



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4717]

Brendon Gagne: 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 (the FD&C Act) debaring Brendon Gagne 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. Gagne was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Gagne's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Gagne 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 January 5, 2024 (30 days after receipt of the notice), Mr. Gagne had not responded. Mr. Gagne's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

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

ADDRESSES: Any application by Mr. Gagne for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2023-N-4717. Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will

review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240-402-8743, or 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 August 31, 2023, Mr. Gagne was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for Western District of Michigan when the court accepted

his plea of guilty and entered judgment against him for two offenses, one of which was for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545. The underlying facts supporting the conviction are as follows: As contained in the indictment from Mr. Gagne's case, filed on March 1, 2022, in the transcript from his guilty plea proceeding which was held on February 27, 2023, and from the Defendant's sentencing brief filed on August 15, 2023, beginning in or about 2018 and continuing until in or about October 2021, several individuals ran a website, www.ExpressPCT.com, which sold misbranded prescription drugs, as well as some Schedule III and Schedule IV controlled substances, in the United States without requiring a prescription. The drugs were manufactured overseas and then shipped in bulk to the United States to domestic redistributors. The packages did not declare their illicit contents and instead took steps to conceal their true nature. Once the packages entered the United States, the redistributors sent the bulk orders to second tier U.S.-based distributors who then finally shipped the drugs to the customers, making the purchasers think their drugs came from the United States and not from overseas. Part of Mr. Gagne's role in the scheme was to receive, repackage, and reship prescription drugs he received from other co-conspirators outside of the United States that were purchased by customers on the website www.ExpressPCT.com. In addition, Mr. Gagne recruited, managed and, using the profits from the sale of the misbranded prescription drugs, paid others engaged in the scheme who also received, repackaged, and reshipped prescription drugs they received from other co-conspirators outside of the United States.

As a result of this conviction, FDA sent Mr. Gagne, by certified mail, on November 30, 2023, 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. Gagne's felony conviction under Federal law for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545, was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Gagne was involved in a scheme to illegally import and introduce misbranded prescription drugs

into the United States. 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. Gagne's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Gagne 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. Gagne received the proposal and notice of opportunity for a hearing on December 6, 2023. Mr. Gagne 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. Brendon Gagne 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. Gagne 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 by, with the assistance of, or at the direction of Mr. Gagne is a prohibited act.

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

