

- (3) Best Practices in the Approval Process
- (4) Target Animal Safety Technical Section Overview
- (5) Effectiveness Technical Section Overview
- (6) Chemistry, Manufacturing, and Controls Technical Section Overview
- (7) Human Food Safety Technical Section Overview
- (8) Environmental Impact Technical Section Overview
- (9) Minor Technical Sections Overview

The conference will also contain Q&A sessions during which FDA will address specific questions from the in-person and virtual audience as time allows. Future educational conferences will take a more in-depth approach to these and other topics based on questions and comments received during this conference, as well as questions and comments submitted to the docket.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, email, and telephone number. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend the conference. Registrants will receive confirmation when their registration has been received and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at https://fda.zoomgov.com/webinar/register/WN_cSFEyfDpQK6RuGrwPznG9A no later than July 10, 2024. Onsite registration will be provided on the day of the conference on a first-come, first-served basis, until the room capacity is reached. Onsite registration will open at the conference site at 8 a.m. on July 17, 2024. If room capacity is reached, individuals will be offered the

opportunity to observe the conference from an overflow room located at the conference site.

If you need special accommodations due to a disability, please contact Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**) no later than July 10, 2024.

Transcript: Transcripts of the educational conference will be available on FDA's website at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings> approximately 30 days after the conference. Please be advised that as soon as a transcript of the educational conference is available, it will be accessible at <https://www.regulations.gov>, and may also be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

Recording of Conference: Please be advised that as soon as a recording of this conference is available, it will be accessible at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13303 Filed 6–17–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASaff@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.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of January 23, 2024 (89 FR 4315), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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]
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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