DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

5/23/2011

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0165

Dear Mrs. Seldon:

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 multiple felonies 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 November 19, 2008, a jury found you guilty on counts one through fifteen of the indictment filed June 27, 2007. On March 27, 2009, judgment was entered against you in the United States District Court for the District of Nevada for Mail Fraud, in violation of 18 U.S.C. §1341, Aiding and Abetting, in violation of 18 U.S.C. §2, and Misbranding a Drug While Held for Sale, in violation of 21 U.S.C. §§ 331(k) and 333(a)(2). The underlying facts supporting this conviction are as follows.

You were the manager of your husband's medical practice called A New You Medical Aesthetics (A New You) in Las Vegas, Nevada. As the office manager of A New You, your responsibilities included ordering supplies, paying bills, managing personnel and managing the bank accounts.

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]

Toxin Research International, Inc. (TRI), an Arizona corporation marketed and sold a "Botulinum Neurotoxin Type A" (TRI-toxin) that was neither approved nor licensed by FDA for use on humans.[2]

From on or about October 15, 2003, until on or about September 16, 2005, in the State and Federal District of Nevada and elsewhere you and your husband, aided and abetted by each other, devised a scheme and artifice to fraudulently obtain money from patients by substituting the cheaper, non-FDA approved TRI-toxin in treatments provided to patients at A New You, while falsely and fraudulently representing to the patients that they were receiving injections of the more expensive, FDA-approved BOTOX®.

As part of the scheme you ordered and caused to be ordered 38 vials of TRI-toxin between October 2003 and September 2004 while at the same time the practice stopped purchasing the approved BOTOX® from Allergan in October 2003. In January 2005, as part of the scheme and artifice, you arranged for a secret purchase of, and received, 132 vials of TRI-toxin for use at A New You.

You and your husband defrauded patients by misleading them to believe that they were receiving the FDA-approved drug BOTOX®, when, in fact, the patients were receiving TRI-toxin, which was not FDA-approved, thereby exposing the patients to severe health risk. On or about January 12, 2005, you caused to be falsified your office's computerized medical records by deleting references to Botox® and changing these entries to the generic notation "Cosmetic Procedure." In furtherance of your scheme, you and your husband caused 28 vials of TRI-toxin to be returned to the FDA, seeking to create the misleading impression that you were returning 28 vials of the original 38 vials purchased from TRI. In fact, your husband had used all of the original TRI-toxin on patients at A New You, and you were returning vials that were a part of your secret purchase of 132 vials.

You and your husband also caused advertisements to be placed in local magazines offering BOTOX®, creating the false impression that your office was using Allergan's approved BOTOX® when, in fact, patients were being injected with TRI-toxin. You also caused patients to sign consent forms that fraudulently represented that your husband would be injecting approved BOTOX® when

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[1] FDA licensed BOTOX® in 1991, and approved a supplement for the indication of treatment of glabellar lines in 2002. Products for this latter indication are marketed and labeled as BOTOX® Cosmetic. Although it is likely that the practice used product labeled BOTOX® Cosmetic rather than product labeled BOTOX®, it is not clear from the criminal proceedings which product the practice actually used. This difference is not relevant for these purposes because the products are identical with the exception of different labeling. For the sake of consistency with the related criminal proceedings, the product used will continue to be referred to in this letter as BOTOX®.

[2] 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 TRI-toxin product will continue to be referred to in this letter as Botulinum Neurotoxin Type A, as the active ingredient in Botox®/Botox Cosmetic® is described in those proceedings.

you knew he would be injecting them with TRI-toxin. Your misrepresentation of TRI-Toxin as BOTOX® resulted in the drug being misbranded in violation of 21 U.S.C. §§ 331(k) and 333(a)(2).

FDA's Finding

Section 306(a)(2)(B) of the 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 Act. As described above, you caused a drug to be misbranded in violation of sections 301(k) and 303(a)(2) of the Act (21 U.S.C. § 331(k) and 333(a)(2)), and engaged in mail fraud in violation of 18 U.S.C. § 1341. FDA finds that your Federal felony convictions for these violations relate to the regulation of drug products under 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-0165 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/
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-7/Nancy Boocker
HFD-300/ Deborah Autor
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Constance Lewin
HFD-45/Sherbert Samuels
HFV-200/Daniel G. McChesney

HFA-305 (Docket No. FDA-2011-N-0165)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF