sooner as determined by CMS. DNV GL—Healthcare (DNV GL) current term of approval for their hospital accreditation program expires September 26, 2018.

II. Provisions of the Proposed Notice

A. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of DNV GL's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether DNV GL's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

B. Evaluation of Deeming Authority Request

DNV GL submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on February 28, 2018. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of DNV GL will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of DNV GL's standards for hospitals as compared with CMS' hospital CoPs.
- DNV GL's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of DNV GL's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ DNV GL's processes and procedures for monitoring a hospital found out of compliance with the DNV GL's program requirements. These monitoring procedures are used only when the DNV GL identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9(c).

++ DNV GL's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ DNV GL's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of DNV GL's staff and other resources, and its financial viability.

++ DNV GL's capacity to adequately fund required surveys.

++ DNV GL's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ DNV GL's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

C. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of public comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: April 9, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–07982 Filed 4–16–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Fresh Empire Campaign on Tobacco

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0788. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign

OMB Control Number 0910–0788—Extension

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (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 youth-targeted public education campaign ('Fresh Empire') to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaign features events, advertisements on television and radio and in print, digital communications including social media, and other forms of media.

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 multicultural public education campaign will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences specific cognitive outcomes related to tobacco use that are targeted by the campaign.

FDA is in the process of evaluating the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that follows the multiple, discrete waves of media advertising planned for the campaign. All information collected is integral to that evaluation.

FDA's *Fresh Empire* youth tobacco public education campaign aims to reduce tobacco use among youth who affiliate with a hip-hop peer crowd, predominantly among African American, Hispanic, and Asian/Pacific Islander youth. The outcome evaluation of the campaign consists of a pre-test survey of youth aged 12 to 17 before campaign launch followed by a series of post-test surveys beginning approximately 6 months after the campaign launch. The post-test surveys are conducted among youth who participated in one or more surveys (the embedded longitudinal cohort) and new participants who are recruited to make up for attrition. Eligible youth were initially 12 to 17 years old and influenced by the hip-hop peer crowd. Youth in the embedded longitudinal cohort may reach the age of 18 over the course of the evaluation.

To date, the pre-test and three post-test surveys have been conducted. Information has been collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information has also been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information is voluntarily provided and is being collected through in-person and web-based questionnaires. Youth respondents were recruited from two sources: (1) A sample drawn from 30 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation, and (2) targeted social media (*e.g.,* Facebook, Instagram).

This study is being conducted in support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to educate the population about the risks and potential risks of tobacco use. The information being collected is necessary to inform FDA's efforts towards these goals and to measure the effectiveness and public health impact of the campaign. Data from the outcome evaluation are being used to estimate awareness of and exposure to the campaign among youth in target markets where the campaign is active. Data are also being used to examine statistical associations between exposure to the campaign and subsequent changes in specific outcomes of interest, which include knowledge, attitudes, and beliefs related to tobacco use.

FDA requests OMB approval to extend OMB approval of the evaluation of FDA's multicultural youth tobacco public education campaign and to add two additional waves of data collection with existing youth in the study. To accommodate these two additional surveys, FDA requests approval to increase the number of burden hours under the existing control number. The fourth post-test survey will begin in July 2018. The fifth post-test survey will begin in February 2019. As was done in earlier post-test surveys, new youth will be recruited to participate to make up for attrition.

A total of 2,100 youth will voluntarily complete questionnaires for the fourth post-test survey, and the same number will complete questionnaires for the fifth post-test survey. These respondents will include existing youth who have participated in one or more surveys previously (''Longitudinal Cohort'') and new youth recruited via a mail-based screener or social media ads (''Cross-Sectional Refresher Sample''). Based on earlier response rates and longitudinal respondents aging out of the eligibility criteria (over the age of 18), we expect to need to recruit a larger number of cross-sectional respondents than in previous waves. We estimate that approximately 600 longitudinal youth and 1,500 cross-sectional youth will voluntarily participate in each of the fourth and fifth post-test surveys. With an estimated burden of 45 minutes per respondent, this adds 450 hours for longitudinal respondents and 1,125 hours for cross-sectional respondents for each of the fourth and fifth post-test evaluation surveys.

A mail-based screener was one of the methods used to identify eligible youth for the pre-test survey. This method will be used during the fourth post-test survey to recruit new youth aged 12 to 17 to ensure that the sample composition is similar across rounds of data collection. As was done during the pre-test survey, parents or guardians will be asked to provide consent and their contact information on this form. For the fourth post-test survey, the 5-minute youth screener and the 1-minute parental consent will be completed by 9,869 households for a total of 822 burden hours for youth and an additional 164 hours for the parents or guardians. This method will not be used during the fifth post-test survey, for which new participants will be recruited only via social media.

We will continue to recruit new youth through social media (*e.g.,* Facebook, Instagram) as a secondary strategy to recruit youth aged 13 to 17. An online version of the screener described above will continue to be used to identify eligible youth. The screener will take 5 minutes to complete and will be taken by an additional 4,000 youth during each of the fourth and fifth post-test surveys, for a total of 8,000 additional youth respondents and 666 total additional burden hours. The new total number of voluntary participants for the youth online post-test screener will be 32,000 and the total burden will be 2,666 hours. This includes the originally approved 24,000 participants and 2,000 burden hours.

As was done previously, eligible youth aged 13 to 14 who complete the

online screener will be asked to provide their parents' or guardians' contact information to provide parental consent for the main survey. The process of parents and guardians providing consent for eligible youth will take approximately 1 minute. For the fourth and fifth post-test surveys, we estimate that an additional 700 adults will be contacted to provide consent for eligible youth for a total of 11 additional burden hours. Added to the original 6,000 parents and 100 burden hours, the total number of parental online screeners and consents will be 6,700 and the total burden will be 111 hours.

With these additions, the estimated number of voluntary respondents/responses for all waves of data collection for the study is 107,743, and the total burden is estimated at 15,135 hours—an estimated increase of 4,813 hours from the last approval.

In the **Federal Register** of December 26, 2017 (82 FR 61003), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, this comment was not PRA related.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Mail screener-outcome survey	23,685	1	23,685	0.0833 (5 minutes)	1,973
Cross-Sectional Youth Refresher Sample, Post-test and assent/consent process-outcome surveys 1–5.	4,920	1	4,920	0.75 (45 minutes)	3,690
Youth Pre-test and assent/consent process-outcome survey.	2,194	1	2,194	0.50 (30 minutes)	1,097
Longitudinal Youth Cohort, Post-test and assent/consent process-outcome surveys 1–5.	6,039	1	6,039	0.75 (45 minutes)	4,530
Youth Online screener-outcome survey	40,000	1	40,000	0.0833 (5 minutes)	3,332
Adult parental permission process-outcome survey	30,905	1	30,905	0.0166 (1 minute)	513
Total	107,743				15,135

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

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07971 Filed 4–16–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0705. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

513(g) Request for Information

OMB Control Number 0910–0705—Extension

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.