DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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P.O. Box 13900
Seattle, WA 98198

08-05-2016

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2016-N-1162

Dear Mr. Smith:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order permanently debarring you 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)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) (21 U.S.C. § 335a(l)(1)(A)) of felonies under Federal law for the introduction of a misbranded drug into interstate commerce, and the smuggling of a misbranded bulk drug ingredient, and an Agency finding that the conduct underlying these felony convictions relates to the development or approval, including the process for development or approval, of a drug product and otherwise relating to the regulation of a drug product under the Act.[1] This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On May 27, 2015, you were convicted, as defined in section 306(l)(1)(A) of the FD&C Act (21 U.S.C. § 335a(l)(1)(A)), in the United States District Court for the Eastern District of Washington, when a jury found you guilty of one count of conspiracy, in violation of 18 U.S.C. § 371; three counts of introducing misbranded drugs into interstate commerce with intent to defraud or mislead, 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)); and smuggling in violation of 18 U.S.C. § 545. Judgment was entered against you on October 27, 2015. The underlying facts supporting this conviction are as follows.

You were a managing member of PGL International, LLC (PGL), a Nevada corporation which marketed and sold various health-related products, including Miracle Mineral Solution (MMS), a mixture of sodium chlorite and water, through the website projectgreenlife.com. Sodium chlorite is an industrial chemical used as a pesticide and for hydraulic fracking and wastewater treatment. Sodium chlorite cannot be sold for human consumption and suppliers of the chemical include a

[1] We note that section 306(a)(2) of the FD&C Act (21 U.S.C. § 335a(a)(2)) requires debarment if the Secretary finds that an individual has been convicted of a felony described in section 306(a)(2)(A) or section 306(a)(2)(B). Accordingly, either prong alone serves as a sufficient basis for debarment in this case.

warning sheet stating that it can cause potentially fatal side effects if swallowed. You served as the director of PGL's operations and you used various email accounts to communicate with co-conspirators and customers. In furtherance on your conspiracy, you, along with your co-conspirators, conspired and agreed with others to obtain chemicals needed to manufacture the misbranded drug MMS without revealing to regulators and suppliers the true purpose of the chemicals; to use those chemicals to manufacture the misbranded drug MMS in a facility that was hidden from regulators; to offer MMS for sale on websites you had established and to enrich yourself by obtaining money from the interstate sales of the misbranded drug MMS.

From on or about September 11, 2004 to at least on or about July 16, 2012, in the Eastern District of Washington and elsewhere, in violation of 18 U.S.C. § 371, you conspired and agreed with others to commit an offense against the United States by:

a) introducing, delivering for introduction into interstate commerce, and causing the introduction and delivery for introduction into interstate commerce, with the intent to defraud or mislead, misbranded drugs, 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)),

b) knowingly defrauding the United States and its agencies by impeding, impairing, and defeating the lawful government functions of the U.S. Food and Drug Administration, specifically, the FDA's duty to protect the health and safety of the public by ensuring that drugs marketed and distributed in the U.S. are safe and effective for their intended uses, are manufactured in establishments which are registered with the Secretary of Health and Human Services, and that the labeling of such drugs bears true and accurate information, including the name and place of business of the manufacturer; and

c) importing merchandise contrary to law, and receiving, concealing, selling, and facilitating the concealment and sale of smuggled merchandise, in violation of 18 U.S.C. § 545.

With the intent to defraud and mislead you introduced, and delivered for introduction into interstate commerce, a drug, bottled MMS, that was misbranded under Section 502(b) of the FD&C Act (21 U.S.C. § 352(b)), in that the label did not bear the name and place of business of the manufacturer, and under section 502(o) of the FD&C Act (21 U.S.C. § 352(o)), in that the drug was manufactured in an establishment which was not registered with the Secretary of Health and Human Services, as required under section 510 of the FD&C Act (21 U.S.C. § 360), all 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)).

You fraudulently and knowingly imported merchandise, sodium chlorite, contrary to section 301(a) of the FD&C Act (21 U.S.C. § 331(a)), in that the sodium chlorite was a bulk drug ingredient that was misbranded pursuant to sections 502(a) and 502(f)(1) of the FD&C Act (21 U.S.C. §§ 352(a) and 352(f)(1)), and knowingly and fraudulently received, concealed, bought, sold, and facilitated the transportation, concealment, and sale of this merchandise, after importation, knowing the same to have been imported into the United States contrary to law, all in violation of 18 U.S.C. § 545.

FDA's Finding

Section 306(a)(2) of the Act (21 U.S.C. § 335a(a)(2)) 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 development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the Act. As described above, you introduced misbranded drugs into interstate commerce with intent to defraud or mislead and you fraudulently smuggled a bulk drug ingredient into the United States.

FDA finds that the conduct underlying these felonies relates to the development or approval, including the process for development or approval, of any drug product, or otherwise relates to the regulation of drug products under the Act because your actions, including introduction of a misbranded drug into interstate commerce and the smuggling of a misbranded bulk drug ingredient, undermined FDA's regulatory oversight over drug products marketed in the United States.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2) of the Act (21 U.S.C. § 335a(a)(2)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act (21 U.S.C. § 335a) 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.

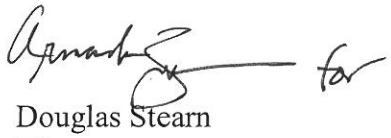
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. You should understand that the facts underlying your conviction are not at issue in this proceeding. A hearing will 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.

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-1162, 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.

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 & Import Operations within the Food and Drug Administration.

Sincerely,



Douglas Stearn
Director
Office of Enforcement & Import Operations