DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1162]

Louis Daniel Smith: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Louis Daniel Smith 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 Mr. Smith was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or otherwise relating to the regulation of a drug product under the FD&C Act. Mr. Smith was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Smith failed to respond. Mr. Smith's failure to respond constitutes a waiver of his 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, Division of Enforcement, Office of Enforcement and Import Operations, 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(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) 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. Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act.

On October 27, 2015, the U.S. District Court for the Eastern District of Washington entered judgment against Mr. Smith for 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 section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which according to section 303(a)(2) of the FD&C Act (21 U.S.C. 333(a)(2)) constitutes a felony, and one count of smuggling in violation of 18 U.S.C. 545.

The factual basis for this conviction is as follows: Mr. Smith was a managing member of PGL International, LLC (PGL), and served as the director of PGL's operations. PGL is a Nevada corporation, which marketed and sold various health-related products, including Miracle Mineral Solution (MMS), a mixture of sodium chlorite and water. 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

warning sheet stating that it can cause potentially fatal side effects if swallowed. Mr. Smith obtained chemicals needed to manufacture the misbranded drug MMS without revealing to regulators and suppliers the true purpose of the chemicals; used those chemicals to manufacture the misbranded drug MMS in a facility that was not disclosed to regulators; offered the misbranded drug MMS for sale on Web sites Mr. Smith had established; and sold that drug in interstate commerce.

From on or about September 11, 2004, to at least on or about July 16, 2012, in the Eastern District of Washington and elsewhere, Mr. Smith introduced, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce, with the intent to defraud or mislead, misbranded drugs. In addition, he knowingly defrauded the United States and also impeded the lawful government functions of FDA, specifically, FDA's duty to protect the health and safety of the public by, among other things, ensuring that drugs marketed in the United States are safe and effective for their intended uses and are manufactured in establishments that are registered with FDA, and that the labeling of such drugs bears true and accurate information.

As a result of this conviction, FDA sent Mr. Smith by certified mail on August 5, 2016, a notice proposing to permanently debar him 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) of the FD&C Act, that Mr. Smith was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or conduct otherwise relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Smith an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the

request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Smith received the proposal on August 8, 2016. Mr. Smith did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his 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) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Louis Daniel Smith has been convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Louis Daniel Smith 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) (21 U.S.C. 321(dd)), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act). 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 Louis Daniel Smith, in any capacity during his 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 Mr. Smith provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he 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 from Mr. Smith during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Smith for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-1162 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 will be placed in the docket, and will be viewable at http://www.regulations.gov or at the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2016,

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

[FR Doc. 2016-27417 Filed: 11/14/2016 8:45 am; Publication Date: 11/15/2016]