



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Testing as Used by the Food and Drug Administration Center for Tobacco Products

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 quantitative testing as used by the Food and Drug Administration Center for Tobacco Products.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@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.

Quantitative Testing as Used by the Food and Drug Administration Center for Tobacco Products
(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 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 such health communication messages have the highest potential to be received, understood, and are accepted by those for whom they are intended, FDA's 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 they are still in the developmental stage.

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

Table 1.--Estimated Annual Recordkeeping Burden¹

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: July 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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