Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product SYMVESS (acellular tissue engineered vessel-tyod). SYMVESS is indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. Subsequent to this approval, the USPTO received a patent term restoration application for SYMVESS (U.S. Patent No. 9,657,265) from Humacyte Global, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SYMVESS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SYMVESS is 3,069 days. Of this time, 2,694 days occurred during the testing phase of the regulatory review period, while 375 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 27, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 27, 2016.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 11, 2023. The applicant claims December 8, 2023, as the date the biologics license application (BLA) for SYMVESS (BLA 125812) was initially submitted. However, FDA records indicate that BLA 125812 was submitted on December 11, 2023.

3. *The date the application was approved:* December 19, 2024. FDA has verified the applicant's claim that BLA 125812 was approved on December 19, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,572 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.)

Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03312 Filed 2–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0345]

Justin 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 Justin 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 Mr. 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 Mr. Insprucker's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Insprucker 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 June 16, 2025 (30 days after receipt of the notice), Mr. Insprucker had not responded. Mr. Insprucker'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 19, 2026.

ADDRESSES: Any application by Mr. 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–0345. 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, Mr. Insprucker was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for Middle District of Florida, when the court accepted his plea of guilty and entered judgment against him 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 his case, in or about December 2022 Sherri Insprucker responded to an online posting from a person referred in court documents as Individual #1. Mr. Insprucker agreed, along with Sherri Insprucker, to receive parcel shipments sent in interstate commerce to his residence that Mr. Insprucker would repackage and ship to individuals and businesses throughout the United States for pay. Mr. Insprucker and Sherri Insprucker received packages of misbranded sildenafil and tadalafil delivered to a Post Office (P.O.) Box at a U.S. Postal Service (USPS) location under the name American Wellness LLC, and/or the Insprucker residence. Mr. 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 Mr. Insprucker and Sherri Insprucker's residence and to the American Wellness LLC P.O. Box for parcels containing misbranded sildenafil and tadalafil shipped in interstate commerce and destined for Mr. Insprucker and Sherri Insprucker's residence and/or P.O. Box. The notices of FDA action informed Mr. 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 Mr. Insprucker and Sherri Insprucker's residence and/or P.O. Box. OCI's investigation also revealed that Mr. Insprucker and Sherri 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, Mr. Insprucker and Sherri 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 Mr. Insprucker's residence. Mr. 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, Mr. Insprucker admitted that he received shipments of misbranded sildenafil and tadalafil that

came from overseas and/or out of state which Mr. Insprucker would repackage and ship to customers in interstate commerce. Mr. Insprucker told investigators that he knew the drugs he was receiving require a prescription. Finally, Mr. Insprucker told investigators that he recruited another person to receive parcels containing misbranded sildenafil and tadalafil and to also repack and reship the drugs to other locations.

FDA sent Mr. Insprucker, by certified mail, on May 9, 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. 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 Mr. Insprucker illegally received foreign unapproved prescription drugs which he repackaged and sent out to consumers throughout 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. Insprucker's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Insprucker 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. Insprucker received the proposal and notice of opportunity for a hearing on May 16, 2025. Mr. Insprucker 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. Justin 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, Mr. 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 Mr. Insprucker is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03253 Filed 2–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1309]

Revocation of Authorization of Emergency Use of ExThera Medical Corporation Seraph 100 Microbind Affinity Blood Filter (Seraph 100); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to ExThera Medical Corporation, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100). FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the ExThera Medical Corporation Seraph 100 Microbind Affinity Blood Filter (Seraph 100) is effective as of November 24, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Michael Hoffman, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2410, Silver Spring, MD 20993–0002, 301–796–6476 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On April 17, 2020, FDA issued the Authorization to ExThera Medical Corporation, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100), subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website.

The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Request

In a request received by FDA on October 21, 2025, ExThera Medical Corporation, requested the withdrawal of, and on November 24, 2025, FDA revoked, the Authorization for the ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter (Seraph 100). ExThera Medical Corporation notified FDA that as of the date of this revocation, no viable Seraph 100 Microbind Affinity Blood Filter (Seraph 100) remained under EUA