4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2099]

Lisa Marie Coroniti: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Lisa Coroniti 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 Ms. Coroniti was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Coroniti was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Coroniti failed to request a hearing. Ms. Coroniti's failure to request a hearing 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 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 Drive, Element Bldg., rm. 4144, 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 8, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Ms. Coroniti for one count of introducing misbranded drugs into interstate commerce, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Ms. Coroniti was a sales representative for Gallant Pharma International Inc. (Gallant Pharma) between June 2011 and August 2013, and was responsible for selling injectable cosmetic drugs and devices, and intravenous chemotherapy drugs, to doctors and hospitals in Philadelphia, Pennsylvania. Some of the drugs Ms. Coroniti facilitated the sale of were misbranded within the meaning of the FD&C Act.

Ms. Coroniti admitted that she sold drugs which were not approved by the FDA for use on patients in the United States. She further admitted that the drugs she sold on behalf of Gallant Pharma were misbranded in that they did not bear adequate directions for use and were not

subject to an exemption from that requirement, and they were accompanied by non-FDA approved packaging and inserts.

Between June 2011 and August 2013, Ms. Coroniti admitted to selling misbranded drugs to 15 distinct doctors and medical practices in Pennsylvania and generated more than $1.1 million in illegal proceeds from these sales. She admitted that, as of April 26, 2013, she became willfully blind to the illegality of Gallant Pharma's business. Nonetheless, she continued her sales activity with Gallant Pharma until her arrest in August 2013.

Between April 26, 2013, and August 7, 2013, Ms. Coroniti personally sold more than $367,000 in misbranded drugs and devices to doctors and medical practices in the Philadelphia, Pennsylvania, area. On or about July 30, 2013, Ms. Coroniti sold five vials of misbranded BOTOX to a doctor in Philadelphia, Pennsylvania, in exchange for $1,900.00, thereby causing a misbranded drug to be introduced into interstate commerce. She further admitted that the loss amount attributable to her personal sales was between $200,000 and $400,000.

As a result of her conviction, on March 25, 2015, FDA sent Ms. Coroniti 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 the finding, under section 306(a)(2)(B) of the FD&C Act, that Ms. Coroniti was convicted of a felony under Federal law for conduct related to the regulation of a drug product. FDA determined that Ms. Coroniti's felony conviction was related to the regulation of drug products because the conduct underlying her conviction, including intentionally introducing into interstate commerce misbranded drug products, undermined FDA's regulatory oversight over drug products marketed in the United States. The proposal also offered Ms. Coroniti 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 May 1, 2015. Ms. Coroniti 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 and Import Operations, 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 Lisa Marie Coroniti has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Section 306(c)(2)(A)(ii) of the FD&C Act (21 USC 335a(c)(2)(A)(ii)) requires that Ms.Coroniti's debarment be permanent.

As a result of the foregoing findings, Lisa Marie Coroniti 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 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). 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 Lisa Marie Coroniti, in any capacity during her 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 Ms. Coroniti 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 (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Lisa Marie Coroniti during her period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Ms. Coroniti for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2014-N-2099 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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