4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2102]

Syed Huda: 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 debarring Syed Huda 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. Huda was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product. Mr. Huda was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Huda failed to respond. Mr. Huda'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 May 16, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Huda for one count of importation contrary to law, in violation of 18 U.S.C. 545 and 2, one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. 331(a), 333(a)(2), and 18 U.S.C. 2, 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), and 18 U.S.C. 2, and one count of wire fraud, in violation of 18 U.S.C. 1343.

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. Huda 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. Huda was primarily responsible for the United States based portion of the conspiracy, including: (1) Identifying a drop shipper willing to accept illegal importations of behalf of Gallant Pharma, (2) locating space for Gallant

Pharma to store misbranded and non-FDA approved drugs and devices, (3) establishing relationships with customers in the Washington, D.C. metropolitan area,(4) interviewing and hiring sales representatives in other parts of the United States, and (5) establishing merchant accounts with credit card processors, for receipt of illegal proceeds via wire transfer into Canadian 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. Huda acquired were not approved by the FDA for use on patients in the United States. Mr. Huda 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 Gallant Pharma 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, Mr. Huda 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 Gallant Pharma 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. Huda personally solicited orders on behalf of Gallant Pharma, and on or about October 19, 2010, he sold 10 vials of misbranded TAXOTERE to a physician in Oceanside, CA,

in exchange for $2450, thereby causing misbranded drugs to travel in interstate commerce from the Eastern District of Virginia. Mr. Huda was aware of several occasions in which physicians complained after receiving drugs with packaging and inserts written in language other than English, and he authorized a price reduction upon receiving such complaints.

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. Huda admitted that he was an organizer or leader of this criminal activity and 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 May 20, 2015, FDA sent Mr. Huda 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. Huda was convicted of felonies under Federal law for conduct related to the regulation of a drug product. The proposal also offered Mr. Huda 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 May 26, 2015. Mr. Huda 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 Syed Huda 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, Syed Huda 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 Syed Huda, 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. Huda 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. In addition, FDA will not accept or review any abbreviated new drug applications from Syed Huda during his period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Mr. Huda for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2014-N-2102 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: September 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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