TABLE 2—PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS AND PARTIAL LIMITATIONS—Continued

21 CFR section	Device type	Product code	Partial limitations
884.4530	Tenaculum, uterine	HDC	Exemption is limited to manual mechanical devices.
884.5160	Pump, breast, powered	HGX	Exemption is limited to devices that meet the following conditions: 1. Device is a tabletop breast pump that has a vacuum pressure <250 mmHg, uses AC/DC power only, and does not include a battery; and 2. Device does not utilize internet, wireless connection, communication ports (*e.g.,* USB) capable of updating software or transmitting information, or a mobile application.
884.5300	Lubricant, personal	NUC	Exemption is limited to devices that meet the following conditions: 1. Device is made entirely of silicone (*i.e.,* dimethicone, dimethiconol, cyclopentasiloxane) with no additional ingredients; 2. Water activity is <0.3 Aw per USP<1112> (Application of Water Activity Determination to Nonsterile Pharmaceutical Products); and 3. Device is not intended for treatment of medical conditions or specific patient populations.
884.6170	System, water, reproduction, assisted, and purification.	MTW	Exemption is limited to assisted reproduction water and does not include water purification systems.
890.5500	Laser, comb, hair	OAP	Exemption is limited to devices that meet the following conditions: 1. Device emitters have a maximum output that cannot produce intensities at the scalp surface that exceed 68 J/cm^2; and 2. Device only uses red light.
890.5650	Massager, powered inflatable tube.	IRP	Exemption is limited to devices that meet the following conditions: 1. Device is pneumatic with operating pressures between 0 mmHg and 200 mmHg positive pressures; 2. Device is indicated for adults in good health, for the temporary relief of minor muscle aches and/or pains, for temporary increase in circulation to the treated areas, and/or to simulate kneading and stroking of tissues; 3. Device is not intended for use on neck and/or head; 4. If device compresses thoracic (chest, back) and/or abdominal areas, the device does not exceed pressure of 120 mmHg; 5. Device is not intended to heat or cool a patient; and 6. Device is not intended to be used for direct skin contact.

If the proposed exemptions for the device types listed in table 2 are finalized, FDA will assign new product codes to the device types that will be exempt subject to the corresponding partial limitations of exemptions in order to ensure that these devices can be identified distinctly from devices that do not fall within the partial limitations of exemptions (which will continue to be assigned to the existing product code). Exempt and non-exempt devices within a device type will therefore have different product codes.

V. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* Although FDA verified the website address in this document, please note that websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Lowell M. Zeta,

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

[FR Doc. 2026–02377 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

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 February 6, 2026.

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.

[FR Doc. 2026–02337 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2033]

Agency Information Collection Activities; Proposed Collection; Comment Request; Expedited Programs for Serious Conditions—Accelerated Approval of Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection relating to the draft guidance, ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.''

DATES: Either electronic or written comments on the collection of information must be submitted by April 7, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 7, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2033 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Expedited Programs for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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. If you do not wish your name and