



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2191]

Raymond Sean Brown: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarment Dr. Raymond Sean Brown from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Brown was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Brown was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Brown failed to request a hearing. Dr. Brown's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

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

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade (ELEM-4144), Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On April 2, 2015, the U.S. District Court for the Eastern District of Tennessee entered judgment against Dr. Brown for one count of receiving and distributing misbranded drugs in interstate commerce with intent to defraud and mislead in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(c)), which according to section 303(a)(2) of the FD&C Act (21 U.S.C. 333(a)(2)) constitutes a felony.

FDA's finding that the debarment is appropriate based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Dr. Brown was a licensed medical doctor in the state of Tennessee with a practice address listed in Cleveland, TN. The Tennessee Department of Health also lists Bradley PM&R as a licensed health care facility. Dr. Brown was the medical director of Bradley PM&R, and Dr. Brown's medical practice was listed at the same address. As a part of the treatment of patients for pain management, Bradley PM&R purchased assorted prescription drugs, including Botulinum Toxin Type A, also known as Botox Onabotulinumtoxin A (hereinafter referred to as "Botox"), which was prescribed by Dr. Brown and was administered and dispensed through Bradley PM&R. Prior to 2009, Botox[®]/Botox[®]

Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product licensed by FDA for use in humans for any indication, including pain management.

Axon Medical Supplies was a business operating in Surry, BC, Canada. Axon offered for sale to physicians and other health care providers in the United States drugs that had been obtained from foreign sources and that had not been approved by FDA for distribution or use in the United States.

From May 2008 until December 2012, Dr. Brown received \$7,482,968 in reimbursement from Medicare for Botox injections alone, with none of these payments resulting from properly payable claims for FDA approved Botox injections.

Beginning in or about January 2007 and continuing through in or about December 2012, Dr. Brown ordered 254 vials (25,400 units) of Botox from Axon Medical Supplies that were misbranded within the meaning of the FD&C Act in that the drug's labeling failed to bear adequate directions for use and all words, statements, or other information required by or under authority of the FD&C Act to appear on the label and labeling were not present, in fact many of the words were not in the English language. These misbranded drugs were sent to Bradley PM&R clinic and Dr. Brown injected these drugs into his patients, while purporting them to be FDA-approved drugs.

Dr. Brown billed Medicare for all of these Botox units as if they were FDA-approved drugs. Dr. Brown also provided diluted Botox injections and billed as if they were full doses. Dr. Brown billed Medicare for an additional 15,865 vials that he did not inject into patients. Dr. Brown admitted that he received the Botox in interstate commerce for delivery that was misbranded and he acted with intent to defraud and/or mislead. Dr. Brown's conduct constituted

a violation of section 303(c) of the FD&C Act, which according to section 303(a)(2) constitutes a felony.

As a result of this conviction, FDA sent Dr. Brown by certified mail on October 28, 2016, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Brown was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Dr. Brown's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug products marketed in the United States--Dr. Brown knowingly received and distributed misbranded drugs in interstate commerce with intent to defraud and mislead. The proposal also offered Dr. Brown 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. The proposal was received on October 31, 2016. Dr. Brown did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Dr. Raymond Sean Brown has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the

FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Dr. Brown's debarment be permanent.

As a result of the foregoing finding, Dr. Raymond Sean Brown is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES) (see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Brown, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Brown provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Dr. Brown during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Brown for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-2191 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

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

Dated: February 13, 2017.

Armando Zamora,

Deputy Director,

Office of Enforcement and Import Operations,

Office of Regulatory Affairs.

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