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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1600]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

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 **[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 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 0910-0915. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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.

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

OMB Control Number 0910-0915--Revision

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. FDA's Center for Tobacco Products (CTP) was created to carry out the authorities granted under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) to educate the public about the dangers of tobacco use and to serve as a public health resource for tobacco and health information. CTP's tobacco education mission directly contributes to advancing the goals of Executive Order 14212: Establishing the President's Make America Healthy Again Commission, including the Make Our Children Health Again assessment, in three ways. First, CTP works to reduce tobacco use, the leading cause of chronic disease and mortality in the United States. Second, CTP protects the health of children; public education campaigns and other CTP efforts decrease the likelihood that youth initiate or escalate tobacco use. Third, CTP uses gold-standard science to develop, implement, and evaluate its programs.

FDA launched “The Real Cost” educational campaigns in February 2014, seeking to reduce tobacco use among at-risk youth in the United States who are open to using or

have already experimented with cigarettes or electronic nicotine delivery systems (ENDS). As with CTP as a whole, FDA's "The Real Cost" Youth Cigarette and E-Cigarette Prevention Campaigns aim to reduce chronic disease and protect the health of children. "The Real Cost" campaigns use evidence-based messaging distributed through multiple channels, including paid media advertising, to highlight the negative health consequences of tobacco use to U.S. youth. The Real Cost Campaign Outcomes Evaluation Study, also known as the Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT) study, uses gold-standard science to measure exposure, awareness, and impact of "The Real Cost" campaigns among youth in the United States.

The first ExPECTT study (Cohort 1) assessed the campaign's impact on outcome variables of interest from November 2013 to November 2016. The second ExPECTT study (Cohort 2; OMB Control No. 0910-0753) assessed the campaign's impact on outcome variables of interest from June 2018 to August 2022. The third ExPECTT study (Cohort 3; OMB Control No. 0910-0915) has been assessing the campaign's impact on outcome variables of interest starting in February 2023. To continue assessing the impact of "The Real Cost" campaigns, FDA intends to extend implementation of the ExPECTT Cohort 3 study. The study consists of multiple waves of data collection, including a baseline survey and up to eight continuing follow-up (FU) surveys, conducted approximately 6-9 months apart. The online surveys are conducted with youth ages 11-17 at baseline (for mail-based recruitment).

The purpose of FDA's ExPECTT Cohort 3 study is to provide credible evidence that changes in key outcomes can be attributed to exposure to the campaign. Using gold-standard science, FDA can determine the strength of the attribution and rule out

alternative explanations for observed changes in key outcomes. In the ExPECTT study, FDA has been measuring variation in both potential campaign exposure (e.g., market-level delivery) and self-reported campaign exposure to media advertising and how those exposures relate to key outcomes.

The goal of ExPECTT Cohort 3 is to determine whether future waves of "The Real Cost" public education campaigns will continue to influence the following key outcomes[1]:

- Awareness of campaign messages
- Tobacco use behaviors (such as initiation, escalation, cessation)
- Specific beliefs targeted by messages (message-targeted beliefs)
- Psychosocial predictors or precursors of tobacco use behavior
    - ○ Health and addiction risk perceptions
    - ○ Perceived loss of control or threat to freedom expected from tobacco use
    - ○ Anticipated guilt, shame, and regret from tobacco use
    - ○ Perceptions of prevalence, approval, and popularity of tobacco use
    - ○ Pro-health changes in normative beliefs about tobacco product use
    - ○ Tobacco use susceptibility
    - ○ Intention or willingness to use tobacco
    - ○ Intention to quit and/or reduce daily consumption

In support of the provisions of the Tobacco Control Act (Pub. L. 111–31) that require FDA to protect the public health and to reduce tobacco use by minors, FDA

[1] MacMonegle, A., Zarndt, A. N., Wang, Y., Bennett, M., Malo, V., Pitzer, L., . . . & Duke, J. (2025). The Impact of "The Real Cost" on E-cigarette Initiation among US Youth. *American Journal of Preventive Medicine*

requested and received OMB approval to collect information to evaluate CTP's public education campaign ‘‘The Real Cost’’ through the Evaluation Study: Cohort 3 under the OMB control number 0910-0915. This notice requests an extension of the currently approved data collection.

In the *Federal Register* of July 14, 2025 (90 FR 31229), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA-related comment was received.

(Comment) The commenter strongly supported FDA's proposed "Real Cost" Campaign Outcomes Evaluation Study (Cohort 3), emphasizing the campaign's proven effectiveness and urges continued funding of the campaigns and evaluation studies. The comment highlights that "'The Real Cost" Youth E-Cigarette Prevention Campaign has been "instrumental in reversing the trajectory of youth vaping, driving rates down from a peak of 5.4 million in 2019 to about 1.6 million today" and that "The Real Cost" Youth Cigarette Prevention Campaign demonstrated exceptional cost-effectiveness by generating "$180 in savings for every dollar of the nearly $250 million invested in its first two years." The commenter recommends that the proposed information collection reaches communities historically targeted by the tobacco industry. Finally, the commenter advocated for inclusion of questions related to gender in the information collection.

