United States Food and Drug Administration

Center for Tobacco Products

NATIONAL YOUTH TOBACCO SURVEY, 2024 - 2026

OMB Control No. 0910-0932

SUPPORTING STATEMENT PART A

- **Goal of the study**

The goal of the National Youth Tobacco Survey (NYTS) is to collect tobacco use behavioral data among 6th through 12th grade students in 2024, 2025, and 2026. The purpose of the survey is to assess use of tobacco products and the associated correlates.

- **Intended use of the resulting data**

The NYTS data will be used to inform policy decision-making and regulatory actions regarding youth access to tobacco products, exposure to tobacco marketing, and use of tobacco products. Additionally, the NYTS will be used as a benchmark for state-level trends, to measure progress towards achieving Healthy People 2030 tobacco objectives, and to inform comprehensive evidence-based interventions.

- **Methods to be used to collect**

Teachers will be provided a URL to the web based NYTS that will be active for a designated period of time (e.g., week (s)). The survey can be administered during a class period and the students will be allowed to take the survey in any location where they are receiving educational instruction (e.g. school, home or some other place).

- **The subpopulation to be studied**

Contingent upon final analytic sample size, NYTS will provide data among subpopulations of youth, by race and ethnicity, sexual orientation, mental health status (depression/anxiety), and academic achievement.

- **How data will be analyzed**

The NYTS data will be weighted to provide nationally representative estimates. Data sets and documentation for the NYTS are available online (National Youth Tobacco Survey (NYTS) | CDC). The data will be analyzed using statistical packages, such as SAS, SAS-Callable SUDAAN, R or STATA to produce descriptive results of national patterns of tobacco product use behaviors and correlates among youth.

Terms of Clearance: If terms of clearance exist, please summarize and address here. Otherwise, no mention is necessary. Example: In its last approval OMB instructed FDA to report findings regarding the deployment of the collection instrument "electronic Form FDA 3978." We have discussed this under Section 8, below.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

The justification for the implementation of the NYTS is based on three factors: (1) public health implications of tobacco product use; (2) the burden of tobacco product use; and (3) mandates to monitor, reduce, and alter attitudes toward tobacco product use and reduce exposure to pro-tobacco influences found in Section 301 of the Public Health Service Act (42 USC 241) (Attachment A1). Specifically, the following factors make it necessary for FDA to conduct the NYTS:

- The NYTS provides data to support several strategic planning priorities for the U.S. Department of Health and Human Services (DHHS), including activities mandated by the Family Smoking Prevention and Tobacco Control Act and DHHS's Tobacco Control Strategic Action Plan (USDHHS, 2012). The NYTS is also the data source for seven Healthy People 2030 objectives related to reducing adolescent prevalence of: current use of any tobacco products; current use of e-cigarettes; current use of cigarettes; current use of cigars, cigarillos, and little cigars; current use of flavored tobacco products; current use of smokeless tobacco products; and exposure to tobacco product marketing.

- Publications based on past cycles of the NYTS are listed in Attachment C.

The NYTS serves as a national benchmark against which states can measure their progress in tobacco control and prevention. Many states conduct a Youth Tobacco Survey (YTS) using comparable methodology to the NYTS. States therefore can measure their program's progress relative to national trends.

FDA requests OMB approval to conduct the NYTS in 2026 (OMB No. 0910-0932; exp. 5/31/2027). The survey instrument has been developed to include items that are relevant to tobacco prevention and control efforts among youth. Burden allocation for instrument development and testing has been calculated to allow for psychometric testing related to potential questionnaire updates that might occur after 2026. The estimated burden per response to complete the actual survey has not changed.

2. Purpose and Use of the Information Collection

Tobacco product use among youth is a serious public health concern. Youth use of tobacco products in any form - including e-cigarettes - is unsafe. Such products contain nicotine, and nicotine exposure during adolescence can lead to long-term addiction and harm the parts of the brain that control attention, learning, mood, and impulse control. Additionally, e-cigarette aerosol is not harmless. It can contain harmful and potentially harmful substances, including nicotine, heavy metals like lead, volatile organic compounds, and cancer-causing agents.

