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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection titled Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0180 for "Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications." Received comments, those filed in a timely manner (see ADDRESSES), will

be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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, including each proposed extension of an existing 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.

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

OMB Control Number 0910-0810--Extension

This information collection supports Food and Drug Administration (FDA, us or we) programs. 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.

Under this umbrella generic FDA's Center for Tobacco Products (CTP) conducts research and uses a variety of media to inform and educate stakeholders (e.g., 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 educational and public information programs have the highest potential to be received, understood, and accepted by those for whom they are intended, CTP conducts research to understand and identify and develop health messages relating to the control and prevention of disease. In conducting such research, FDA uses quantitative methods for studies about tobacco products, including but not limited to surveys, experimental studies, quasi-experimental studies and the collection and analysis of digital metrics. These studies are used to collect information related to foundational research informing message development; formative pretesting of tobacco communication messages and other materials directed at consumers; understanding the impact of tobacco public education materials in the digital environment; awareness of and receptivity to tobacco public education materials; and developing and testing survey measures to inform future research. This type of research may involve: (1) assessing audience knowledge, attitudes, intentions, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, dissemination strategies, and public information programs; (2) testing health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions, as well as after they have been disseminated to consumers; and (3) adding to the tobacco control, public health communication, and regulatory science knowledge base. Quantitative studies play an important role in exploring areas of

research and gathering information because they can be used to summarize a population of interest on key variables or reveal systematic relationships between variables.

This foundational research has helped FDA to understand audiences and inform message development and the testing of messages in communicating the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco. Obtaining this information has allowed FDA to improve messages, materials and implementation strategies while revisions are still affordable and possible.

The voluntary information collected serves the primary purpose of providing FDA information about various measures of ad performance including, but not limited to, message comprehension, perceived effectiveness, emotional responses and knowledge, attitudes, and behavioral intentions to assess the ability of messages, advertisements, and materials to reach and successfully communicate with their intended audiences. Additionally, this information collection provides FDA with insights into how to best measure public education message performance. Quantitative testing of messages and other materials with a sample of the target audience allows FDA to refine and assess messages, advertisements, and materials directed at consumers.

In addition, quantitative information is collected under this umbrella generic by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge and attitudes about tobacco products, including post-marketing surveillance of tobacco products. In addition, quantitative information is collected by FDA to track changes in response to policy and regulatory actions and to expand the tobacco regulatory science base by providing information on changing behaviors, knowledge, and attitudes about tobacco products, including postmarketing surveillance of tobacco products.

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
Screener	1,360,000	1	1,360,000	0.083 (5 minutes)	113,334
Self-Administered Surveys	204,000	1	204,000	0.33 (20 minutes)	68,000
Informed Consent/Assent	204,000	1	204,000	.033 (2 minutes)	6,800
Total	1,768,000				188,134

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

Our estimated burden for the information collection reflects an overall increase of 96,269 hours and a corresponding increase of 1,106,692 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years. A greater number of quantitative studies will be conducted over the next 3 years due to the need to develop new creative messages and content. Recent years have seen a dramatic change in media. With the shift to digital media, FDA must adapt to communicate effectively in a digital environment. As digital tobacco use prevention/interventions are still in their infancy, we must better understand the types of digital channels available. To impact public health outcomes, we need to understand how to reach our intended audience. New foundational studies are needed (including those on digital metrics, measurement, and implementation) to support activities and initiatives that will enable the public to receive evidence-based, timely, and clear health communication and education. As a result, we have adjusted our burden estimate and revised the number of respondents to the information collection.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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