4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0987]

# 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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications." Also include the FDA docket number found in brackets in the heading of this document.

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

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 (CTP) 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 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 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 July 17, 2014 (79 FR 41696), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received, but only two comments were PRA-related.

(Comment 1) One comment was supportive of the information collection, stating they "support CTP's proposal to conduct formative pretests to ensure that health communication messages are received, understood and accepted by the intended audiences" and that they believe the proposed information collection is necessary and will have practical utility. The comment also stated that CTP's projection of the burden of the proposed collection effort seems

reasonable. In addition, the comment suggested that FDA consult with FDA's Risk Communication Advisory Committee on proposed information collections.

(Response) FDA agrees that the request in this collection of information is necessary and that the proposed burden is reasonable. Consultation with other U.S. Department of Health and Human Services (HHS) Agencies, FDA advisory committees, and/or the public will occur when appropriate.

(Comment 2) One comment was supportive of the data collection stating that the "collections are, in fact, essential." That comment also made suggestions about what the specific goals of messages tested in information collections included under this generic collection should focus on, and suggested that those collections be made available for further public comments.

(Response) FDA agrees that the request in this collection of information is essential to the mission of FDA as a science-based Agency in its implementation of the Tobacco Control Act. Although we appreciate suggestions for the content of future submissions submitted under this generic clearance, ultimately such decisions will be driven by needs determined by the Agency in consultation with other HHS Agencies and the public when appropriate.

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

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 |
|---|---|---|---|---|---|
| Self-Administered Surveys | 30,300 | 1 | 30,300 | 0.33 (20 minutes) | 9,999 |

[1] There 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.

Dated: November 20, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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