DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark E. Van Wormer, MD
314 3rd Ave
Clayton, NM 88415-3302

12-17-2010

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0479

Dear Dr. Van Wormer:

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 and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On December 13, 2007, you entered a guilty plea to one felony count of misbranding a drug while held for sale in violation of 21 U.S.C. §§ 333(a)(2), 331(k) and 352(i)(3), and judgment was entered against you in the United States District Court, District of New Mexico. The underlying facts supporting this conviction are as follows.

You were a physician licensed by the New Mexico State Board of Medicine and you owned and operated the Union County Medical Center, also known as the Union County Medical, Diagnostic Imaging and Laser Surgery Center, PC, located in Clayton, New Mexico; the Physicians GreatSkin® Clinic, located in Albuquerque, New Mexico; and the GreatSkin® Clinic and Spa of Amarillo, located in Amarillo, Texas. 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 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.

From on or about January 13, 2004, through on or about November 9, 2004, you admit that you advertised the use of Allergan's Botox® at your Greatskin® clinic in Albuquerque, New Mexico, for use in treatment of forehead wrinkles. However, during that time you knowingly used TRI-toxin, an unapproved Botulinum Toxin Type A product that you purchased from Toxin Research International, Inc. (TRI), a company located in Tucson, Arizona.

You purchased approximately 20 vials of the TRI-toxin over eleven months in 2004, asking that each shipment be mailed from Arizona to New Mexico. Upon receipt, you injected the unapproved substance into your patients for forehead wrinkles. You did not inform your patients that they were being injected with an unapproved substance rather than with Allergan's approved Botox®. Although the TRI-toxin was cheaper than Allergan's Botox®, you charged your patients as if they were receiving Allergan's product.

Before using the TRI-toxin, you learned from TRI that the substance contained Botulinum Toxin Type A, which is defined as both a drug and a biologic under the Food, Drug and Cosmetic Act, and is regulated by the FDA.

You admit in your plea agreement that by advertising the use of Allergan's Botox® while actually using TRI-toxin, and never informing your patients of that fact, you misbranded the TRI-toxin because you used and sold it under the name of Allergan's Botox® in violation of 21 U.S.C §§ 331(k), 333(a)(2) and 352(i)(3). You admit to doing this while intending to defraud and mislead your patients. You injected approximately 120 patients with the TRI-toxin, charging patients an approximate total of $65,000 for the injections.

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 your patients, you misbranded a drug 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 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-2010-N-0479 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.

You also may notify the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) (21 U.S.C. § 335a(c)(2)(B)).

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-3/Daniel J. Davidson

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

HFA-305 (Docket No. FDA-2010-N-0479)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF