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4164-01-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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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	No. of Respondents	No. 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.

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