



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2103]

Talib Khan: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarment Talib Khan from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Khan was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product. Mr. Khan was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Khan failed to respond. Mr. Khan's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [**INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade (ELEM-4144), Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C 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 FD&C Act.

On March 11, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Khan 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.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: Mr. Khan was a cofounder 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 cofounder and co-owner of Gallant Pharma, Mr. Khan was primarily responsible for the international aspect of the conspiracy, including: (1) Determining which drugs and devices to sell in the United States; (2) establishing relationships with international suppliers; (3) directing those suppliers to send drugs and devices to transshippers in Canada and the United Kingdom; (4) arranging for transshipment from Canada and the United Kingdom to the United

States; (5) interviewing, hiring, and training sales representatives in the United States; (6) 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 Mr. Khan acquired were not approved by the FDA for use on patients in the United States. Mr. Khan admitted 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. The drugs Mr. Kahn's 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, and some drug packaging and inserts were written solely in languages other than English.

Immediately after establishing Gallant Pharma's presence in the Eastern District of Virginia, on or about September 25, 2009, Mr. Khan 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 Mr. Khan's company that its 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."

Mr. Khan 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 coconspirator's medical license had expired, Mr. Khan altered the expiration date on the medical license to make it appear that the license was still valid.

On at least 18 occasions, Mr. Khan personally completed false customs declarations and thereby illegally imported misbranded drugs and devices from Canada to the Eastern District of Virginia. Mr. Khan also personally accepted and processed orders for Gallant Pharma customers.

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. Mr. Khan admitted that he was an organizer or leader of this criminal activity and he additionally admitted that his actions were in all respects knowing, voluntary, and intentional, and did not occur by accident, mistake, or for another innocent reason.

As a result of his conviction, on March 19, 2015, FDA sent Mr. Khan a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Khan was convicted of felonies under Federal law for conduct related to the regulation of a drug product. The proposal also offered Mr. Khan an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 23, 2015. Mr. Khan failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to

him (Staff Manual Guide 1410.35), finds that Talib Khan has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Talib Khan is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES)(see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Talib Khan, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Khan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications from Talib Khan during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))).

Any application by Mr. Khan for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2014-N-2103 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2015.

Douglas Stearn,

Director,

Division of Compliance Policy,

Office of Enforcement,

Office of Regulatory Affairs.

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