advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss new drug application (NDA) 219694, for atropine sulfate ophthalmic solution 0.01%, submitted by Sydnexis. Inc. The proposed indication (use) is for slowing of myopia progression in children 3 years of age or older.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 19, 2026, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:00 p.m. and 2:00 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before October 14, 2026, 5:00 p.m. Eastern Time. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by October 15, 2026. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the HHS Press Room at *https://www.hhs.gov/press-room/index.html* or 202–690–6343.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19700 Filed 9–24–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6692]

Jeffrey Thies: 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 Jeffrey Thies 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. Thies was convicted of two felony counts under Federal law for trafficking in counterfeit goods and aiding and abetting. The factual basis supporting Mr. Thies's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Thies 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 July 13, 2026 (more than 30 days after receipt of the notice), Mr. Thies had not responded. Mr. Thies'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 September 25, 2026.

ADDRESSES: Any application by Mr. Thies 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–6692. 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. 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, 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 August 6, 2025, Mr. Thies was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Pennsylvania, when the court accepted his plea of guilty and entered judgment against him on two counts for the felony offenses of trafficking in counterfeit goods in violation of 18 U.S.C. 2320(a)(1) and aiding and abetting in violation of 18 U.S.C. 2. The underlying facts supporting the conviction are as follows:

As contained in the Indictment and in the Government's Change of Plea Memorandum, from in or around 2020 through in or around January 2023, Mr. Thies operated websites, including ''*sexpillshop.com*,'' through which he trafficked counterfeit ''sex pills.'' In order to obtain and manufacture the counterfeit pills, Mr. Thies smuggled counterfeit Viagra and Cialis pills and packaging and the active ingredients sildenafil and tadalafil into the United States from foreign suppliers in China and India. Viagra and Cialis are prescription drug products that are approved by FDA for distribution within the United States for certain medical conditions. Under Federal law, and in order to ensure public health safety, genuine prescription drug products must be manufactured and distributed under strict quality control standards and may be dispensed only upon a doctor's prescription and by a licensed pharmacist.

On or about December 16, 2020, a federal agent acting in an undercover capacity visited a website controlled by Mr. Thies. The website advertised for sale a large number of pills listed as ''male enhancement products,'' which were available for purchase in various quantities and packages. The agent placed an order for two packs of ''sex pills'': ''80 Pill Steal Variety Pack'' and ''50 Pill All Imports Variety Pack.'' The agent paid a total of $99.98 to an account controlled by Mr. Thies. Two days later, on December 18, 2020, the agent received an email from *sexpillshop@gmail.com* that confirmed the pills were shipped by U.S. mail, provided a tracking number, and offered a cell phone number registered to Mr. Thies for any additional assistance. When the agent sent a follow-up email, Mr. Thies responded and apologized for the delay.

On or about January 13, 2021, the agent received a parcel with his order of pill packs in an undercover mailbox. The parcel sent by Mr. Thies contained a variety of pills. Some pills were in unmarked blister packs; others were in capsules and packaging with names including ''Superman,'' ''Black Mamba,'' and ''Blue Rhino.'' Much of the wording on the packaging was in a foreign language. The parcel also included a blue and silver box labeled ''U.S.A. Viagra'' with a glass vial labeled ''U.S.A. Viagra,'' which contained 10 blue almond-shaped tablets imprinted with ''USA'' on each side. Law enforcement identified fingerprints on the parcel and its contents that matched Mr. Thies's fingerprints. The Viagra packaging and pills were counterfeit.

