



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0717]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's General Market 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 (PRA), Federal Agencies are required to publish a 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 (1) an extension of the study conducted with the original longitudinal youth cohort developed and surveyed for the outcome evaluation of FDA's General Market Youth Tobacco Prevention Campaign, (2) the development of a second longitudinal cohort for the purpose of continuing the evaluation, (3) an extension of the time period for the outcome evaluation of the Rural Male Youth Smokeless Tobacco Campaign, (4) and an extension of the media tracking survey.

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: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2013-N-0717 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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 docket, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns--

OMB Control Number 0910-0753--Extension

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 youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages; and whether campaign exposure influences beliefs about tobacco, susceptibility to tobacco use, and tobacco use behavior. All of the information collected is integral to that evaluation.

FDA is in the process of conducting three studies to evaluate the effectiveness of its youth tobacco prevention campaigns: (1) An outcome evaluation study of its General Market Youth Tobacco Prevention Campaign, (2) an outcome evaluation of the Rural Male Youth Smokeless Tobacco Campaign, and (3) a media tracking survey. The timing of these studies follows the multiple, discrete waves of media advertising planned for the campaigns.

Evaluation of the General Market Youth Tobacco Prevention Campaign

The General Market Youth Tobacco Prevention Campaign targets youth who are at-risk for smoking, or who have experimented with but not progressed to regular smoking. The outcome evaluation of the campaign consists of an initial baseline survey of youth aged 11 to 16 before campaigns launch, followed by a number of longitudinal follow-up surveys of the same youth at approximate 8 month intervals. To date, the baseline and three follow-up surveys have been conducted. A baseline survey was also conducted with the parent or legal guardian of each youth, to collect data on household characteristics and media use. Because the cohort aged over the study period, data have been collected from youth aged 11 to 18. Information has been collected about youth awareness of and exposure to campaign advertisements and about youth knowledge, attitudes, and beliefs related to tobacco use. In addition, the surveys have measured tobacco use susceptibility and current use. Information has been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

Evaluation of the Rural Male Youth Smokeless Tobacco Campaign

Baseline data collection for the Rural Male Youth Smokeless Campaign evaluation will begin in January 2016. The three follow up surveys will begin in August 2016, March 2017, and October 2017. The evaluation of the Rural Male Youth Smokeless Campaign differs from the

General Market Campaign evaluation, in that only males in the age range will be considered eligible.

Media Tracking Survey

The media tracking survey consists of assessments of youth aged 13 to 18 conducted periodically during the campaign period. The tracking survey assesses awareness of the campaign and receptivity to campaign messages. These data provide critical evaluation feedback to the campaigns and are conducted with sufficient frequency to match the cyclical patterns of media advertising and variation in exposure to allow for mid-campaign refinements.

All information is being collected through in-person and web-based questionnaires. Youth respondents were recruited from two sources: (1) A probability sample drawn from 90 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluations, and (2) an Internet panel for the media tracking survey. Participation in the studies is voluntary.

The studies are being conducted in support of the provisions of the Tobacco Control Act, which require FDA to protect the public health and to reduce tobacco use by minors. The information being collected is necessary to inform FDA's efforts towards those goals and to measure the effectiveness and public health impact of the campaigns. Data from the outcome evaluation of the General Market and Rural Male Youth Smokeless campaigns is being 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, as well as behavioral outcomes including tobacco use. Data from the media tracking survey is being used to estimate awareness of and exposure to the campaigns among youth nationally as well as among youth in geographic areas targeted by the campaign.

FDA requests OMB approval to collect additional information for the purpose of extending the evaluation of FDA's general market youth tobacco prevention campaign. Specifically, FDA requests approval to conduct a fourth follow-up survey with youth who are part of the first longitudinal cohort, and who participated in the baseline and first through third follow-up surveys. Based on earlier response rates, we estimate that 1,607 will participate in this survey, for a total of 6,666 annualized participants (including 5,059 previously approved). At 0.75 hours per survey, this adds 1,205 annualized burden hours to the 3,794 previously approved hours for a total of 5,000 annualized burden hours. Baseline data collection for this cohort, approved for 2,288 participants (1,144 burden hours at 30 minutes per survey) is complete.

