



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0777]

Adrian Vela: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Adrian Vela for a period of 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 Mr. Vela was convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Vela was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 3, 2012 (30 days after receipt of the notice), Mr. Vela had not responded. Mr. Vela'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, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., 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 21, 2011, Mr. Vela was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U. S. District Court for the Southern District of Florida accepted his plea of guilty and entered judgment against him for the following offenses: One count of conspiracy to falsely label and misbrand food, in violation of 18 U.S.C. 371; one count of false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. 3372(d)(2); and one count of misbranding food in violation of 21 U.S.C. 331(a).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: As alleged in the criminal information filed against Mr. Vela, he was the operating manager and sole shareholder of Sea Food Center, a seafood wholesaler engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products.

Beginning on or about June 30, 2008, and continuing through on or about June

29, 2009, he knowingly combined, conspired, confederated, and agreed with his co-conspirators to commit an offense against the laws of the United States related to the importation of food. The purpose of the conspiracy was for Mr. Vela and his co-conspirators to unlawfully enrich themselves by introducing what the criminal information describes as a less marketable substituted seafood product into the U.S. seafood market. Those products--“Shrimp, Product of Thailand,” “Shrimp, Product of Malaysia,” and “Shrimp, Product of Indonesia”---were misbranded, marketed, and intended to be marketed as “Shrimp, Product of Panama,” a seafood product that the criminal information describes as more readily marketable. Mr. Vela instructed employees at Sea Food Center’s Tampa facility to divide the shrimp received from Thailand, Malaysia, and Indonesia into smaller portions, and mark them as “Shrimp, product of Panama,” on the individual packages, and then place them in boxes, also marked as “Shrimp, product of Panama.” Employees under the direction of Mr. Vela’s co-conspirator managed and directed the labeling operations at Sea Food Center by providing instructions and other directives to Mr. Vela. The relabeled shrimp were then sold to a food wholesaler based in Keene, NH, which in turn sold the shrimp to a supermarket chain headquartered in Landover, MD. This conduct was in violation of 18 U.S.C. 371.

On or about July 8, 2008, Mr. Vela knowingly engaged in an offense that involved the sale and purchase of, the offer of sale and purchase of, and the intent to sell and purchase shrimp, with a market value greater than \$350.00. He knowingly made and caused to be made individual labels, pre-printed bags, and other documents falsely identifying the shrimp as being “Shrimp, Product of Panama,” when in fact the shrimp

were “Shrimp, Product of Thailand,” “Shrimp, Product of Malaysia,” and “Shrimp, Product of Indonesia.” This conduct was in violation of 16 U.S.C. 3372(d)(2).

On or about July 8, 2008, Mr. Vela engaged in an offense that involved the introduction or delivery for introduction into interstate commerce of a food that was misbranded, with the intent to defraud or mislead, in that he created or caused to be created individual labels, pre-printed bags, and other documents falsely identifying the shrimp. This conduct was in violation of 21 U.S.C. 331(a).

As a result of his conviction, on September 28, 2012, FDA sent Mr. Vela a notice by certified mail proposing to debar him for a period of 5 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. Vela was convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food because he: Conspired to and committed offenses related to the importation of shrimp into the United States, falsely conveyed information about the shrimp’s country of origin; introduced or delivered for introduction misbranded food into interstate commerce; and falsely labeled seafood under the Lacey Act. 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. Vela should be subject to a 5-year period of debarment. The proposal also offered Mr. Vela 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. Vela 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 Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), finds that Mr. Adrian Vela has been convicted of three felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Vela 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 (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 Mr. Vela is a prohibited act.

Any application by Mr. Vela for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0777 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: February 8, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs,

Office of Regulatory Affairs.

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