4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1677]

Karis Copper Delong: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Karis Copper Delong for a period of 12 years 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. Delong was convicted of four misdemeanor counts under the FD&C Act for introducing, delivering for introduction, and causing the introduction and delivery for introduction of a misbranded drug into interstate commerce, which relates to the regulation of drug products under the FD&C Act. In addition, FDA determined that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Ms. Delong was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Delong failed to request a hearing. Ms. Delong'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 Regulatory Affairs (ELEM-4144), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a misdemeanor under federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On June 9, 2015, in the U.S. District Court for the Eastern District of Washington, judgment was entered against Ms. Delong after she entered a plea of guilty to four counts of shipment of misbranded drugs in interstate commerce, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which according to section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)) constitutes a misdemeanor.

FDA's finding that debarment is appropriate is based on the misdemeanor convictions referenced herein. The factual basis for these convictions is as follows: Beginning as early as April 2008, Ms. Delong assisted Louis Daniel Smith and others in the operation of Project Green Life (PGL). PGL was a Nevada corporation with physical operations at various locations in Spokane, WA. PGL marketed and sold various health-related products over the Internet. PGL's

flagship product was the Miracle Mineral Solution (MMS), a mixture of sodium chlorite and water.

Although Ms. Delong acted primarily at the direction of Louis Daniel Smith, she had access to PGL's operations. On various occasions, she handled shipping for PGL, including the delivery of packages containing MMS for shipment in interstate commerce to PGL customers nationwide and internationally. Although at times PGL marketed MMS as a water purification product, Ms. Delong knew that MMS was also used by consumers to treat disease. At times, PGL provided instructions to consumers that directed consumers to mix MMS with a citric acid solution and consume orally to treat various diseases. Ms. Delong knew that PGL provided such instructions to consumers.

At no time did Ms. Delong or anyone else employed by PGL register their MMS manufacturing facilities with FDA as required under section 510 of the FD&C Act (21 U.S.C. 360). In addition, bottled MMS that PGL shipped to consumers did not bear labeling that bore the full place of business of the manufacturer.

On or about November 1, 2010, November 12, 2010, November 16, 2010, and June 30, 2011, Ms. Delong or another person involved with PGL, delivered for introduction into interstate commerce a number of packages containing bottled MMS. These packages contained MMS that Ms. Delong knew was primarily intended as a treatment for disease.

As a result of these convictions, FDA sent Ms. Delong by certified mail on October 12, 2016, a notice proposing to debar her for 12 years 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(b)(2)(B)(i)(I) of the FD&C Act, that Ms. Delong was convicted of misdemeanors under Federal law for conduct relating to the regulation of drug products under

the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

The proposal offered Ms. Delong 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. Ms. Delong received the proposal on October 20, 2016. Ms. Delong did not request a hearing 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(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Karis Copper Delong has been convicted of four misdemeanor counts under federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

Based on consideration of the factors under section 306(c)(3) of the FD&C Act, FDA finds that each offense be accorded a debarment period of 3 years. Under section 306(c)(2)(A) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 3-year period of debarment for each of the four offenses of conviction need to be served consecutively, resulting in a total debarment period of 12 years.

As a result of the foregoing finding, Karis Copper Delong is debarred for a period of 12 years 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 sections 306(c)(1)(B), (c)(3), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(3), and 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 Karis Copper Delong, in any capacity during Ms. Delong'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 Ms. Delong 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 Karis Copper Delong during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Ms. Delong for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-1677 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 will be placed in the docket, and will be viewable at https://www.regulations.gov or at the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2017.

Armando Zamora,

Deputy Director,

Office of Enforcement and Import Operations,

Office of Regulatory Affairs.

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