4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0250]

Ildiko M. Knoll: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Ildiko M. Knoll 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. Knoll engaged in a pattern of importing or offering for import misbranded drugs (i.e., in an amount, frequency, or dosage that is inconsistent with personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Ms. Knoll 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 May 29, 2023 (30 days after receipt of the notice), Ms. Knoll had not responded. Ms. Knoll'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. Knoll for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted 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-2023-N-0250.

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 Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, 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)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import (i.e., in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Ms. Knoll had engaged in numerous instances of importing or offering for import misbranded drugs. Specifically, between November 24, 2021, and November 29, 2022, Ms. Knoll imported or offered for import 100 parcels containing a total of 100 products (18,435 pieces, 9,495 tablets) that contained tadalafil and sildenafil. FDA determined that these products were misbranded drugs because their labeling lacked adequate directions for use, as required by section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and/or they were prescription drugs and their labels failed to bear the symbol "Rx only," as required by section 503(b)(4)(A) of the FD&C Act (21 U.S.C. 353(b)(4)(A)). All the parcels containing the misbranded drugs serving as the basis for this action were intercepted by FDA at the John F. Kennedy International Mail Facility and were addressed to Ms. Knoll at an address connected to her.

As a result of this pattern of importing or offering for import (i.e. in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Ms. Knoll, by United Parcel Service on April 27, 2023, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The attachment to that notice contained a table listing all the parcels intercepted by FDA that contained the misbranded drugs serving as a basis for this action. Among other pieces of information, that table contained the submission date of the entry, the product contained in the package, the quantity of the product, and the product violation FDA found for each entry. That attachment is posted to the docket and can be accessed by the public at https://www.regulations.gov. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Knoll's pattern of conduct and concluded that her conduct warranted the imposition of a 5-year period of debarment. The proposal informed Ms. Knoll of the proposed debarment and offered her an opportunity to request a hearing, providing 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. Knoll received the proposal and notice of opportunity for a hearing on April 29, 2023. Ms. Knoll 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Knoll has engaged in a pattern of importing or offering for import (i.e. in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct 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. Knoll 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 Ms. Knoll is a prohibited act.

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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