4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0932]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings

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 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 Experimental Study on Warning Statements for Cigarette Graphic Health Warnings that is being conducted in support of the graphic label statement provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

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: 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): 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-2017-N-0932 for "Agency Information Collection Activities, Proposed Collection; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://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 https://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 dockets, 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 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

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.

Experimental Study on Warning Statements for Cigarette Graphic Health Warnings

OMB Control Number--0910-NEW

The health risks associated with the use of cigarettes can be significant and far-reaching. In 2009, Congress enacted the Tobacco Control Act (Pub. L. 111-31), which 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 the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require FDA to issue "regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)." Section 202(b) of the Tobacco Control Act further amends section 4 the FCLAA by adding that the Secretary, through notice and comment rulemaking, may adjust the "text of any of the label requirements…if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products."

In the Federal Register of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled "Required Warnings for Cigarette Packages and Advertisements," which specified nine images to accompany the new textual warning statements for cigarettes. Although the rule was scheduled to become effective 15 months after it issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported

FDA's intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Preliminary research has been underway since 2013. Informed by the previous court decisions on this matter, including on the First Amendment, the next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning revised textual warning statements for use with new images as part of cigarette graphic health warnings, and their potential impact on public understanding of the risks associated with the use of cigarettes.

As currently proposed, this Experimental Study on Warning Statements for Cigarette Graphic Health Warnings is a voluntary online experiment conducted with consumers. The purpose of the proposed study is to assess whether potential textual warnings statements, which have been revised from those enumerated in section 4 of FCLAA, promote greater public understanding of the negative health consequences of cigarette smoking. The study will collect data from various groups of consumers, including adolescent (under age 18) current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult (ages 18- to 24) current cigarette smokers, and older adult (ages 25 and above) current cigarette smokers. The results will inform the Agency's development of cigarette graphic health warnings to be tested in future studies with the goal of implementing the mandatory graphic warning label statement consistent with section 4(d) of FCLAA and the First Amendment.

Proposed Study Overview: In this study, adolescent current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers, and older adult current smokers will be recruited from an Internet panel of more than 1.2 million people and screened for inclusion into the study. Participants who meet the inclusion criteria will be randomized into one of 17 conditions in a between-subjects design. In each

condition, participants will be exposed to a series of nine warning statements, presented sequentially. Participants randomized to the control condition will view all nine of the warning statements listed in section 4(a)(1) of FCLAA:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Participants randomized to 1 of the 16 experimental conditions will view 8 of the warning statements listed in section 4(a)(1) of FCLAA (above) plus 1 statement that is a revised version of a statutory text warning. The revised warning statements being tested in this proposed study are:

- WARNING: Smoking causes mouth and throat cancer.
- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking during pregnancy causes premature birth.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking during pregnancy causes premature birth and low birth weight.

- WARNING: Secondhand smoke causes respiratory illnesses in children, like pneumonia.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking causes COPD, a lung disease that can be fatal.
- WARNING: Smoking causes serious lung diseases like emphysema and chronic bronchitis.
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking raises blood sugar, which can cause type 2 diabetes.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

In all conditions, after viewing each statement, participants will respond to a small number of questions about that specific statement. Following viewing all nine statements, participants will respond to a larger set of questions. Next, participants will view an additional nine revised warning statements, drawn from the revised statements listed above, and respond to an additional set of questions. Primary study outcomes include beliefs and knowledge of the negative health consequences of cigarette smoking. Prior to the main data collection, two pretests, each with 50 participants, will take place to ensure correct programming and to identify any issues with the proposed study design and implementation.

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

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

Portion of Study	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Screening for pretest	762	1	762	.033 (2 minutes)	25
Pretest	100	1	100	.25 (15 minutes)	25
Screening for main data collection	19,082	1	19,082	.033 (2 minutes)	630
Main data collection	2,500	1	2,500	.25 (15 minutes)	625
Total					1,305

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

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Screening potential participants for the 2 pretests will occur with 762 respondents (487 adults and 275 adolescents) identified and recruited through the Internet panel. This brief screening will take an average of 2 minutes (0.033 hours) per respondent. Each of the 2 pretests will consist of 50 respondents (34 adults and 16 adolescents) conducted during a single session and take an average of 15 minutes (0.25 hours) per respondent. Screening potential participants for the main data collection will occur with 19,082 respondents (11,925 adults and 7,157 adolescents) identified and recruited through the same Internet panel as used for the pretests. This brief screening will take an average of 2 minutes (0.033 hours) per respondent. Recent national estimates of the numbers of adolescent current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers, and older adult current cigarette smokers informed the estimates of 13.9 percent qualification rate for adults and 11.6 percent qualification rate for adolescents. Applying these estimates and other assumptions from previous experience conducting similar studies to the number of adolescents and adults to be screened results in the desired sample size for the main data collection of 2,500 participants, of which 1,667 will be adults and 833 will be adolescents. The main data collection will occur with those 2,500 respondents during a single session. The main data collection will take an average of 15 minutes (0.25 hours) per respondent. The total estimated burden is 1,305 hours (25 hours + 25 hours + 630 hours + 625 hours).

Dated: March 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-06078 Filed: 3/27/2017 8:45 am; Publication Date: 3/28/2017]