Our surveillance shows that every day, almost 1,600 youth smoke their first cigarette and nearly 200 youth start smoking every day. Over 90% of adults who smoke cigarettes daily started smoking before age 18 years. In 2022, 3.08 million youth reported current use of any tobacco product, including 2.55 million who reported current use of e-cigarettes. Of those who used e-cigarettes, 42% used them on 20 days or more of the past 30 days and 28% used them daily. Among high school e-cigarette users, 11% reported that they also smoke cigarettes (dual use); 17% of middle school e-cigarette users also reported cigarette dual use. From 2023 to 2024, NYTS findings showed declines in e-cigarette use among middle and high school students (from 7.7% to 5.9%). In 2024, among all students, e-cigarettes remained as the most commonly used tobacco product (5.9%), followed by nicotine pouches (1.8%), cigarettes (1.4%), cigars (1.2%), smokeless tobacco (1.2%), other oral nicotine products (1.2%), heated tobacco products (0.8%), hookahs (0.7%), and pipe tobacco (0.5%). Approximately 10.0% (2.8 million) of all students reported currently using any tobacco product in 2024.

It is important to maintain surveillance among youth for all forms of tobacco product use and associated factors to inform the development of public health policy and action at the national, state, and community levels. The NYTS is the only nationally representative survey of U.S. middle and high school students to assess tobacco product use patterns and associated factors.

NYTS collects information on the use of tobacco products; knowledge of and attitudes toward tobacco; exposure to secondhand smoke; and exposure to pro- and anti-tobacco influences such as portrayals of tobacco products in advertising and mass media, social determinants of health such as family/household affluence, provision of school- and community-based interventions, and enforcement of minors' access laws. Data collected through the NYTS can: (1) inform the development of health policy and guidelines that protect nonsmokers from secondhand smoke; (2) help researchers and policy makers to better understand youth exposure to pro-tobacco influences; (3) provide comprehensive tobacco product use data to support tobacco control programs; and (4) inform the implementation of other key evidence-based policies that will prevent youth initiation, decrease the number of tobacco product users, and save lives.

Annually, NYTS data will be used, not only by FDA, but also by several other federal agencies, including the CDC, Health Resources and Services Administration (HRSA), National Cancer Institute (NCI), and the Office of the Surgeon General. Additionally, the NYTS data can be used by state and local governments, nongovernmental organizations, academic institutions, and others in the private sector.

- FDA: uses NYTS data to track trends over time to inform and monitor its regulatory authority over the manufacture, distribution, and marketing of tobacco products.

- CDC: uses NYTS data for evaluation of comprehensive tobacco control policies; measuring progress in reaching national objectives (e.g., Healthy People 2030 objectives); policy and program development; and technical assistance to state, local, and other partners.

- Health Resources and Services Administration (HRSA): uses NYTS data to support HRSA, Maternal and Child Health Bureau (MCHB), and the American Academy of Pediatrics' *Bright Futures Health Supervision Guidelines* which formulates specific risk-

reduction recommendations to prevent and assess tobacco product use and exposure for children, and adolescents.

- National Cancer Institute (NCI): uses NYTS data to help inform its educational efforts, demonstration projects focused on youth tobacco product use prevention, and the determinants of cessation.

- Office of the Surgeon General (OSG): uses and references the NYTS results to assess the need for focused use of resources for tobacco prevention and control efforts targeting youth. NYTS data have figured prominently in recently released reports. Based on findings from the 2018 NYTS (FDA, 2018; CDC, 2019), the U.S. Surgeon General issued an advisory on e-cigarette use among youth, declaring the increased use as an epidemic. (OSG, 2018).

- State and local governments: use NYTS data as an index against which state and local health and education agencies can compare their state YTS results. Attachment B lists state tobacco control reports that cite NYTS data. State and local law enforcement officials also can use findings from the NYTS to determine national compliance with the Synar Amendment, which bans the sale of tobacco products to youth aged <18 years.

- Nongovernmental organizations, foundations, and academic institutions (e.g., American Cancer Society; The Robert Wood Johnson Foundation; The California Cancer Research Fund for the University of California; the Truth Initiative; the American Medical Association; and The National Academy of Medicine): have extensively used NYTS data in official reports, white papers, and fact sheets. Additionally, academic researchers use data from NYTS for research and surveillance.

