generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product TECELRA (afamitresgene autoleucel). TECELRA is indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA–A*02:01P, –A*02:02P, –A*02:03P, or –A*02:06P positive and whose tumor expresses the MAGE–A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. This indication is approved under accelerated approval based on overall response rate and duration of response.

Subsequent to this approval, the USPTO received a patent term restoration application for TECELRA (U.S. Patent Nos. 11,572,400 and 11,725,040) from Adaptimmune Limited, and the USPTO requested FDA's assistance in determining this patents' eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TECELRA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TECELRA is 2,775 days. Of this time, 2,534 days occurred during the testing phase of the regulatory review period, while 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* December 28, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 28, 2016.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 5, 2023. FDA has verified the applicant's claim that the biologics license application (BLA) for TECELRA (BLA 125789) was initially submitted on December 5, 2023.

3. *The date the application was approved:* August 1, 2024. FDA has verified the applicant's claim that BLA 125789 was approved on August 1, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 297 or 392 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.)

Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13054 Filed 7–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2025–N–1600]

Agency Information Collection Activities; Proposed Collection; 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 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 extension of the currently approved collection ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 12, 2025.

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 September 12, 2025. 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–2025–N–1600 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.'' 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: Amber Sanford, 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: 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.

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

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Household Recruitment Study Materials—Mail: Baseline Recruitment & Follow-up Replenishments.	776,719	1	776,719	0.05 (3 min)	38,836
Household Screener—Mail: Baseline Recruitment & Follow-up Replenishments.	159,314	1	159,314	0.08 (5 min)	13,756
Household Roster—Mail: Baseline Recruitment & Follow-up Replenishments.	19,511	1	19,511	0.08 (5 min)	1,561
Parent Permission at Recruitment—Mail: Baseline Recruitment & Follow-up Replenishments.	31,183	1	31,183	0.08 (5 min)	2,495
Invitation Emails–Mail: Baseline Recruitment & Follow-up Replenishments	24,798	1	24,798	0.02 (1 min)	496
Eligibility Letter/Emails—Mail: Baseline Recruitment & Follow-up Replenishments.	713	1	713	0.03 (2 min)	21
Email/Text Reminder—Mail: Baseline Recruitment & Follow-up Replenishments.	24,798	1	24,798	0.03 (2 min)	744
Recruitment Study Materials—Social Media: Baseline Recruitment only	13,888	1	13,888	0.02 (1 min)	278
Youth Screener—Social Media: Baseline Recruitment only	9,444	1	9,444	0.08 (5 min)	756
Invitations and Study Materials: Follow-up waves	80,494	1	80,494	0.17 (10 min)	13,684
Youth Assent: Baseline and Follow-up waves	70,798	1	70,798	0.08 (5 min)	5,664
Parent Permission at Recontact: Follow-up waves *	10,630	1	10,630	0.08 (5 min)	850
Youth Survey: Baseline and Follow-up waves	70,798	1	70,798	0.50 (30 min)	35,399
Youth Incentive Thank You Letter: Baseline and Follow-up waves	70,798	1	70,798	0.02 (1 min)	1,416
Total					115,956

* We have received a waiver of parental permission from IRB for youth 14+, so not all respondents require parental permission.
[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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 totals exactly due to rounding.

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

[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.*

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 FU 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. Our estimated burden for the information collection reflects an overall decrease of 557 hours and an increase of 507,886 responses. We are proposing up to 3 additional follow-up waves of data collections, including up to 2 additional replenishment samples. In addition, we updated the estimated burden per response based on past data collections for the baseline and first follow-up wave.

Dated: July 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13047 Filed 7–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

0991–ZA57

Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA); Interpretation of ''Federal Public Benefit''

AGENCY: Office of the Secretary, HHS.

ACTION: Notice; 30-day comment period.

SUMMARY: This notice sets forth the interpretation that the U.S. Department of Health and Human Services (HHS) uses for the term ''Federal public benefit'' as used in Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Public Law 104–193, 8 U.S.C. 1611. In doing so, this notice revises the interpretation of the term set forth in a prior notice, 63 FR 41658 (Aug. 4, 1998) (''the 1998 HHS PRWORA Notice'' or ''1998 Notice''). This notice also describes and preliminarily identifies the HHS programs that provide ''Federal public benefits'' within the scope of PRWORA, including HHS programs that were not listed in the 1998 HHS PRWORA Notice.

DATES: To be assured consideration, comments must be received no later