Dated: November 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27330 Filed 11–14–16; 8:45 am]

BILLING CODE 4164–01–P

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 November 15, 2016.

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 11–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2017 Through September 30, 2018

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for Fiscal Year 2018 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2017 through September 30, 2018. This notice announces the calculated FMAP rates, in accordance with sections 1101(a)(8) and 1905(b) of the Act, that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV–E Foster Care Maintenance payments, Adoption Assistance payments and Guardianship Assistance payments, and the eFMAP rates for the Children's Health Insurance Program (CHIP) expenditures. Table 1 gives figures for each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice reminds states of available disaster-recovery FMAP adjustments for qualifying states, and adjustments available for states meeting requirements for negative growth in total state personal income. At this time, no states qualify for such adjustments.

This notice also contains the increased eFMAPs for CHIP as authorized under the Patient Protection and Affordable Care Act (Affordable Care Act) for fiscal years 2016 through 2019 (October 1, 2015 through September 30, 2019).

Programs under title XIX of the Act exist in each jurisdiction. Programs under titles I, X, and XIV operate only in Guam and the Virgin Islands. The percentages in this notice apply to state expenditures for most medical assistance and child health assistance, and assistance payments for certain social services. The Act provides separately for federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Social Security Act (the Act) require the Secretary of HHS to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas in sections 1905(b) and 1101(a)(8), and calculations by the Department of Commerce of average income per person in each state and for the Nation as a whole. The percentages must fall within the upper and lower limits specified in section 1905(b) of the Act. The percentages for the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 states.

Federal Medical Assistance Percentage (FMAP)

Section 1905(b) of the Act specifies the formula for calculating FMAPs as follows:

'' ''Federal medical assistance percentage'' for any state shall be 100 per centum less the state percentage; and the state percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such state bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent. . .''.

Section 4725(b) of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the FMAP for the District of Columbia for purposes of titles XIX and XXI shall be 70 percent. For the District of Columbia, we note under Table 1 that other rates may apply in certain other programs. In addition, we note the rate that applies for Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands in certain other programs pursuant to section 1118 of the Act. The rates for the States, District of Columbia and the territories are displayed in Table 1, Column 1.

Section 1905(y) of the Act, as added by section 2001 of the Patient Protection and Affordable Care Act of 2010 (''Affordable Care Act''), provides for a significant increase in the FMAP for medical assistance expenditures for individuals determined eligible under the new adult group in the state and who will be considered to be ''newly eligible'' in 2014, as defined in section 1905(y)(2)(A) of the Act. This newly eligible FMAP is 100 percent for Calendar Years 2014, 2015, and 2016, gradually declining to 90 percent in 2020 where it remains indefinitely. In addition, section 1905(z) of the Act, as added by section 10201 of the Affordable Care Act, provides that states that had expanded substantial coverage to low-income parents and nonpregnant adults without children prior to the enactment of the Affordable Care Act, referred to as ''expansion states,'' shall receive an enhanced FMAP beginning in 2014 for medical assistance expenditures for nonpregnant childless adults who may be required to enroll in benchmark coverage. These provisions are discussed in more detail in the Medicaid Eligibility proposed rule published on August 17, 2011 (76 FR 51172) and the final rule published on March 23, 2012 (77 FR 17143). This notice is not intended to set forth the newly eligible or expansion state FMAP rates.