DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2294]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Multicultural Youth Tobacco Prevention Campaigns

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 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 evaluation of FDA's multicultural youth tobacco prevention campaigns.

DATES: Submit either electronic or written comments on the collection of information by March 6, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: 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 Multicultural Youth Tobacco Prevention Campaigns (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 youth-targeted public education campaigns to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaigns 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 multicultural youth tobacco prevention campaigns. 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 conduct two studies to evaluate the effectiveness of each of its multicultural youth tobacco prevention campaigns: (1) An outcome evaluation study and (2) a media tracking survey. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

Outcome Evaluation Studies

The outcome evaluation studies consist of baseline surveys of multicultural youth aged 12 to 18 before each campaign's launch. The baseline will be followed by three cross-sectional surveys of the target audience of youth at approximate 6-month intervals after the campaign's 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.

Media Tracking Surveys

The media tracking surveys consist of assessments of youth aged 13 to 18 conducted at 3, 9, and 15 months postcampaign launch—timing that complements the outcome evaluation's timing. The media tracking surveys will assess awareness of the campaigns and receptivity to campaign messages. These data will provide critical evaluation feedback to the campaigns and will be conducted with sufficient frequency to match the cyclical patterns of events and media advertising and variation in exposure to allow for midcampaign refinements.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be recruited from four 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, (2) an Internet panel for the media tracking surveys, (3) intercepts at various locations (*e.g.,* mall, events), and (4) targeted social media (*e.g.,* Facebook). Participation in the studies is voluntary.

The information collected is necessary to inform FDA's efforts and measure the effectiveness and public health impact of the campaigns. Data from the media-tracking surveys will be used to estimate awareness of and exposure to the campaigns among youth in target markets where the campaigns

are active. Data from the outcome evaluation studies will be used to examine statistical associations between exposure to the campaigns and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, beliefs, and intentions 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. To obtain the target number of completed surveys (completes) for the outcome evaluation studies, 48,000 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response is 5 minutes, for a total of 4,000 hours. An estimated 16,800 surveys will be completed in the baseline and 3 postcampaign cross-sectional surveys. The estimated burden per response is 35 minutes for each survey wave, for a total of 9,800 hours.

To obtain the target number of completes for the media tracking survey, a total of 90,000 respondents will be contacted for the 3 survey waves through an online invitation. The estimated burden per response is 2 minutes, for a total of 3,000 hours for all waves of the Media Tracking Screener. An estimated 2,000 youth will be recruited to complete each of the 3 waves of the media tracking survey. The estimated burden per response is 30 minutes for each questionnaire, for a total of 3,000 hours for all of the three waves of the Media Tracking Questionnaire.

The total number of respondents is 160,800. The total estimated burden is 19,800 hours.

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
General Population.	Screener and Consent Process (Youth and Parent)—Baseline/Wave 1—outcome study.	12,000	1	12,000	0.0833 (5 min.)	1,000
General Population.	Screener and Consent Process (Youth and Parent)—Wave 2—outcome study.	12,000	1	12,000	0.0833 (5 min.)	1,000
General Population.	Screener and Consent Process (Youth and Parent)—Wave 3—outcome study.	12,000	1	12,000	0.0833 (5 min.)	1,000
General Population.	Screener and Consent Process (Youth and Parent)—Wave 4—outcome study.	12,000	1	12,000	0.0833 (5 min.)	1,000
Multicultural Youth aged 12–18 in select media markets.	Baseline (Wave 1) youth outcome evaluation questionnaire.	4,200	1	4,200	0.5833 (35 min.)	2,450
	Wave 2 youth outcome evaluation questionnaire.	4,200	1	4,200	0.5833 (35 min.)	2,450
	Wave 3 youth outcome evaluation questionnaire.	4,200	1	4,200	0.5833 (35 min.)	2,450
	Wave 4 youth outcome evaluation questionnaire.	4,200	1	4,200	0.5833 (35 min.)	2,450
Multicultural youth aged 13–18 in the select media markets.	1st Media Tracking Screener	30,000	1	30,000	0.03333 (2 min.)	1,000
	1st Media Tracking Questionnaire.	2,000	1	2,000	0.5 (30 min.)	1,000
	2nd Media Tracking Screener	30,000	1	30,000	0.03333 (2 min.)	1,000
	2nd Media Tracking Questionnaire.	2,000	1	2,000	0.5 (30 min.)	1,000
	3rd Media tracking Screener	30,000	1	30,000	0.03333 (2 min.)	1,000
	3rd Media Tracking Questionnaire.	2,000	1	2,000	0.5 (30 min.)	1,000
Total	.....	160,800	.....	.....	.....	19,800

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

Dated: December 29, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30808 Filed 1–2–15; 8:45 am]

BILLING CODE 4164–01–P