DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0346]

Jeffrey A. Styron: Final 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 (FD&C Act) debarring Jeffrey A. Styron 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. Styron was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Styron was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 29, 2021 (30 days after receipt of the notice), Mr. Styron has not responded. Mr. Styron's failure to respond and request a hearing constitutes a waiver of Mr. Styron's right to a hearing concerning this matter.

DATES: This order is applicable December 15, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

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 March 9, 2021, Mr. Styron was convicted as defined in section 306(l)(1)(A) of the FD&C Act, in the U.S. District Court for the Eastern District of North Carolina, when the court accepted Mr. Styron's plea of guilty and entered judgment against him for the offense of Lacey Act False Labeling and Aiding and Abetting in violation of 16 U.S.C. 3372(d), 3372(d)(1), 3372(d)(2), 3373(d)(3)(A)(i), 3373(d)(3)(A)(ii), and 18 U.S.C. 2.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Plea Agreement filed in his case on September 3, 2020, Mr. Styron admitted that he knowingly made or submitted and caused to be made or submitted a false record, account, label for, or identification of any fish or wildlife, as set forth in the Criminal Information. The Criminal Information, filed July 22, 2020, sets forth that Mr. Styron was an owner-operator of Garland Fulcher Seafood Company, Inc. (GFS) and the manager and supervisor of the company's facility in North Carolina. GFS was in the business of purchasing, processing, packaging, and selling seafood, including crabmeat. Beginning at least as early as January 2014 and continuing through December 2017, Mr. Styron and his company were unable to satisfy customer demand for domestically harvested blue crab. Mr. Styron caused the company to purchase foreign crabmeat from South America and Asia. Mr. Styron then directed his employees to repack foreign crabmeat into containers labeled ''Product of the USA,'' which was then sold to customers as jumbo domestically harvested ''fresh'' blue crab. Mr. Styron knew that the crabmeat sold during that time period was labeled and represented as domestically harvested crabmeat when, in truth and in fact, it was or contained foreign crabmeat. Within this time period, at his direction GFS purchased and repackaged thousands of pounds of foreign jumbo crabmeat from South America and Asia. The foreign jumbo crabmeat was repacked into containers labeled ''Product of USA.''

As a result of this conviction FDA sent Mr. Styron, by certified mail on August 18, 2021, a notice 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. Styron's felony conviction of violating the Lacey Act False Labeling and Aiding and Abetting in violation of 16 U.S.C. 3372(d), 3372(d)(1), 3372(d)(2), 3373(d)(3)(A)(i), 3373(d)(3)(A)(ii), and 18 U.S.C. 2 constitutes conduct relating to the importation into the United States of an article of food because the offense involved Mr. Styron and his company falsely labeling crabmeat that was imported from a number of foreign countries as crabmeat that was a ''Product of USA.''

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Styron should be subject to a 5-year period of debarment. The proposal also offered Mr. Styron an opportunity to request a hearing, providing Mr. Styron 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Styron that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Styron 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Styron has been convicted of a 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 5-year period of debarment.

As a result of the foregoing finding, Mr. Styron 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**). 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 Jeffrey A. Styron is a prohibited act.

Any application by Mr. Styron for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0346 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0505]

Julia Fees: Final 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 (FD&C Act) debarring Julia Fees for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Fees was convicted of one felony count under Federal law for conspiracy to commit offenses against the United States. The factual basis supporting Ms. Fees' conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Fees was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of September 12, 2021 (30 days after receipt of the notice), Ms. Fees had not responded. Ms. Fees' failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable December 15, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) 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 drug or controlled substance.

On May 5, 2021, Ms. Fees was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Pennsylvania, when the court entered judgment against her for the offense of conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 2 and 371. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the indictment in Ms. Fees' case, filed August 22, 2017, to which she plead guilty, from on or about April 2015 and continuing until May 2017, Ms. Fees was involved in the operation of a website, *www.etizy.com,* through which she sold and distributed a drug known as etizolam to consumers throughout the United States. Etizolam is a drug known as thienodiazepine, which is chemically similar to benzodiazepines and carries risks of dependency, toxicity, and the possibility of fatal overdose. Etizolam is not FDA-approved in the United States. Ms. Fees and her co-conspirator illegally bought etizolam from an overseas supplier in India, which she then arranged to have smuggled into the United States through the use of multiple post office boxes controlled by her and her co-conspirator. To avoid Federal regulators, she used false and misleading labeling and generally misrepresented the nature of the products sold on the website she operated. Ms. Fees reshipped the misbranded etizolam to customers located in the United States.

As a result of this conviction, FDA sent Ms. Fees, by certified mail, on August 3, 2021, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Fees' felony conviction under Federal law for conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally imported, relabeled, and then introduced unapproved etizolam products into interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Fees' offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Fees of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Fees received the proposal and notice of opportunity for a hearing on August 13, 2021. Ms. Fees failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Julia Fees has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Fees is debarred for a period of 5 years from importing or offering for import any drug 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 any drug or controlled substance by, with the assistance of, or at the direction of Ms. Fees is a prohibited act.

Any application by Ms. Fees for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0505 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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