

price products on its formularies by charging fees to manufacturers that are based on list price. Specifically, Section VI provides that compensation received by ESI from drug manufacturers related to ESI's "standard offering" to plan sponsors will not be based, directly or indirectly, on a drug's list price.

Section VII addresses allegations that ESI obscures net price information from plan sponsors. Specifically, Section VII increases transparency for plan sponsors by requiring ESI to provide as part of its standard offering an annual report disclosing each drug's costs and pharmacy claim-level reporting, as well as any compensation paid to consultants or brokers in connection with ESI's provision of pharmacy benefit services.

Section VIII addresses ESI's pharmacy reimbursement practices. Section VIII requires ESI to develop a standard offering to retail community pharmacies (defined as a pharmacy business with three or fewer retail stores) that will:

- Compensate retail community pharmacies based on the actual cost of acquiring prescription drugs plus a dispensing fee;
- Make additional payments for all non-dispensing services performed by a retail community pharmacy; and
- Not exclude any retail community pharmacy willing to agree to the terms and conditions for participation from its standard offering to retail community pharmacies.

Section IX provides that ESI will advertise its standard offerings; clearly and conspicuously disclose their existence and availability in material created to advertise, market, or otherwise promote its products to plan sponsors and retail community pharmacies; not disparage its standard offerings; and not require or coerce plan sponsors or retail community pharmacies to adopt terms that differ from its standard offerings. Section X provides that ESI will move its GPO, Ascent, from Switzerland to the United States.

Section XI provides that nothing in Sections II, III, IV, V, and VIII shall prevent ESI from responding to a written request for terms other than the standard offering from a plan sponsor or retail community pharmacy. With respect to plan sponsors, if ESI and a plan sponsor agree to terms other than the standard offering, ESI must then obtain a written acknowledgement that the plan sponsor has received, read, and understood the explanation of benefits of the standard offering attached as Exhibit A to the Decision and Order. Cigna's fully-insured health plans are excluded from Section XI's "meeting competition" exception.

Section XII appoints a monitor for a term beginning shortly after the Order issues and ending three years after the Implementation Date (defined as no later than January 1, 2027). The monitor has the authority to observe ESI's compliance with the obligations set forth in the Proposed Order, to act in consultation with, and make inquiries on behalf of, the Commission or its Staff, and to make annual reports to the Commission.

Sections XIII, XIV, and XV contain provisions designed to ensure the effectiveness of the relief, including: obtaining information from ESI that it is complying with the Order; requiring ESI to submit compliance reports; and requiring ESI to notify the Commission of certain changes in its corporate structure. Section XVI provides that ESI will cooperate with the ongoing Insulin Litigation, including by providing a certain number of witnesses for depositions and for trial.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

By direction of the Commission.

Joel Christie,

Acting Secretary.

[FR Doc. 2026-02844 Filed 2-11-26; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0435]

Jeremy Spencer Brown: 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 Jeremy Spencer Brown 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. Brown was convicted of one felony count under Federal law for introduction of unapproved drugs into interstate commerce with intent to defraud or mislead. The factual basis supporting Mr. Brown's conviction, as

described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Brown 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 May 21, 2025 (30 days after receipt of the notice), Mr. Brown had not responded. Mr. Brown'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 12, 2026.

ADDRESSES: Any application by Mr. Brown 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-0435. 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 February 3, 2025, Mr. Brown was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Vermont, when the court accepted his plea of guilty and entered judgment against him for the felony offense of introduction of unapproved drugs into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. 331(d), 333(a)(2), and 355(a) (sections 301(d), 303(a)(2), and 505(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, Mr. Brown was the owner and operator of the company Warrior Labz SARMs and its multiple websites. Beginning in March 2019 and until December 2023, Mr. Brown owned and operated Warrior Labz SARMs and the website [warriorlabzarms](http://warriorlabzarms.com) (the “Original SARMs Site”), which offered certain drugs for sale. In January 2023, Mr. Brown created the website warriorlabzvip.com (the “VIP SARMs Site”), which required customers to create a username and password.

Through his company’s websites, Mr. Brown offered for sale drugs such as numerous selective androgen receptor modulators (“SARMs”), including Cardarine, Ostarine, Ligandrol, and YK–11. Mr. Brown also offered for sale through his company’s websites Viagra-Max Sildenafil and Cialis-Max Tadalafil, which were unapproved versions of the prescription drugs Viagra and Cialis. In addition, Mr. Brown also offered for sale an unapproved version of drug products containing semaglutide, the active pharmaceutical ingredient in the FDA approved prescription drugs Ozempic, Wegovy, and Rybelsus. None of the drugs Mr. Brown sold through his website was approved by FDA. Mr. Brown included on his websites disclaimers that he knew were false and misleading, including falsely stating the drugs offered for sale were for “research purposes only” and “not for human consumption.”

