4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0521]

David J. Kempema: 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 David J. Kempema 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. Kempema was convicted of one felony count under Federal law which FDA has determined is for conduct relating to the importation into the United States of a drug or controlled substance. The factual basis supporting Mr. Kempema's conviction is described in further detail below. Mr. Kempema 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 14, 2022 (30 days after receipt of the notice), Mr. Kempema had not responded. Mr. Kempema'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: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4144), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) 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 March 15, 2022, Mr. Kempema was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for Northern District of Iowa, when the court entered judgment against him for the offense of Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud After Having Been Previously Convicted of an Offense under 21 U.S.C. 331 and 333 in violation of sections 301(a), 301(k), and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a), 331(k), and 333(a)(2)). FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Information, filed on October 4, 2021, and in the Plea Agreement from Mr. Kempema's case, Mr. Kempema was previously convicted, on February 8, 2012, of one count of introducing and causing the introduction of misbranded drugs into interstate commerce, and causing the misbranding of drugs held for sale after shipment in interstate commerce with intent to defraud or mislead, in violation of sections 301(a), 301(k), and 303(a)(2) of the FD&C Act in *U.S.* v. *David Kempema*, No. 5:11-cr-04140-MWB (N.D. Iowa). In that case, between October 2009 and July 2011, Mr. Kempema ordered pills from India that contained the same active ingredients as Viagra and Cialis, but that had not been approved by FDA for sale in the United States. Mr. Kempema then sold the non-FDA approved pills to U.S. consumers as Viagra and Cialis.

Subsequently, from about February 2014 through about December 2018, Mr. Kempema was the owner and operator of Canned Ads, a business located in Iowa. During that time, he obtained Silditop, Aurogra, and Tadalista pills from India and/or Germany. Mr. Kempema found suppliers by searching the internet for generic Viagra and Cialis. He then purchased the drugs online from vendors overseas and received the products at the location of his business Canned Ads in Iowa. Both Silditop and Aurogra were new drugs that contained sildenafil, the active ingredient in Viagra, while Tadalista was a new drug that contained tadalafil, the active ingredient in Cialis. Silditop, Aurogra, and Tadalista had not been approved by FDA for sale or distribution in the United States. FDA approved drugs containing the active ingredients sildenafil and tadalafil are only available by prescription, and the labeling for those products includes numerous warnings, including a warning that those drugs can cause blood pressure to drop suddenly to an unsafe level if taken with certain other medications.

Mr. Kempema placed advertisements that made claims about male enhancement dietary supplements in men's restrooms in businesses in Iowa, in truck stops along the Interstate 29 corridor, and other locations. If a customer placed an order with Mr. Kempema for male enhancement dietary supplements, he would supply the customer with Silditop, Aurogra, and/or Tadalista. Mr. Kempema did not identify the drugs he sold as Silditop, Aurogra, and/or Tadalista. Instead, Mr. Kempema offered the drugs for sale under the names of other drugs, such as "All Natural Male." Mr. Kempema shipped the drugs to customers both inside and outside of the State of Iowa. The labeling on the drugs he shipped customers did not contain adequate directions for use and Mr. Kempema dispensed these prescription drugs without the prescription of a practitioner licensed by law to administer the drugs. During the course of this offense, Mr. Kempema obtained and attempted to obtain at least 4,059 pills for resale.

An undercover FDA agent made 3 controlled purchases from Mr. Kempema over a period of time for a product Mr. Kempema characterized as a dietary supplement called "All Natural Male" which came in the form of tablets in a pack of 10 at a cost of $5 per tablet.

During the first controlled purchase, the agent purchased $50 worth of tablets from Mr. Kempema, which he shipped to the agent. FDA testing later revealed that the tablets the undercover FDA agent purchased contained sildenafil, an undeclared erectile dysfunction drug. After the FDA undercover agent made the second controlled purchase, Mr. Kempema shipped the agent two 10-count blister packs of Silditop 100 Sildenafil Citrate tablets IP 100mg. The labeling for the products indicated they had been manufactured in India by Centurion Remedies PVT.LTD, for Healing Pharma, and FDA confirmed the products were not approved for sale or distribution in the United States. After the third controlled purchase, Mr. Kempema shipped the undercover FDA agent two 10-count blister packets with labeling that indicated the products were "Aurogra 100" Sildenafil Tablets 100mg. The labeling listed the manufacturer as "Aurochem Pharmaceuticals" of India, and FDA confirmed the products were not approved for sale or distribution in United States.

As a result of this conviction, FDA sent Mr. Kempema, by certified mail, on August 9, 2022, 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 Act that Mr. Kempema's felony conviction under Federal law for Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud After Having Been Previously Convicted of an Offense under sections 301(a), 301(k), and 303(a)(2) of the FD&C Act was for conduct relating to the importation into the United States of any drug or controlled substance because he 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 it considered applicable to Mr. Kempema's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Kempema 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. Kempema received the proposal and notice of opportunity for a hearing on August 15, 2022. Mr. Kempema 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. David J. Kempema 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. Kempema 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 Mr. Kempema is a prohibited act.

Any application by Mr. Kempema for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2022-N-0521 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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