Based on an evaluation of the information collection, we are retaining the currently approved estimates. Our assumptions regarding the time needed for the respective activities is based on our experience with the information collection and informal communications with respondents.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3070]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Youth Tobacco Survey

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 21, 2026.

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 0910–0932. 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.

National Youth Tobacco Survey 2027–2029

OMB Control Number 0910–0932—Revision

This information collection supports the development and implementation of the National Youth Tobacco Survey (NYTS), which is a key component of FDA's youth tobacco surveillance. By providing national estimates of youth tobacco use, the NYTS directly contributes to FDA's ability to effectively regulate tobacco use and prevent youth access to tobacco products in the United States. 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 surveillance research, including the NYTS, directly contributes to advancing the goals of Executive Order 14212: Establishing the President's Make America Healthy Again Commission, including the Make Our Children Healthy Again assessment, in three ways. First, the NYTS helps FDA CTP evaluate the effect of policies and regulations on efforts to reduce tobacco use, the leading cause of chronic disease and mortality in the United States. Second, the NYTS protects the health of children by influencing policies, regulatory action, public education campaigns, and compliance and enforcement efforts designed to decrease the likelihood of youth tobacco initiation and reduce youth tobacco use. Third, the NYTS gathers information about youth tobacco use by means of rigorous scientific methods.

The NYTS has been conducted since 1999 and serves as the gold-standard source of nationally representative estimates of youth tobacco use in the United States. In 2025, FDA assumed leadership of the NYTS from the Centers for Disease Control and Prevention (CDC). The collection was previously approved under OMB Control No. 0920–0621. The NYTS supports FDA's CTP in its efforts to reduce tobacco related disease and protect the health of children.

The survey will be conducted among a nationally representative sample of students attending public and private schools in grades 6–12. The survey will be digital, web-based, anonymous, self-administered, and will be taken on school or personal computers, tablets, or mobile devices. Information supporting the NYTS also will be collected from state-, district-, and school-level administrators and teachers. Information collected through the NYTS will be used to identify trends in youth tobacco use over time, and to inform the development of public education campaigns, policies and rules, and compliance and enforcement programs for tobacco products.

The survey will examine the following topics: use of e-cigarettes, cigarettes, cigars, smokeless tobacco (chewing tobacco, snuff, dip), hookahs, pipes, snus, nicotine pouches, other oral nicotine products, bidis, heated tobacco products, and roll-your-own cigarettes; knowledge and attitudes; media and advertising; access to tobacco products and enforcement of restrictions on access; secondhand smoke and e-cigarette aerosol exposure, and cessation.

In the **Federal Register** of May 4, 2026 (91 FR 23995), FDA published a 60-day notice requesting public comments on the proposed collection of information. Eight comments were responsive to the Paperwork Reduction Act (PRA) information collection topics solicited.

(Comment) Seven commenters expressed support for the continuation of the NYTS, with several describing it as the ''gold-standard'' and only nationally representative, school-based survey focused exclusively on youth tobacco use. Commenters emphasized the survey's value in tracking product trends, identifying emerging tobacco products, informing regulatory and enforcement actions, and supporting public health programs at the federal, state, and local levels. The State Attorneys General specifically endorsed the proposed sample size increase to maintain statistical rigor in light of declining school-based response rates.

(FDA response) FDA acknowledges and appreciates the strong support for NYTS continuation expressed across all comments. The NYTS has been administered since 1999 and has served as an essential surveillance tool for identifying trends in youth tobacco and nicotine product use, informing regulatory action, guiding public health programs, and supporting enforcement at the federal and state levels. FDA remains committed to the annual administration of the NYTS and to maintaining the scientific rigor necessary for the data to serve these functions.

(Comment) One commenter expressed support for the continuation of the NYTS and urged FDA to publish the 2025 NYTS analysis and results consistent with prior years, noting that the release of raw data without an accompanying analysis limits the

accessibility and utility of the data for clinicians, public health practitioners, and policy makers. The commenter also made recommendations regarding FDA's review of premarket tobacco applications for flavored electronic nicotine delivery systems.

(FDA response) FDA appreciates the commenter's support for the NYTS and acknowledges the concern regarding the timely publication of analysis and results. FDA is committed to ensuring that NYTS findings are made publicly available in a timely manner. To comply with Executive Order 14303, titled ''Restoring Gold Standard Science,'' FDA plans to simultaneously release the public use dataset to coincide with the first publication for a given year of the NYTS. The commenter's recommendations regarding premarket tobacco product applications are outside the scope of this information collection request and will not be addressed here.