Thus, to maintain NYTS data collection for use by FDA and other federal partners, state and local governments, nongovernmental organizations, academic institutions, and others, FDA submits this Information Collection Request to administer the NYTS in 2026.

3. Use of Improved Information Technology and Burden Reduction

The NYTS transitioned from a paper and pencil survey to an electronic survey in 2019. This transition allowed for the programming of skip logic so that respondents only need to answer items that pertain to their individual behaviors and characteristics. In addition to improving both the overall validity and reliability, the transition resulted in reduced time to complete the survey. Estimates of overall time to complete the survey was reduced from one class period (~45 mins.) to an average of 12.5 to 15 minutes, although each student is allowed one class period to complete.

4. Efforts to Identify Duplication and Use of Similar Information

To minimize duplication of data collection and the burden on survey participants, FDA and CDC's Office on Smoking and Health (OSH) collaborated in the past. Now that OSH has been eliminated, FDA plans to continue to leverage the NYTS as a single data source to inform national objectives for tobacco product use prevention and control among youth.

The NYTS population, which is students enrolled in grades 6-12, is distinct from other youth surveys such as the National Youth Risk Behavior Survey (grades 9-12); and Monitoring the Future (grades 8, 10, and 12). While other multi-purpose household surveys also sample youth such as the National Survey on Drug Use and Health (NSDUH) and the National Health and Nutrition Examination Survey (NHANES) and contain some tobacco-related content, the scope of these tobacco-specific questions cannot meet the needs specific to the evaluation of national tobacco prevention and control activities.

Enhanced review procedures for the NYTS were instituted in 2013 to promote overall efficiency and quality in federally sponsored data collection. An interagency workgroup was established under the HHS Data Council with representatives from HHS OPDIVS and programs collecting tobacco related data. The role of the group is to build infrastructure and connections to facilitate coordination and communication during the developmental stage of survey design to reduce duplication, improve response rates, reduce respondent burden, and promote standardization of estimates, where feasible. Federal agencies consulted through this process include NCHS, NIH/NCI, NIH/NIDA, and SAMSHA.

5. Impact on Small Businesses or Other Small Entities

The planned data collection does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

NYTS is conducted annually. Conducting it less than annually will adversely impact the ability to assess emerging trends. This will be particularly important for assessing progress toward reaching Healthy People 2030 national targets for tobacco control. The tobacco product environment evolves rapidly. FDA and other public health agencies need annual data to identify and track emerging products and issues, such as new e-cigarette devices and flavors that are attractive to youth. For example, after increasing from 2017-2019 (FDA, 2018; CDC, 2019a), (FDA-CDC, 2019; CDC, 2019b), e-cigarette use decreased among high school students between 2022 and 2024 (CDC, 2023; CDC 2024; FDA-CDC, 2024). Current use of any tobacco also declined between 2023 and 2024 among middle and high school students (CDC, 2023; CDC, 2024). At the same time, in 2024, for the first time, nicotine pouches were the second most commonly used tobacco product among middle and high school students in the NYTS (CDC, 2024), suggesting the need for continued monitoring of this and other emerging products. Less frequent NYTS administration would not have been able to track these nuanced changes in e-cigarette use and resulting changes in overall tobacco product use among youth. The NYTS assists the FDA with its requirement to conduct annual monitoring of youth tobacco product use behavior to inform and evaluate tobacco regulatory policies. For example, in July 2024, FDA sent warning letters to five online retailers who were selling unauthorized disposable e-cigarettes (FDA, 2024). FDA took this action after noticing an increase in youth use of these products (FDA, 2024).

Administering the NYTS on an annual basis will help federal agencies, as well as other stakeholders, to obtain important information about changes in youth tobacco use behaviors that

will inform strategies that are appropriately targeted to what the youth are exposed to, have access to and their use of specific products.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data collection will be implemented in a manner consistent with 5 CFR 1320.5. The 2024 questionnaire, previously approved by OMB, included a question that aligns with the *Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD-15). The race and ethnicity question in the 2024 questionnaire used the item in* "Figure 2. Race and Ethnicity Question with Minimum Categories Only and Examples."

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Federal Register Announcement

A 60-day Federal Register Notice (Attachment A2) was published in the Federal Register on June 5, 2023, Docket no. CDC-2023-0043, volume 88, no 107, document no. 2023-11858, pages 36585-36586.

