DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 19, 2015

Talib Khan/80718-053
FDC Philadelphia
Federal Detention Center
P.O. Box 562
Philadelphia, PA 19105

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

Dear Mr. Khan:

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 two 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 March 11, 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 conspiracy, in violation of 18 U.S.C. §371, and one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§331(a) and 333(a)(2), and 18 U.S.C. § 2. The underlying facts supporting this conviction are as follows.

You were the co-founder and co-owner of Gallant Pharma International Inc. (Gallant Pharma), between August 2009 and August 2013. Gallant was a company dedicated to the illegal importation and sale of misbranded and non-FDA approved chemotherapy drugs and injectable cosmetic drugs and devices in the United States.

As co-founder and co-owner of Gallant Pharma, you were primarily responsible for the international aspect of the conspiracy, including: determining which drugs and devices to sell in the United States; establishing relationships with international suppliers; directing those suppliers to send drugs and devices to trans-shippers in Canada and the United Kingdom; arranging for trans-shippment from Canada and the United Kingdom to the United States; interviewing, hiring, and training sales representatives in the United States; and paying suppliers, sales representatives, and office employees out of foreign bank accounts. Gallant Pharma was not licensed as a prescription drug

wholesaler by the Commonwealth of Virginia. Some of the drugs and devices that you acquired were not approved by the FDA for use on patients in the United States. You admit that the drugs sold by

Gallant Pharma were prescription only, and were misbranded in that, among other things: they did not bear adequate directions for use and were not subject to an exemption from that requirement; and they were accompanied by non-FDA-approved packaging and inserts. Sometimes, the drug packaging and inserts were written solely in languages other than English. The drugs your company sold also lacked the FDA-required pedigree, which protects patient health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient.

Immediately after establishing Gallant Pharma's presence in the Eastern District of Virginia, on or about September 25, 2009, you received a cease and desist letter from a law firm on behalf of Medicis, the exclusive authorized marketer of Restylane and Perlane in the United States and Canada. The letter informed your company that your marketing of these drugs violated the FD&C Act and could subject Gallant Pharma to substantial criminal and civil penalties. The letter included Gallant Pharma's marketing materials, which falsely claimed that Gallant Pharma had been "strictly working with the current FDA rules and regulations for almost 10 years."

You purchased drugs and devices from suppliers in, among other places, Turkey, Switzerland, the United Kingdom, and the United Arab Emirates. In or around March 2011, after a co-conspirator's medical license had expired, you altered the expiration date on the medical license to make it appear that the license was still valid.

On at least 18 occasions, you personally completed false customs declarations and thereby illegally imported misbranded drugs and devices from Canada to the Eastern District of Virginia. You also personally accepted and processed orders for Gallant Pharma customers. For example, on or about February 8, 2011, you sold two vials of misbranded Zometa and one vial of misbranded Gemzar to a customer in Cary, North Carolina, in exchange for $1,400, thereby causing misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

Between August 2009 and August 2013, Gallant Pharma received illegal proceeds of at least $12,400,000 from the sale of misbranded and non-FDA-approved drugs and devices in the United States. You admitted that you were an organizer or leader of this criminal activity and you additionally admitted that your actions were in all respects 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 knowingly and intentionally conspired with other persons to, with the intent to defraud and mislead, introduce into interstate commerce misbranded drugs in violation of 21 U.S.C. §§331(a) and 333(a)(2)You also, with the intent to mislead and defraud, introduced into interstate commerce misbranded drugs in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

As noted above, you were primarily responsible for the international aspect of the conspiracy, including determining which drugs and devices to sell in the United States; establishing international

suppliers; directing those suppliers to send drugs and devices to trans-shippers in Canada and the United Kingdom; arranging for trans-shipment from Canada and the United Kingdom to the United States; interviewing, hiring, and training sales representatives in the United States; and paying suppliers, sales representatives, and office employees out of foreign bank accounts. On at least 18 occasions, you personally completed false customs declarations and thereby illegally imported misbranded drugs from Canada to the Eastern District of Virginia. You also personally accepted and processed orders for Gallant Pharma customers; for example, on or about February 8, 2011, you sold two vials of misbranded Zometa and one vial of misbranded Gemzar to a customer in Cary, North Carolina.

FDA finds that the conduct underlying these felonies relates to the regulation of drug products under the Act because your actions undermined FDA's regulatory oversight over drug products marketed in the United States. As you stipulated in your plea agreement, you "imped[ed], impair[ed], and defeat[ed] the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs distributed in the United States were safe and effective from the time of manufacturing to the delivery of the entity that sells or dispenses the product to the ultimate consumer or patient."

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,

/s/

Douglas Stearn
Director
Office of Enforcement & Import Operations