DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Resent

11-30-2012

Shu Bei Yuan/57727-112
FCI Dublin
Federal Correctional Institution
5701 8th St. Camp Parks
Dublin, CA 94568

11-05-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-1044

Dear Ms. Yuan:

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 five 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 Act) (21 U.S.C. § 335a(l)(1)(B)), of a felony 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 June 22, 2012, you were convicted, as defined in section 306(l)(1)(B) of the Act, when the United States District Court for the Northern District of Illinois accepted your plea of guilty and entered judgment against you, for 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.

In or around March 2005 and continuing until in or around November 2005, you conducted a scheme to fraudulently enter goods into the United States by means of false statements and documents, in violation of 18 U.S.C. § 542. The purpose of your scheme was to import, enter, and sell Chinese-origin honey into the United States and avoid the payment of antidumping duties by falsely declaring to the United States Department of Homeland Security, Bureau of Customs and Border Protection (CBP) that the imported honey originated from countries other than China, including South Korea, when in fact you knew that the honey originated from China.

Specifically, you worked for and with Hung Ta Fan and others to enter and import Chinese honey into the U.S. by means of false documents. Fan owned and operated multiple California based

honey import companies. You worked for and with Fan from approximately June 2004 through September 2005, and handled the books and records of Fan's companies. Fan used multiple companies to import and enter Chinese origin honey into the U.S. to avoid scrutiny by CBP.

Between approximately August and November 2005, you and others caused the fraudulent import and entry into the U.S. of approximately 26 entries of Chinese origin honey falsely declared as Korean honey, having a total declared entry value of approximately $808,287, thereby avoiding antidumping duties totaling approximately $1,485,631. One of those entries occurred on August 23, 2005 when you entered and introduced, and caused others to enter and introduce, into the commerce of the U.S., imported merchandise by means of a false and fraudulent practice, false statement, and fraudulent or false paper, including records and CBP entry forms that falsely declared that approximately 37,120 kilograms of Chinese origin honey in fulfillment of a purchase order, with a declared value of approximately $31,552, originated from Korea, when in fact the honey originated in China, thereby causing losses to the U.S. in uncollected antidumping duties.

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 conviction for entry of goods by means of false statement, in violation of 18 U.S.C. §542, was for 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 conviction 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 an offense under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years. 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 three 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 entry of goods and causing the entry of goods into the United States by means of false and fraudulent statements and documents, in violation of 18 U.S.C. § 542.

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 caused the submission of false information to CBP, which relied on this information, for the purpose of importing, and selling Chinese-origin honey in the U.S.. Your false and fraudulent statements and documents caused 26 entries comprised of Chinese-origin honey falsely declared as Korean-orgin honey having a total declared value upon entry into the U.S. of at least $808,287, thereby avoiding antidumping duties otherwise applicable to Chinese-origin honey of approximately $1,485,631. Accordingly, FDA considers the nature and seriousness of the offenses involved as an unfavorable factor.

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

You were convicted of entering, and causing to be entered, goods into the United States by means of false and fraudulent statements and documents. You did not properly declare the origin of the merchandise as required by United States law. 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. You took no steps to mitigate the impact on the public of your actions, which undermined the integrity of FDA's regulation of the importation of food into the United States and the introduction of food into interstate commerce.

The facts support the belief that you displayed a wanton disregard for the food importation regulatory process and the impact of your actions on the public. Accordingly, FDA considers your failure to take any steps to mitigate the impact on the public as an unfavorable factor.

3. 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

Weighing all factors, FDA concludes that the facts supporting the unfavorable factors outweigh those in support of the favorable factors and warrant the maximum five-year period of debarment. You pled guilty to one count of entry of goods by means of false statements, in violation of 18 U.S.C. § 542, for importing honey for which you falsely declared the country of origin to avoid paying anti-dumping duties of approximately $1,485,631. FDA finds that this conviction was for conduct relating to the importation of an article of food. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the Act debarring you from importing articles of food or offering such articles for import into the United States for a period of five years.

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-2012-N-1044 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) (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act and under authority delegated to the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

Sincerely,

Reynaldo Rodriquez, Jr.
Acting Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs

cc:
HF-22/Matthew Warren
HFC-300/ Jeffrey Ebersole
HFM-100
HFC-180/Anthony Taube
HFC-170/Domenic Veneziano
HFS-605/Jennifer Thomas
HFS-600/Michael Roosevelt
HFC-1Michael Verdi
GCF-1/Joy Dawson
GCF-1/Ann Wion
GCF-1/Jessica O'Connell
GCF-1/Rebecca Goldberg
HFC-230/Debarment File
HFC-200/CF