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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.

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