4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0246]

Kelly Dean Shrum: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Kelly Dean Shrum, 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. Shrum was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Shrum was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Shrum failed to respond. Dr. Shrum'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,

Division of Compliance Policy (HFC-230),

Office of Enforcement,

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 September 30, 2011, the U.S. District Court for the Eastern District of Arkansas entered judgment against Dr. Shrum for misbranding, a class A misdemeanor in violation of 21 U.S.C. sections 331(a), 333(a)(1), 352(c), and 352(f)(1), and health care fraud, a class C felony in violation of 18 U.S.C. sections 1347 and 2.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the regulation of a drug product. The factual basis for this conviction is as follows: Dr. Shrum was a licensed physician practicing in the state of Arkansas. Dr. Shrum offered gynecological and obstetric services to women, including providing forms of birth control. Dr. Shrum favored the intrauterine device (IUD) known as MIRENA, which 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 21-225.

From in or about June of 2009, in the Eastern District of Arkansas and elsewhere, Dr. Shrum purchased a foreign version of MIRENA for use in his 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. Dr. Shrum was listed as the only physician affiliated with that clinic, and he signed the Medicaid provider contract on behalf of the Arkansas Center for Women. Dr. Shrum submitted claims to the Arkansas Medicaid Program under the clinic's provider number for the FDA-approved MIRENA IUD, which was specific to Bayer's FDA-approved product.
From on or about January 15, 2008 through on or about June 12, 2009, Dr. Shrum caused to be submitted claims for reimbursement to the Arkansas Medicaid Program, which included false representations. Specifically, he billed the Arkansas Medicaid Program as if he were administering the FDA-approved version of MIRENA, when he was actually administering a non-FDA approved IUD.

As a result of his convictions, on May 9, 2012, FDA sent Dr. Shrum 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 a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Shrum was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

The proposal also offered Dr. Shrum 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 11, 2012. Dr. Shrum failed to respond 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, 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 Kelly Dean Shrum has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Shrum 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 306(c)(1)(B) and (c)(2)(A)(ii) of the FD&C Act and section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))). 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 Dr. Shrum in any capacity during Dr. Shrum's debarment, will be subject to civil money penalties (section 307(a)(6) of the Act (21 U.S.C. 335b(a)(6))). If Dr. Shrum 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 Dr. Shrum during his period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Dr. Shrum for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2012-N-0246 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(j).

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

Dated: August 8, 2012.

Armando Zamora,
Acting Director,
Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012-20784 Filed 08/22/2012 at 8:45 am; Publication Date: 08/23/2012]