DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Albert Poet, MD
1327 Mill Creek Road
Manahawkin, NJ 08050

12-13-2010

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0478

Dear Dr. Poet:

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 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 March 20, 2007, you were found guilty of thirteen counts of mail fraud in violation of 18 U.S.C. §§ 2, 1341 and one count of causing a drug to be misbranded while it was held for sale after shipment in interstate commerce with the intent to defraud or mislead in violation of 21 U.S.C. §§ 331(k) and 333(a)(2) and 352(i)(3). On September 28, 2007, judgment was entered against you on those charges in the United States District Court District of New Jersey. The underlying facts supporting this conviction are as follows.

During 2003-2004, you were a physician licensed to practice medicine in the state of New Jersey. You owned and operated the Shore Laser Center in Manahawkin and PEAU in Montclair, both located in New Jersey. As a part of your practice, you injected patients with BOTOX, a Botulinum Toxin Type A drug. Prior to 2009, BOTOX®/BOTOX® Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product licensed by 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.

According to the indictment, from on or about December 4, 2003, through in or about December 2004, you knowingly and willfully devised a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises. You maintained a website and placed regular advertisements in local newspapers offering "Botox" treatments at your offices. Between December 4, 2003 and November 8, 2004, you placed thirteen orders for a total of (b) (4) vials of TRI-toxin, a Botulinum Toxin Type A drug manufactured by Toxin Research

International, Inc. TRI-toxin was labeled "For Research Purposes Only, Not for Human Use." You then injected many of the approximately (b) (4) patients who sought Botox® treatments with unapproved TRI-toxin between January 1, 2004 and December 1, 2004. The informed consent forms you provided to most of the new patients seeking Botox® injections advised patients of the risks of injection with Botox®. As part of your scheme to defraud, you did not inform most of your patients receiving the TRI-toxin injections that they were receiving injections of a product not approved by FDA. You charged patients the same price for the cheaper, unapproved TRI-toxin and the approved Botox®. For purposes of executing the scheme and artifice, you knowingly and willfully caused the Tri-toxin to be delivered by private and commercial interstate carrier.

Your conduct violated Title 21 U.S.C. Sections 331(k), 333(a)(2), 352(i)(3), and Title 18, U.S.C. Sections 2, 1341.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) mandates that FDA 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. FDA finds that the felony convictions for mail fraud are sufficient to support debarment because the conduct underlying the convictions related to the use of an unapproved drug. Further, you misbranded or caused the misbranding of a drug while it was held for sale after shipment in interstate commerce with intent to defraud in violation of the Act. FDA, therefore, finds that this type of conduct, which served as a basis for your convictions, relates to the regulation of drugs.

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-0478 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-0478)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFM-100
HFC-200/CF