Five comments were received through the 60-day FRN. CDC's responses to these comments are provided in Attachment A3.

Consultations

FDA established a working group to obtain guidance and suggestions for new items on the NYTS questionnaire that would help facilitate the measurement of key data needed to address the agency's mission.

Consultations on the design, instrumentation, products, and statistical aspects of the NYTS have been made with these experts to ensure the technical soundness and user relevance of survey results; to verify the importance, relevance, and accessibility of the information sought in the survey; to assess the clarity of instructions; and to minimize respondent burden. Some of these experts are shown in Table 1 below.

Table 1: Consultants for 2024-2026 NYTS

Center for Tobacco Products, Food and Drug Administration 10903 New Hampshire Avenue, Silver Spring, MD 20993	
Karen Cullen, Ph.D., M.P.H. Chief, Epidemiology Branch 2 Division of Population Health Science Phone: 240-402-4513 E-mail: Karen.Cullen@fda.hhs.gov	Eunice Park-Lee, Ph.D., M.S. Survey Statistician, Epidemiology Branch 2 Division of Population Health Science Phone: 301-837-7342 E-mail: Eunice.Park-Lee@fda.hhs.gov

Michael Sawdey, Ph.D., M.P.H. Epidemiologist, Epidemiology Branch 2 Division of Population Health Science Phone: 301-796-3452 Email: Michael.Sawdey@fda.hhs.gov	Kimberly Snyder, M.P.H. Social Scientist, Evaluation Branch Division of Research and Knowledge Integration Phone: 240-402-2216 E-mail: Kimberly.Snyder@fda.hhs.gov
Maria Cooper, Ph.D. Health Scientist, Epidemiology Branch 1 Division of Population Health Science Tel: 240-402-5726 Maria.Cooper1@fda.hhs.gov	Roberto Valverde, M.P.H. Statistician, PATH Branch Division of Research and Knowledge Integration Phone: 240-402-3055 E-mail: Roberto.Valverde@fda.hhs.gov
Hannah Cowan, M.P.H Epidemiologist, Epidemiology Branch 2 Division of Population Health Science Tel: 240-402-4794 Hannah.Cowan@fda.hhs.gov	Brittany Merson, Ph.D. Social Scientist, Social Science Branch 1 Division of Population Health Science Tel: 301-796-8519 Brittany.Merson@fda.hhs.gov
Samantha E. DiMisa, Ph.D. Social Scientist, Social Science Branch 1 Division of Population Health Science Tel: 240-402-2694 Samantha.DiMisa@fda.hhs.gov	

9. Explanation of Any Payment or Gift to Respondents

Schools will be given $750 in appreciation for their participation in NYTS. This was increased from $500 because of inflation; the incentive has not increased since at least 2009. No payments will be offered or made to student respondents on the NYTS survey. OMB first suggested that CDC offer school incentives on surveys as a means of improving school response rates and, thereby, improving the generalizability of results. FDA believes that offering school incentives helps maintain, or increase, school participation rates despite the growing number of competing, non-instructional demands placed on schools, including standardized testing. Students participating in cognitive testing interviews will be provided with $50 in appreciation for their participation; each student participating in cognitive testing will participate in 2 separate one-hour interviews and will be given $50 for each interview.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this submission because NYTS is not considered a “record” as defined by the Privacy Act: the collected data will not include individuals’ financial transactions, medical history, criminal or employment history, name, or the identifying number, symbol, or other identifier assigned to any individual, such as a finger or voice print or a photograph. No individually identifiable information is collected on the NYTS survey; therefore, there is no way to connect students’ names to their response data. Participation in the NYTS should pose little or no effect on the respondent’s privacy. Participation is voluntary and respondents will be assured that there is no penalty if they decide not to respond, either to the information collection as a whole or to any particular question. Participants can choose to leave the study at any point. Participants also can choose to skip any questions they find uncomfortable.

Data will be kept private to the extent allowed by law. The NYTS does not collect any student-level personal identifiers. School-level identifiers and sub-national level identifiers (e.g., state code, month and date of survey) are not included in the final analytic dataset to protect the privacy and confidentiality of individual respondents. The sampling variables in the dataset, required for use in analysis using complex sampling procedures, have been modified so that users cannot identify locations based on these variables. To reduce disclosure risk, primary sampling units (PSUs) with only one school will be collapsed with another PSU in the same stratum to create the PSUs used in the analysis. The variable on the analytic dataset that identifies the PSUs will be devoid of any information that can be used to identify the characteristics of the PSU.

