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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0169]

Chung Po Liu; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Chung Po Liu's (Liu) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Liu for 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Liu was convicted of a felony for conduct relating to the importation of an article of food into the United States. In determining the appropriateness and period of Liu's debarment, FDA has considered the relevant factors listed in the FD&C Act. Liu has failed to file with the Agency information and analysis sufficient to create a basis for 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 Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8618.

SUPPLEMENTARY INFORMATION:

I. Background

On August 26, 2010, Chung Po Liu pleaded guilty to the felony crime of entering honey, a food, into the commerce of the United States by means of a false statement, in violation of 18 U.S.C. 542 and 2. Liu admitted that he had caused his customs broker to declare Thailand to be the country of origin of one honey shipment, although the majority of the honey originated in China, and to declare the Philippines to be the country of origin of a second honey shipment, although the honey originated in China. Liu admitted that, in each instance, he had documents in his possession establishing that the honey originated in China, that the declaration of country of origin was false, and that he was without reasonable cause to believe it was true. Liu also admitted that the United States began requiring the deposit of estimated anti-dumping duties of between 183 percent and 221 percent on all non-exempt honey of Chinese origin beginning in 2001. Liu did not deposit estimated anti-dumping duties for either of these two shipments of imported honey. Liu also pleaded guilty to the misdemeanor crime of introducing adulterated food into interstate commerce in violation of sections 301(a), 303(a)(1), and 402(a)(2)(C)(i) of the FD&C Act (21 U.S.C. 331(a), 333(a)(1), and 342(a)(2)(C)(i)). Liu admitted that he had introduced honey that contained the unsafe food additive ciprofloxacin, an antibiotic, into interstate commerce. On December 20, 2010, the U.S. District Court for the Western District of Washington entered a criminal judgment against Liu under his guilty plea.

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) authorizes FDA to debar a person from importing articles of food or offering food for importation into the United States based on a finding, under section 306(b)(3) of the FD&C Act, that the person was convicted of a felony for conduct relating to the importation of food into the United States. By letter dated April 25, 2011, in accordance with section 306(i) of the FD&C Act and 21 CFR 10.50(c)(20) and 12.21(b), FDA, Office of Regulatory Affairs (ORA) notified Liu that the Agency proposed to debar him for 5 years from importing any articles of food or offering such articles for importation into the United States and offered an opportunity to request a hearing on the proposed order of debarment to resolve disputed issues of material fact. ORA advised Liu that 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.

In a letter dated May 24, 2011, Liu requested a hearing on his proposed debarment. On June 11, 2011, Liu submitted materials in support of his hearing request. In these materials, which were submitted in accordance with 21 CFR 12.22, Liu acknowledges his felony conviction. However, he urges FDA not to exercise its authority to debar him based on that conviction. In the alternative, he argues that any debarment should be limited to the 1-year period of supervised release that the court ordered him to serve after his release from custody after serving his sentence of incarceration of 1 year and 1 day.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (the Director) has considered Liu's submission. FDA will grant a hearing only if the material submitted shows that there is a genuine and substantial issue of fact for resolution at the hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions,

or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). Based on this review, the Director has concluded that Liu has failed to raise a genuine and substantial issue of fact for resolution at a hearing and that a hearing is not justified. Accordingly, Liu’s request for a hearing is denied, and FDA is issuing this notice to explain the basis for this decision (see 21 CFR 12.24(a) and 12.28).

## II. Arguments

Liu raises two primary arguments in support of his hearing request. Liu first contends generally that debarment is “unwarranted in law and without justification by the facts in the case.” He also urges that FDA should not debar him due to his advanced age and ill health, or, alternatively, that FDA should debar him for a time period of less than 5 years, the debarment period proposed in the Notice of Opportunity for Hearing.

