4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2126]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Campaign to Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults

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 Evaluation of FDA's Multicultural Youth Tobacco Prevention Campaigns.

DATES: Submit either electronic or written comments on the collection of information by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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 Campaign to Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults

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 public education campaigns to help prevent and reduce tobacco use among lesbian, gay, bisexual and transgender (LGBT) young adults and thereby reduce the public health burden of tobacco. Overall 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, FDA requests OMB approval to collect information needed to evaluate FDA's campaign to reduce tobacco use among LGBT young adults. 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 its LGBT young adult tobacco prevention campaign: (1) An outcome evaluation study to evaluate the effectiveness of its LGBT young adult tobacco prevention campaign, and (2) a media tracking questionnaire to

assess awareness of and receptivity to campaign messages. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

- Outcome Evaluation Study

The outcome evaluation study begins with a baseline survey of LGBT young adults aged 18 to 24 before the campaign launch. The baseline will be followed by three follow-up surveys of the target audience of young adults at approximately 6-month intervals after the campaign's launch. Information will be collected about young adult awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions and use, as well as use of other tobacco products (e-cigarettes, hookah, cigars, smokeless tobacco), marijuana and alcohol. Information will also be collected on demographic variables including sexual orientation, age, sex, race/ethnicity, education, and primary language.

All information will be collected through in-person and web-based questionnaires. Young adult respondents will be recruited in 30 U.S. cities (15 campaign and 15 comparison cities) from two sources: (1) Intercept surveys in LGBT social venues (e.g., bars and nightclubs) identified using a time location sampling approach, and (2) through social media advertisements on Facebook and Twitter targeted at LGBT 18 to 24-year-olds, living in the same 30 U.S. cities. Participation in the study is voluntary.

- Media Tracking Survey

The media tracking survey consists of assessments of LGBT young adults aged 18 to 24 conducted once yearly post campaign launch--timing that complements the outcome evaluation's timing. The media tracking survey will assess awareness of the campaign 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 mid-campaign refinements. For the media tracking surveys, we will recruit LGBT young adults aged 18 to 24 from all campaign cities through social media.

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 young adults in target markets where the campaigns are active. Data from the outcome evaluation study will be used to examine statistical associations between awareness of and 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 studies similar to the Agency's plan presented in this document, as well as previous research using social media advertising to recruit young adult participants. To reduce overall burden hours, participants who screen and complete the baseline outcome evaluation questionnaire will be re-contacted to complete the first follow up campaign evaluation questionnaire, those who complete the first follow up campaign evaluation questionnaire will be re-contacted to complete the second follow up campaign evaluation questionnaire, and so on. Re-contacted individuals will not need to complete the screener again. We expect a 50 percent response rate for individuals recruited in person and a 30 percent rate for individuals recruited via social media. In each successive round of data collection, we expect 50 percent of re-contacted individuals to complete the follow up questionnaire, therefore, additional screenings will be conducted for each follow up in order to maintain the target sample size for each follow up questionnaire.

To obtain the target number of completed questionnaires ("completes") for the outcome evaluation study, 18,376 young adults (11,810 recruited in person and 6,566 recruited via social media) will participate in a screening process ("screener"). The estimated burden per screener is 5 minutes (0.083), for a total of 1,525 hours (980 hours for participants recruited in person and 545 hours for persons recruited via social media). A total of 12,600 LGBT young adults (9,448 of those screened in person and 3,152 of those screened through social media) will complete questionnaires in 4 rounds of data collection (baseline and three post-campaign rounds). The estimated burden per complete is 30 minutes (0.5 hour) for the baseline questionnaire and 40 minutes (0.667 hour) for each follow up complete, for a total of 7,878 hours (5,906 hours for those recruited in person and 1,972 hours for those recruited via social media).

To obtain the target number of completes for the media tracking survey, 5,000 young adults will be recruited via social media ads to complete a screener for all three waves of the media tracking survey. The estimated burden per screener response is 5 minutes (0.083 hour), for a total of 414 hours for all waves of media tracking screener. An estimated 500 LGBT young adults will complete each of the three waves of the media tracking survey (assuming a 30 percent response rate to screeners via social media). The estimated burden per completed media tracking questionnaire is 40 minutes (0.667 hour), for a total of 1,002 hours for the three waves. The total burden for the media tracking survey (screeners and completes) is 1,416 hours.

The target number of completed campaign questionnaires (screeners and questionnaires for both the outcome evaluation and media tracking survey) for all respondents is 37,477. The total estimated burden is 10,819 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 – Recruited in person (50% response rate)	Screener -Baseline – outcome study	4,724	1	4,724	0.083 (5 min.)	392
	Screener -First follow up– outcome study	2,362	1	2,362	0.083 (5 min.)	196
	Screener -Second follow up– outcome study	2,362	1	2,362	0.083 (5 min.)	196
	Screener -Third follow up– outcome study	2,362	1	2,362	0.083 (5 min.)	196
LGBT young adults aged 18-24 in select media markets – Recruited in person	Baseline -outcome evaluation questionnaire	2,362	1	2,362	0.5 (30 min.)	1181
	First follow up young adult outcome evaluation questionnaire	2,362	1	2,362	0.667 (40 min.)	1575
	Second follow up young adult outcome evaluation questionnaire	2,362	1	2,362	0.667 (40 min.)	1575
	Third follow up young adult outcome evaluation questionnaire	2,362	1	2,362	0.667 (40 min.)	1575
General population – Recruited via social media (30% response rate)	Screener -Baseline – outcome study	2,627	1	2,627	0.083 (5 min.)	218
	Screener -First follow up– outcome study	1,313	1	1,313	0.083 (5 min.)	109
	Screener -Second follow up– outcome study	1,313	1	1,313	0.083 (5 min.)	109
	Screener -Third follow up– outcome study	1,313	1	1,313	0.083 (5 min.)	109
LGBT young adults aged 18-24 in select media markets - Recruited via social ,media	Baseline - outcome evaluation questionnaire	788	1	788	0.5 (30 min.)	394
	First follow up young adult outcome evaluation questionnaire	788	1	788	0.667 (40 min.)	526
	Second follow up young adult outcome evaluation questionnaire	788	1	788	0.667 (40 min.)	526

	Third follow up young adult outcome evaluation questionnaire	788	1	788	0.667 (40 min.)	526
LGBT young adults aged 18-24 in the select media markets - Recruited via social media	1st media tracking screener	1667	1	1667	0.083 (5 min.)	138
	1st media tracking questionnaire	500	1	500	0.667 (40 min.)	334
	2nd media tracking screener	1667	1	1667	0.083 (5 min.)	138
	2nd media tracking questionnaire	500	1	500	0.667 (40 min.)	334
	3rd media tracking screener	1667	1	1667	0.083 (5 min.)	138
	3rd media tracking questionnaire	500	1	500	0.667 (40 min.)	334
Total		37,477				10,819

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

Dated: June 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-16020 Filed: 6/29/2015 08:45 am; Publication Date: 6/30/2015]