

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

distribution and requested FDA withdraw the ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter (Seraph 100). FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at <https://www.regulations.gov/>.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are

met, FDA has revoked the EUA of ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter (Seraph 100). The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164-01-P



November 24, 2025

Ann Vu, JD, RAC
Chief of Staff
ExThera Medical Corporation
757 Arnold Drive Suite B
Martinez, CA 94553 USA

Re: Revocation of EUA200165

Dear Ann Vu,

This letter is in response to the request from ExThera Medical Corporation (ExThera), in an email dated October 21, 2025, that the U.S. Food and Drug Administration (FDA) formally withdraw the Emergency Use Authorization (EUA200165) issued on April 17, 2020, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100). We are considering your request a request to revoke this EUA. FDA understands that, as of the date of this letter, there remains no viable Seraph 100 device distributed under the EUA in distribution in the United States. The distribution permitted under the Investigational Device Exemption Expanded Access program of Seraph 100 or Oncobind devices is not affected by the requested revocation.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ExThera has requested that FDA revoke the EUA for the Seraph 100, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200165 for the Seraph 100 Microbind Affinity Blood Filter, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Seraph 100 Microbind Affinity Blood Filter is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

Ellen J. Flannery
-S

Digitally signed by Ellen J.
Flannery -S
Date: 2025.11.24 12:55:50
-05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-03250 Filed 2-18-26; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0498]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe Processing and Importing of Fish and Fishery Products

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 the information collection associated with safe and sanitary processing and importing of fish and fishery products.

DATES: Either electronic or written comments on the collection of information must be submitted by April 20, 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 20, 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-2026-N-0498 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe Processing and Importing of Fish and Fishery Products." 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 contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." 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 to read background documents or the electronic and written/paper comments received, 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRABranch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical