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Dated: December 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26561 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2126]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration's Research and Evaluation Survey for the Public Education Campaign on Tobacco Among the Lesbian Gay Bisexual Transgender Community

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 January 7, 2019.

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 0910–0808. 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.

Food and Drug Administration's (FDA's) Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) Among the LGBT Community

OMB Control Number 0910–0808—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. In May 2016, FDA began implementing a public education campaign 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. The campaign continues to be implemented in 12 U.S. cities and features events, television and radio and print advertisements, digital communications, including videos, social media, and other forms of media. For the purpose of this notice, these campaign elements will be referred to as ''advertisements'' or ''ads.''

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.

To evaluate the effectiveness of FDA's RESPECT at reducing tobacco use among LGBT young adults aged 18 to 24, FDA contracted with RTI International to conduct Web-based surveys with the target population in the 12 campaign cities and 12 comparison cities. The surveys include measures of tobacco-related knowledge, attitudes, beliefs, intentions, and use as well as measures of audience awareness of and exposure to campaign events and advertisements. The voluntary surveys also collect information on demographic variables, including sexual orientation, age, sex, race/ethnicity, education, and

primary language. Baseline data collection for RESPECT was conducted between February and May 2016. Four subsequent waves of data collection were conducted with new (cross-sectional) and returning (longitudinal) respondents. This design facilitated analysis of relationships between individuals' exposure to campaign activities and baseline to followup changes in outcomes of interest between campaign and comparison cities. Information collection for baseline and the first four followups was reviewed and approved by OMB.

FDA will continue to implement RESPECT in 12 U.S. cities through April 2019. To complete the evaluation of RESPECT, FDA is requesting an extension of the previously approved information collection in order to conduct two additional waves of data collection with the target population. The proposed sixth and seventh waves of data collection (*i.e.,* fifth and sixth followups after baseline) will coincide with the official end of the campaign, and will serve as an assessment of the campaign at completion. Continued evaluation is necessary in order to determine the campaign's impact on outcomes of interest.

As in previous waves, new and returning survey respondents will be invited to complete the online questionnaire. New (or cross-sectional) respondents will be recruited at LGBT social venues and via social media (*i.e.,* Facebook and Twitter). In-person recruitment will take place in a variety of LGBT venues. The owners or managers of potential recruitment sites will be asked a series of questions to determine the appropriateness of its clientele for participation in the study. For the fifth and sixth followups, an estimated 60 new venues (20 annualized) will be assessed at 5 minutes per assessment, for an additional 5 hours (1.67 annualized). A total of 1,980 venues (660 annualized) will be assessed during the evaluation study, for a total of 165 hours (55 annualized).

Our goal is to recruit 75 percent of the sample via intercept interviews and 25 percent via social media. To obtain the target number of completed fifth and sixth followup questionnaires, an additional 11,904 adults (3,968 annualized) recruited in person and 2,736 adults (912 annualized) recruited via social media will complete screening questionnaires. For the entire evaluation study, a total of 33,717 adults (11,239 annualized) recruited in person will complete screening questionnaires along with 10,617 adults (3,539 annualized) recruited via social media. The estimated burden to complete the screening questionnaire is 5 minutes (0.083 hour), for a total of 2,799 hours (933 annualized) for in-person recruits and 881 hours (294 annualized) for social media recruits.

Based on analysis of response rates from prior waves of data collection, we expect 65 percent of intercept respondents will be deemed eligible and 50 percent of those will complete the fifth followup questionnaire. We expect 30 percent of those recruited via social media will be deemed eligible and complete the fifth followup questionnaire. Lastly, we expect 50 percent of returning (or longitudinal) respondents to complete the fifth and sixth followup questionnaires. We estimate that approximately 2,100 new respondents (700 annualized) and 6,678 returning (2,226 annualized) respondents will complete the fifth and sixth followup questionnaires, for a total of 8,778 responses (2,926 annualized).

OMB previously approved 3,156 (1,052 annualized) respondents recruited via social media and 9,456 (3,152 annualized) respondents recruited in person to complete the first four followup questionnaires. Adding the fifth and sixth followups brings the total estimated number of followup questionnaires completed by social media recruits to 5,256 (1,752 annualized) and by in-person recruits to 16,134 (5,378 annualized). At 40 minutes per completed questionnaire, the total burden is 3,507 hours (1,169 annualized) for social media respondents and 10,761 hours (3,587 annualized) for in-person respondents.

