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 Qualitative 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 Qualitative 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 Qualitative Data on Tobacco Products and Communications--(OMB Control Number 0910-New)

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs.

In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research including focus groups and/or in-depth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve two major purposes. First, formative research will provide critical knowledge about target audiences. FDA must first understand people's knowledge and perceptions about tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, initial testing will allow FDA to assess consumer understanding of survey/research questions and study stimuli. Focus groups and/or IDIs with a sample of the target audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, analyze, and interpret information gathered through this generic clearance in order to: (1) Better understand characteristics of the target audience--its perceptions, knowledge, attitudes, beliefs, and behaviors--and use these in the development of appropriate survey/research questions, study stimuli, or communications; (2) more efficiently and effectively design

survey/research questions and study stimuli; and (3) more efficiently and effectively design experimental studies.

FDA is requesting approval of this new generic clearance for collecting information through the use of qualitative methods (i.e., individual interviews, small group discussions, and focus groups) for studies involving all tobacco products regulated by FDA. This information will be used as a first step to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the Agency. This information may also be used to help identify and develop communication messages, which may be used in education campaigns. Focus groups play an important role in gathering information because they allow for an in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. Focus group research serves the narrowly defined need for direct and informal public opinion on a specific topic.

In the Federal Register of August 1, 2014 (79 FR 44779), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. However, only one comment was PRA-related.

(Comment) One comment was supportive of the information collection, stating that such "collections are, in fact, essential." The 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 the 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, FDA advisory committees, and/or the public when appropriate.

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

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

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
In Person Individual In-Depth Interviews	350	1	350	1	350
General Public Focus Group Interviews	18,850	1	18,850	1.5	28,275
Telephone Screening Interviews	4,800	1	4,800	.08 (5 minutes)	384
Telephone Individual In-Depth Interviews	50	1	50	1	50
Total	24,050				29,059

[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 pretest may vary depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the "Hours per Response" figures.

Dated: December 1, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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