(FDA Response) FDA appreciates the comment in response to the 60-day notice. FDA agrees with the commenter that continued campaign evaluation is "crucial to maintaining the ongoing success of 'The Real Cost'" campaigns through rigorous gold standard research, and that this information collection has strong practical utility. Specifically, the proposed information collection will continue to assess the campaign's

impact on reducing chronic disease among youth through decreased tobacco initiation and identify opportunities to enhance program effectiveness and adapt to changing public health challenges. The proposed information collection is designed to collect high-quality data with a longitudinal cohort design that will follow youth participants over time to assess changes in tobacco-relevant outcomes due to campaign exposure. The data collected has strong practical utility and will provide essential insights for campaign optimization by identifying messages that are most effective in preventing and reducing youth tobacco use and while providing vital campaign evaluation data to ensure FDA is advancing public health goals in protecting children from the harmful effects of tobacco use.

The goal of the current information collection is to assess the reach and impact of "The Real Cost" Youth E-Cigarette and Cigarette Prevention campaigns for the general population of youth (aged 12-17) in the United States who are at risk of tobacco use. This information collection focuses on all U.S. youth (ages 12-17) because, as the commenter states, the tobacco industry has historically targeted young people in their marketing strategies (U.S. DHHS, 2012), and most adult tobacco users begin using during this critical age range (U.S. DHHS, 2014).

FDA's approach to this evaluation study is conducted in full compliance with all applicable Executive Orders and current Administration priorities regarding federal research and data collection activities. Preventing tobacco initiation among U.S. youth is essential to combat the chronic disease caused by tobacco use. The focus of this proposed information collection is the general population U.S. youth. While examining specific racial, ethnic, or demographic subgroups is not a primary aim of the study, FDA is able to

assess campaign reach and impact for various population segments among the youth sample. The study collects demographic data that can support examination of campaign effectiveness among different groups of youth who may be at varying levels of risk for tobacco initiation and use. For example, the survey collects data on participant race and ethnicity items in compliance of Office of Management and Budget's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.

Additionally, the commenter requests for the inclusion of survey items to assess gender in the information collection, which would not be in compliance with Executive Order 14168 "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government." FDA does not assess or examine gender or gender identity in this study. To be in compliance with Executive Order 14168 "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," we are unable to assess or examine gender or gender identity in this study. We include one item on sexual orientation: "Which of the following best represents how you think of yourself?" (Response options: Straight or heterosexual, Bisexual, Gay or lesbian). We also include one item on sex: "Are you female or male?" (Response options: Male, Female). The inclusion of these two items enables us to examine differences in exposure and responses to campaign messages among demographic groups in a manner that is compliant with Executive Orders.

FDA estimates the burden of this collection of information during the extension period as follows.

Table 1.--Estimated Annual Reporting Burden[1-3]

Respondent/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Household Recruitment Study Materials--Mail: Baseline Recruitment & Follow-up Replenishments	305,000	1	305,000	0.05 (9 mins)	15,250
Household Screener--Mail: Baseline Recruitment & Follow-up Replenishments	65,000	1	65,000	0.08 (5 mins)	5,200
Household Roster--Mail: Baseline Recruitment & Follow-up Replenishments	7,661	1	7,661	0.08 (5 mins)	613
Parent Permission at Recruitment-Mail: Baseline Recruitment & Follow-up Replenishments	12,245	1	12,245	0.08 (5 mins)	980
Invitation Emails-Mail: Baseline Recruitment & Follow-up Replenishments	9,738	1	9,738	0.02 (1 min)	195
Eligibility Letter/Emails-Mail: Baseline Recruitment & Follow-up Replenishments	280	1	280	0.03 (2 mins)	8
Email/Text Reminder-Mail: Baseline Recruitment & Follow-up Replenishments	9,738	1	9,738	0.03 (2 mins)	292
Invitations and Study Materials: Follow-up waves	57,729	1	57,729	0.17 (10 mins)	9,814
Youth Assent: Baseline and Follow-up waves	44,768	1	44,768	0.08 (5 mins)	3,581
Parent Permission at Recontact: Follow-up waves	7,336	1	7,336	0.08 (5 mins)	587
Youth Survey: Baseline and Follow-up waves	44,768	1	44,768	0.50 (30 mins)	22,384
Youth Incentive Thank You Letter: Baseline and Follow-up waves	44,768	1	44,768	0.02 (1 min)	895
Total					**59,799**

*We received a waiver of parental permission from IRB for youth 14+, so not all respondents require parental permission at recontact.

[1]Note that all values in the table are rounded to the nearest hundredths place (for the Average Burden per Response column) or to the nearest whole number (for all other columns); therefore, sums may not equal the exact totals due to rounding.

[2] Note that values in the table are not annualized. These values reflect the full burden hours required for the study

3There are no capital costs or operating and maintenance costs associated with this collection of information.

