



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1655]

Paul Zachary Lamberty: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Paul Zachary Lamberty for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lamberty was convicted of two felonies under Federal law; one felony count for conspiracy and one felony count for introduction of misbranded drugs with intent to defraud and mislead. The factual basis supporting Mr. Lamberty's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lamberty 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 September 8, 2025 (30 days after receipt of the notice), Mr. Lamberty had not responded. Mr. Lamberty'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: Any application by Mr. Lamberty for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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-2025-N-1655. 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, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743, or debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act 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 30, 2025, Mr. Lamberty was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for District of Massachusetts when the court accepted his plea of guilty and entered judgment against him for the felony offenses of one felony count for conspiracy in violation of 18 U.S.C. 371 and one felony count for introduction of misbranded drugs with intent to defraud and mislead in violation of 21 U.S.C. 331(a) (section 301(a) of the FD&C Act). The underlying facts supporting the conviction are as follows:

As contained in the Information, and in the Plea Agreement from his case, from on or about February 2017, through on or about August 2021, Mr. Lamberty operated the websites, www.encern.com and www.ohmod.com. Through these websites Mr. Lamberty advertised and sold etizolam. Etizolam is a drug known as a thienodiazepine. Thienodiazepines are a class of drug chemically related to benzodiazepines. Benzodiazepines are a class of drug that produces central nervous system depression. In the United States, practitioners can prescribe FDA approved products containing benzodiazepines to treat insomnia and anxiety. However, benzodiazepines carry a risk of dependency, toxicity, and even fatal overdose particularly when combined with other central nervous system depressants. Thienodiazepines carry similar health risks as benzodiazepines. FDA has not approved any drugs containing etizolam. The websites Mr. Lamberty operated included disclaimers stating the products he was selling were for "For Research Purposes Only" and "Not for Human Use." However, despite these disclaimers, Mr. Lamberty knew and intended that the products he sold would be used by humans as drugs intended to affect the structure or any function of the human body. Mr. Lamberty obtained the etizolam he sold from suppliers in China. Mr. Lamberty mislabeled the etizolam before and during importation into the United States to avoid detection by Customs and Border Protection (CBP) and he knew he imported the etizolam contrary to the law. In addition, Mr. Lamberty received the etizolam he purchased from China at multiple addresses and post office boxes as a tactic to avoid CBP detection. After Mr. Lamberty received the etizolam he imported, he sold his drug product to customers in the United States who had ordered them on the websites he

operated. Mr. Lamberty sent the etizolam to his customers with false labeling stating that the product was sold "For Research Purposes Only" and "Not for Human Consumption." Despite the disclaimers on the products themselves, Mr. Lamberty knew the etizolam products he sold would be used by humans as drugs. The etizolam products Mr. Lamberty sold through his website were misbranded because their labeling was false and misleading and because their labeling failed to bear adequate directions for use.

FDA sent Mr. Lamberty, by certified mail, on July 29, 2025, a notice proposing to debar him for a 10-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. Lamberty's felony conviction under Federal law for conspiracy in violation of 18 U.S.C. 371 and one felony count for introduction of misbranded drugs with intent to defraud and mislead in violation of 21 U.S.C. 331(a) (section 301(a) of the FD&C Act), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Lamberty illegally imported the unapproved drug etizolam and sold it to customers in 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 the Agency considered applicable to Mr. Lamberty's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Lamberty 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. Lamberty received the proposal and notice of opportunity for a hearing on August 8, 2025. Mr. Lamberty 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Paul Zachary Lamberty has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Lamberty is debarred for a period of 10 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Lamberty is a prohibited act.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.