DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karis Copper Delong
(b) (6)

10/12/2016

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2016-N-1677

Dear Mrs. Delong:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order debarring you for a period of sixteen years 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, as defined in section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act)(21 U.S.C. § 335a(1)(1)(B)) of four misdemeanor counts under Federal law for the introduction of a misbranded drug into interstate commerce and an Agency finding that the conduct underlying your conviction relates to the regulation of a drug product under the Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

Conduct Related to Conviction

On June 9, 2015, you entered a plea of guilty to four counts of shipment of misbranded drugs in interstate commerce, in violation of sections 301(a) and 303(a)(1) of the Act (21 U.S.C. §§ 331(a) and 333(a)(1)) and judgment was entered against you in the United States District Court for the Eastern District of Washington. The underlying facts supporting this conviction are as follows.

Beginning as early as April 2008, you 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, Washington. 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.

You were a managing member of PGL who frequently handled financial transactions for PGL. You also recruited family and friends to participate in PGL's business.

Although you acted primarily at the direction of Louis Daniel Smith, you had access to PGL's operations. On various occasions, you 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, you and others employed by PGL knew that MMS was also used by consumers to treat disease. At times, PGL provided instructions to consumers which directed consumers to mix MMS with a citric acid solution and consume orally to treat various diseases. You knew that PGL provided such instructions to consumers.

At no time did you or anyone else employed by PGL register your MMS manufacturing facilities with FDA as required under section 510 of the Act (21 U.S.C. § 360). In addition, bottled MMS which you and others shipped to consumers did not bear labeling which 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, you or another person involved with PGL, delivered for introduction into interstate commerce a number of packages containing bottled MMS. These packages contained MMS which you and others involved with PGL knew was primarily intended as a treatment for disease.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(i)(I)) permits FDA to debar 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 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. You pleaded guilty to shipment of misbranded drugs in interstate commerce in violation of the Act by handling the delivery of packages containing MMS for shipment in interstate commerce nationwide and internationally. FDA finds that shipment of misbranded drugs, which served as a basis for your conviction, relates to the regulation of drug products under the Act and undermines the process for the regulation of drugs because the introduction and causing the introduction of a misbranded drug into interstate commerce are prohibited by the Act.

The maximum period of debarment for each offense under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years and the Agency may determine whether debarment periods should run concurrently or consecutively in the case of a person debarred for multiple offenses. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in any offense involved; (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

FDA is responsible for protecting the health and safety of the American public by enforcing the FD&C Act. FDA's responsibilities under the FD&C Act include regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

FDA finds that your conduct created a risk of injury to consumers due to the shipment of a misbranded drug, and undermined the integrity of the Agency's regulation of drug products. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. Nature and extent of management participation.

In determining the appropriate period of debarment, FDA also considers the nature and extent of your management participation in the offense. You were a managing member of PGL who frequently handled financial transactions for PGL. You recruited family and friends to participate in PGL's business. Although the record states that you were a managing member of PGL, it does not address the nature and extent of your management participation in the offenses. Accordingly, the Agency finds this factor not applicable here.

3. Nature and extent of voluntary steps to mitigate impact on the public

FDA will next consider the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including among other things, full cooperation with any investigations (including extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. Although you acted primarily at the direction of Louis Daniel Smith, you had access to aspects of PGL's operations. The record does not indicate that you took any steps to mitigate the impact on the public of your actions or that you took any action to limit the potential or actual adverse effects of your conduct on the public health. The Agency will consider this as an unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Weighing all factors, the Agency has determined that the unfavorable factors outweigh the favorable factors, and therefore warrant the imposition of a twelve year period of permissible debarment in this case.

You were a managing member of PGL. On or about November 1, 2010, November 12, 2010, November 16, 2010, and June 30, 2011, in the Eastern District of Washington, you introduced, delivered for introduction, and caused the introduction or delivery for introduction into interstate commerce a drug. The drug was misbranded in that the label did not bear the name and place of business of the manufacturer and the drug was manufactured in an establishment which was not registered with FDA as required by law. These facts favor consecutive periods of debarment because [XXXXX].

<u>Proposed Action and Notice of Opportunity for Hearing</u>

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(2)(B)) debarring you for a period of sixteen years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of four counts of shipping a misbranded drug, a Federal misdemeanor offense under

the Act. FDA proposes that each offense be accorded a debarment period of three years. Under section 306(c)(2)(A) of the Act (21 U.S.C. § 335a(c)(2)(A)), in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. Given the analysis above, FDA has concluded that the unfavorable factors outweigh the favorable factor and that the three- year period of debarment for each of the four offenses of conviction need to be served consecutively, resulting in a total debarment period of twelve years.

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)).

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(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(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-2016-N-1677 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.

You also may notify the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) of the Act (21 U.S.C. § 335a(c)(2)(B)).

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.

/s/
Sincerely,

Douglas Stearn
Director,
Office of Enforcement & Import Operations
Office of Regulatory Affairs