4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1311]

Paul S. Singh: 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 Paul S. Singh 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 Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Singh was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Singh failed to request a hearing. Dr. Singh's failure to request a hearing 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, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs (ELEM-4144), 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 July 31, 2015, the U.S. District Court for the Eastern District of California entered judgment against Dr. Singh for one count of mail fraud, in violation of 18 U.S.C.1341.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Dr. Singh was the President and Secretary of Paul S. Singh, DO, Inc., and provided obstetric and gynecological services to women. Beginning on or about May 2008, and continuing to at least on or about June 2012, within the Eastern District of California and elsewhere, Dr. Singh devised a scheme and artifice to defraud health care benefit programs, patients, and others of money and property by means of materially false and fraudulent pretenses, representations, and promises.

During the time period described, Dr. Singh provided his patients forms of birth control, including the insertion of an intrauterine device ("IUD"). IUDs are regulated by FDA. At the relevant time, FDA had only approved one IUD, which used copper as its active ingredient, the ParaGard T-380A IUD. ParaGard T-380A was sold only by its manufacturer and was not available on third-party Web sites.

The insertion of a non-FDA approved copper IUD risks a patient's health and safety. Dr. Singh knew of this risk and knew that inserting a non-FDA approved copper IUD was prohibited by FDA. Despite this, Dr. Singh obtained non-FDA approved copper IUDs by purchasing them on the Internet and inserted them in his patients. Dr. Singh failed to inform his patients that he had inserted a non-FDA approved copper IUD, and none of his patients consented to the insertion of one. On or about August 17, 2010, FDA agents met with Dr. Singh and warned him that he could not insert non-FDA approved copper IUDs, and he agreed that he would stop doing so. Notwithstanding this warning, Dr. Singh continued to insert non-FDA approved copper IUDs in his patients and falsely claimed to his patients that he was inserting FDA-approved copper IUDs.

Dr. Singh billed at least 10 different health care benefit programs for payment for the insertion of non-FDA approved copper IUDs in his patients. In submitting these claims, Dr. Singh knowingly misrepresented the type of IUD he had inserted. Dr. Singh caused the U.S. mails to be used to carry out an essential part of his scheme. At all relevant times, Dr. Singh acted with the intent to defraud. As a result of Dr. Singh's conduct, he made false claims of over $83,000 to health care benefit programs, his patients, and others.

As a result of this conviction, FDA sent Dr. Singh by certified mail on August 17, 2016, a notice 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 a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Dr. Singh's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug

products marketed in the United States--it involved using and misrepresenting as approved unapproved IUDs that presented health risks to patients. The proposal also offered Dr. Singh 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 August 23, 2016. Dr. Singh did not request a hearing and has, therefore, waived his opportunity for a hearing and 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 sections 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Paul S. Singh has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Dr. Singh's debarment be permanent.

As a result of the foregoing finding, Paul S. Singh 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 sections 201(dd) (21 U.S.C. 321(dd)), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act). 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 Paul S. Singh, 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 Dr. Singh 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 Paul S. Singh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Singh for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-1311 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 will be placed in the docket, and will be viewable at http://www.regulations.gov or at the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2016,

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

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