DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

04-03-2012 Resent to

(b) (6) [redacted]

03-27-2012

Sami Arshak Yanikian/60037-112
CI Taft
Correctional Institution
P.O. Box 7001
Taft, CA 93268

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2012-N-0063

Dear Mr. Yanikian:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order debarring you for a period of ten 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 two counts of introducing unapproved new drugs into interstate commerce. The conduct that served as the basis for the your conviction relates to the development or approval, including the process for development or approval, of drug products and relates to the regulation of drug products under the Federal Food, Drug, and Cosmetic Act (the Act). In addition, 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.

Conduct Related to Conviction

On June 29, 2011 you were found guilty of two counts of introduction of an unapproved drug in interstate commerce, in violation of 21 U.S.C. §§ 331(d), 355(a), 333(a)(1) and of aiding and abetting, in violation of 18 U.S.C. § 2(b) 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.

On or about November 22, 2006, you introduced and delivered for introduction, and caused to be introduced and delivered for introduction, into interstate commerce, two unapproved new drugs. This conduct was in violation of 21 U.S.C. §§ 331(d), 355(a), 333(a)(1).

On March 17, 2005, FDA sent you a warning letter regarding your marketing and sale of the following products: Novel natural formulation for atrial fibrillation, Super Nasal Drops, and Sams No Tinnitus Formulation. The warning letter described the claims being made on your website pertaining to these products and informed you that your claims caused these products to be "drugs" as defined by the Act because they were intended to cure, mitigate, treat, or prevent disease. You were informed that your products were "new drugs" and that a new drug may not be introduced or

delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. The warning letter additionally noted that none of the products described had an approved application and that their introduction or delivery for introduction into interstate commerce violated 21 U.S.C. § 331(d). You were advised to immediately correct these violations.

In response, on April 11, 2005, you wrote a reply letter to FDA in which you referred to the products addressed in the warning letter and stated, "These products are mailed for sale outside the U.S. to hospitals that deal with natural health products." You further noted that your products were not intended for sale as over-the-counter or for single individuals in the U.S. until they were approved by the FDA.

Despite knowing that you were not allowed to sell these unapproved new drugs in the U.S. without FDA approval, and despite your repeated representations to the FDA that you were not selling your products to customers in the U.S., you subsequently sold your unapproved new drug products to an undercover agent first in November 2005, and again in November 2006.

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 development or approval, including the process for development or approval, of any drug product or 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. As described above, you were found guilty of two counts of introducing unapproved new drugs into interstate commerce, in violation of sections 331(d), 355(a), 333(a)(1) of the Act and 18 U.S.C. § 2(b). As described in detail below, FDA finds that the conduct underlying your federal misdemeanor conviction relates to the development or approval, including the process for development or approval, of drug products and relates to the regulation of drug products under the Act and undermines the process for the regulation of drugs because the introduction and causing the introduction of unapproved new drugs into interstate commerce are prohibited by the Act.

The maximum period of debarment under section 306(c)(2)(A)(iii) 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 to mitigate the impact on the public; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

You were found guilty of introducing unapproved new drugs into interstate commerce in violation of sections 331(d), 355(a), 333(a)(1) of the Act. Despite knowing that you were not allowed to sell new drugs in the U.S. without FDA approval, and despite your repeated representation to FDA that you were not selling your products to customers in the U.S., you subsequently sold your unapproved new drug products to an undercover agent on two occasions. FDA finds that your conduct created a risk of injury to your customers, undermined the development or approval, including the process for

development or approval, of drug products, 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. During a August 2010 interview by agents from the FDA's Office of Criminal Investigations, you admitted that a website offering drugs for sale was in fact your website. You admitted to making and packaging the drug products in your apartment. Therefore, FDA has reason to believe that you managed the criminal scheme to market unapproved new drugs in the U.S. Accordingly, the Agency will consider this as an unfavorable factor.

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

FDA has no information demonstrating that you took any voluntary steps to mitigate the impact of your actions on the public. Accordingly, the Agency considers your failure to take voluntary steps to mitigate the offense you committed to be 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 unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a ten-year permissive 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 ten years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of two counts of introducing unapproved new drugs into interstate commerce. As explained above, this offense is in violation of the applicable provisions of section 306 of the Act. In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (21 U.S.C. § 335a(c)(2)(A)). Given the analysis above, FDA has concluded that the unfavorable factors cumulatively far outweigh the sole favorable factor and that the five-year period of debarment for each of the offenses need to be served consecutively, resulting in a total debarment period of ten years.

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-2012-N-0063 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.

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Acting Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs

cc:

HF-22/Matthew Warren
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Bernstein
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

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