(Comment) One comment raised methodological concerns regarding declining school-based response rates, which fell from 77.2% in 2019 to 36.0% in 2025. This decline was attributed in part to the proliferation of state laws requiring active parental consent for youth surveys and expressed concern about potential nonresponse bias and diminished representativeness of recent NYTS estimates. The commenter recommended FDA: (1) conduct and publish an updated nonresponse bias analysis; (2) explore passive (opt-out) parental consent procedures where permissible; (3) evaluate alternative or complementary sampling approaches, such as address-based sampling; (4) enhance transparency around methodology changes and data limitations; and (5) support triangulation with other national and subnational data sources to validate findings.

(FDA response) FDA shares the concern about declining response rates and recognizes that this trend may have meaningful implications for the representativeness and comparability of NYTS data. The proposed increase in the total numbers of schools and students sampled for 2027–2029 reflects FDA's effort to accommodate declining response rates in school-based surveys and continue producing nationally representative data. Responses to each recommendation are as follows:

(1) *Nonresponse bias analysis:* FDA conducts a nonresponse bias analysis each year in accordance with OMB requirements. While the full nonresponse bias report is not made publicly available due to concerns about the potential disclosure of school-level information that could compromise respondent confidentiality, the publicly available methodology report provides a detailed description of the development of nonresponse bias-adjusted weights and calibration procedures. Additionally, a recently published paper reported findings from a nonresponse bias analysis assessing the impact of early termination of the 2025 NYTS data collection (Park-Lee et al., 2026).

(2) *Passive parental consent:* NYTS already employs passive parental consent as its default procedure. Unless a school requires active parental permission, NYTS follows passive parental consent procedures. Based on recent NYTS data collection cycles, approximately 10% of respondents are estimated to require active parental consent. FDA will continue to monitor developments in state-level consent requirements and their potential effects on survey participation and representativeness.

(3) *Alternative or complementary sampling:* Meaningful changes to the NYTS sampling design would need to be evaluated carefully against potential impacts on data comparability, the financial and logistical resources required, and the ability to maintain the precision of national estimates and estimates of population groups. FDA will consider assessing the feasibility of alternative or complementary sampling strategies, including address-based sampling (ABS).

(4) *Transparency around methodology and data limitations:* FDA remains committed to transparency regarding methodological changes and data limitations. The annual methodology report published with the public-use files provides clear guidance on the appropriate interpretation of NYTS data, including the implications of weighting adjustments and changes in sampling procedures.

(5) *Triangulation with other data sources:* As part of its nonresponse bias analysis and dissemination efforts, FDA triangulates with other national and subnational data sources to validate and contextualize estimates. These include both school-based and household surveys, including the Youth Risk Behavior Survey (YRBS), Monitoring the Future (MTF), the Population Assessment of Tobacco and Health (PATH) Study, and the National Survey on Drug Use and Health (NSDUH). Continued cross-survey triangulation enables FDA to identify potential nonresponse bias and assess consistency of trend estimates.

(Comment) Another comment suggests FDA to: (1) include brand-specific product images alongside brand-name response options for e-cigarette use questions, citing published studies and original analyses of NYTS 2024–2025 data demonstrating substantial discordance between self-reported brand use and reported device type and flavor; and (2) reinstate the 2024 NYTS follow-up question on the age of social sources of e-cigarettes, which was removed from the 2025 survey, to help assess the potential impact of device-access restrictions.

(FDA response) FDA appreciates the recommendations regarding the visual presentation of product options and the reinstatement of a follow-up question on social sources of e-cigarettes.

(1) *Brand-specific product images:* FDA acknowledges the evidence of discordance between self-reported brand use and reported device type and flavor. However, NYTS includes selected non-branded product images because a brand encompasses a wide variety of products, and it is not feasible to include every product available on the market. Non-branded images representing commonly recognizable device types are intended to aid respondent comprehension of the product category, and respondent burden is considered when evaluating expansions to the image set.

(2) *Reinstatement of the follow-up question on age of social sources:* Question-level decisions reflect careful consideration of scientific priority, policy relevance, and respondent burden. FDA will consider the recommendation as part of its ongoing review of the NYTS questionnaire for future data collection cycles.