Liu notes that, under section 306(b), the decision whether to debar him is committed to FDA’s discretion, and that FDA is authorized to debar him “as a result of conviction of certain crimes” (June 21 submission at 1). Indeed, section 306(b)(3) of the FD&C Act states that a person is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the United States of any food. Liu does not dispute that he was convicted of a felony crime in violation of 18 U.S.C. 542 and 2, or that his conviction was based on conduct relating to the importation of honey, a food. In the plea agreement Liu signed, which he does not now refute, he admitted that: (1) he entered or introduced, or attempted to enter or introduce, into the commerce of the United States, imported merchandise; (2) he did so by means of any fraudulent or false invoice, declaration, affidavit, letter, paper, or by means of any false statement, written or verbal; and (3) he was without reasonable cause to believe the truth of such statement or procured the making of any such false statement as to any matter material thereto

without reasonable cause to believe the truth of such statement (Plea Agreement at 2). He further admitted that this conduct related to the importation of honey, a food (see, for example, Plea Agreement at 11-12, June 21 submission at 2-3). Accordingly, Liu is subject to debarment under section 306(b)(3) on the basis of that felony conviction.

Since Liu's felony conviction for conduct relating to the importation into the United States of honey establishes a predicate from which FDA may choose to exercise its authority to debar him, Liu's June 21 submission in support of his request for a hearing attempts to raise factual issues concerning the application of the factors in section 306(c)(3) that FDA is required to consider in determining the appropriateness and the period of debarment. These are the applicable criteria: (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 FDA.

Significantly, the health and age of an individual subject to debarment are not included as factors relevant to FDA's exercise of the Agency's debarment authority. Although a defendant may sometimes argue that poor health and advanced age should be considered in mitigation of

punishment, debarment under 21 U.S.C. 335a is not a punitive sanction. Instead it is remedial in purpose. (See DiCola v. FDA, 77 F.3d 504, 507 (D.C. Cir. 1996) (permanent debarment of convicted individual is not punishment, but instead is a remedy to protect the integrity of the drug industry and public confidence in that industry); Bae v. Shalala, 44 F.3d 489, 493 (7th Cir. 1995) (purpose of statute establishing debarment authority was to restore consumer confidence in generic drugs by eradicating widespread corruption in generic drug approval process).) In determining whether to debar Liu, as well as the length of a term of debarment, FDA acts to protect the public health and not to punish Liu. Because we are acting for this remedial, not punitive, purpose, Liu's arguments concerning his health and age are not relevant to this proceeding.

I address each of the relevant factors in turn.

#### A. The Nature and Seriousness of the Offense

Liu emphasizes that he was not convicted of the charge for which he was originally indicted, conspiracy to violate 18 U.S.C. 545 by conspiring to enter goods into the United States through false statement, and to smuggle goods. He urges that conviction under the original charge would have required proof that he acted “knowingly and intentionally” (June 21 submission at 3). He devotes much of his submission to his argument that he did not act “knowingly and intentionally.” According to Liu’s June 21 submission, Liu’s accomplices, Yong Xiang Yan, the owner of Changge Jixiang Bee Products, Ltd. of Henan China, and Boa Zhong Zhang, a vice-president and part owner of Changge, established a scheme to transship and import into the United States Chinese honey, using Indigo Distribution Corp. in the Philippines. He disclaims knowledge of the nature and extent of their operations (June 21 submission at 4).

However, these allegations are not relevant. Liu's conviction was not for violating, or conspiring to violate, 18 U.S.C. 545. The offense that must be considered is his felony violation of 18 U.S.C. 542 and 2, which was based on Liu's causing the false declarations to be made even though he was without reasonable cause to believe the truth of such statements. Even in his June 21 submission, Liu expressly acknowledges that he had documents in his possession indicating that, as described in the Plea Agreement and as charged in the superseding information to which he pleaded guilty, two shipments of honey he imported actually originated in China (June 21 submission at 3). He leaves unchallenged the factual basis for his conviction: That, without reasonable cause to believe the truth of the statements, he caused his customs broker to falsely state that the shipments originated in Thailand (December 20, 2006, shipment) and the Philippines (February 14, 2007, shipment). Although he dismisses these as a "few emails . . . among many hundreds of documents relating to the importation of honey found in Mr. Liu's house" (June 21 submission at 3), he fully admits that these communications were in his possession. Liu has raised no factual issue for resolution at a hearing concerning whether he acted without reasonable cause to believe the truth of the statements concerning where the honey was produced.

