DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

07-29-2011

Gayle Rothenberg, MD
(b) (6)

08-22-2011 [Resent]

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0444

Dear Dr. Rothenberg:

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 of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On March 15, 2010, you entered a guilty plea to one felony count of, with intent to defraud and mislead, misbranding a drug while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 333(a)(2), 352(i)(3) and 18 U.S.C. § 2 and one felony count of intentionally and knowingly, in a matter within the jurisdiction of the FDA, making a false statement to an agent of the FDA in violation of 18 U.S.C. § 1001. Judgment was entered against you in the United States District Court, Southern District of Texas on April 20, 2010. The underlying facts supporting this conviction are as follows.

You were a physician licensed by the Texas State Board of Medical Examiners for the State of Texas as a medical doctor with a specialty in the area of Anesthesiology. In or about October 2003, you served as the medical director and operated a medical clinic in the Southern District of Texas named the "Center For Image Enhancement." The medical clinic provided and performed services related to the enhancement of the physical appearance of clients and included Botox injections.

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 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]

[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

On or about December 22, 2003, your clinic received a notice from Allergan that the price of Botox® and Botox® Cosmetic was increasing and the notice also indicated that as a valued customer you could purchase five 100-unit vials at the old price.

Beginning in February 2004, and continuing through September 2004, you and your office manager caused staff members to order Botulinum Toxin Type A (TRI-toxin) from Toxin Research International Inc. (TRI) located in Tucson, Arizona and did not order any Botox® or Botox® Cosmetic from Allergan. Subsequently, you informed staff members that a new Botox product would be used to treat patients. When the orders from TRI were received, the invoice accompanying the order as well as the packaging and labeling on each vial indicated that the TRI-toxin was "For Research Purposes Only, Not for Human Use." You also received a material safety data sheet from TRI that indicated that the TRI-toxin was not for human use. You were aware that the product was not intended for human use. You, however, performed injections and used the TRI-toxin on patients at your medical practice from February 2004 through September 2004. You misrepresented to patients that they were receiving injections of authentic Botox® and Botox® Cosmetic when in fact you knew the patients were receiving injections of non-FDA approved TRI-toxin.

On January 20, 2005, agents of the FDA traveled to the Center for Image Enhancement and spoke to you about whether any TRI-toxin had been ordered and used on patients of the medical clinic. You confirmed that the clinic had ordered the TRI-toxin, but stated that it had only been administered to friends and family. You also stated that you did not have any marketing materials or documents regarding the TRI-toxin.

On February 28, 2005, agents of the FDA again traveled to the Center for Image Enhancement and presented to you ten invoices showing that the clinic had ordered the TRI-toxin. This time you stated that the TRI product had been used on patients without your knowledge and approval. You indicated that approximately 210 patients received injections of the TRI-toxin during the period of February 4, 2004 and September 8, 2004. Agents of the FDA reviewed billing statements of the Center for Image Enhancement and determined that the clinic received approximately $98,000 from patients who received injections of the non-FDA approved TRI-toxin.

You admit in your plea agreement to, with intent to defraud or mislead, misbranding a drug while held for sale after shipment in interstate commerce, in violation of Title 21 U.S.C. §§ 331(k), 333(a)(2), 352(i)(3) and Title 18 U.S.C. § 2, and to making a false statement to an agent of the FDA in violation of Title 18 U.S.C. § 1001.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) mandates FDA to 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. Intending to defraud or mislead, you misbranded a drug after shipment in interstate commerce in violation of the Act, namely by offering a drug that had not been approved for use, Tri-toxin, to patients and then injecting the unapproved drug into patients while representing the drug to be another drug. FDA, therefore, finds that this type of

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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.

conduct, which served as a basis for your conviction, relates to the regulation of drugs because the misbranding of drugs is prohibited by the Act.

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.

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(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(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-0444 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,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs