manufacturer/processor to gather the information needed to be placed on a list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. We estimate that a firm will require 1 hour to read the guidance, gather the information needed, and prepare a communication to FDA that contains the information needed to request that the manufacturer/processor be placed on a list.

To be placed on a list, manufacturers/processors should provide FDA with evidence that they have obtained third-party certification from a CNCA-acknowledged certifier that the manufacturer/processor complies with the standards, laws, and regulations of China according to relevant requirements specified in AQSIQ Decree 145. Based on our experience with other certification programs, FDA estimates that it will take each new manufacturer/processor about 21 hours to complete the third-party certification process for a total of 7,770 burden hours (370 manufacturers/processors × 21 hours).

Under the guidance, every 2 years each manufacturer/processor on the lists must provide updated information in order to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, or 555 manufacturers/processors (1,110 manufacturers/processors × 0.5 = 555), will resubmit the information to remain on the lists. We estimate that a manufacturer/processor already on the lists will require 1 hour to biennially update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 555 hours.

During the biennial update, manufacturers/processors also need to be recertified by a third-party certifier to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, 555 manufacturers/processors (1,110 manufacturers/processors × 0.5 = 555), will get recertified. We estimate that it will take each manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

FDA expects that, each year, approximately 100 manufacturers/processors will need to submit an occasional update and each manufacturer/processor will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 50 hours.

Dated: September 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19890 Filed 9–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0932]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 October 19, 2017.

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–NEW and title ''Experimental Study on Warning Statements for Cigarette Graphic Health Warnings.'' Also include the FDA docket number found in brackets in the heading of this document.

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

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 (TCA) (Pub. L. 111–31), which amends the Federal Food, Drug, and Cosmetic 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 of 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 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 (age 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 1 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 (first bulleted list in this document) plus 1 revised warning statement. 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 causes type 2 diabetes, which raises blood sugar.
- 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 (Section A in the questionnaire). After viewing the nine statements per their condition, participants will respond to a larger set of questions (Section B in the questionnaire). Next, participants in the experimental conditions will view an additional nine revised warning statements, drawn from the revised statements listed in this document, and respond to an additional set of questions (Section C in the questionnaire). Primary study outcomes include knowledge of the negative health consequences of cigarette smoking. Prior to the main data collection, 2 pretests, each with 50 participants, will take place to ensure correct programming and to identify any issues with the proposed study design and implementation.

In the **Federal Register** of March 28, 2017 (82 FR 15359), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 13 comment submissions. Eight submissions were PRA related, and some included multiple comments.

(Comment) Three comments suggested that the textual warning statements should be evaluated together with accompanying images because the impact of the final cigarette graphic warning labels will be a combination of the effects of both the text and images.

(Response) FDA declines to make this change at this time. This current phase of the research, which includes the study proposed here, is an effort by FDA to collect data concerning revised textual warning statements that may later be used with new images as part of cigarette graphic health warnings. In the future, FDA will conduct research pairing warning statements with images.

(Comment) One comment suggested using a longitudinal study design to understand the long-term effects of the warning statements.

(Response) FDA declines to make this change. A longitudinal study, while providing useful data, is beyond the scope of the research questions being addressed in the present study.

(Comment) One comment recommended FDA use a baseline assessment of understanding of risks associated with cigarette smoking in the form of a pre-exposure assessment of current awareness of negative health outcomes associated with cigarette smoking to evaluate respondents' baseline knowledge.

(Response) FDA declines to make this change. The measurement of baseline level of understanding of risk should be evenly distributed throughout the conditions due to the randomized nature of the experiment.

(Comment) One comment suggested that FDA implement prescreening measures and collect information about the study respondents.

(Response) Prior to randomization to condition, FDA will implement a screener to collect information about potential study participants to confirm eligibility. A copy of the screener is part of the overall package submitted to OMB for review through the public Web site *https://www.reginfo.gov.* Participant demographics will be assessed in the questionnaire and additional demographics will be provided by the Internet panel for all participants.

(Comment) Two comments suggested that FDA change the control group of warning statements to which the revised textual warning statements would be compared in this study.

(Response) FDA declines to make this change. The purpose of the proposed study is to test if the revised textual warning statements promote greater public understanding of the negative health consequences of cigarette smoking compared to the warnings enumerated in the TCA. Therefore, the

TCA warning statements are the appropriate comparison group.

(Comment) One comment questioned whether the use of an Internet panel is the most appropriate method for obtaining the desired information in this study, as compared to in-person interviews.

(Response) With respect to the sample, the large heterogeneous sample that can be obtained through the Internet panel will allow FDA to test outcomes across a range of individuals, thus strengthening the conclusions and generalizability of the study.

(Comment) Two comments suggested that the timing of the administration of Section B of the questionnaire (administered after viewing eight TCA warnings with one revised warning, but before viewing a second set of nine revised warnings) could introduce bias. One of those comments also suggested FDA remove Section B.

(Response) FDA declines to make such a change at this time. Section B includes the primary outcome measures necessary to assess participants' understanding of the negative health consequences of cigarette smoking as described in the revised warning statements compared to the TCA statements. Further, knowledge gained from exposure to questions in Section B is expected to be minimal and consistent across conditions. Therefore, any such knowledge gained from exposure to Section B would suggest that any differences found between conditions are robust.

