4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-7055]

Kimberly Schaff Kiehl: 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 Kimberly Schaff Kiehl 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 Ms. Kiehl was convicted of two felonies under federal law. The factual basis supporting Ms. Kiehl's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Kiehl 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 March 9, 2026 (30 days after receipt of the notice), Ms. Kiehl had not responded. Ms. Kiehl'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. Kiehl 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-7055. 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, at 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 July 3, 2025, Ms. Kiehl was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Middle District of Florida, Tampa Division, when the court

accepted her plea of guilty and entered judgment against her for the felony offenses of mail fraud in violation of 18 U.S.C. 1341 and causing counterfeit drugs to be made, sold, or held for sale in violation of 21 U.S.C. 331(i)(3) and 333(a)(2) (sections 301(i)(3) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows:

As contained in the Superseding Information and in the Plea Agreement from her case, Ms. Kiehl was the registered agent and authorized member for Focus Beauty, LLC (Focus Beauty) and she operated Focus Beauty's website to market and offer for sale drugs and other products. Between January 2020 and September 2021, several packages destined for Ms. Kiehl's address were seized by the Department of Homeland Security (DHS). Additionally, Ms. Kiehl received notices from the FDA and/or Customs and Border Protection about the violative nature of the products she was importing from China and other foreign countries.

On or about April 1, 2020, a DHL package shipped from China and destined for Ms. Kiehl's residence was intercepted. The package was addressed to the fake name of "Cathy Ryan" and the shipping documents identified the contents as engraving pen kits and glass bottles. Special Agents from DHS Homeland Security Investigations (HSI) conducted a border search of the package and determined that it contained 15 boxes marked "Restylane Injectable 1 x 1 ML;" eight boxes marked "Galderma Restylane Injectable Lyft Lidocaine 1 ML, The Perlane Collection, Injectable Gel with Lidocaine;" and, seven boxes marked "Galderma Restylane Injectable Lidocaine 1 ML, Injectable Gel with Lidocaine."

Following this seizure, and others, on September 2, 2021, a Special Agent from FDA's Office of Criminal Investigations acting in an undercover capacity purchased items through the website www.focusisbeauty.com. The agent ordered, (1) Intense Repair Serum, which bore the image of Botox, and was found in the section of the website titled: "Botox, Anesthetics, & Diluents;" and, (2) Intense Repair Serum, which bore the image of a product titled Daewoong Boulinum Toxin Type A Nabota and was found in the section of the website titled: "Botox, Anesthetics, & Diluents."

On or about September 17, 2021, agents retrieved the box shipped by Ms. Kiehl. The box contained five products marked as “Botox” with writing in the Turkish language. The products were determined to be counterfeit versions of the Botox product manufactured for and only distributed in Turkey. Botox is the brand name, owned by AbbVie Inc. (AbbVie), of a drug derived from botulinum toxin type A. Botulinum toxin type A is a highly potent toxin which can cause the disease botulism when present in human beings in a sufficient amount. The FDA has approved a biological products license for Botox and a supplement to the license application for the treatment of what is commonly referred to as wrinkles. Both FDA approved licenses for Botox products limits them to use pursuant to a prescription from a licensed practitioner. While Botox products may be purchased through intermediary sources, all purchases are shipped from an AbbVie warehouse facility in Houston, Texas. This occurs to meet the strict temperature controls required for botulinum toxin-containing products.

On October 14, 2021, a search warrant was executed at Ms. Kiehl’s residence. During the execution of the warrant, agents discovered hundreds of counterfeit products violative of the FD&C Act that were imported into the United States from foreign countries. These products were discovered throughout the residence, including in a freezer among frozen food items, in a pantry among dry goods, and hidden behind a false wall. Ms. Kiehl was present during the execution of the search warrant and agreed to speak with agents. Ms. Kiehl acknowledged ordering and receiving drugs and other products from foreign countries. She admitted to using fake recipient names on packages shipped to her from China, in an effort to avoid the seizure of the products, which were violative products. When using fake names did not stop the packages from being seized, Ms. Kiehl began using her son’s address to receive the products, which were violative products. Ms. Kiehl acknowledged selling unapproved and counterfeit drugs and other products on the website, www.focusisbeauty.com, and shipping those products in interstate commerce to customers.

Shipping records obtained by DHS/HSI revealed approximately 176 foreign based packages were imported by Ms. Kiehl and shipped to her residence between January 9, 2019, and September 19, 2021. Additionally, between approximately July 2017, and October 2021, Ms. Kiehl received approximately $341,218 for the sale of misbranded and counterfeit drugs and other products that lacked the required FDA approval.

FDA sent Ms. Kiehl, by certified mail, on February 3, 2026, a notice proposing to debar her 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 Ms. Kiehl's felony conviction under Federal law for mail fraud in violation of 18 U.S.C. 1341 and causing counterfeit drugs to be made, sold, or held for sale in violation of 21 U.S.C. 331(i)(3) and 333(a)(2) was for conduct relating to the importation of any drug or controlled substance into the United States because she illegally imported and introduced misbranded prescription 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. Kiehl's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Ms. Kiehl 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. Kiehl received the proposal and notice of opportunity for a hearing on February 7, 2026. Ms. Kiehl 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 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 Ms. Kimberly Schaff Kiehl 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 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Kiehl 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 Ms. Kiehl is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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