Mr. Brown obtained the bulk of the drugs he sold through his websites from China. Mr. Brown did not ask his Chinese suppliers about the shipping or storage conditions of the drugs he obtained from them, nor did he use a lab or other method to verify the contents of the drugs he received from China. However, on one of Mr. Brown’s company’s websites, he included assertions on the Original SARMs site that he used only the highest quality pharmaceutical grade ingredients and U.S. manufacturing practices; Mr. Brown knew that these assertions were false. In addition, the labeling on the

drugs Mr. Brown sold through his website falsely stated that the drugs were made in the United States; Mr. Brown also knew that these claims were false.

On June 12, 2023, Mr. Brown received a Warning Letter from FDA. The Warning Letter stated that FDA had reviewed the Original SARMs Site and determined that the products the site offered for sale, including Ostarine and Ligandrol, were unapproved new drugs sold in violation of the FD&C Act. The Warning Letter also stated that even though the products were marketed “for research purpose only” and “not for human consumption,” evidence from his company’s website established the products were in fact intended for human use. The Warning Letter advised Mr. Brown that FDA had safety concerns about products containing SARMs, including possible life-threatening reactions and the potential to increase the risk of heart attack and stroke. The Warning Letter stated that Mr. Brown was responsible for investigating the cause of any violations, preventing their reoccurrence, preventing the occurrence of other violations, and ensuring Mr. Brown’s company complied with all requirements of Federal law, including FDA regulations.

Despite reading and fully understanding the Warning Letter FDA sent Mr. Brown, he continued operating the Original SARMs website, but he no longer listed Viagra-Max Sildenafil, Cialis-Max Tadalafil, and semaglutide for sale. However, Mr. Brown continued offering SARMs through the Original SARMs site but removed certain claims about the product from the site. Mr. Brown also continued operating his VIP SARMs site in the same manner as before he received the Warning Letter, including by continuing to offer for sale SARMs alongside claims that they were intended to affect the structure and/or function of the human body, except that he began directing customers of the Original SARMs website to his VIP SARMs site. In response to FDA’s Warning Letter, Mr. Brown stated that he had taken corrective actions to address the violations. Mr. Brown knew that this statement was misleading.

Between March 2023 and December 2023, Mr. Brown made numerous sales to an FDA undercover investigator posing as a customer of the SARMs websites. FDA laboratories tested the products obtained. Many tested positive for substances not listed on the Warrior Labz SARMs product labels; some were found not to contain the ingredients listed on those labels. For instance, of the substances received from an August

2023 undercover purchase, one drug was labeled as containing Ostarine and another as containing Ligandrol though neither contained Ligandrol, and both contained Ostarine and a substance not included on the label, Clomiphene. Clomiphene is an unapproved version of a prescription drug approved by FDA to treat infertility in women by inducing ovulation.

Between March 2019 and December 2023, Mr. Brown received at least \$1,183,985.60 from sales of unapproved new drugs through his websites.

FDA sent Mr. Brown, by certified mail, on April 16, 2025, 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. Brown's felony conviction under Federal law for introduction of unapproved drugs into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. 331(d), 333(a)(2), and 355(a) (sections 301(d), 303(a)(2), and 505(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. Brown illegally imported and introduced misbranded prescription 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 the Agency considered applicable to Mr. Brown's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Brown 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. Brown received the proposal and notice of opportunity for a hearing on April 21, 2025. Mr. Brown 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. Jeremy Spencer Brown 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. Brown 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. Brown is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1197]

Certification Process for Designated Medical Gases; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled "Certification Process for Designated Medical Gases." This guidance explains how FDA administers the certification process and describes the annual reporting requirements for designated medical gases (DMGs). Specifically, the guidance discusses what products qualify as DMGs, who must submit a certification request, what information must be submitted, and how FDA will evaluate and act on the request. This draft guidance is being issued to reflect new and revised regulations in several areas to reduce the regulatory burden, as appropriate, for the medical gas industry. This draft guidance revises and replaces the draft guidance of the same name issued in November 2015, which was withdrawn on December 18, 2025.

DATES: Submit either electronic or written comments on the draft guidance by April 13, 2026 to ensure that the

Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

Submit electronic or written comments on the proposed collection of information in the draft guidance by April 13, 2026.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-2012-D-1197 for "Certification Process for Designated Medical Gases." Received comments 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.