

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) debaring 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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