All selected schools, students, and their parents will be informed that anonymity will be maintained throughout data collection, that all data will be safeguarded closely, and that no institutional or individual identifiers will be used in study reports. Anonymity and protection of privacy are promised to students on parental permission forms (Attachments H2, H3, H4, H5). Students will be reminded by the teacher that their responses are anonymous at the start of the survey administration session and the teacher will distribute a 5-digit classroom access code to all students in a given classroom. Teachers read verbatim to eligible students a prepared script (Attachment I2) that emphasizes anonymity and the voluntary nature of the survey. Access controls used to secure and protect collected data are listed in Table 2.

In the 2024-2026 administration, protection of participant confidentiality and privacy will be maintained during and after virtual administration of the survey. On the day of scheduled survey administration, the teacher will provide students with the survey URL and a unique classroom-specific access code. Students will use the classroom code to access the survey. Students are informed that, once they complete the survey or are inactive, the results are not stored in the browser they are using. Classroom access codes cannot be linked back to individuals. Use of the classroom-level access code avoids linking survey responses to individual students. If a student loses internet access during the survey or if they need to step away from the survey prior to submitting their responses, they can re-enter their classroom code on the same computer to resume the survey. Responses are locked after submission of the survey or after 30 minutes of inactivity. This procedure ensures that the student’s responses remain private and that they can resume the survey where they left off. Access controls are outlined in Table 2.

Table 2: Access Controls

Technical Controls	Physical Controls	Administrative Controls
• User identification • Passwords • Multiple Factor Authentication • Firewall • FedRAMP approved Encryption of data at rest and in transit	• Guards/Security Officers • 24-hour maintenance of Video/Audio of all data centers and all offices • Identification badges • Key Cards • Least privilege access to data centers • Security logs of access and appointments • CCTV surveillance at physical access points	1. No directly identifying information will be collected (thus, the Privacy Act does not apply). 2. Methods will be in place to ensure least privilege access. Data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. 3. All contractor staff involved with the project are required to take trainings on protection of information and privacy required by the government and contractor organizations. 4. NYTS data are currently stored on the FDA network in an access-restricted FDA shared directory folder. Two versions of this shared directory have been created, one version providing read-only access to files and the other version providing full access. The NYTS project leader, Dr. Karen Cullen, manages access to the shared directory. Currently, the files containing the raw and final data for each year of the NYTS are only accessible to the NYTS implementation team members.

11. Justification for Sensitive Questions

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. The CTP Research Involving Human Subjects Committee's (RIHSC) has determined that the National Youth Tobacco Survey (NYTS) meets the definition of "Public health surveillance activities" and therefore it does not constitute research as defined by the 2018 Common Rule (Attachment J). As such, the NYTS is not subject to review by FDA IRB.

Sensitive Questions

Certain questions asked during the survey about tobacco product use could be considered by some individuals to be sensitive. The survey instrument, previously approved by OMB for use in the 2024-2026 NYTS, includes questions about sexual orientation and gender identity, depression and anxiety, discrimination, and family/household affluence, all of which are associated with higher tobacco product use. The survey also captures information about neighborhood safety. In order to comply with the Executive Order 14168 (issued on January 20, 2025), titled "*Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,"* we propose to make the following updates to the sexual orientation and gender identity questions in the survey instrument for use in the 2026 NYTS: 1) combine response options for sexual orientation question to include "Straight or heterosexual," "Not heterosexual," and "Don't know/Decline to answer"; 2) remove questions on gender identity. Participants may choose to skip any question they are not comfortable answering. Furthermore, no protected personal information is being collected in this study that could trace responses back to individual students. Furthermore, no protected personal information is being collected in this study that could trace responses back to individual students.

The 2024 psychometric testing plan (attachment M), previously approved by OMB, proposed to examine four specific constructs: e-cigarettes, sexual orientation, and gender identity (SOGI), socio-economic status (family affluence, parental education level), and social determinants of health or health equity (neighborhood environment, discrimination). However, given that we propose to revise the sexual orientation question and remove questions on gender identity from the 2026 survey instrument to comply with the Executive Order 14168, we will remove comparable questions from the cognitive testing screener (attachment N4) and cognitive interview questionnaire (attachment N5) and remove a population segment for recruitment (20% of study participants to be individuals identifying as SOGI).