OMB also previously approved 393 hours (approximately 132 annualized) for social media respondents and 1,182 hours (394 annualized) for in-person respondents to complete baseline questionnaires. OMB also approved the pilot test of procedures in bars (6 hours (2 annualized)). As these study components are complete, the corresponding burden will not change. Lastly, the original study design included a media tracking component, which included a burden of 414 hours (138 annualized) for completing a 5-minute screening questionnaire and 999 hours (333 annualized) for completing the media tracking questionnaire. However, this component was dropped from the study; hence, the related burden has been deducted from the total study burden.

In the **Federal Register** of August 2, 2018 (83 FR 37817), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received a total of nine comments from the public, of which five were PRA-related.

(Comment) Two commenters indicated support for FDA's efforts to evaluate media campaigns targeting smoking within the LGBT community.

(Response) FDA appreciates the public's support of its efforts to meet its mission to promote and protect public health.

(Comment) One commenter questioned the need for further data collection on this topic.

(Response) FDA disagrees. This collection of information is necessary for FDA to meet its mission to promote and protect public, and in its implementation of the Tobacco Control Act.

(Comment) One commenter questioned whether the evaluation is collecting sufficient data on the campaign's impact on the target population's thinking about smoking.

(Response) The campaign is intended to influence the target population's attitude towards smoking. To evaluate the effectiveness of the campaign, FDA is asking questions about the target population's tobacco use-related knowledge, attitudes, beliefs, and intentions before and after seeing the campaign's ads to test whether those have changed over time as a result of exposure to the campaign.

(Comment) One commenter questioned the utility of collecting data on smoking among LGBT young adults without first gathering information on smoking rates in this population, and also suggested specific modes for participant recruitment.

(Response) Multiple peer-reviewed studies have found that LGBT populations of all age groups are significantly more likely to smoke cigarettes and use other tobacco products compared to non-LGBT populations. FDA appreciates the detailed review of the evaluation's recruitment approach. Consistent with the commenter's recommendation, this information collection recruits participants both online via social media platforms and in person at LGBT social venues. This information collection does not recruit on the street or advertise via television.

(Comment) Several comments raised questions about the appropriateness of the target population and implementation approach of the public education campaigns being conducted by FDA.

(Response) FDA notes that these comments address the content, focus, or implementation of an existing public education campaign, and are therefore outside the scope of this information

collection, which is being conducted to evaluate the campaign.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent type and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Venue Owners and Managers	660	1	660	0.083 (5 minutes)	55
General Population: Pilot test of Procedures in Bars.	27	1	27	0.083 (5 minutes)	2
General population—outcome screener (in person).	11,239	1	11,239	0.083 (5 minutes)	933
General population—outcome screener (social media).	3,539	1	3,539	0.083 (5 minutes)	294
LGBT young adults outcome baseline (social media).	263	1	263	0.5 (30 minutes)	132
LGBT young adults outcome baseline (in person).	788	1	788	0.5 (30 minutes)	394
LGBT young adults outcome followup questionnaire (social media).	1,752	1	1,752	0.667 (40 minutes)	1,169
LGBT young adults outcome followup questionnaire (in person).	5,378	1	5,378	0.667 (40 minutes)	3,587
Totals					6,566

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

To accommodate the additional waves of data collection, FDA requests approval to increase the number of burden hours under the existing control number. The previous number of approved responses was 53,967 (17,989 annualized), and the previous burden was 14,031 hours (4,677 annualized). The fifth and sixth followups add 23,478 responses (7,826 annualized), which include responses to new venues assessments, screening questionnaires, and the followup questionnaires, for a total of 7,074 additional burden hours (2,357 annualized). Removing the media tracking component deducts 6,507 responses (2,169 annualized) and 1,413 burden hours (471 annualized). The totals for the entire evaluation study are increasing by 16,971 responses (5,657 annualized) and 5,661 hours (1,887 annualized) for a new total of 70,938 responses (23,646 annualized) and 19,692 burden hours (approximately 6,566 annualized).

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26555 Filed 12–6–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4000]

Framework for a Real-World Evidence Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on a framework created by the Center for Drug Evaluation and Research and the Center for Biologic Evaluation and Research for implementing a program to evaluate the potential use of real-world evidence (RWE) in regulatory decision making. This framework is entitled ''Framework for the Real-World Evidence Program.'' The 21st Century Cures Act (Cures Act) was enacted on December 13, 2016, and requires that FDA establish a framework for implementing a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to help support or satisfy postapproval study requirements. FDA has created this framework to satisfy the Cures Act mandate and is establishing a docket to receive public comments.

DATES: Submit either electronic or written comments on the draft document by February 5, 2019 to ensure that the Agency considers your comment before it begins work to implement the program.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: