I. Background

This draft guidance provides recommendations for clinical performance testing and evaluation to support premarket submissions for cuffless non-invasive blood pressure measuring devices. A cuffless blood pressure measuring device generally is a non-invasive blood pressure measurement system that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through sensors. This guidance does not include the totality of information that should be included in a premarket submission.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cuffless Non-invasive Blood Pressure Measuring Devices—Clinical Performance Testing and Evaluation.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. As we develop any final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Cuffless Non-invasive Blood Pressure Measuring Devices—Clinical Performance Testing and Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007066 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01288 Filed 1–22–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1331]

Tyler Jordan Hall: 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 Tyler Jordan Hall 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. Hall was convicted of a felony under Federal law for introduction of unapproved drugs into interstate commerce. The factual basis supporting Mr. Hall's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Hall 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 September 2, 2025 (30 days after receipt of the notice), Mr. Hall had not responded. Mr. Hall'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 January 23, 2026.

ADDRESSES: Any application by Mr. Hall 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–1331. 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 (21 U.S.C. 335a(b)(3)(C)), 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 May 15, 2025, Mr. Hall was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Montana Missoula Division, 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 under 21 U.S.C. 331(d) and 333(a)(2) (sections 301(d) and 303(a)(2) 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, from on or about June 17, 2020, through on or about March 30, 2022, Mr. Hall operated a business known as Rat's Army, LLC (Rat's Army) to, among other things, import, create, bottle, and label misbranded drugs which he sold through the Rat's Army website to customers throughout the United States. Specifically, Mr. Hall primarily focused on selling selective estrogen receptor modulators (SERMs) and other unapproved new drugs. SERMs are a class of prescription drugs primarily intended to block the effects of estrogen in breast tissue. Products containing SERMs are often marketed and sold for bodybuilding purposes to reduce male breast enlargement, a commonly occurring side effect of the use of anabolic steroids and other synthetic chemicals. Examples of drugs Mr. Hall sold through Rat's Army's website included Raloxifene, Tamoxifen, and Pramipexole. The FDA approved version of Raloxifene Hydrochloride is indicated for the treatment of osteoporosis. The FDA approved version of Tamoxifen Citrate is indicated for the treatment of breast cancer. The FDA approved version of Pramipexole Dihydrochloride is indicated for the treatment of Parkinson's disease. All three of these FDA-approved drugs are not safe for use except under the supervision of a practitioner licensed by law to administer prescription drugs. The FDA-approved labeling for Raloxifene Hydrochloride and Tamoxifen Citrate display a boxed warning emphasizing serious potential side effects. Throughout this period, Mr. Hall knowingly took steps to mislead the FDA about the true nature of the products sold on the Rat's Army website. In order to avoid seizure by United States Customs and Border Protection officers of the materials that Mr. Hall shipped internationally, Mr. Hall falsely claimed that they were supplements or vitamins. While Mr. Hall represented his business as a ''pharmaceutical manufacturer'' he was never a pharmacist, he did not employ a licensed pharmacist at Rat's Army, and he never registered his business with the FDA as a pharmaceutical manufacturing facility. Specifically, Mr. Hall attempted to conceal the nature of his products by falsely portraying them as ''research chemicals'' and ''not for human consumption,'' despite knowing and intending that the products were for ingestion by humans to affect the structure and function of their bodies. Mr. Hall also took steps to mislead and defraud the consumers to whom he was offering the sale of the drugs he sold. Specifically, Mr. Hall posted misleading Certificates of Analysis on the Rat's Army website to convince consumers Rat's Army was manufacturing products which were legitimate and safe to consume. Mr. Hall also falsely claimed that, ''you do not need a prescription'' or ''access to a pharmacy or pharmacist'' to obtain products through Rat's Army. Between on or about June 17, 2020, through on or about March 30, 2022, Mr. Hall obtained proceeds from Rat's Army of approximately $3,805,470.

FDA sent Mr. Hall, by certified mail, on July 28, 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 (21 U.S.C. 335a(b)(3)(C)) Act that Mr. Hall's felony conviction under Federal law for introduction of unapproved drugs into interstate commerce under 21 U.S.C. 331(d) and 333(a)(2) (sections 301(d) and 303(a)(2) of the FD&C Act), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Hall illegally imported materials for use in developing his products and he introduced these unapproved new 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. Hall's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Hall 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.

Hall received the proposal and notice of opportunity for a hearing on August 2, 2025. Mr. Hall 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, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act (21 U.S.C. 335a(b)(3)(C)), under authority delegated to the Director, Division of Enforcement, finds that Mr. Tyler Jordan Hall 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. Hall 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Hall is a prohibited act.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01296 Filed 1–22–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the first meeting of 2026, HHS will introduce and swear in a new slate of Advisory Council members. Federal agencies will provide an overview of their work under the National Alzheimer's Project Act since 2011, and the Advisory Council will discuss a plan for updating the National Plan to Address Alzheimer's Disease for 2026–2035. The meeting will also include presentations on innovative approaches in Alzheimer's disease interventions.

DATES: The meeting will be held on Monday, February 9, 2026, from 10:00 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be a hybrid of in-person and virtual and will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at *www.hhs.gov/live*.

Comments: Time is allocated on the agenda to hear public comments from 4:00 p.m. to 4:25 p.m. The time for oral comments will be limited to two (2) minutes per individual. To provide a public comment, please register by emailing your name to *napa@hhs.gov* by Monday, February 2, 2026. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. Note: There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:45 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. Public commenters will not be admitted to the virtual meeting before 3:30 p.m. but are encouraged to watch the meeting at *www.hhs.gov/live.* Should you have questions during the session, please email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

To ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Wednesday, February 11, 2026. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Wednesday, February 11, 2026, to Maria-Theresa Okafor, Ph.D., MCG, OASPE, 200 Independence Avenue SW, Room 438F.7, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, 771–223–7102, *maria-theresa.okafor@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live*.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Alzheimer's disease-related dementias, risk reduction, and research.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available after the meeting. This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. Participants joining in person should note that seating may be limited. Those wishing to attend the meeting in person must send an email to *napa@hhs.gov* and put ''February Meeting Attendance'' in the subject line by Monday, February 2 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email. Please note that individuals entering HHS owned, leased, or operated facilities must present a REAL ID compliant credential or another federally approved form of identification. Below is the list of acceptable forms of ID.

- State-issued Enhanced Driver's License
- U.S. passport
- U.S. passport card
- DHS trusted traveler cards (Global Entry, NEXUS, SENTRI, FAST)
- U.S. Department of Defense ID, including IDs issued to dependents
- Permanent resident card
- Border crossing card
- An acceptable photo ID issued by a federally recognized Tribal Nation/ Indian Tribe, including Enhanced Tribal Cards (ETCs)
- HSPD–12 PIV card
- Foreign government-issued passport
- Canadian provincial driver's license or Indian and Northern Affairs Canada card
- Transportation worker identification credential
- U.S. Citizenship and Immigration Services Employment Authorization Card (I–766)
- U.S. Merchant Mariner Credential