12. Estimates of Annualized Burden Hours and Cost

Federal tobacco control and surveillance activities must adapt to a dynamic product environment. From time to time, FDA may modify instrument content to reflect changes in the federal government's need for information to inform public health and regulatory activities. These modifications will be submitted to OMB through the Change Request mechanism.

12a. Annualized Hour Burden Estimate

Table 3a.--Estimated Annual Reporting Burden

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Total Annual Responses	Average burden per response	Total Hours
State administrators	State-level Recruitment Script	42	1	42	0.5 (30 min)	21
District administrators	District-level Recruitment Script	384	1	384	0.5 (30 min)	192
School administrators	School-level Recruitment Script	546	1	546	0.5 (30 min)	273
Teachers	Data Collection Administration Script	1,365	1	1,365	0.25 (15 min)	341
Students	National Youth Tobacco Survey	28,704	1	28,704	0.75 (45 min)	21,528
	Screening for Cognitive Interviews	300	1	300	0.17 (10min)	50
	Cognitive Interviews	30	2	60	2 (120 min)	120
	Pilot Testing	100	1	100	0.75 (45 min)	75
Total		31,471		31,501		22,600

The planned information collection involves administration of the NYTS questionnaire (Attachment H1) to independent samples of students during the spring semester. Respondents include state-level, district-level, and school-level administrators who provide information asked in the Recruitment Scripts for the NYTS (Attachments D2, E2, and F3), teachers who use the script to launch the web-based student survey (Attachment I2). Historically, an initial sample size of 420 schools was sufficient for recruiting the targeted number of schools and students. However, overall response rates have decreased drastically since the COVID-19 pandemic, ranging from 30.5% to 45.2% during 2020-2024 compared with pre-pandemic response rates of 63.4% to 84.8% during 1999-2019. Consequently, additional schools need to be recruited for the 2026 NYTS to reach the goal of obtaining at least 250 participating schools and produce nationally representative estimates. For the 2026 cycle of data collection, the total estimated number of respondents, by type, will include: state-level administrators (n=42), district-level administrators (n=384), and school-level administrators (n=546) who provide information in the Recruitment Script for the NYTS; teachers (n=1,365) who deliver the teacher script; and students (n=28,704) who receive instructions for and complete the NYTS questionnaire. There are no costs to respondents except their time.

Burden estimates are based on expected sample sizes and budget under the current contract for conducting the 2026 NYTS cycle. Due to changes in the relevant product environment, patterns of tobacco product use, or other factors, testing may be needed to assess new questions, changes in the wording of existing questions, or the response options associated with individual

questions. The burden table includes an allocation of 245 annualized burden hours for instrument testing activities. Cognitive testing of questionnaire content will typically be conducted in semi-structured interviews of two hours or less (30 interviews per year @ two hours per each of two interviews with the same respondent = 120 burden hours). In addition, FDA may conduct pilot tests to ensure that each year's NYTS questionnaire can be completed within one class period (100 tests per year @ 45 minutes each = 75 hours). Finally, the allocation for testing includes screening of up to 300 youth prior to participation in these testing activities (300 youth @ 10 minutes/response = 50 hours). Such respondent screening is needed to ensure that testing is conducted with individuals whose characteristics are similar to the NYTS target population of youth in grades 6-12. The configuration of testing activities may vary from year to year. Of those 300 screening respondents, no more than 30 may participate in cognitive testing (two responses @ two hours per response) and no more than 100 may participate in survey pretesting activities (@ 45 minutes a response). Each testing activity will be submitted to OMB as a Change Request.

Estimated burden for teachers and students remains the same per participant, with an increased number of each participant type. Students still have up to one 45-minute class period to complete the survey.

The total burden estimated for the NYTS and associated support activities is 22,600 hours. Totals for this cycle are provided in Table 3a.

