DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anoushirvan Sarraf/82785-083
FCI Cumberland
Federal Correctional Institution
Satellite Camp
P.O. Box 1000
Cumberland, MD 21501

03-09-2015

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2014-N-2101

Dear Dr. Sarraf:

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, as defined in section 306(l)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. § 335a(l)(1)(A)) of seven felonies under Federal law for conduct relating to the regulation of a drug product. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On May 6, 2014, you were convicted, as defined in section 306(l)(1)(A) of the FD&C Act, when a jury found you guilty of one count of conspiracy, in violation of 18 U.S.C. §371, three counts of importation contrary to law, in violation of 18 U.S.C. §§545 and 2, two counts of receipt and delivery of misbranded drugs, in violation of 21 U.S.C. §§331(c), 333(a)(2), and 18 U.S.C. §2, and one count of unlicensed wholesale distribution of prescription drugs, in violation of 21 U.S.C. §§331(t)), 333(b)(1)(D), 353(e)(2)(A), 353(e)(3)(B), and 18 U.S.C. §2. On July 23, 2014, judgment was entered against you in the United States District Court for the Eastern District of Virginia. The underlying facts supporting this conviction are as follows.

You were a physician and owner of Aphrodite in McLean, Virginia, in the Eastern District of Virginia. You provided your medical license to Gallant Pharma International Inc. (Gallant Pharma), for use by international co-conspirators, received importations in your and Aphrodite's name on behalf of Gallant Pharma, and you purchased misbranded and non-FDA approved drugs and devices from Gallant Pharma. In exchange for the use of your medical license and mailing name and address, you received discounted pricing from Gallant Pharma.

Beginning in or around June 2009, and continuing until at least August 2013, in the Eastern District of Virginia and elsewhere, you did knowingly and intentionally conspire and agree, to commit offenses against the United States by: fraudulently and knowingly importing and bringing into the

United States merchandise contrary to law, in that the merchandise consisted of misbranded drugs, you knowingly engaged in the wholesale distribution in interstate commerce of prescription drugs in the State of Virginia without being licensed to do so, you received in interstate commerce and delivered and proffered delivery thereof for pay and otherwise misbranded drugs, and you defrauded the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public.

You provided Gallant Pharma with your medical license to enable Gallant Pharma to order non-FDA-approved chemotherapy and cosmetic drugs from around the world, and allowed those drugs to be shipped into the United States to Aphrodite. When the drugs arrived, you alerted individuals at Gallant Pharma to retrieve the illegal drugs. You additionally would take some of the misbranded and non-FDA-approved drugs from the packages intended for Gallant Pharma for use on your patients at Aphrodite.

Between August 2009 and August 2012, you received and handed off, at least forty shipments containing illegally imported drugs and devices. Between August 2009 and August 2012, you purchased approximately $250,000 in misbranded and non-FDA-approved drugs and devices from Gallant Pharma, all in violation of 18 U.S.C. §371.

Beginning in or around June 2009, and continuing until at least August 2013, in the Eastern District of Virginia you knowingly imported and brought into the United States merchandise contrary to law, and received, concealed, bought, sold, and facilitated the transportation, concealment and sale of misbranded drugs after importation, knowing the merchandise was imported into the United States contrary to law, in violation of 21 U.S.C. §§331(c) and 333(a)(2).

You knowingly engaged in the wholesale distribution in interstate commerce of prescription drugs without being licensed by the State of Virginia, in violation of 21 U.S.C. §§331(t), 333(b)(l)(D), and 353(e)(2)(A).

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the Act. As described above, you received in interstate commerce and delivered and proffered delivery thereof for pay and otherwise misbranded drugs to Gallant Pharma. For example, on August 31, 2011, you received and subsequently delivered to Gallant Pharma Xeomin, the labeling of which did not bear adequate directions for use. Additionally, you engaged in the wholesale distribution in interstate commerce of prescription drugs in the Commonwealth of Virginia without being licensed to do so, in violation of 21 U.S.C. §§331(t), 333(b)(1)(D), 353(e)(2)(A), and 352(e)(3)(B). For example, between October 1, 2010 and August 1, 2012, you received from outside the Commonwealth of Virginia and distributed intravenous chemotherapy prescription drugs intended for Gallant Pharma, which were further distributed.

FDA finds that the conduct underlying these felonies relates to the regulation of drug products under the Act because your receipt in interstate commerce of misbranded drugs which you delivered for pay and otherwise undermined FDA's regulatory oversight over drug products marketed in the

United States, as did your unlicensed wholesale distribution of prescription drugs in interstate commerce.

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. You should understand that the facts underlying your conviction are not at issue in this proceeding. 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.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2014-N-2101 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 Director, Office of Enforcement & Import Operations within the Food and Drug Administration.

Sincerely,

Douglas Stearn
Director
Office of Enforcement & Import Operations