-230/Debarment File
HFC-200/CF