DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

08-17-2016

Paul S. Singh/72813-097
USP LOMPOC
U.S. Penitentiary
3901 Klein Blvd.
Lompoc, CA 93436

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2016-N-1311

Dear Dr. Singh:

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 under Federal law[1] of a felony for conduct relating to the regulation of a drug product under the Act. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On July 31, 2015, you plead guilty and judgment was entered against you in the United States District Court for the Eastern District of California for mail fraud in violation of 18 U.S.C. §1341. The underlying facts supporting this conviction are as follows.

You were a licensed medical doctor in the Eastern District of California. You were 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, you devised and intended to devise a scheme and artifice to defraud health care benefit programs, patients, and others of money and property, and obtained money and property from health care benefit programs, patients, and others, by means of materially false and fraudulent pretenses, representations, and promises.

[1] Under section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act ("the Act") (21 U.S.C. §335a(l)(1)(B)), for debarment purposes, a person is considered to have been convicted of a criminal offense when a plea of guilty has been accepted by a Federal court.

During the above described time period, you provided to your patients forms of birth control, including the insertion of an intrauterine device ("IUD"). IUDs are regulated by the FDA. At the relevant time, FDA had only approved one IUD which uses copper as its active ingredient, the

ParaGard T-380A IUD. ParaGard T-380A was sold only by its manufacturer,[2] and was not available on third party websites.

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

You then billed at least 10 different health care benefit programs for payment for the insertion of non-FDA approved copper IUDs in your patients. In submitting these claims, you knowingly misrepresented the type of IUD you had inserted, representing that you had inserted an FDA-approved IUD when in fact you had not. You caused the United States mails to be used to carry out an essential part of the scheme. For example, on or about September 22, 2010, you received a check from Tri-Care via the U.S. postal service in the amount of $783.79 as payment for a fraudulent claim you submitted related to one of your patients.

At all relevant times, in carrying out these actions, you acted with the intent to defraud. As a result of your conduct, you made false claims of over $83,000 to health care benefit programs, your patients, and others.

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, your conduct included obtaining and inserting non-FDA approved copper IUDs into your patients despite knowing that inserting non-FDA approved IUDs was prohibited by the FDA and presented health risks to patients. You did this as part of a scheme to defraud health care benefit programs, patients, and others. FDA finds that the conduct for which you were convicted relates to the regulation of drug products under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

[2] ParaGard T-380A was manufactured by Teva Women's Health (formerly doing business as Duramed Pharmaceuticals). It was approved by the FDA on November 15, 1984.

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-2016-N-1311 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