On January 11, 2023, law enforcement executed a federal search warrant at Mr. Thies's home in Philadelphia, Pennsylvania. In his residence, agents found a pill laboratory in the basement work area where Mr. Thies manufactured, packaged, and prepared to ship counterfeit pills to consumers. Agents seized his computers, phones, and other items consistent with the trafficking of counterfeit pills, such as pill bottles, pill presses, baking flour, various packages of male enhancement pills, other packaging and shipping materials, empty capsules, and counterfeit Viagra and Cialis pills. Most of these items were found on and

around a dirty, non-sterile bench area in the basement laboratory where multiple house cats also lingered. Specifically, agents seized from Mr. Thies's residence 90 tablets purporting to be Viagra and 90 tablets purporting to be Cialis. The Viagra and Cialis packaging and pills were counterfeit. The counterfeit marks and trade names, ''Viagra'' and ''Cialis,'' used by Mr. Thies were identical or substantially indistinguishable from the genuine marks owned by Pfizer, Inc./Viatris, Inc. and Eli Lilly & Company, and Mr. Thies used the marks in connection with purported ''sex pills,'' which were likely to confuse or deceive consumers into believing that the product was made by the genuine owner of the trademark. Mr. Thies was present at his residence at the time of the search.

During the search, Mr. Thies admitted to law enforcement that he sold male enhancement pills on his websites, including on *sexpillshop.com*, sometimes receiving up to three orders a day. On January 13, 2023, Mr. Thies met with law enforcement agents and again admitted that he sold male enhancement pills on his websites for years. He also stated he previously sold pills on eBay and social media platforms, but that his accounts were closed upon being told that he could not sell counterfeit products on those platforms.

Law enforcement searched and reviewed the email accounts Mr. Thies operated, including *sexpillshop@gmail.com* and *jeffmetthies@gmail.com.* These email accounts contained lengthy correspondence between Mr. Thies and foreign suppliers of male enhancement pills, ingredients, and packaging, including suppliers from China and India, and customers who purchased pills from his website. At times, Mr. Thies faced impediments to importing counterfeit pills and packaging from foreign countries. When his shipments were seized or took longer to arrive, Mr. Thies would direct his foreign suppliers to use different names and different shipping addresses, in order to disguise or conceal the destination of the shipments. In an email on April 28, 2021, for example, Mr. Thies told a supplier, ''CHANGE IT TO [an alias name] AND MAKE IT APARTMENT #3 INSTEAD OF #1.'' On June 7, 2021, Mr. Thies was made aware through an email from a global shipping company that his package had been detained by United States Customs and Border Protection. Mr. Thies responded by stating, ''I have 2 options[,] contesting isn't one of them.'' In other emails, Mr. Thies was told by foreign suppliers that they were disguising or concealing the contents of shipments to avoid policies that prohibited the sale of certain drugs. For example, Mr. Thies received an email from a Chinese supplier stating, ''[s]ince Alibaba [a Chinese e-commerce marketplace] forbids the sale of sildenafil [the active ingredient in Viagra], we drafted the credit order under the name of NMN, and the real goods are sildenafil.'' Mr. Thies sold over $90,000 worth of pills to consumers throughout the United States during the relevant time period.

FDA sent Mr. Thies, by certified mail, on June 8, 2026, 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. Thies's felony convictions under Federal law for trafficking in counterfeit goods in violation of 18 U.S.C. 2320(a)(1) and aiding and abetting in violation of 18 U.S.C. 2 were for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Thies illegally smuggled and trafficked counterfeit prescription drug products into the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C that the Agency considered applicable to Mr. Thies's offenses and concluded that the offenses warranted the imposition of a 10-year period of debarment, consisting of two 5-year debarment periods for each felony count to run consecutively.

The proposal informed Mr. Thies 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. Thies received the proposal and notice of opportunity for a hearing on June 11, 2026. Mr. Thies 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. Jeffrey Thies 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, consisting of two consecutive 5-year debarment periods as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Thies 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 (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. Thies during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19655 Filed 9–24–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NIH Policy on Sharing Summary Level Study Results With Clinical Research Participants

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: NIH seeks public input on its proposed NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants, including ways to promote and enable the research community to share summary level study results with clinical research participants.

DATES: To ensure consideration, comments must be submitted on or before October 26, 2026.

ADDRESSES: Comments must be submitted electronically to: *https://osp.od.nih.gov/comment-form-draft-sharing-summary-results-policy/.* Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.