Four waves of data collection (a baseline survey and 3 follow-up surveys) are scheduled to be conducted prior to the start of the extension period. The extension period includes up to 5 additional follow-up surveys with sample replenishment at 2 of those waves of

data collection. We detail below the recruitment activities and data collection materials for the full range of the study, including data collections prior to the extension period and during the extension period.

Data Collection Recruitment

Baseline Recruitment

This study includes a baseline survey and up to eight continuing follow-up surveys, conducted approximately 6-9 months apart. There are two ways that we recruited initial participants to the study at baseline, which took place in 2023: mail-based recruitment (the primary mode of recruitment) and supplemental social media-based recruitment. The recruitment sample for the mail-based data collection included youth ages 11-17. We mailed 326,709 recruitment/study material packages to households at baseline (3 minutes per response) and received 64,314 completed screeners (5 minutes per response) by adults within those households. For the 8,207 households identified as eligible for the study during the screening process (*i.e.,* the presence of one or more youth ages 11 to 17), we asked the adult completing the screener to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We randomly selected up to 2 eligible youth per household. We asked parents to provide permission for each eligible youth to participate in the study (5 minutes). If more than one youth was selected, parental permission was required for each child. In some cases, the adult taking the screener was not the parent of the eligible youth(s). We then reached out by email and/or with a letter to notify the parent of their child(ren)s' eligibility (2 minutes) and a request parental permission (N = 300). All youth with parental permission (n = 10,431) were sent an invitation email to participate in the study (1 minute). We also sent reminder

emails and texts out to eligible youth during data collection who had not yet completed the survey (2 minutes).

In addition to the primary mail-based data collection at baseline in 2023, we recruited an additional sample using a social media-based recruitment from a subpopulation of respondents at increased risk for initiating use of cigarettes and ENDS products. This supplemental data collection consisted of online self-administered surveys of participants recruited through social media advertisements. The recruitment sample for this data collection was youth ages 14 to 20 who met the subpopulation criteria. At baseline, 13,888 respondents were invited to take the screener through social media ads (1 minute). We screened 9,444 respondents (5 minutes per screener response) and identified 1,501 eligible respondents. This is a longitudinal study, so participants from the social media sample will be retained in the sample because they were members of the original study cohort.

Follow-Up (Replenishment) Recruitment

We estimate that we will lose approximately 15 percent of the original baseline sample at each follow-up wave. Replenishing the sample will ensure we maintain an adequate longitudinal sample at each study wave and continue to have representation from younger respondents in our aging sample. We will replenish the sample up to 4 times during the study period. We will send out recruitment/study material packages to an additional 450,000 households in total (3 minutes per response) over the course of the study period. We expect to receive an estimated 95,000 completed screeners (5 minutes per response). For households identified as eligible for the study during the replenishment screening process (*i.e.,* the presence of 1 or more youth ages 11 to 17), we will ask the

parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We will randomly select up to 2 eligible youth per household. We will ask parents to provide permission for each eligible youth to participate in the study (5 minutes). If more than one youth is selected, parental permission will be required for each child. In some cases, where the adult taking the screener is not the parent of the eligible youth(s), we will reach out by email and/or letter with a notice of eligibility (2 minutes) and a request to provide parental permission. All youth with parental permission will be sent an invitation email to participate in the study (1 minute). We will also send reminder emails and texts out to eligible youth during data collection who have not yet completed the survey (2 minutes). We will not use social media to recruit any respondents for the replenishment samples.

Youth Survey Materials

Baseline

For the main data collection at baseline in 2023, we collected data from 5,354 youth respondents recruited by mail. For the supplemental social media data collection at baseline in 2023, we collected data from 1,501 youth respondents. These 6,855 youth respondents provided baseline assent (5 minutes per response) and completed the survey (30 minutes per response). Following completion of the study, we mailed an incentive letter (1 minute). For the 5,354 youth respondents recruited for the main data collection, we asked the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We received a waiver of parental permission for youth 14+ and did not require parental permission for respondents from the social media data collection.

Follow-Up Waves

As this is a longitudinal data collection, participants who complete the baseline survey or any follow-up replenishment survey will be recontacted for each subsequent follow-up wave. We will send invitations and study materials to sample respondents for up to eight follow-up waves (10 minutes per respondent). Including youth recruited in the replenishment, this will be up to 14,053 youth at each wave. At each of the eight follow-up waves, respondents are estimated to provide assent (5 minutes per respondent) and complete the survey (30 minutes per respondent). Where required, we will ask the parent/guardian to provide permission (5 minutes per respondent) for the youth to participate in the study. For youth who complete the survey, we will also mail an incentive letter (1 minute per respondent).

To align with Executive Order 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, we are revising this information collection to remove questions relating to gender. Since publication of the 60-day notice, the burden estimates have been updated. Overall, the estimated burden reflects a decrease of 455 burden hours and an increase of 507,886 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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