(Comment) One commenter expressed support for the continuation of the NYTS and raised concerns about the timeliness and transparency of the NYTS data dissemination, recommending that FDA publish a prospective calendar of NYTS milestones, including questionnaire availability, fielding periods, data release dates, and report publication timelines, and that datasets be released concurrently with initial findings rather than in a piecemeal fashion. With respect to survey content, it was recommended that FDA incorporate emerging product categories and brands as response options more quickly and increase stakeholder engagement to inform timely survey updates; consider a supplemental fall NYTS to provide more frequent trend monitoring; add consumption frequency and initiation questions across all product categories; expand reasons-for-use questions to cover heated tobacco products, nicotine pouches, and oral nicotine products; and refine access source measures to

better distinguish between commercial and social sources of tobacco products.

(FDA response) Regarding the timeliness of survey results and data dissemination, there are several factors that affect how quickly analysis results are released, including the peer-review process for publications and several levels of internal and external review. Because publication schedules and timelines vary across products we cannot always predict publication dates in advance. To comply with Executive Order 14303, titled 'Restoring Gold Standard Science,' FDA plans to simultaneously release public-use datasets to coincide with the first publication for a given year of the NYTS. FDA will also explore opportunities to improve transparency around the NYTS process and timeline to the extent practicable. Additionally, as part of the PRA review process, the proposed survey instrument is made publicly available in the docket, allowing the public to view the instrument. A copy of the questionnaire is also included with the release of the public-use dataset and its accompanying documentation, providing further transparency and access for researchers and other data users. With respect to incorporating emerging product categories, NYTS is a federal survey subject to the Paperwork Reduction Act and regulated by OMB. Thus, NYTS is not designed as a rapid surveillance tool with the opportunity to add new items quickly in response to emerging products. FDA conducts environmental scans using a variety of sources to predict potential items to add or remove in advance of seeking OMB approval and consults with subject matter experts and stakeholders. Regarding the recommendation for a supplemental fall NYTS, any meaningful change to the frequency or structure of NYTS data collection would require additional OMB approval and careful evaluation of associated burden and resource implications. Within these constraints, FDA will take the commenter's survey content recommendations under consideration for future data collection cycles.

(Comment) One commenter recommends that FDA add a standalone NYTS measure for ''premium cigars'' as a distinct product category, using the definition codified at 21 CFR 1107.12, accompanied by plain-language descriptors and respondent clarifications to help youth distinguish premium cigars from cigarillos, filtered cigars, flavored cigars, and other mass-market cigar products. The commenter argues that the current aggregation of premium cigars with other cigar product types is inconsistent with FDA's own regulatory treatment of premium cigars and produces data of insufficient utility for FDA's current regulatory functions.

(FDA response) FDA appreciates the commenter's recommendation and acknowledges that premium cigars are treated as a distinct product category under 21 CFR 1107.12. However, FDA does not believe it is appropriate or feasible to incorporate this regulatory definition into the NYTS instrument. The definition requires that a product satisfy eight specific technical criteria. Even with plain-language descriptors and clarifications, it is unlikely that youth could reliably identify whether a product they used meets this definition, introducing significant measurement error. The explanatory text necessary to operationalize this definition for youth would also substantially increase respondent burden. Additionally, available evidence suggests that premium cigars, as defined under 21 CFR 1107.12, represent a small share of cigar use among youth, who are more likely to use mass-market products such as cigarillos and filtered cigars.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	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.	555	1	555	0.5 (30 min)	278
Teachers	Data Collection Administration Script.	1,388	1	1,388	0.25 (15 min)	347
Parents/guardians	Active Consent Script	3,500	1	3,500	0.17 (10 min)	595
Students	National Youth Tobacco Survey.	29,579	1	29,579	0.75 (45 min)	22,184
	Screening for Cognitive Interviews.	417	1	417	0.08 (5 min)	33
	Cognitive Interviews	97	1	97	1 (60 min)	97
Total		35,962				23,747

Our estimated burden for the information collection reflects an overall increase of 1,147 hours and a corresponding increase of 4,461 responses. For 2027–2029, there are no changes to the frequency of data collection for the survey instrument. The burden per response is approximately the same for state and district administrators, school administrators, and teachers. We added burden estimates for parents who complete active consent forms (*i.e.,* forms that must be returned in order for their child to participate) to account for states' increased reliance on this type of consent. The total number of students sampled increased slightly between 2024–2026 and 2027–2029, increasing the burden slightly. This change is to accommodate declining response rates for school-based studies, in other words, the need to sample a greater number of students to get the same number of survey responses. The burden for cognitive interviews is roughly equivalent.

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