We further note that the statement of facts, which Liu admitted in his plea agreement, provides additional information concerning his actions which demonstrate the financial motive behind this offense. Had Liu instructed his customs broker to declare the country of origin as China, he and his companies would have been responsible for anti-dumping duties in the amount of 221 percent of the value of the honey (Plea Agreement at 11-12). Liu's misrepresentation was thus both material and meaningful in the imports process, and it could not have been lost on Liu

how important the country of origin was in the context of the anti-dumping duties for Chinese honey.

Finally, I note that Liu’s conviction did not rest on a single false statement. Instead, he pleaded guilty to a superseding information that included false statements with respect to two separate entries of imported Chinese honey, 2 months apart. His conviction did not rest on a single isolated incident, but on a repeated violation.

Therefore, it is undisputed that Liu was responsible for multiple material false statements that resulted in the avoidance of significant duties for the importation of two shipments of honey with a total declared value of \$186,912. As such, I agree with ORA’s evaluation of this consideration and find that the nature and seriousness of Liu’s felony offense weighs strongly in favor of debarment.

#### B. The Nature and Extent of Management Participation in the Offense

Next, I consider whether Liu’s response raised specific facts showing that there is a genuine and substantial issue of fact that requires a hearing concerning the nature and extent of management participation in the offense, including whether corporate policies and practices encouraged the offense, and whether inadequate institutional controls contributed to the offense.

In the Notice of Opportunity for a Hearing, ORA stated, “As the owner of the importing companies, you were responsible for the accuracy of declarations made to United States customs officials. You were without reasonable cause to believe the truth of these declarations regarding the origins of the honey. Further, you directly profited from the domestic sale of the imported honey.”

Liu has not challenged these statements, and all of the descriptions of Liu’s actions in the June 21 submission show him to act alone, as the individual responsible for importing these

two shipments of honey. I agree with ORA that, based upon these facts, the nature and extent of Liu's management participation in the offense weighs in favor of debarment.

C. The Nature and Extent of Voluntary Steps to Mitigate the Impact on the Public

Next, I consider whether Liu has raised specific facts showing that there is a genuine and substantial issue of fact that requires a hearing concerning the nature and extent of voluntary steps to mitigate the impact of his offense on the public, 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.

In the Notice of Opportunity for a Hearing, ORA stated, "You took no steps to mitigate the impact on the public of your actions." Liu has not challenged this statement. As such, I agree with ORA that the nature and extent of Liu's voluntary steps to mitigate the impact to the public weighs in favor of debarment.

D. The Impact of Changes in Ownership, Management, or Operations

In the Notice of Opportunity for Hearing, ORA determined that this factor was not applicable for consideration. Liu has not challenged that determination.

E. Prior Convictions Under the FD&C Act or Related Acts

In the Notice of Opportunity for Hearing, ORA acknowledged that the Agency was unaware of any prior convictions involving matters within the jurisdiction of FDA. The lack of previous violations of the FD&C Act or related statutes by Liu weighs against debarment.

**III. Findings and Order**

The Director of the Office of Scientific Integrity, under section 306(b)(3)(A) of the FD&C Act and under authority delegated to him, finds that Liu has been convicted of a felony

for conduct relating to the importation of food into the United States. Accordingly, FDA may debar Liu from importing articles of food or offering such articles for import into the United States for a period of not more than 5 years.

I have considered the arguments raised by Liu regarding the relevant factors listed in section 306(c)(3) of the FD&C Act and have determined that Liu has raised no genuine and substantial issues of fact that require resolution at an evidentiary hearing. I have considered the factors in section 306(c)(3) of the FD&C Act. The nature and seriousness of Liu's offense, Liu's management participation in the offense, and the lack of any voluntary steps to mitigate the impact of the offense weigh in favor of debarring. Although Liu appears to have no prior criminal convictions involving matters within the jurisdiction of FDA, that consideration does not counterbalance to a sufficient degree the remaining considerations to warrant decreasing the period of debarment. Of particular note is the nature and seriousness of the offense, in light of the volume of honey that was imported, the amount of duties that were avoided, and the fact that false statements were made with regard to two shipments of honey. I agree with ORA's proposed period of debarment and find that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Liu is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Under section 301(cc) of the FD&C Act, 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 Liu is a prohibited act.

Any application by Liu for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2011-N-0169 and sent to the Division of Dockets Management Branch (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 Branch between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov>.

Dated: June 25, 2015.

Nathan Doty,

Director, Office of Scientific Integrity.

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