4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1137]

Nicole Shelby Randall: 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 Nicole Shelby Randall 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 Ms. Randall was convicted of one felony count under Federal law for introduction of an adulterated drug into interstate commerce. The factual basis supporting Ms. Randall's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Randall was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of July 30, 2025 (30 days after receipt of the notice), Ms. Randall had not responded. Ms. Randall's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application by Ms. Randall 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-1137. 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, 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 January 22, 2025, Ms. Randall was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Oregon, when the court accepted her plea of guilty and entered judgment against her for the felony offense of introduction of an

adulterated drug into interstate commerce in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)). The underlying facts supporting the conviction are as follows: As contained in the Information and Plea Agreement from her case, beginning on or about February 2020, and continuing through on or about May 2022, Ms. Randall along with co-conspirators operated a scheme to import and distribute GS-441524, a new drug, within the United States. This drug, GS-441524, has not been approved by FDA for human or animal use. To mislead and defraud U.S. Customs and Border Protection (CBP) officers, Ms. Randall imported GS-441524 from China and Hong Kong disguised in boxes marked "Facial Mask" and "Pet Shampoo" and declared to CBP as "Beauty Essence Products," "Cosmetics," "Essence Water," and "Beauty Facial Masks." Through the private Facebook Group, "FIP Warriors 5.0," Ms. Randall marketed GS-441524. Despite having no veterinary or prescriber licenses, Ms. Randall defrauded and mislead her customers by "diagnosing" their cats and kittens with Feline Infectious Peritonitis (FIP) and "prescribing" GS-441524 for the animal's consumption. On or about August 12, 2021, and as part of an undercover law enforcement operations, Ms. Randall "diagnosed" a healthy cat with FIP and "prescribed" GS-441524 for consumption. After receiving payment, Ms. Randall introduced GS-441524 into interstate commerce by mailing it to the undercover agents.

FDA sent Ms. Randall, by certified mail, on June 25, 2025, a notice proposing to debar her 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 Ms. Randall's felony conviction under Federal law for introduction of an adulterated drug into interstate commerce in violation of sections 301(a) 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 Ms. Randall illegally imported and introduced misbranded 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 Ms. Randall's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Randall of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Randall received the proposal and notice of opportunity for a hearing on June 30, 2025. Ms. Randall failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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, under authority delegated to the Director, Division of Enforcement, finds that Ms. Nicole Shelby Randall 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, Ms. Randall 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 Ms. Randall is a prohibited act.

Lowell M. Zeta,

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

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