DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-02-2011

Adrien E. Aiache, MD
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0471

Dear Dr. Aiache:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of five years 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 misdemeanor under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act), and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. 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 June 26, 2007, you entered a plea of guilty to one count of receipt and delivery of a misbranded drug in interstate commerce, in violation of 21 U.S.C. §§ 331(c), 333(a)(1) and 352(f), and judgment was entered against you in the United States District Court for the Central District of California. The underlying facts supporting this conviction are as follows.

During 2003-2004, you were a physician with an office in Beverly Hills, California. As part of your practice prior to September 3, 2003, you injected patients with BOTOX®, a Botulinum Toxin Type A drug product for treatment of glabellar lines. Prior to 2009, BOTOX®/BOTOX® Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product approved 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]

In 2003, you began ordering an unapproved Botulinum Toxin Type A drug, TRI-toxin, manufactured by Toxin International, Inc. (TRI), instead of BOTOX®/BOTOX® Cosmetic. TRI-

[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.

toxin was marketed as a cheaper alternative to BOTOX®/BOTOX® Cosmetic. From on or about September 3, 2003, and continuing to on or about October 25, 2004, you placed sixteen orders for a total of thirty-four vials of TRI-toxin which you had shipped from Tucson, Arizona to California. You then administered the TRI-toxin to other persons for the treatment of facial wrinkles, all in violation of 21 U.S.C. §§ 331(c), 333(a)(1), and 352(f). The TRI-toxin did not come with labeling or directions on how to dilute the product for injection. The TRI-toxin label stated "for research purposes only" and "not for human use," as did the TRI invoices. You admitted in an interview on May 13, 2005, that you had injected the TRI-toxin into your family members, medical staff personnel, personal friends, and yourself.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. You received a misbranded drug, TRI-toxin, in interstate commerce, and delivered or proffered it for delivery for pay or otherwise. FDA, therefore, finds that this type of conduct, which served as a basis for your conviction, relates to the regulation of drug products under the Act and undermines the process for the regulation of drugs because a drug that lacks adequate directions for use is misbranded under § 502(f) of the Act, and receiving a misbranded drug in interstate commerce and delivering or proffering it for delivery for pay or otherwise is prohibited by section 301(c) of the Act.

The maximum period of debarment under section 306(b)(2)(B)(i)(I) of the Act is five years. 21 U.S.C. 335a(c)(2)(A)(iii). Section 306(c)(3) of the Act (21 U.S.C. 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in this offense; (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

The FDA regulates the manufacture and distribution of drugs in the United States. The FDA also regulates the manufacture and distribution of biological products, which include toxins like Botulinum Toxin Type A. As noted above, only one Botulinum Toxin Type A product was licensed by the FDA prior to 2009. FDA licensed BOTOX® in 1991, and approved a supplement for the indication of treatment of glabellar lines in 2002. Products for the latter indication are marketed and labeled as BOTOX® Cosmetic. TRI-toxin has never been licensed or approved by FDA for any use. In your plea agreement, you admitted to receiving TRI-toxin, a misbranded drug, in interstate commerce, and delivering or proffering it for delivery, for pay or otherwise, by administering it to other persons. .

FDA finds that your conduct created a risk of injury due to the use of an unapproved and misbranded drug, undermined the Agency's oversight of an approved drug product, and seriously undermined

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(b)(2)(B) of the Act (21 U.S.C. 335a(b)(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-0471 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,

for

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-0471)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF