4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0444]

Gayle Rothenberg: 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 Gayle Rothenberg, MD, from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Rothenberg was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Rothenberg was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Rothenberg failed to respond. Dr. Rothenberg's failure to respond constitutes a waiver of her 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,

Office of Regulatory Affairs (HFC-230),

Food and Drug Administration,

5600 Fishers Lane,

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 April 20, 2010, the U.S. District Court for the Southern District of Texas entered judgment against Dr. Rothenberg for one felony count of, with intent to defraud and mislead, misbranding a drug while held for sale after shipment in interstate commerce in violation of 21 U.S.C. 331(k), 333(a)(2), 352(i)(3) and 18 U.S.C. 2, and one felony count of intentionally and knowingly, in a matter within the jurisdiction of FDA, making a false statement to an agent of FDA in violation of 18 U.S.C. 1001.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for this conviction is as follows: Dr. Rothenberg was a physician licensed by the State of Texas as a medical doctor with a specialty in the area of anesthesiology. Dr. Rothenberg served as the medical director and operated a medical clinic in the Southern District of Texas. The medical clinic provided and performed services related to the enhancement of the physical appearance of clients and included BOTOX injections.

From February to September 2004, Dr. Rothenberg and her office manager caused staff members to order a botulinum toxin type A (TRI-toxin) product from Toxin Research International, Inc. (TRI) that was not approved by FDA. Dr. Rothenberg informed staff members that a new BOTOX product would be used to treat patients. When the orders from TRI were received, the invoice accompanying the order as well as packaging and labeling on each vial indicated that the TRI-toxin was for research purposes only and not for human use. Dr. Rothenberg was aware that the product was not intended for human use; however, she performed injections and used the TRI-toxin on patients at her medical practice from February through September 2004. Dr. Rothenberg misrepresented to patients that they were receiving injections of authentic BOTOX and BOTOX Cosmetic when in fact she knew the patients were receiving injections of non-FDA approved TRI-toxin.

On January 20, 2005, agents of FDA traveled to Dr. Rothenberg's clinic and spoke to her about whether any TRI-toxin had been ordered and used on patients of the medical clinic. Dr. Rothenberg confirmed that the nonapproved product had been ordered but stated that it had only been administered to friends and family. On February 28, 2005, agents of FDA again traveled to Dr. Rothenberg's clinic and presented 10 invoices showing that the clinic had ordered the TRI-toxin. This time Dr. Rothenberg stated that the product had been used on patients without her knowledge and approval. Dr. Rothenberg indicated that approximately 210 patients received injections of the TRI-toxin during the period of February 4 and September 8, 2004. Agents of FDA reviewed billing statements from Dr. Rothenberg's clinic and determined that the clinic received approximately $98,000 from patients who received injections of the non-FDA approved TRI-toxin.

Dr. Rothenberg pleaded guilty to, with intent to defraud or mislead, misbranding a drug while held for sale after shipment in interstate commerce, in violation of Title 21 U.S.C. 331(k), 333(a)(2), 352(i)(3) and 18 U.S.C. 2, and to making a false statement to an agent of FDA in violation of 18 U.S.C. 1001.

As a result of her convictions, on August 22, 2011, FDA sent Dr. Rothenberg a notice by certified mail proposing to permanently debar her 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. Rothenberg was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Dr. Rothenberg an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her 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 30, 2011. Dr. Rothenberg failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her 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 the Director (Staff Manual Guide 1410.35), finds that Gayle Rothenberg has been convicted of felonies 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. Rothenberg 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. Rothenberg, in any capacity during Dr. Rothenberg's 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. Rothenberg provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she 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 submitted by or with the assistance of Dr. Rothenberg during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Rothenberg for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2011-N-0444 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: October 25, 2011.

Armando Zamora,

Acting Director,

Office of Enforcement, Office of Regulatory Affairs.

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