DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ivyl W. Wells, MD
1255 18th E.
Mountain Home, ID 83647

11-22-2010

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0407

Dear Dr. Wells:

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

Conduct Related to Conviction

On July 12, 2006, you entered pleas of guilty to Counts One, Thirteen, Forty, Forty-one, and Forty-Two of the indictment filed August 10, 2005. On December 11, 2006, judgment was entered against you in the United States District Court for the District of Idaho for, among other things, Mail Fraud, in violation of 18 U.S.C. 1341 and 1346, Adulterating a Drug While Held for Sale, in violation of 21 U.S.C. 331(k) and 333(a)(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 a physician licensed by the Idaho State Board of Medicine and, you owned and operated the Skinovative Laser Center, also called the Perfect Skin Laser Center (the Center), in the District of Idaho. Through the Center, you offered and advertised BOTOX®/BOTOX® Cosmetic treatments for wrinkle reduction. 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.

Between late 2003 and early 2004, you attended training sponsored by TRI-Toxin International (TRI), an Arizona corporation. During the TRI seminar you learned that the TRI Botulinum Toxin Type A (TRI-toxin) was not approved for use in humans. You directed one of your employees to establish an account with TRI for the purpose of purchasing TRI-toxin. Beginning in February 2004, you began ordering TRI-toxin for use in treatments in human patients at the Center. The TRI-toxin came with invoices and labels on the vials of toxin that stated the product was "for research purposes only, not for human use." You then mixed the TRI-toxin with BOTOX®/BOTOX® Cosmetic, causing the drug to become adulterated in violation of 21 U.S.C. 331(k) and 333(a)(2), and then injected the mixture into patients, representing the injection as BOTOX®/BOTOX® Cosmetic.

From approximately February through November, 2004, you defrauded approximately two hundred patients who received injection treatments intended to reduce wrinkles. You defrauded patients by representing and selling the Botulinum toxin mixture as BOTOX®/BOTOX® Cosmetic. Patients injected with the Botulinum toxin mixture received pre-treatment consultations during which they were informed that they were receiving BOTOX®/BOTOX® Cosmetic and during which they were never informed that they would be injected with a Botulinum toxin mixture not approved for use in humans. Patients injected also signed a consent form entitled, "Botox Consent Form" and were told by Skinovative employees that they were receiving BOTOX®/BOTOX® Cosmetic. Patients who received the Botulinum toxin mixture were charged prices for treatments that were the same as, or similar to, patients who had received BOTOX®/BOTOX® Cosmetic. Your misrepresentation of the Botulinum toxin mixture as BOTOX®/BOTOX® Cosmetic 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 misbranded a drug and caused a drug to be adulterated in violation of sections 301(k) and 303(a)(2) of the Act (21 U.S.C. 331(k) and 333(a)(2)). 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-2010-N-0407 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-600/ Gary Buehler
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Lauren Iacono-Connor
HFV-200/Daniel G. McChesney

HFA-305 (Docket No. FDA-2010-N-0407)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFM-100
HFC-200/CF