

Portal Discharge Tab, presented as an appendix to the form.

○ Add “Concurrent Planning: Additional Potential Sponsors” segment to Family Reunification Section with the following fields (which will auto-populate from the Sponsor Assessment (Form S–5, currently approved under this information collection):

- Potential Sponsor Name.
- Relationship to Child.
- Sponsor Category.

○ Split the “Know Your Rights Presentation and Legal Screening” into two distinct fields to capture the completion date for each more accurately, acknowledging that they

typically are not completed on the same day.

○ Add “Back-Up Case Manager” segment to Case Manager Information Section to designate an alternative Case Manager who may take actions on behalf of the primary Case Manager when they are unavailable. The corresponding fields mirror those for primary case manager and will either be system-generated or auto-populate with user account data already entered the system. The fields include:

- Back-up Case Manager Name.
- Back-up Case Manager Email Address.
- Back-up Case Manager Phone Number.

■ Back-up Case Manager Organization.

■ Assigned on (MM/DD/YYYY).  
○ Adjust the burden estimate to account for an increase in the number of care provider facilities and number of children placed in ORR care, as well as the addition of the above listed new segments and fields. The annual number of respondents increased from 216 to 300, the annual number of responses per respondent increased from 278 to 327, and the average burden hours per response increased from 0.08 hours to 0.25 hours.

*Respondents:* ORR grantee and contractor staff.

*Annual Burden Estimates:*

ANNUAL BURDEN ESTIMATE FOR RESPONDENTS

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Foster Care Travel Req. Form (S–14) .....	138	178	0.25	6,141
Admission (S–18) .....	300	327	0.33	32,373
UC Authorized/Restricted Call List and Call Log (S–20) .....	300	15,711	0.08	377,064
Case Manager Call Log and Case Notes (S–23) .....	300	8,183	0.08	196,392
UC Case Status (S–27) .....	300	327	0.25	24,525
Estimated Annual Burden Hours Total .....				636,495

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* 6 U.S.C. 279; 8 U.S.C. 1232.

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–0180]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 December 26, 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 0910–0810. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JennaLynn Capezuto, 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](mailto: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 Quantitative Data on Tobacco Products and Communications**

*OMB Control Number 0910–0810—Extension*

This information collection supports FDA 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, 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 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.

In the **Federal Register** of June 21, 2024 (89 FR 52055), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondents	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	0.033 (2 minutes) .....	6,800
<b>Total .....</b>	<b>1,768,000</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>188,134</b>

<sup>1</sup> 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: November 19, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

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