DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Albert Ronald Cioffi, MD
(b) (6)

06-01-2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0159

Dear Dr. Cioffi:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of five years 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 of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act), and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On January 9, 2008, based upon your plea of guilty to one count of misbranding a drug while held for sale after shipment in interstate commerce, in violation of 21 U.S.C. §§ 331(k), 333(a)(1) and 352(i)(3), a judgment was entered against you in the United States District Court for the Southern District of Florida. The underlying facts supporting this conviction are as follows.

During 2004, you were a physician licensed to practice medicine in the State of Florida. In February 2004 you became the medical director of Body Rx, a medical office located in Boca Raton, Florida. In July 2004 you became the sole owner of Body Rx. Body Rx specialized in cosmetic procedures, including the treatment of forehead wrinkles. Prior to 2009, BOTOX®/BOTOX® Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product approved by the FDA for use in humans for any indication, including for the temporary improvement in appearance of moderate to severe glabellar lines associated with corrugator and /or procerus muscle activity commonly described as the treatment of facial wrinkles.[1]

When you began working at Body Rx, you learned that BodyRx had been treating patients for forehead wrinkles with unapproved drug derived from botulinum Toxin Type A (TRI-toxin), sold by

[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.

Toxin Research International (TRI). You spoke to TRI representatives and learned that TRI-toxin was not approved by FDA for treatment of facial wrinkles. Nonetheless, you continued to purchase and use the unapproved drug from TRI. On four separate occasions between February and November of 2004, Body Rx purchased a total of eight vials of unapproved TRI-toxin at your direction. You used the unapproved TRI-toxin to inject approximately 30 patients at BodyRx. You never informed these patients that they were receiving an unapproved version of Botulinum Toxin Type A. Rather, you told patients that they were purchasing and being injected with the approved BOTOX® Cosmetic. Moreover, you indicated in these patients' medical records that they were receiving the approved BOTOX® Cosmetic, rather than the unapproved TRI-toxin.

From in or about February 2004, and continuing through in or about November 2004, in the Southern District of Florida, and elsewhere, you did misbrand a drug, namely Botulinum Toxin Type

A distributed by Toxin Research International, Inc., while it was held for sale and after shipment in interstate commerce, in that you offered the unapproved Botulinum Toxin Type A for sale by injection to patients under the name of another drug, all in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 352(i)(3), and 18 U.S.C. § 2.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. You misbranded or caused the misbranding of a drug in violation of the Act, namely, by offering a drug that had not been approved for use, TRI-toxin, for sale to patients under the name of another drug that is approved, namely BOTOX® Cosmetic. FDA, therefore, finds that this type of conduct, which served as a basis for your conviction, relates to the regulation of drug products under the Act and undermines the process for the regulation of drugs.

The maximum period of debarment under section 306(b)(2)(B)(i)(I) of the Act is five years. 21 U.S.C. 335a(c)(2)(A)(iii). Section 306(c)(3) of the Act (21 U.S.C. 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in this offense; and (3) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

The FDA regulates the manufacture and distribution of drugs in the United States. The FDA also regulates the manufacture and distribution of biological products, which include toxins like Botulinum Toxin Type A. As noted above, only one Botulinum Toxin Type A product was licensed by the FDA prior to 2009. FDA licensed BOTOX® in 1991, and approved a supplement for the indication of treatment of glabellar lines in 2002. Products for the latter indication are marketed and labeled as BOTOX® Cosmetic. TRI-toxin has never been licensed or approved by FDA for any use. On four separate occasions between February and November 2004, you directed Body Rx to purchase eight vials of unapproved TRI-toxin, and you administered TRI-toxin to approximately 30

Body Rx patients. You failed to inform patients that they were being injected with an unapproved product; rather you represented to patients that you had purchased and that they were being injected with the approved BOTOX® Cosmetic. You maintained medical records indicating that patients had been injected with BOTOX® Cosmetic, rather than the unapproved TRI-toxin.

You pleaded guilty to misbranding a drug while held for sale after shipment in interstate commerce, in that you offered TRI-toxin for sale under the name of another drug, namely BOTOX® Cosmetic. FDA finds that your conduct created a risk of injury due to the use of an unapproved and misbranded drug, undermined the Agency's oversight of an approved drug product, and seriously undermined the integrity of the Agency's regulation of drug products. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. Nature and extent of management participation.

In determining the appropriate period of debarment, FDA also considers the nature and extent of your management participation in the offense, and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. During the relevant period, you were a physician licensed to practice medicine. As a licensed physician, you held a position of authority and public trust. When you became the medical director at Body Rx in February 2004, you learned that Body Rx had been purchasing the unapproved TRI-toxin. You became sole owner of Body Rx in July 2004. Between February and November 2004, Body Rx continued to purchase TRI-toxin at your direction.

The foregoing facts indicate that in your position of authority as the medical director and later as sole owner of Body Rx, you directed the purchase of an unapproved drug for Body Rx and offered this unapproved drug for sale to patients under the name of another drug, BOTOX® Cosmetic. Accordingly, the Agency will consider this as an unfavorable factor.

3. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Weighing all factors, the Agency has determined that the unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a five-year permissive debarment in this case.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) debarring you for a period of five years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of misbranding a drug while held for sale, a Federal misdemeanor offense under the Act. As explained above, this offense relates to the regulation of drug products under the Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a five-year debarment period.

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.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2011-N-0159 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 within the Food and Drug Administration.

Sincerely,

Howard R. Sklamberg
Director
Office of Enforcement
Office of Regulatory Affairs

cc:

HF-22/Matthew Warren
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Deborah Autor
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Constance Lewin
HFD-45/Sherbet Samuels
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF