DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marilyn Mehlmauer, MD
10 Congress Street, Suite 320
Pasadena, CA 91105-3084

01-19-2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0476

Dear Dr. Mehlmauer:

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 four 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 November 13, 2007, judgment was entered against you in the United States District Court for the Central District of California on one count of receipt and delivery of a misbranded drug in interstate commerce in violation of 21 U.S.C. 331(c) and 333(a)(1) and 352(f). The underlying facts supporting this conviction are as follows.

During 2003-2004 you were a physician with an office located in Pasadena, California. As a part of your practice prior to August 27, 2003, you injected patients with BOTOX, a Botulinum Toxin Type A drug.[1] 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.[2]

---

[1] Although it is likely that you used product labeled BOTOX® Cosmetic rather than product labeled BOTOX®, it is not clear from the criminal proceedings which product you 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

In August 2003, you began ordering an unapproved drug product represented to be a Botulinum Toxin Type A drug product manufactured by Toxin International, Inc. (TRI), located in Tucson, Arizona (TRI-toxin). From on or about August 27, 2003, and continuing to on or about November 22, 2004, you placed 12 orders for a total of 26 vials of TRI-toxin, which you had shipped to your office. The TRI-toxin did not come with labeling or directions on how to dilute the product for injection, and therefore was misbranded pursuant to 21 U.S.C. 352(f) in that it lacked adequate directions for use. The TRI-toxin label stated "for research purposes only" and "not for human use," as did TRI's invoices. In a July 11, 2005 interview with a representative of FDA's Office of Criminal Investigations, you admitted to injecting the unapproved TRI-toxin into yourself and patients. You also stated during that interview that on some occasions you represented the TRI-toxin to be BOTOX®/BOTOX® Cosmetic. In sum, you delivered and proffered for delivery the unapproved, misbranded TRI-toxin when you ordered, received and administered it to other persons, all in violation of 21 U.S.C. 331(c), 333(a)(1), and 352(f).

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 and offered an unapproved drug that was misbranded for failure to include adequate directions for use, TRI-toxin, for sale to patients, and delivered that unapproved misbranded drug by injecting it into patients. FDA 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 the receipt and delivery of misbranded drugs is prohibited by 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.

FDA regulates the manufacture and distribution of drugs in the United States. FDA also regulates the manufacture and distribution of biologic products, which includes 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 this 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 the receipt of a misbranded drug and after receiving this drug to

---

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.

delivering it to approximately 156 patients, in the form of injections, for monetary compensation.[3] In addition, you represented to some of these patients that the product was BOTOX®/BOTOX® Cosmetic.

FDA finds that your conduct created a risk of injury to consumers due to the use of an unapproved drug, undermined the Agency's oversight of an approved drug product by representing to some of your patients that you used an approved drug while substituting an unapproved drug it its place, and seriously undermined the integrity of the Agency's regulation of drug products. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. Nature and extent of management participation.

In determining the appropriate period of debarment, FDA also considers the nature and extent of your management participation in the offense, and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. You admitted to ordering the TRI-toxin for use in your practice, and admitted to injecting patients with the drug, knowing that it was not approved for use on humans. You were the owner and operator of your medical practice and, as a licensed physician and owner, you held a position of authority in which you served as an example for your employees. Therefore, the pattern of conduct you engaged in is considered more serious than if you were an employee. Accordingly, the Agency will consider this as an unfavorable factor.

3. Nature and extent of voluntary steps to mitigate impact on the public

FDA will next consider the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including, among other things full cooperation with any investigations (including extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. The sentencing memorandum filed on your behalf states that once confronted by FDA's Office of Criminal Investigations, you immediately admitted your conduct and was completely forthright without trying to minimize or lie about your actions. You additionally provided invoices and other documents to the agents as requested. Mehlmauer Sent. Mem. at 7, 8, *U.S. v. Mehlmauer*, Crim. Case No. CR 07-647 (C.D. Cal. Oct. 23, 2007). The government did not contest these factual representations. The Agency will consider this a favorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Weighing all factors, the Agency has determined that the unfavorable factors outweigh the favorable factors, and therefore imposition of a four-year permissible debarment is warranted in this case. You were the owner and operator of a medical practice and physician holding a position of trust who

[3] FDA licensed BOTOX®/BOTOX® Cosmetic pursuant to the Agency's authority set forth in Section 351(a) of the Public Health Service Act (PHSA), 42 U.S.C. 262(a). The misbranding provisions of the Act apply to products licensed under the PHSA. See 42 U.S.C. 262(j) ("[t]he Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) applies to a biological product subject to regulation under this section").

engaged in the practice of injecting patients with an unapproved misbranded drug creating a risk of injury. The nature and seriousness of the conduct underlying your conviction warrant a four-year period of debarment.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) debarring you for a period of four years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of receipt and delivery of a misbranded drug, a Federal misdemeanor offense under the Act. As explained above, this offense relates to the regulation of drug products under the Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a four-year debarment period.

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-0476 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