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

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 [**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-NEW and title "Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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-NEW)

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) amended 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 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 will feature events, advertisements on television and radio and in print, digital communications including social media, and other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information needed to evaluate FDA's 'Fresh Empire' multicultural youth tobacco prevention campaign. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they

are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to evaluate the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that will be designed to follow the multiple, discrete waves of media advertising planned for the campaign.

The outcome evaluation study consists of a pre-test survey of multicultural youth aged 12 to 17 before campaign launch. The pre-test survey will be followed by ongoing cross-sectional surveys of the target audience of youth beginning approximately 3 months following campaign launch. Information will be collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information will also be collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be 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 studies and (2) targeted social media (e.g., Facebook). Participation in the study is voluntary.

The information collected is necessary to inform FDA's efforts and measure the effectiveness and public health impact of the campaign. Data will be used to estimate awareness of and exposure to the campaign among youth in target markets where the campaign is active. Data will also be used to examine statistical associations between exposure to the campaign and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, and beliefs, related to tobacco use.

FDA's burden estimate is based on prior experience with in-person and Internet panel studies similar to the Agency's plan presented in this document. Since the 60-day notice published, FDA has revised the estimated burden. The original burden estimate accounted for evaluation of more than one FDA multicultural campaign. The current burden estimate accounts for the evaluation of one campaign, FDA's 'Fresh Empire' Youth Tobacco Prevention Campaign.

A mail-based screener will be one of the methods used to identify eligible youth. Parents or guardians will be asked to provide consent and their contact information on this form. For the pre-launch survey, the 5-minute screener will be completed by 13,816 households for a total of 1,151 burden hours for youth and an additional 230 hours for the parents or guardians. For the pre-test survey, 2,100 youth will complete a questionnaire with an estimated burden of 30 minutes per respondent, for an annualized total of 1,050 hours. For the post-test screening survey, the estimated burden is 3,453 hours for youth and 691 hours for adults. For the post-test surveys, the estimated burden is 45 minutes per respondent, for a total of 4,725 burden hours.

We will also recruit youth through social media (e.g., Facebook, Twitter) as a secondary strategy to recruit youth 13 to 17. An online version of the screener described above will be used to identify eligible youth (included in Attachment 3). Eligible youth will be asked to provide their parents' or guardians' contact information. The screener will take 5 minutes and will be completed by 2,500 youth for the pre-test survey for a total of 208 burden hours. Of these, 500 will be eligible and complete the pre-test survey for a total of 250 burden hours. For the post-test survey, 10,500 youth will complete the 5-minute screener, for 875 burden hours. Of these, 2,100 will be eligible and complete the post-test survey online (up to 45 minutes), for a total of 1,575 burden hours.

The target number of completed campaign questionnaires for all respondents is 134,528, and the annualized response burden is estimated at 14,208 hours.

In the Federal Register of January 5, 2015 (80 FR 230), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however, only one was PRA related.

Comment: One comment stated that the media tracking survey and the outcome evaluation study proposed by FDA are critical to FDA's efforts to develop and implement an effective multicultural youth tobacco prevention campaign.

Response: FDA agrees that this collection of information is necessary to the Agency's efforts to promote and improve public health.

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 aged 12 to 17 in the United States	Screener and Consent Process--Pre-test outcome survey	13,816	1	13,816	0.0833 (5 min.)	1,151
Adults 18 and older in the United States	Screener and Consent Process--Pre-test outcome survey	13,816	1	13,816	0.0166 (1 min.)	230
Youth aged 12 to 17 in the United States	Screener and Consent Process--post-test outcome survey	41,448	1	41,448	0.0833 (5 min.)	3,453
Adults 18 and older in the United States	Screener and Consent Process--post-test outcome survey	41,448	1	41,448	0.01666 (1 min.)	691
Multicultural Youth aged 12-17 in select media markets	Pre-test outcome evaluation survey	2,100	1	2,100	0.5 (30 min.)	1,050
	Post-test evaluation survey	6,300	1	6,300	0.75 (45 min.)	4,725

Multicultural youth aged 13-17 in the select media markets recruiting through social media	Pre-test online screener	2,500	1	2,500	0.0833 (5 min.)	208
	Pre-test online survey	500	1	500	0.5 (30 min.)	250
	Post-test online screener	10,500	1	10,500	0.0833 (5 min.)	875
	Post-test online survey	2,100	1	2,100	0.75 (45 min.)	1,575
Total		134,528				14,208

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

Dated: April 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-08466 Filed: 4/10/2015 08:45 am; Publication Date: 4/13/2015]