July 6, 2026

The Honorable Kyle Diamantas
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Submitted electronically via regulations.gov

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; National Youth Tobacco Survey

Dear Acting Commissioner Diamantas,

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,500 family physicians and medical students across the country, we appreciate the opportunity to comment on the notice published in the Federal Register on May 4, 2026, regarding the National Youth Tobacco Survey (NYTS). The FDA states that 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.

On behalf of family physicians who routinely care for patients with smoking- and tobacco-related chronic diseases, the AAFP strongly recommends the FDA:

- Continue current and future annual data collection of youth tobacco use through the National Youth Tobacco Survey;
- Publish data analysis and results of the 2025 National Youth Tobacco Survey in alignment with previous years;
- Enforce FDA's risk-proportionate evidentiary standard for premarket tobacco product applications by withdrawing recent approvals of harmful flavored electronic nicotine delivery systems (ENDS).

Since its annual implementation in 2004, the NYTS has been the only nationally representative survey that provides annual data on tobacco and nicotine use among middle school students and the most comprehensive dataset for high school students. It captures a wide range of products, including cigarettes, cigars, e-cigarettes, heated tobacco products, nicotine pouches, and emerging synthetic products. This breadth is critical in a rapidly

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evolving marketplace. In addition to measuring product use, the NYTS provides data on the factors that influence youth behavior, including exposure to tobacco-related messaging, perceptions of risk, social influences, access points, dependence indicators, and cessation behaviors. It also analyzes vital contextual measures such as mental health and school connectedness.

NYTS data are central to FDA's ability to meet its statutory obligations under the Family Smoking Prevention and Tobacco Control Act. The timeliness of NYTS data and analysis has been particularly instrumental in identifying and responding to rapid shifts in youth behavior. During the surge in youth e-cigarette use in the late 2010s, NYTS was the only national source capturing both the scale and pace of uptake, informing federal enforcement actions, product restrictions, and critical policies including *Tobacco 21* legislation which raised the minimum purchase age to 21.[i] NYTS findings have also been used to evaluate public education campaigns and identify populations at higher risk, supporting targeted interventions at the federal, state, and local levels. Without consistent, annual data, the agency's ability to monitor trends, assess product-specific risks, and evaluate the impact of regulatory actions would be significantly limited. **For these reasons, the AAFP encourages the FDA to maintain annual administration of the NYTS and supports the proposed scope of topics covered.**

However, we are concerned that the FDA did not publish an accompanying analysis or report for the 2025 NYTS, despite doing so in prior years. While the release of raw data is important, it is not sufficient. Most stakeholders, including clinicians, public health practitioners, patient advocates, and policymakers, rely on FDA's analysis to interpret findings and understand their implications. The absence of a 2025 report represents a departure from established practice and limits the accessibility and utility of the data. **Accordingly, we urge the FDA to publish the 2025 NYT analysis and results, consistent with prior years.** Timely publication of clear, agency-led analysis is a core component of effective public health surveillance. It ensures that findings are interpretable, supports transparency, and enables evidence-based regulatory action to protect American children and young adults from nicotine addiction.

Further, the continued proliferation of flavored ENDs continues to drive youth initiation, accelerating nicotine dependence, and imposing substantial and avoidable health and economic burdens. Despite modest declines since 2018, millions of adolescents continue to use e-cigarettes, with nearly 90% of whom use flavored products that mask harshness, facilitate uptake, and promote sustained use.[ii] Several qualitative studies further demonstrate that flavored, high-nicotine products mask the harshness of tobacco, lowering barriers to experimentation and promoting continued use among youth.[iii,iv]

Early exposure to flavored ENDS creates a clear pathway to long-term nicotine dependence and increased risk of chronic disease in adulthood. This risk is compounded by product characteristics, including high nicotine concentrations, disposable designs, and emerging "smart" technologies that promote habitual use. Substantial evidence demonstrates that

nicotine exposure during adolescence adversely affects brain development, worsens mental health outcomes, and increases the likelihood of long-term tobacco use.[v,vi] Longitudinal evidence from the Population Assessment of Tobacco and Health (PATH) study further show that youth whose first tobacco product was flavored are significantly more likely to become persistent tobacco users compared to those who initiate with non-flavored products.[vii]

Market trends reinforce these concerns. Nicotine concentrations in ENDS products have increased disproportionately relative to overall product sales, indicating intentional amplification of addictive potential. At the same time, the widespread availability of unauthorized products, many of which are flavored and youth-oriented, continues to undermine regulatory controls and exacerbate youth uptake.[viii,ix]

Collectively, these data make clear that flavored ENDS products pose substantial population-level risks that far outweigh the limited and inconsistent evidence of adult cessation benefit. Notably, recent raw data from the FDA's 2025 National Youth Tobacco Survey indicate that candy and mint flavors may be associated with comparable levels of youth ENDS use. This evidence makes clear that youth appeal is not always confined to any single flavor category and cautions against regulatory approaches that rely on flavor-based distinctions alone. While tobacco-flavored products represent comparatively lower risk to youths compared to non-tobacco flavors, **current evidence does *not* consistently demonstrate that non-tobacco flavors confer meaningful improvements in long-term cessation outcomes.**

Consistent with this evidence, the AAFP's longstanding policy on ENDS does not recommend the use of ENDS as a smoking cessation device. Youth initiation introduces new nicotine-dependent individuals into the population, expanding the overall burden of addiction and disease. By contrast, adult ENDS use most often reflects substitution among individuals who already use nicotine and does not reliably lead to complete or sustained cessation. Accordingly, the AAFP reiterates our prior comments on FDA's draft guidance for flavored ENDS premarket authorizations, that products with demonstrated youth appeal should not meet the statutory "Appropriate for the Protection of the Public Health" (APPH) standard absent clear and compelling causal evidence of sustained adult cessation benefit. The FDA's regulatory framework must align evidentiary expectations with the magnitude of youth risk, consistent with its obligation under Section 910(c)(4) of the Federal Food, Drug, and Cosmetic Act to evaluate population-level harms and benefits.

The AAFP further urges the FDA to rigorously apply the proposed risk-proportionate evidentiary standard in its review of premarket tobacco product applications, as outlined in its draft guidance. **This includes reassessing—and, where appropriate, withdrawing—recent authorizations of flavored ENDS products that fail to demonstrate a clear net public health benefit.** Doing so is necessary to uphold the integrity of the APPH standard, strengthen the PMTA review process, and ensure that regulatory decisions consistently prioritize youth protection and long-term disease prevention.

We thank you for the opportunity to provide comments on this important issue. Should you have any questions, please contact Sahana Chakravartti, Regulatory Specialist, at schakravartti@aafp.org.

Sincerely,

Jen Brull, MD, FAAFP
American Academy of Family Physicians, Board Chair

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