DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
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Kelly Dean Shrum, D.O.
(b) (6)

05-09-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2012-N-0246

Dear Dr. Shrum:

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 of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On November 17, 2010, you were convicted by a jury of one count of Misbranding, a class A misdemeanor in violation of 21 U.S.C.§§ 331(a), 333(a)(1), 352(c) and 352(f)(1), and one count of Health Care Fraud, a class C felony in violation of 18 U.S.C.§§ 1347 and 2. On September 30, 2011 the United States District Court for the Eastern District of Arkansas entered judgment against you. The underlying facts supporting this conviction are as follows.

You were a licensed physician practicing in the state of Arkansas. You offered gynecological and obstetric services to women, including providing forms of birth control. Your favored form of contraception was a levonorgestrel-releasing intrauterine device (IUD) known as Mirena. Mirena was made for BHCP, Inc. by Bayer Schering Pharma OY (Bayer). The only version of Mirena approved by FDA for marketing in the United States was approved on December 6, 2000 in New Drug Application (NDA) 21-225.

From in or about June of 2009, in the Eastern District of Arkansas and elsewhere, you purchased a foreign version of Mirena for use in your patients that was not FDA-approved. The labeling of the unapproved IUD was not in English, and did not include adequate directions for use. Arkansas Center for Women, Ltd. was registered with the Arkansas Medicaid Program. You were listed as the only physician affiliated with that clinic, and you signed the Medicaid provider contract on behalf of the Arkansas Center for Women. You submitted claims to the Arkansas Medicaid Program under the clinic's provider number for procedure code J7302, Levonorgestrel Releasing Intrauterine Contraceptive (Mirena). This procedure code is specific to Bayer's FDA-approved Mirena product and any item billed under this procedure code must be the FDA-approved version of Bayer's Mirena.

From on or about January 15, 2008 through on or about June 12, 2009, you caused to be submitted claims for reimbursement to the Arkansas Medicaid Program, which included false representations. Specifically, you billed the Arkansas Medicaid Program as if you were administering the FDA-approved version of Mirena, when you were actually administering a non-FDA-approved IUD.

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 willfully caused to be executed and attempted to cause to be executed a scheme and artifice to defraud the Arkansas Medicaid Program, and to obtain by fraudulent pretense and representations money under the custody and control of the Arkansas Medicaid Program, in connection with the delivery of or payment for health care benefits, items, or services, all in violation of Title 18 U.S.C. §§ 1347 and 2.[1] FDA finds that the conduct underlying this felony conviction relates to the regulation of a drug product under the Act because the use of an unapproved and misbranded drug undermines the drug approval process and FDA's regulatory oversight over drug products marketed in the United States.

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)).

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[1] As noted above, you were also convicted of causing the introduction and delivery for introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. §§ 331(a), 333(a)(1), 352(c), and 352(f)(1), a misdemeanor. This conviction independently could form the basis for permissive debarment under section 306(b)(2)(B) of the Act; however, FDA declines to make a determination regarding permissive debarment at this time in light of your felony conviction.

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. 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.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2012-N-0246 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 within the Food and Drug Administration.

Sincerely,

for Armando Zamora
Acting Director
Office of Enforcement
Office of Regulatory Affairs

cc:

HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-300/Ilisa Bernstein
HFD-003/Keith Webber
HFC-2/ Michael Verdi
HF-22/Matthew Warren

HFD-45/Ball, Leslie
HFD-45/Constance Lewin
HFD-45/Cummins, Susan K.
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF