



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0964]

Jun Yang: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jun Yang for a period of 4 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Yang was convicted, as defined in the FD&C Act, of one felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Yang was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 7, 2014 (30 days after receipt of the notice), Mr. Yang had not responded. Mr. Yang's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division Of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM-4144), Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

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 if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On November 14, 2013, Mr. Yang was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Northern District of Illinois accepted his plea of guilty and entered judgment against him for the following offense: One count of smuggling goods into the United States, in violation of 18 U.S.C. 545.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows:

On or about February 10, 2012, Mr. Yang 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 his fraudulent practice, Mr. Yang 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 anti-dumping duties, thereby causing losses to the United States of approximately \$97,625.

Mr. Yang admitted that he operated and controlled National Honey, Inc., which did business as National Commodities Company, and served as the principal point of contact for brokering the sale of honey between overseas honey suppliers and U.S. customers. Mr. Yang further admits that between 2009 and 2012 he 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 anti-dumping duties. Mr. Yang continued this practice even though he 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.

Mr. Yang also admitted that he 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 the country of origin before it passed through a U.S. customs house as non-Chinese origin honey. Mr. Yang 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. Mr. Yang and National Commodities benefitted from the company's filing customs entry forms that falsely and fraudulently declared all the honey as originating from Malaysia and India. Mr. Yang 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.

Mr. Yang also admitted that he 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 he knew to be false and fraudulent. These records were used to declare Chinese-origin honey as having originated from Malaysia and India. Mr. Yang also instructed an undercover law enforcement agent to destroy unfavorable test results that showed purported Vietnamese honey that he 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 FDA, Mr. Yang knowingly concealed and covered up three laboratory reports showing the presence of chloramphenicol.

As a result of his conviction, on October 1, 2014, FDA sent Mr. Yang a notice by certified mail proposing to debar him for a period of 4 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Yang's felony conviction for smuggling of goods into the United States in violation of 18 U.S.C. 545 constitutes conduct relating to the importation into the United States of an article of food because he committed an offense related to the importation of Chinese honey into the United States.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Yang should be subject to a 4-year period of debarment. The proposal also offered Mr. Yang an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Yang failed to respond within the timeframe

prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Jun Yang has been convicted of one felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 4-year period of debarment.

As a result of the foregoing finding, Jun Yang is debarred for a period of 4 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Jun Yang is a prohibited act.

Any application by Mr. Yang for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2014-N-0964 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. 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.

Dated: March 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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