12b. Annualized Cost Burden Estimate

There are no direct costs to the respondents themselves or to participating schools. However, the cost for administrators, teachers, and students can be calculated in terms of their time. In each category, the estimated respondent burden hours have been multiplied by an estimated average hourly salary for persons in that category. Wages are based on May 2023 national data on occupational employment and wages published by the U.S. Bureau of Labor Statistics (USBLS 2023). The estimated burden cost in terms of the value of time students spend in responding are based on a minimum wage for students aged less than 20 years of $4.25/hour. The total estimated respondent burden cost for conducting the 2026 NYTS is $131,811 (Table 3b).

Table 3b—Annualized Estimated Cost to Respondents

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Hourly Wage Rate	Total Respondent Costs
State administrators	State-level Recruitment Script	42	1	0.5 (30 min)	$58.65	$1,232
District administrators	District-level Recruitment Script	384	1	0.5 (30 min)	$58.65	$11,261
School administrators	School-level Recruitment Script	546	1	0.5 (30 min)	$53.75	$14,674
Teachers	Data Collection Administration Script	1,365	1	0.25 (15 min)	$35.48	$12,108
Students	National Youth Tobacco Survey	28,704	1	0.75 (45 min)	$4.25	$91,494
	Screening for Cognitive Interviews	300	1	0.17 (10min)	$4.25	$213
	Cognitive Interviews	30	2	2 (120 min)	$4.25	$510
	Pilot Testing	100	1	0.75 (45 min)	$4.25	$319
Total		31,471				$131,811

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There will be no respondent capital and maintenance costs.

14. Annualized Cost to the Federal Government

The NYTS currently is funded through 2027 under Contract No. 75F40120A0017. The current OMB application covers the 2024, 2025, and 2026 administrations of the NYTS. The total contract award to RTI International (Research Triangle Park, NC) to conduct the 2026 and 2027 NYTS is $4,996,564. The estimated cost of the contract, annualized over the two years of this clearance request, is $2,498,282. These costs cover the activities in Table 4 below.

Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of the study and in conducting data analysis. It is estimated that six FDA's CTP employees will be involved: two employees for approximately 20% of time (one at a salary of $53.66, another at a salary of $71.54 per hour), two employees 10% of time (both at salaries of $77.38 per hour), one employee 15% of time at a salary of $93.53 per hour, and one employee

60% of time at a salary of $79.65 (based on 2025 General Schedule Locality Pay Tables [Denver, CO; San Francisco, CA; Washington, DC]; for federal personnel, 100% time = 2,080 hours annually). The direct annual costs in FDA staff time will be approximately $52,083 + $32,190 + $29,181 + $99,403 = $212,858 annually. The total estimated annualized cost for the study, including the contract cost and federal government personnel cost, is $2,711,139.

Table 4: Estimated Annualized Study Cost

Activity	**Cost**
Contract Costs	
Design and plan	$27,679
Programming and developing	$153,677
Recruitment and preparation	$360,091
Printing and distribution	$0
Recruiting and training	$689,915
Collection of data	$794,865
Processing, cleaning, weighting and developing data files	$117,775
Dissemination and reporting of results	$354,280
Subtotal	$2,498,282
Federal Employee Time Cost	
20% time for two FTEs	$52,083
10% time for two FTEs	$32,190
15% time for one FTE	$29,181
70% time for one FTE	$99,403
Subtotal	$212,858
Total* Estimated Annualized Cost to the Federal Government	$2,711,139

**Components may not sum to this figure due to rounding; FDA's CTP funds are from user fees, not from appropriations.*

15. Explanation for Program Changes or Adjustments

The content of the 2026 instrument remains largely consistent with the past NYTS surveys. For 2024-2026, there are no changes to the estimated burden per response, the frequency of data collection for the survey instrument, the recruitment scripts, or the checklist used by teachers.

The overall burden is somewhat higher than the previous cycle due to the increased sample size because of declining response rates. The 2024-2026 NYTS approval was based on 30,806 annualized responses and 22,086 annualized burden hours for 2024. The 2026 NYTS is estimated to include 31,471 responses and 22,600 annualized burden hours.

