4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0309]

Sherrie R. McCain: 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 Sherrie R. McCain 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. McCain was convicted of a felony under Federal law for introduction into interstate commerce of a misbranded drug. The factual basis supporting Ms. McCain's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. McCain 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 April 17, 2025 (30 days after receipt of the notice), Ms. McCain had not responded. Ms. McCain'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. McCain 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-0309. 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 October 24, 2024, Ms. McCain was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Northern District of Alabama when the court accepted her plea of guilty and entered judgment against her for the felony offense of introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) 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 her case, between in and around December 2017 until in or around July 2021, Ms. McCain received foreign unapproved prescription drugs at her residence in Alabama. On or about September 5, 2019, U.S. Customs and Border Protection (CBP) agents seized at a border port a package containing approximately 4,000 prescription Tramadol pills and approximately 2,000 prescription Carisoprodol pills that was addressed to Ms. McCain at her residence in Alabama. Subsequent to the seizure, law enforcement executed a search warrant at Ms. McCain's residence. During the execution of the search warrant, law enforcement found approximately 27,950 foreign unapproved prescription drug pills along with shipping and repackaging material. The shipping material found at her residence listed the description of contents as "Candy and Merchandise" and "Hair Care Product Set." These labels were inconsistent with the actual contents of the packages, which were prescription drug pills.

After the execution of the state search warrant on or about September 10, 2019, Ms. McCain was interviewed by law enforcement. During that interview, Ms. McCain stated than an individual with initials S.M. shipped the pills to her and provided her with a list of orders to fill. Ms. McCain stated that once the pills arrived at her residence, she would repackage and ship them to various individuals across the United States. A review of the evidence seized at her home showed Ms. McCain had shipped numerous packages to individuals in more than 25 states within the last two years. For her part in the shipping operation, Ms. McCain received on a weekly basis between $200 and $2,000. Ms. McCain also received packages addressed to

different aliases that were variations of her actual name on shipping labels. Specifically, law enforcement discovered a shipping label dated September 13, 2019, addressed to "Sherri Mohan," as well as a shipping label dated March 31, 2021, addressed to Renee McCain.

On or about June 23, 2021, CBP agents seized at a border port a package containing approximately 2,000 prescription Alprazolam pills that were addressed to Ms. McCain at her residence in Alabama. On or about July 13, 2021, Ms. McCain was again interviewed by law enforcement. Ms. McCain told agents that individuals from India contacted her approximately six to eight months after the search warrant was executed at her residence in September 2019 and asked her to continue shipping foreign pills for them. Ms. McCain told agents that she received three to four foreign packages containing foreign drugs. Ms. McCain said she would remove the blister packs from the box, repackage them, and then ship them to customers. Ms. McCain said she would use the U.S. Postal Service to ship the drugs. Ms. McCain said the reason she started to repackage and ship the foreign prescription drugs again was for the money. Ms. McCain told agents that she knew at the time what she was doing was illegal. Ms. McCain showed the agents images, texts, and emails on her iPhone that corroborated her illegal conduct. Ms. McCain also provided consent for law enforcement to search her residence. During that search, law enforcement found approximately 3,600 foreign unapproved prescription drug pills, including Carisoprodol, Tramadol, Sildenafil Citrate, Gabapentin, Pregabalin, and Ephedrine. During the search, law enforcement also found shipping boxes and labels. Ms. McCain would repackage foreign prescription drugs in her home and then provide them to customers without a valid prescription written by a licensed practitioner. The drugs Ms. McCain shipped included 180 Carisoprodol pills, 180 Gabapentin pills, 90 Tramadol pills, and 180 Gabapentin pills. In total, between in or around December 2017 and in or around July 2021, Ms. McCain shipped misbranded drugs to individuals in approximately 25 different states outside of Alabama.

FDA sent Ms. McCain, by certified mail, on March 10, 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. McCain's felony conviction under Federal law for introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. 331(a) and 333(a)(2) (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. McCain illegally received foreign unapproved prescription drugs which she repackaged and sent out to consumers throughout the U.S. 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. McCain's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. McCain 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. McCain received the proposal and notice of opportunity for a hearing on March 18, 2025. Ms. McCain 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. Sherrie R. McCain 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. McCain 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. McCain is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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