DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cathryn Lyn Garcia
(b) (6)

01-05-2011

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2010-N-0443

Dear Ms. Garcia:

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 March 14, 2006, you entered a plea of guilty to one count of misdemeanor misbranding of a drug. On August 14, 2010, judgment was entered against you in the United States District Court for the District of Oregon for misdemeanor misbranding a drug, in violation of 21 U.S.C. §§ 331(k) and 333(a)(1). The underlying facts supporting this conviction are as follows.

You were a registered nurse, licensed by the Oregon Board of Nursing. According to your Plea Agreement, throughout 2004, you assisted a co-defendant in operating two clinics that offered treatments that you and your co-defendant claimed could combat the effects of aging, including injection with BOTOX®.

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.[1]

[1]On July 31, 2009, FDA approved a supplemental application to the license for BOTOX®/BOTOX® Cosmetic, which in relevant part changed the established, or 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 non-proprietary 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.

From August 2004 through December 2004, you offered a Botulinum toxin called "Refinex" for sale for injection to patients under the name of another drug, BOTOX®. Refinex is manufactured by the Shandong BioResearch Institute in the People's Republic of China and has never been approved or licensed by FDA for any use

You pleaded guilty to one count of misbranding, admitting that during and around the period of August 2004 through December 2004, in the District of Oregon, you misbranded a drug, namely Botulinum Toxin Type A manufactured by the Shandong BioResearch Institute and known as Refinex, while it was held for sale and after shipment in interstate commerce, in that you offered Refinex for sale by injection to patients under the name of another drug that is approved, namely BOTOX®, all in violation of Title 21 U.S.C. §§ 331(k) and 333(a)(1).

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 misbranded or caused the misbranding of a drug in violation of the Act, namely, by offering a drug that had not been approved for use, Refinex, for sale by injection to patients under the name of another drug that is approved, namely BOTOX® and then injecting the unapproved drug into patients in your clinic. FDA finds that your conduct relates to the regulation of drug products under the Act, and the type of conduct which served as a basis for your conviction undermines the process for the regulation of drugs because the misbranding of 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. 333a(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; and (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of any offense involved.

FDA regulates the manufacture and distribution of drugs in the United States. FDA also regulates the manufacture and distribution of biological products, which includes toxin like Botulinum Toxin Type A. As noted above, only one Botulinum Toxin Type A product was licensed by 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. Refinex has never been licensed or approved by FDA for any use. In your plea agreement, you admitted to misbranding a drug.[2] Specifically, you admitted that from August 2004

[2]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").

to December 2004 you offered for sale by injection in patients a misbranded drug, namely Refinex, to patients under the name of BOTOX®. According to the Plea Agreement, you further admitted that you and your co-defendant injected over eight hundred patients with unapproved forms of Botulinum Toxin Type A, including Refinex, while representing to patients that they were receiving BOTOX®.

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 that you were offering for sale by injection in patients the approved drug while actually substituting an unapproved drug in 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 any offense involved

In determining the appropriate period of debarment, FDA also shall consider 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. Throughout 2004, you assisted a co-defendant in operating clinics that offered treatments that you and your co-defendant claimed could combat the effects of aging, including injection with BOTOX®. You have admitted that you and your co-defendant told patients that you would use BOTOX®, while, in fact, nearly every patient was injected with a form of botulinum toxin that was unapproved by FDA for use on humans, including Refinex.

As a manager at the clinics, you engaged in a pervasive pattern of misbranding and use of an unapproved drug. Your conduct served as an example for the employees of the clinics. Therefore, the pattern of misbranding you engaged in is considered more serious than if you were an employee. Accordingly, the Agency will consider this an unfavorable factor.

3. The nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved

FDA is unaware of any voluntary steps taken to mitigate the impact on the public of any offense involved. The Agency will consider this an unfavorable 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 facts supporting the unfavorable factors far outweigh those in support of the favorable factors, and therefore warrant the imposition of a five year permissible debarment in this case.

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 five years from providing

services in any capacity to a person having an approved or pending drug product application. You were convicted of misbranding a 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 five-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-0443 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-0443)
HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF