FDA receives reports through the MedWatch website (*https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm*), which are then entered into the FDA Adverse Event Reporting System for subsequent analysis. Because the volume of reports is large and because reporting entities (product manufacturers and the professional or lay public) need only suspect a possible link between product exposure and an adverse event, FDA employs specific tools and strategies to assess postmarket safety reports and potential signals that arise from review of these reports. The process for receipt and assessment of such postmarket safety information is referred to as pharmacovigilance.

FDA has a specific regulatory mandate to perform pediatric pharmacovigilance and to present or make available the results of such pediatric pharmacovigilance to the Pediatric Advisory Committee.

II. Topics for Discussion at the Public Workshop

In this workshop, FDA will gather information on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools.

III. Participation in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://www.eventbrite.com/e/advancing-the-development-of-pediatric-therapeutics-5-adept5-tickets-46654530958* by Thursday, September 6, 2018, midnight Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Onsite registration will not be available.

Registration for onsite participation or via webcast is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (*denise.picabranco@fda.hhs.gov*) or Meshaun Payne (*meshaun.payne@fda.hhs.gov*) no later than Thursday, September 6, 2018.

Streaming Webcast of the Public Workshop: Webcast information will be provided after participants have registered for the workshop. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.*

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: July 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16524 Filed 8–1–18; 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; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) among the Lesbian Gay Bisexual Transgender (LGBT).

DATES: Submit either electronic or written comments on the collection of information by October 1, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 1, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2126 for ''Food and Drug Administration's (FDA's) Research and Evaluation Survey for the Public Education Campaign on Tobacco (RESPECT) among LGBT.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those

submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: 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, including each proposed extension of an existing 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.

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

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 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 (RTI) 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 follow-up changes in outcomes of interest between campaign and comparison cities. Information collection for baseline and the first four follow-ups 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 follow-ups 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 follow-ups, 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 follow-up 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 follow-up questionnaire. We expect 30 percent of those recruited via social media will be deemed eligible and complete the fifth follow-up questionnaire. Lastly, we expect 50 percent of returning (or longitudinal) respondents to complete the fifth and sixth follow-up 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 follow-up 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 follow-up questionnaires. Adding the fifth and sixth follow-ups brings the total estimated number of follow up 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.

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	0.500 (30 minutes)	132
LGBT young adults outcome baseline (in person)	788	1	788	0.500 (30 minutes)	394
LGBT young adults outcome follow-up questionnaire (social media).	1,752	1	1,752	0.667 (40 minutes)	1,169
LGBT young adults outcome follow-up 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 follow-ups add 23,478 responses (7,826 annualized), which include responses to new venues assessments, screening questionnaires, and the follow-up 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: July 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16538 Filed 8–1–18; 8:45 am]

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