Table 5: Annualized Estimates of Respondents and Burden, 2026 NYTS, with changes from 2024-2026 OMB approval

Type of Respondent	Form Name	No. of Respondents	Change from 2024	No. of Responses per Respondent	Average Burden Per Response (In Hours)	Total Burden (In Hours)	Change from 2024
State Administrators	State-level Recruitment Script	42	0	1	0.5 (30 min)	21	0
District Administrators	District-level Recruitment Script	384	+76	1	0.5 (30 min)	192	+38
School Administrators	School-level Recruitment Script	546	+126	1	0.5 (30 min)	273	+63
Teachers	Data Collection Administration Script	1,365	-132	1	0.25 (15 min)	341	-33
Students	National Youth Tobacco Survey	28,704	+595	1	0.75 (45 min)	21,528	+446
	Screening for Cognitive Interviews	300	0	1	0.17 (10min)	50	0
	Cognitive Interviews	30	0	2	2 (120 min)	120	0
	Pilot Testing	100	0	1	0.75 (45 min)	75	0
	Total	**31,471**	**+665**			**22,600**	**+514**

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation Plans

Data will be tabulated in ways that will address the purposes outlined in section 2. Data will be summarized using descriptive analyses, including percentages, means, and interquartile ranges (see Attachment K). Within-group comparisons will be made using chi-squared tests, ANOVA, and F-statistic, as appropriate. Multivariable analyses will be done using regression models.

1. *Estimate the prevalence of tobacco product use behaviors and behavioral determinants among middle and high school students overall and by sex, grade in school, and race/ethnicity*--Descriptive statistics (percentages and confidence intervals) will be calculated to address this objective.

2. *Assess whether tobacco product use behaviors and behavioral determinants vary by sex, grade in school, and race/ethnicity*--Cross tabulations, chi-squared analyses, and regression analysis initially will be conducted to address this objective.

3. *Describe trends in tobacco product use behaviors and correlates among middle and high school students overall and by sex, grade in school, and race/ethnicity*--Multiple regression analyses that control for *sex*, grade in school, and race/ethnicity and that simultaneously assesses linear and higher order time effects will be used.

Attachment K provides example tables demonstrating the analyses listed above.

Publication Plans

This information will be used to inform the development of policy briefs, official reports, and peer reviewed scientific papers for publication in journals. Annually, the official estimates of national youth tobacco product use typically are featured in CDC's *Morbidity and Mortality Weekly Report* (*MMWR)*. However, other NYTS findings have been published in high profile peer review journals such as the *Journal of the American Medical Association (JAMA)*, *American Journal of Public Health*, the *American Journal of Preventive Medicine*, and *JAMA Pediatrics.* Additionally, NYTS results and public-use data sets from 1999-2019 are currently available on the CDC web site at: https://www.cdc.gov/tobacco/about-data/surveys/historical-nyts-data-and-documentation.html . FDA and CDC's Office on Smoking and Health (OSH) collaborated in the past. As FDA plans to continue these collaborations following OSH's elimination, the agency is pursuing alternative dissemination channels to ensure public access to NYTS results and public-use datasets from both completed and upcoming survey cycles. To comply with the Executive Order 14303 (issued on May 23, 2025), titled "*Restoring Gold Standard Science,"* FDA plans to simultaneously release the public-use dataset on the same date as the first publication for that year of NYTS.

Time Schedule for the Project

The following represents our proposed schedule of activities for the NYTS. The end date for data collection is constrained by the dates on which schools close for the summer. In addition, given that some twelfth-grade students may be absent during the final weeks of the school year, it is highly desirable to complete data collection at least one month before schools close for the summer.

Table 6: Proposed Schedule of Activities for 2026 NYTS

Activity	**Time Period**
Recruit and schedule schools	Late Summer-Fall 2025 under current OMB No. 0910-0932, expires 05/31/2027
Program digital survey	<1 to 2 months
Train field data collectors	January 2026 under current OMB No. 0910-0932, expires 05/31/2027

Collect data	1 to 4 months (January to May)
Process data	3 weeks post end of data collection
Weight/clean data	3-4 weeks post end of data collection
Produce data file with documentation	4 weeks post end of data collection
Analyze data	4-7 weeks post end of data collection
Publish findings	8-10 weeks post end of data collection (pending agency clearances)
Release public data file	< 12 months post end of data collection

Data collection is currently scheduled to occur during January through May 2026. Results will be published by Fall 2026 initially and subsequently in peer-reviewed journals.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date of OMB approval of the data collection will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certificate.

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