



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0810. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and
Communications

OMB Control Number 0910-0810--Extension

In order to conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will create and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these health communication messages have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and studies relating to the control and prevention of disease. In conducting such research, FDA will employ formative pretests. Formative pretests are conducted on a small scale, and their focus is on developing and assessing the likely effectiveness of communications with specific target audiences. This type of research involves: (1) assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs and (2) pretesting these health messages, strategies, and program

components while they are in developmental form to assess audience comprehension, reactions, and perceptions.

Formative pretesting is a staple of best practices in communications research. Obtaining voluntary feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about the perceived effectiveness of messages, advertisements, and materials in reaching and successfully communicating with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials, including questionnaires or images, directed at consumers while the materials are still in the developmental stage.

In the *Federal Register* of February 13, 2018 (83 FR 6190), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA-related comment was received.

Comment: The comment recommends that FDA should research and develop communications about educating adults about the continuum of risk, and educating adults to not provide tobacco products to youth.

Response: FDA appreciates the comment. The content and focus on studies submitted through this generic clearance will depend on Agency priorities and needs, and is not yet determined at this time.

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

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screeners	130,500	1	130,500	0.083 (5 minutes)	10,831
Self-Administered Surveys	27,000	1	27,000	0.33 (20 minutes)	8,910
Total					19,741

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

The number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. The burden for this information collection extension is proposed to increase by 12,613 hours since the last OMB approval. The burden increase is due to an increase in the number of respondents and the categories of respondents.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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