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 (PRA).

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 0910-0796. 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 Qualitative Data on Tobacco Products and Communications

OMB Control Number 0910-0796--Extension

Under section 1003(d)(2)(D) of 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, usability testing, and/or in-depth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve three major purposes. First, formative research will provide critical knowledge about target audiences. FDA must understand people's knowledge and perceptions about tobacco-related topics before developing survey/research questions as well as stimuli for experimental studies. Second, by collecting communications usability information, FDA will be able to serve and respond to the ever-changing demands of consumers of tobacco products. Additionally, we will be able to determine the best way to present messages. Third, 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 at FDA. 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 individual 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 November 17, 2017 (82 FR 54351), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment by a private citizen that was PRA-related.

(Comment) The commenter stated that FDA should use the data we have collected in the past instead of collecting new information. The comment does not go in detail or provide any alternatives.

(Response) This collection is a valuable tool for conducting research. The studies FDA has conducted through this collection of information have been essential in helping FDA meet its mission as a science-based regulatory agency and implementing the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31). Future submissions submitted under this generic clearance will continue to assist FDA in its mission to protect and promote public health.

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

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

Type of Interview	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
In-Person Individual IDIs	1,092	1	1,092	1	1,092
IDI Screener	1,800	1	1,800	.083 (5 minutes)	149
Focus Group Interviews	4,701	1	4,701	1.5	7,052
Focus Group Screener	3,996	1	3,996	.25 (15 minutes)	999
Usability Testing	2,322	1	2,322	.5 (30 minutes)	1,161
Usability Testing Screener	2,028	1	2,028	.083 (5 minutes)	168
Total					10,621

[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 a 3-year period. Time to read, view, or listen to the message being tested is built into the "Hours per Response" figures.

FDA has updated the estimated burden that was published in the 60-day notice. The estimated burden for this collection has increased by 4,437 hours from 6,184 to 10,621. FDA attributes this increase to adding usability testing, and increasing the overall number of studies planned the next 3 years.

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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