4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0778]

Agency Information Collection Activities; Proposed Collection; Comment Request; Copy Testing 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 (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 Copy Testing of FDA's General Market 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@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.

Copy Testing of FDA's General Market Youth Tobacco Prevention Campaigns (OMB Control Number--0910--New)

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 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 will feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through other forms of media.

FDA requests OMB approval to collect information needed to assess the potential effectiveness of draft (or "rough-cut") youth tobacco prevention campaign advertisements prior to launch. This information will be collected through copy testing as part of the message development phase. Copy testing involves showing rough-cut versions of campaign advertisements to a small sample of the campaign target audience to ensure understanding of messages and assess any potential unintended consequences. Copy testing of FDA's rough-cut general market youth tobacco prevention campaign advertisements is needed to ensure development and execution of meaningful and effective public education tactics.

FDA plans to conduct three voluntary cross-sectional studies involving youth ages 12 to 17 to copy test the Agency's general market youth tobacco prevention campaign advertisements:

1. Youth Experimenter Copy Testing: The study will be designed to obtain insights into potential effectiveness and unintended consequences of advertisements designed to target general market youth ages 12-17 who are currently experimenting with tobacco products (i.e., have smoked between 1 and 100 cigarettes).

2. Youth Non-Trier Copy Testing: The study will be designed to obtain insights into potential effectiveness and unintended consequences of advertisements designed to target general market youth ages 12-17 who have not tried tobacco but are most at risk of initiation.

3. Youth Rural Smokeless Copy Testing: The study will be designed to obtain insights into potential effectiveness and unintended consequences of advertisements designed to target general market youth ages 12-15 who reside in rural areas, with a focus on males at risk of smokeless tobacco initiation.

In each study, each study participant will view a maximum of two rough cut tobacco prevention advertisements. After reviewing the advertisements, each participant will respond to questions traditionally used in formative testing of advertisements to assess his or her receptivity to the advertisements. Study data will be used to refine rough-cut television advertisements prior to campaign launch. The study data will be collected from participants of an Internet panel.

FDA's burden estimate is based on prior experience with Internet panel studies similar to the Agency's plan presented in this document. To obtain the target number of completed surveys ("completes") for the Youth Experimenter Copy Testing, 3,600 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response for the screening and consent is 5 minutes (0.083 hours) per respondent, for a total of 300 hours. An estimated 1,200 youth respondents will then complete

the copy test survey. The estimated burden per response is 10 minutes (0.17 hours) for the Youth Experimenter Copy Testing survey, for a total of 200 hours.

To obtain the target number of completes for the Youth Non-Trier Copy Testing, 1,800 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response for screening and consent is 5 minutes (0.083 hours) per respondent, for a total of 150 hours. An estimated 600 youth respondents will then complete the copy test survey. The estimated burden per response is 10 minutes (0.17 hours) for the Youth Experimenter Copy Testing survey, for a total of 100 hours.

To obtain the target number of completes for the Youth Rural Smokeless Copy Testing, 1,800 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response for screening and consent is 5 minutes (0.083 hours) per respondent, for a total of 150 hours. An estimated 600 youth respondents will then complete the copy test survey. The estimated burden per response is 10 minutes (0.17 hours) for the Youth Rural Smokeless Copy Testing survey, for a total of 100 hours.

The target number of completed copy testing surveys for all respondents is 2,400. The total estimated burden is 1,000 hours.

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Youth Experimenter Screener and Consent	3,600	1	3,600	0.083 (5 min.)	300
Youth Experimenter Copy Testing	1,200	1	1,200	0.17 (10 min.)	200
Youth Non-Trier Screener and Consent	1,800	1	1,800	0.083 (5 min.)	150
Youth Non-Trier Copy Testing	600	1	600	0.17 (10 min.)	100
Youth Rural Smokeless Screener and Consent	1,800	1	1,800	0.083 (5 min.)	150

Youth Rural Smokeless Copy Testing	600	1	600	0.17 (10 min.)	100
Total	9,600				1,000

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

Dated: June 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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