



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2366]

Justin Ash: Final Debarment Order

AGENCY: Food and Drug Administration, Health and Human Services (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 Justin Ash 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 Mr. Ash was convicted of one felony count under Federal law for conspiracy to commit offenses against the United States. The factual basis supporting Mr. Ash's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Ash was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of April 4, 2021 (30 days after receipt of the notice), Mr. Ash had not responded. Mr. Ash's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

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

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 (ELEM-4029), 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 November 24, 2020, Mr. Ash 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 him for the offense of conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 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 information in Mr. Ash's case, filed December 10, 2019, to which he plead guilty, from on or about January 1, 2016, and continuing until May 8, 2018, he controlled an internet-based business entity known as both DRC and Domestic RCS (hereinafter DRC). During this time, Mr. Ash obtained bulk supplies of clonazepam, diclazepam, flubromazepam, and etizolam (none of which have been approved for use by FDA in the United States) from overseas sources, including from suppliers in China. Mr. Ash caused his overseas suppliers to ship these drugs in smaller quantities to multiple addresses in the United States he controlled to draw less government scrutiny. After receiving these bulk drugs, Mr. Ash caused his employees to press them into pills and package them. Mr. Ash caused the pill packaging to include disclaimers stating that the drugs were for research purposes only, in part to evade detection by regulatory authorities, including FDA. Mr. Ash then had the packages shipped to customers throughout the United States who ordered the drugs through a website he operated.

As a result of this conviction, FDA sent Mr. Ash, by certified mail, on February 26, 2021, a notice proposing to debar him 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 Mr. Ash's 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 he illegally imported, manufactured, repackaged, and then introduced unapproved clonazepam, diclazepam, flubromazepam, and etizolam drug 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 Mr. Ash's offense, and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Ash of the proposed debarment and offered him 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. Ash received the proposal and notice of opportunity for a hearing on March 5, 2021. Mr. Ash failed to request a hearing 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)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Justin Ash 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, Mr. Ash 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 Mr. Ash is a prohibited act.

Any application by Mr. Ash for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-2366 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: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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