FDA also requests approval to develop and survey a second longitudinal cohort which will consist of an entirely new sample of youth, ages 11-16 at baseline. Development of the second cohort will involve screening 52,401 individuals in the general population for a total of 65,814 participants, including 13,413 previously approved. At 10 minutes per screening, this adds 8,908 burden hours to the already approved 2,280 hours for a total of 11,188 annualized burden hours.

We expect this screening to yield 2,667 youth annually who will complete the baseline survey for the new cohort, resulting in a total of 1,334 burden hours for youth. Three follow up surveys are planned for this cohort. We expect a total of 6,270 participants to complete follow up surveys for a total burden of 4,703 annualized burden hours. As was done with the first cohort, parents of the 2,667 youth will also complete surveys for a total of 6,009 parent surveys including the 3,342 previously approved. At 10 minutes per survey, this adds 453 hours to the previously approved 568 hours for a total of 1,021 annualized burden hours.

FDA also requests approval to extend the media tracking survey. This survey is cross sectional and thus necessitates brief screening prior to data collection. We expect 20,000 participants to complete screener for a total of 60,000 participants (including 40,000 previously approved). At two minutes per screener, this adds 600 burden hours to the previously approved 1,200 hours for a total of 1,800 annualized burden hours. We expect the screening process to yield 2,000 participants, for a total of 6,000 including 4,000 previously approved. At 30 minutes per survey, this adds 1,000 burden hours to the already-approved 2,000 for a total of 3,000 annualized burden hours.

FDA also requests approval to extend the time period of the evaluation of the Male Rural Youth Smokeless Campaign. No new burden hours will be required to complete this study. Previously approved burden for the evaluation of the Rural Male Youth Smokeless Campaign include 656 participants (328 burden hours at 30 minutes per questionnaire) for the baseline questionnaire and 1,281 participants (961 burden hours at 0.75 hours per questionnaire).

Table 1.--Estimated Annual Reporting Burden¹

Type of Respondent	Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
General Population	Screener and Consent Process (Youth and Parent)	65,814	1	65,814	0.17 (10 minutes)	11,188
Parent of Youth Baseline Survey Participants	Parent Baseline Questionnaire	6,009	1	6,009	0.17 (10 minutes)	1,022
Youth Aged 11 to 18 (Experimenters and Non-Triers)	Youth Baseline Questionnaire (Experimenters & Non-Triers)	2,288	1	2,288	0.50 (30 minutes)	1,144
	Youth 1st, 2nd, 3rd, 4th Follow-up Questionnaire (Experimenters and Non-Triers)	6,666	1	6,666	0.75 (45 minutes)	5,000
Youth Aged 13 to 17	Media Tracking Screener	60,000	1	60,000	0.03 (2 minutes)	1,800
	Media Tracking Questionnaires 1st, 2nd, and 3rd	6,000	1	6,000	0.50 (30 minutes)	3,000

Male Youth Aged 11 to 18 in U.S. Rural Markets (Male Rural Smokeless)	Youth Baseline Questionnaire (Male Rural Smokeless)	656	1	656	0.50 (30 minutes)	328
	Youth 1st, 2nd, 3rd (Male, Rural Smokeless) Follow-up Questionnaire	1,281	1	1,281	0.75 (45 minutes)	961
Cohort 2--Youth Aged 11 to 18	Cohort 2--Youth Baseline Questionnaire	2,667	1	2,667	0.50 (30 minutes)	1,334
	Cohort 2--Youth 1st, 2nd, 3rd Follow-Up Questionnaire	6,270	1	6,270	0.75 (45 minutes)	4,703
Totals				157,651		30,480

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

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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