DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3710]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the creation of a cohort of cigarette smoking adults between the ages of 25 and 54 for the evaluation of FDA's point of sale tobacco education campaign.

DATES: Submit either electronic or written comments on the collection of information by January 17, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–3710 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of FDA's Point-of-Sale Public Education Campaign

OMB Control Number—0910–NEW

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends

the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a tobacco education intervention at the point of sale to reduce the public health burden of tobacco use. The campaign features advertisements intended to encourage future quit attempts among current smokers in stores that sell tobacco products.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health, FDA requests OMB approval to collect information to evaluate the effectiveness of the point of sale tobacco education campaign. Data from this outcome evaluation study will be used to examine statistical associations between exposure to the campaign and specific outcomes of interest, which include awareness of the campaign and its messaging, campaign-related attitudes, beliefs and risk perceptions, motivation to quit smoking, self-efficacy for quitting, and increased intention to quit.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences campaign-related attitudes, beliefs and risk perceptions, motivation to quit smoking, self-efficacy for quitting, and increased intention to quit. All of the information collected is integral to that evaluation.

Evaluation of the Point of Sale Campaign. This outcome evaluation study will consist of three longitudinal data collection periods each lasting 3–4 months at 4 month intervals between data collection periods, with the first survey (Wave 1) occurring 3 months after campaign launch. Information will be collected from adult smokers, ages 25 to 54, about awareness of and exposure to campaign advertisements, tobacco use, and knowledge, attitudes, and beliefs related to tobacco use. Information will be collected on demographic variables including age, sex, race/ethnicity, and primary language. Participants will also be offered the option to download a smartphone application that will track their exposure to the campaign, and that will ask them to respond to a brief survey about every six months over the 18 month study period.

FDA's media contractor has identified 52 potential counties for the campaign. From this list, FDA's evaluation contractor will randomly select 36 counties to be included in the evaluation. Of these, 24 counties will receive the intervention, while 12 counties will not receive it (control counties).

Data will be collected from a longitudinal cohort that will consist of an entirely new sample of adult cigarette smokers. Addresses will be randomly selected from a predetermined list of U.S. counties and merged with household data on age and demographic characteristics commonly associated with smoking status in order to identify households that are likely to contain one or more adult smokers between the ages of 25 and 54. Pre-paid pre-addressed paper screening surveys will be mailed to approximately 71,875 (23,958 annualized) households that meet this criteria. For the purpose of calculating maximum burden, we assume that all 71,875 (23,958 annualized) households will be screened in one of two ways: (1) When an adult member of the household completes and returns the 10-minute screener they received by mail, or (2) during a 10 minute in-person screening interview conducted by trained field interviewers who visit all the addresses that do not return the screener. At 10 minutes per screening, the maximum potential burden hours for the mail screener is 12,219 (4,073 annualized).

Accounting for nonresponse, we estimate that the mail and in-person screenings will result in 5,750 (1,917 annualized) adults who meet criteria for participation and complete the full Wave 1 survey. The Wave 1 survey will be completed during an in-person visit to the home, either as a stand-alone visit (for households that returned the mail screener) or immediately after the in-person screening is completed (for households that did not return the mail screener). We estimate that the Wave 1 survey will take 40 minutes to complete, resulting in 3,853 (1,284 annualized) burden hours. Adjusting for loss to follow-up between waves, we anticipate that 4,600 (1,533 annualized) participants will complete the Wave 2 survey, which will take 40 minutes and result in 3,082 (1,027 annualized) burden hours, and that 3,772 (1,257 annualized) participants will complete the Wave 3 survey, which will take 40 minutes and result in 2,527 (842 annualized) burden hours. Both the Wave 2 and 3 surveys will also be administered in person by trained interviewers. The total burden hours for all three in-person surveys will be 9,462 (3,154 annualized).

We anticipate that approximately 2/3 of the participants (3,833 people [1,278 annualized]) who complete the Wave 1 survey will download a smartphone application that will deliver additional surveys to them starting one month after the end of the first data collection. These participants will complete 3 surveys lasting 5 minutes each (every 6 months over the course of 18 months), resulting in 307 (102 annualized) burden hours per app-based survey and 921 (307 annualized) burden hours total for all of the app-based surveys. The total burden hours for the screener, 3 in-person surveys, and 3 app-based surveys is 22,600 (7,533 annualized).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Households	Screener	23,958	1	23,958	0.17 (10 minutes)	4,073
Adults smokers ages 25 to 54	Wave 1 questionnaire (Current smokers).	1,917	1	1,917	0.67 (40 minutes)	1,284
	Wave 2 questionnaire	1,533	1	1,533	0.67 (40 minutes)	1,027
	Wave 3 questionnaire	1,257	1	1,257	0.67 (40 minutes)	842
Study participants (opt in)	App-based survey	1,278	3	3,834	0.08 (5 minutes)	307
Totals				32,499		7,533

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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