DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Raymond Sean Brown/46713-074
FPC Montgomery
Federal Prison Camp
Maxwell Air Force Base
Montgomery, Al 36112

10/28/2016

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2016-N-2191

Dear Dr. Brown:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. § 335a(l)(1)(B)) of one count of receiving and distributing misbranded drugs in interstate commerce with intent to defraud and mislead in violation of section 301(c) of the Act (21 U.S.C. § 331(c)), which, according to section (303)(a)(2) of the Act (21 U.S.C. § 333(a)(2)) constitutes a felony. FDA has determined that the conduct that served as the basis for your conviction relates to the regulation of a drug product under the Act. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On April 2, 2015, you were convicted, as defined in section 306(l)(1)(B) of the Act, in the United States District Court for the Eastern District of Tennessee, when the court accepted your plea of guilty and entered judgment against you for one count of receiving and distributing misbranded drugs in interstate commerce with intent to defraud and mislead in violation of 21 U.S.C. § 331(c), which, according to section (303)(a)(2) of the Act (21 U.S.C. § 333(a)(2)) constitutes a felony. The underlying facts supporting this conviction are as follows.

You were a licensed medical doctor in the state of Tennessee with a practice address listed in Cleveland, Tennessee. The Tennessee Department of health also lists a licensed health care facility of Bradley PM&R of which you were the medical director. Bradley PM&R is listed at the same address as your practice. As a part of the treatment of patients for pain management, Bradley PM&R purchased assorted prescription drugs, to include Botulinum Toxin Type A, also known as Botox

Onabotulinumtoxin A (hereinafter referred to as "Botox"), which was prescribed by you 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 the FDA for use in humans for any indication, including pain management.[1]

Axon Medical Supplies was a business operating in Surry, British Columbia, Canada. Axon offered for sale to physicians and other health care providers in the United States drugs which had been obtained from foreign sources and which had not been approved by the U.S. Food and Drug Administration for distribution or use in the United States.

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

Beginning in or about January 2007 and continuing through in or about December 2012, you ordered 254 vials (25,400 units) of Botox from Axon Medical Supplies that were misbranded within the meaning of the 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 FDCA to appear on the label and labeling were not prominently placed theron, in fact many of the words were not in the English language. These misbranded drugs were sent to Bradley PM&R clinic and you injected these drugs into your patients, while purporting them to be FDA-approved drugs.

You then billed Medicare for all of these Botox units as if they were FDA-approved drugs. You also provided diluted Botox injections and billed as if they were full doses. You also billed Medicare for an additional 15,865 vials that you did not inject into patients. You admit that you received the Botox in interstate commerce for delivery for pay which was misbranded and you acted with intent to defraud or mislead. Your conduct constituted a violation of 21 U.S.C. § 331(c), which, according to section (303)(a)(2) of the Act (21 U.S.C. § 333(a)(2)) constitutes a felony .

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) mandates that FDA debar an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of drug products under the Act. FDA finds that the felony conviction for receiving and distributing misbranded drugs in interstate commerce with intent to defraud and mislead is sufficient to support debarment because the conduct underlying the convictions related to the use of an unapproved drug. Further, you injected a misbranded drug into patients while representing it to be an FDA approved drug. FDA, therefore, finds that this type of conduct, which served as a basis for your convictions, relates to the regulation of drugs.

[1] On July 31, 2009, FDA approved a supplemental application to the license for BOTOX®/BOTOX®Cosmetic, which in relevant part changed the proper name of the biological product from Botulinum Toxin Type A to onabotulinumtoxin A. See Letter fr. FDA to Allergan Inc. (July 31, 2009), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/103000s5209s5210ltr.pdf. This nonproprietary name change is not material to these purposes, and for the sake of consistency with the related criminal proceedings, the product will continue to be referred to in this letter as Botulinum Toxin Type A.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2016-N-2191 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the Act (21 U.S.C. 335a) and under authority delegated to the Director, Office of Enforcement and Import Operations within the Food and Drug Administration.

/s/
Sincerely,

Douglas Stearn
Director
Office of Enforcement & Import Operations
Office of Regulatory Affairs