DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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Petersburg, VA 23804

03-09-2015

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2014-N-2103

Dear Mr. Aminzada:

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)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. § 335a(l)(1)(B) of a felony 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 June 10, 2014, you were convicted, as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted your plea of guilty and entered judgment against you for one count of introducing misbranded drugs into interstate commerce with the intent to defraud or mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. §§ 331(a) and 333(a)(2)). On June 10, 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:

Between at least August 2009 and August 2013, you owned and operated several companies dedicated to international sales, including Royal Canadian Imports (headquartered in Canada), and Essa Gulf Trading (headquartered in Dubai, United Arab Emirates).

Between approximately August 2009 and August 2012, you sold misbranded chemotherapy drugs and injectable cosmetic drugs to Gallant Pharma International, Inc. (Gallant Pharma), and to Gallant Pharma co-owners, Talib Kahn and Syed Huda. You were aware that many of the drugs sold to Gallant Pharma would be resold in the United States.

Between August 2009 and August 2012, you sold at least the following drugs to Gallant Pharma, for resale in the United States: Alimta (an intravenous chemotherapy drug for lung cancer), Anzemet (anti-nausea treatment for surgery and chemotherapy patients), Botox (injectable treatment for forehead wrinkles and muscle disorders, which is a cold chain product subject to a black box

warning), Eloxatin (intravenous chemotherapy for breast cancer, another cold chain product), Herceptin (intravenous chemotherapy for breast cancer and a cold chain product subject to a black box warning), and Taxotere (an intravenous chemotherapy for lung and breast cancer, subject to a black box warning). A black box warning is the most serious type of warning imposed by FDA, and signifies that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.

Neither of your companies was licensed as a prescription drug wholesaler anywhere in the United States. You admitted that the drugs you sold to Gallant Pharma for resale in the United States were prescription only, and that many of the drugs were misbranded in that the drugs did not bear adequate directions for use and were not subject to an exemption from that requirement, and were accompanied by non-FDA approved packaging and inserts, which were sometimes written in foreign languages. The drugs you sold to Gallant Pharma also lacked the FDA-required pedigree, which protects patients' health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient. At times, you sold FDA-approved versions of these drugs to Gallant Pharma for resale in the United States, even though you were not authorized to import such drugs into the United States.

For example, on or about February 26, 2010, you offered to sell Anzemet, which the manufacturer had intended for the Dubai market, to Gallant Pharma. Also, on or about January 12, 2011, Kahn and Huda noted that they had received 200 boxes of Anzemet from you, but only three of the boxes were "clean." The rest had smudged packaging, or were labeled "Afghanistan only." Furthermore, on or about October 25, 2011, Huda noted in an e-mail to you that the Taxotere you provided to Gallant Pharma looked like it had been repackaged because, among other things, the drugs contained package inserts that appeared to be inauthentic.

Between August 2009 and August 2012, you received at least $586,798 in wire transfers from Gallant Pharma, representing revenues from sales of such drugs to Gallant Pharma. In your plea agreement, you admitted that your actions were in all respect knowing, voluntary, and intentional, and did not occur by accident, mistake, or for another innocent reason.

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 did, with the intent to mislead and defraud, introduce into interstate commerce misbranded drugs in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. §§ 331(a) and 333(a)(2)).

FDA finds that the conduct underlying the conduct underlying your felony conviction relates to the regulation of drug products under the FD&C Act because you undermined FDA's regulatory oversight over drug products marketed in the United States by intentionally introducing into interstate commerce drug products that did not bear adequate directions for use and were not subject to an exemption from that requirement, and which, among other things, were accompanied by non-FDA approved packaging and inserts.

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-2103 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