TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d); notification	1	1	1	10	10

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13388 Filed 6–17–24; 8:45 am]

BILLING CODE 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, us, or we) 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: Submit written comments (including recommendations) on the collection of information by July 18, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0796. Also include the FDA docket number found in brackets in the heading of this document.

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: 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

This information collection supports FDA's 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.

In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research including but not limited to focus groups, usability and/or psychometric testing, in-depth interviews (IDIs), cognitive interviews and asynchronous qualitative discussions (*e.g.,* online journaling or web-based discussion boards), naturalistic observation and ethnographic studies to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve four major purposes. First, foundational research will provide critical knowledge and insights about intended audiences. FDA must first understand people's knowledge of, perceptions of, and reactions to tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, formative research will provide information about people's responses, thoughts, and feelings regarding potential creative messaging, or stimuli. Third, 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 communicate with intended audiences around tobacco prevention and cessation. Fourth, cognitive 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 intended audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, and interpret information gathered through this generic clearance to: (1) better understand characteristics of the intended 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 an extension of this generic clearance for collecting information using qualitative methods (*e.g.,* interviews, focus groups, asynchronous discussion boards, etc.) for studies involving all tobacco products regulated by FDA. This information will be used 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. Qualitative research plays an important role in gathering information because it allows for an in-depth understanding of

individuals' attitudes, beliefs, motivations, and feelings. Qualitative research serves the narrowly defined need for direct and informal public opinion on a specific topic.

The number of respondents to be included in each new study may vary, depending on the nature of the study (*e.g.,* foundational, formative, etc.), approach (synchronous vs. asynchronous, or virtual vs. in person) and the intended 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 ''Average Burden per Response'' figures.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment on the proposed collection of information in the **Federal Register** of January 9, 2024 (89 FR 1097). FDA received two PRA related comments.

(*Comment*) The comment expressed that the Paperwork Reduction Act was written to reduce burden on the public, but the overuse of surveys is encouraged generically, making it even easier to collect information with no need based. The comment stated further that ''This seems to be counterintuitive to the purpose of the PRA and exactly what the Act was supposed to be protecting us from, another survey we do not have time or resources to complete buy you would like to give us with no specific goal. Overuse.''

(*Response*) FDA disagrees with the comment suggesting that the generic information collection process enables the overuse of surveys and undermines the Paperwork Reduction Act. In response to this comment, FDA has updated Supporting Statement Part A to clarify the necessity of the information collected under this generic clearance for the proper performance of FDA CTP's function and the practical utility of collecting such information. The information collected will support FDA CTP's function by advancing CTP's Strategic Plan and its specific goals: ''Goal 1: Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance'' and ''Goal 4: Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use.'' The practical utility of the collected data is evidenced by its role in facilitating the development of clear and accessible CTP public statements and communications, such as web content, press releases, fact sheets, and retailer resources. Furthermore, the utility is demonstrated by CTP achieving the following objectives with specific audiences:

- Educating youth about the risks of tobacco product use.
- Educating people who use tobacco products about the benefits of cessation.
- Educating adults who smoke about the relative risks of tobacco products.

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.

(Comment) The comment expressed the lack of specificity regarding FDA's public education goals. Specifically, the comment notes that FDA vaguely states it will collect qualitative data to ''explore concepts of interest and assist in the development of quantitative research proposals'' and ''help identify and develop communication messages, which may be used in education campaigns.'' The comment stated further that they encourage ''FDA to prioritize educating adults, particularly adult smokers and physicians and medical staff who advise adult smokers about tobacco harm reduction. [. . .], FDA's public education campaigns should aim to improve understanding among adult smokers where there currently exists significant uncertainty and confusion about materially important issues that are detrimental to public-health efforts. These important issues include ''educating the adult public, particularly adult smokers, about the continuum of risk, and where alternatives to combustible cigarettes fall on that continuum,'' and ''correcting misunderstandings about the absence of any direct causal link between nicotine and tobacco-related diseases.''

(Response) FDA disagrees with the comment suggesting that an overarching purpose or plan for communications, information goals, or target audiences was not provided. In response to this comment, FDA has updated Supporting Statement Part A to clarify that the information collected under this generic clearance is necessary for the proper performance of FDA CTP's function and will be of practical utility in advancing CTP's Strategic Plan and its specific goals. The information collected under this generic clearance will advance CTP's objectives to educate people who use tobacco products about the benefits of cessation and to educate adults who smoke about the relative risks of tobacco products. The following generic information collections were recently approved under 0910–0796. FDA has summarized how they address specific objectives such as educating adults about tobacco products' relative risks:

- ''Consumer Perceptions of Cessation and Harm'': Focus group study with established cigarette smokers ages 25 and up. The objective is to learn about consumer perceptions (and misconceptions) regarding nicotine and tobacco products.
- ''Consumer Perceptions of Modified and Reduced Risk (MoRR)'': Focus group study with current and established cigarette smokers ages 21 and older. The objective is to gain information to inform health communication materials dedicated to modified risk products and/or the continuum of risk. This may help reduce misperceptions and lack of awareness.
- ''Menthol User Audience Research'': In-depth interviews conducted with adult menthol smokers ages 21 and older. The objective is to examine demographic, sociocultural, psychographic, and behavioral characteristics of adult menthol cigarette users; to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging; and to identify communication strategies to support menthol smokers in adopting less harmful behaviors.
- ''Qualitative Study of Product Category Comparison Statements—modified risk tobacco product (MRTPs) and harmful and potentially harmful constituents (HPHCs)'': Focus group study with adult current and former cigarette smokers ages 18 and older. The objective is to understand participants' knowledge, attitudes, beliefs, and perceptions about different tobacco products. This includes a stimulus-driven discussion of HPHC information and MRTP claims.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual In-depth Interviews	4,500	1	4,500	1	4,500
In-depth Interview Screener	22,500	1	22,500	0.083 (5 minutes)	1,875
Focus Group Screener	56,000	1	56,000	0.25 (15 minutes)	14,000
Focus Group Discussion	252,000	1	252,000	1.5	378,000
Discussion Board Screener	8,000	1	8,000	0.083 (5 minutes)	667
Discussion Board Participation	100	1	100	1.5	150
Total					399,192

[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 384,258 hours and a corresponding increase of 314,926 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 qualitative 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). As a result, we have adjusted our burden estimate and revised the number of respondents to the information collection.

Dated: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13386 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Social and Community Influences Across the Lifecourse.

Date: July 10, 2024.

Time: 10:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elia E. Ortenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, 301–827–7189, *femiaee@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–23–318: Mobile Health: Technology and Outcomes in Low and Middle Income Countries Panel A (R21/R33—Clinical Trial Optional).

Date: July 11–12, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria De Jesus Diaz Perez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000G, Bethesda, MD 20892, (301) 496–4227, *diazperezm2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimmune and Neuroinflammation involved in Neurodegenerative Disorders.

Date: July 11–12, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mariam Zaka, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J, Bethesda, MD 20892, (301) 435–1042, *zakam2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Clinical Informatics and Data Analytics.

Date: July 11–12, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, (301) 827–4446, *bellingerjd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Thrombosis and Blood Cells.

Date: July 12, 2024.

Time: 1:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–13359 Filed 6–17–24; 8:45 am]

BILLING CODE 4140–01–P