(Comment) One comment recommended that FDA conduct a power analysis to ensure the sample size is adequate for detecting the expected effect size.

(Response) FDA agrees that it is important to conduct a power analysis; the Agency did conduct a power analysis to ensure the sample size is appropriate for the proposed study.

(Comment) One comment expressed a desire to see the questionnaire to be used in the study as well as an explanation of the study design.

(Response) FDA notes that the questionnaire and supporting statements outlining the study design and methods were available as supporting documents in the docket for public review during the public comment period. Additionally, the study is described in detail as part of the overall package submitted to OMB for review through the public Web site *https://www.reginfo.gov,* and copies of the instrument used to collect this information are also included in that package.

(Comment) Many comments focused on the content of the revised textual warning statements in the proposed study, and provided suggestions for changes to the wording of the warning statements and additional topics on which they should focus.

(Response) The topics being tested in this proposed study include a wide range of health conditions caused by cigarette smoking and are presented with as much information as practicable. The revised warning statements were developed based on opportunities to promote greater public understanding about the negative health consequences of cigarette smoking. In addition, prior to the proposed study, the warning statements have been tested with consumers; vetted by medical and other scientific experts; and revised to ensure that they clearly and understandably convey factual information about the negative health consequences associated with the use of cigarettes. Based on comments about the content of the revised textual warning statements and FDA's ongoing preparation for the proposed study, FDA is changing the warning statement ''WARNING: Smoking raises blood sugar, which can cause type 2 diabetes'' to ''WARNING: Smoking causes type 2 diabetes, which raises blood sugar.'' This change was made to better reflect the causal link between cigarette smoking and diabetes and to clarify that higher blood sugar is a result, not a cause, of diabetes. FDA has updated the questionnaire accordingly.

(Comment) One comment suggested that FDA conduct a ''meaningful pretest'' for the questionnaire.

(Response) As explained in the draft supporting statements included in the docket, the purpose of the pretests is to help ensure understandability of the questionnaire, to reduce participant burden, and to enhance interview administration. The questionnaire uses slightly modified versions of scales and instruments that have already been thoroughly tested and used in previous research.

(Comment) Many comments suggested changes to or addition of specific constructs as study outcomes or suggested how FDA should use the outcomes already included in the study. Measures suggested for FDA consideration included the following: How much the warning statements attract attention; how novel they are; personal identification with the statements; levels of emotion evoked/emotional appeal or emotional reaction; perceived risk or likelihood of the outcome occurring; and perceived effectiveness of the revised warning statements.

(Response) FDA declines to make such changes to the outcome measures, although FDA notes that the questionnaire already includes items assessing perceived effectiveness of the warnings. The purpose of this study is to assess whether potential textual warning statements, which have been revised from those enumerated in section 4 of FCLAA, promote greater understanding of the negative health consequences of cigarette smoking, and the proposed outcome measures focus on just such an evaluation. Therefore, the suggested outcome measures do not contribute to the evaluation of whether the revised warning statements improve public understanding of the negative health consequences of cigarette smoking.

(Comment) One comment noted that the study does not include information that would assist in the design of the graphic images.

(Response) FDA agrees that the proposed study does not include these outcomes, and the Agency declines to make such a change. The focus of this study is on the textual warning statements only to assess whether they promote greater understanding of the negative health consequences of cigarette smoking and not the design of the graphic images.

(Comment) Two comments stated that FDA was including measures of risk perception and suggested that FDA include additional risk perception measures, such as likelihood of the outcome; measures of absolute and comparative perceived risk; and perceptions of these risks over and above any ''background'' risk and other similar outcomes.

(Response) FDA declines to make such changes because this study does not aim to measure risk perceptions. The measures included in this proposed study assess knowledge and understanding of a negative health outcome caused by cigarette smoking. The goal of these measures is not to assess the absolute or relative level of perception of such risks, but rather to investigate the effect that viewing the warning statements has on increasing the understanding of the negative health consequences of cigarette smoking.

(Comment) Two comments suggested that, in order to minimize the burden of the proposed collection, FDA should use best practice methods for survey and focus group research, including developing a statistical analysis plan and involving a private consultant with experience in conducting such research efficiently.

(Response) As stated in the supporting statements included in the docket, FDA is working with a skilled and experienced research contractor to conduct the proposed study. In addition, FDA scientific experts possess skill and expertise in conducting such research. Survey and focus group best practices will be used, including avoiding bias in questions due to wording and question order and developing a statistical analysis plan.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screening for pretest	762	1	762	0.033 (2 minutes)	25
Pretest	100	1	100	0.25 (15 minutes)	25
Screening for main data collection	19,082	1	19,082	0.033 (2 minutes)	630
Main data collection	2,500	1	2,500	0.25 (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: September 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3615]

Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the public meeting on ''Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access'' for which the notice of public meeting appeared in the **Federal Register** of June 22, 2017. In the notice of public meeting, FDA requested comments concerning administration of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to help ensure that the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of public meeting published June 22, 2017 (82 FR 28493). Submit either electronic or written comments by November 17, 2017.

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 November 17, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 17, 2017. 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