4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0342]

Sherri Insprucker: 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 Sherri Insprucker 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 Ms. Insprucker was convicted of one felony count under Federal law for conspiracy to introduce a misbranded drug in interstate commerce with the intent to defraud and mislead. The factual basis supporting Ms. Insprucker's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Insprucker was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of June 16, 2025 (30 days after receipt of the notice), Ms. Insprucker had not responded. Ms. Insprucker's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

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

ADDRESSES: Any application by Ms. Insprucker 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-0342. 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, at 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 December 5, 2024, Ms. Insprucker was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Western District of Texas-San Antonio Division, when the court accepted her plea of guilty and entered judgment against her for the felony offense of conspiracy to introduce a misbranded drug in interstate commerce with the intent to defraud and mislead in violation of 18 U.S.C. 371 and 21 U.S.C. 331(a), 333(a)(2), 352(a)(1), 353(b)(1), and 352(f) (sections 301(a), 303(a)(2), 502(a)(1), 503(b)(1), and 502(f)) 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 her case, in or about December 2022 Ms. Insprucker responded to an online posting from a person referred in court documents as Individual #1. Ms. Insprucker agreed, along with Justin Insprucker, to receive parcel shipments sent in interstate commerce to her residence that Ms. Insprucker would repackage and ship to individuals and businesses throughout the United States for pay. Ms. Insprucker opened a Post Office (PO) Box at a U.S. Postal Service (USPS) location under the name American Wellness LLC. Ms. Insprucker and Justin Insprucker received packages of misbranded sildenafil and tadalafil delivered to the PO Box and/or the Insprucker residence. Ms. Insprucker repackaged these drugs and shipped them to other individuals and businesses in interstate commerce.

An FDA Office of Criminal Investigations (OCI) investigation revealed that from December 2022 through at least October 2023, multiple notices of FDA Seizures were issued to Ms. Insprucker's and Justin Insprucker's residence and to the American Wellness LLC PO Box for parcels containing misbranded sildenafil and tadalafil shipped in interstate commerce and destined for Ms. Insprucker and Justin Insprucker's residence and/or PO Box. The notices of FDA action informed Ms. Insprucker that the products seized were prescription drugs and that the individual boxes inside the parcels did not contain the "Rx only" required description on its label. In September and October 2023, law enforcement seized additional parcels containing misbranded sildenafil and tadalafil that were shipped in interstate commerce and destined for Ms.

Insprucker and Justin Insprucker's residence and/or PO Box. OCI's investigation also revealed that Ms. Insprucker and Justin Insprucker repackaged bulk quantities of the misbranded drugs containing sildenafil and tadalafil in packaging that failed to disclose the drugs contained sildenafil and tadalafil and that falsely claimed the drugs were manufactured in the United States and contained herbal supplements. After repackaging the misbranded drugs, Ms. Insprucker and Justin Insprucker shipped the packages via USPS and other commercial carriers to individuals and businesses located throughout the United States. On November 3, 2023, OCI agents executed a search warrant at Ms. Insprucker's residence. Ms. Insprucker's residence contained a room with several large parcels containing misbranded sildenafil and tadalafil and unused USPS boxes to be used for repackaging the items for delivery. During an interview with agents, Ms. Insprucker admitted that she received shipments of misbranded sildenafil and tadalafil that came from overseas and/or out of state which Ms. Insprucker would repackage and ship to customers in interstate commerce. Ms. Insprucker told investigators that she knew the drugs she was receiving require a prescription. Finally, Ms. Insprucker told investigators that she recruited another person to receive parcels containing misbranded sildenafil and tadalafil and to also repack and reship the drugs to other locations.

FDA sent Ms. Insprucker, by certified mail, on May 9, 2025, a notice proposing to debar her 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 Ms. Insprucker's felony conviction under federal law for conspiracy to introduce a misbranded drug in interstate commerce with the intent to defraud and mislead in violation of 18 U.S.C. 371 and 21 U.S.C. 331(a), 333(a)(2), 352(a)(1), 353(b)(1), and 352(f), was for conduct relating to the importation of any drug or controlled substance into the United States because Ms. Insprucker illegally received foreign unapproved prescription drugs which she repackaged and sent out to consumers throughout the U.S. 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 Ms. Insprucker's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Insprucker of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Insprucker received the proposal and notice of opportunity for a hearing on May 16, 2025. Ms. Insprucker failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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 Ms. Sherri Insprucker 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, Ms. Insprucker 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 Ms. Insprucker is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-03254 Filed: 2/18/2026 8:45 am; Publication Date: 2/19/2026]