

United States Food and Drug Administration

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

OMB Control No. 0910-0810

SUMMARY OF GEN ICs

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
Nicotine Education Project	September 7, 2022 – October 24, 2022	2,003	Results helped to identify key nicotine misperceptions among youth and young adults aged 15 -24, including harms of nicotine, and examine how nicotine misperceptions and health concerns vary by product type (cigarettes, vapes, and nicotine replacement therapies (NRTs) and other characteristics. Information obtained through this study also helped FDA assess youth and young adults’ awareness and relative harm/addictiveness perceptions of synthetic nicotine and the extent to which nicotine-related knowledge, attitudes, and behaviors vary by age and tobacco use history.	901
The Real Cost Campaign: Media Tracking Study	March 5, 2024 – April 9, 2024	451	The objective of the study was to monitor awareness and receptivity of FDA’s public education efforts, as well monitor and validate changing knowledge, attitudes, beliefs, and behaviors related to tobacco use in youth and young adults. Information obtained through this research has helped to optimize advertising concepts designed to	351

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
			prevent tobacco use among youth aged 13 to 17 and young adults aged 18 to 20 who either: 1) are at risk of initiating use of vaping products, or 2) have experimented with vaping products.	
Formative Research Support: Outcomes and Awareness Measurement Research	July 28, 2022 – September 19, 2022	4,009	Results provided valuable insights that has informed the ongoing evaluation of the Real Cost media campaign. An online survey was conducted among youth aged 13-17 to 1) examine the extent to which the distribution and accuracy of self-reported awareness varies across different awareness assessment approaches; and 2) led to the development of comprehensive, valid, multi-item scales to measure outcomes such as addiction perceptions, expectations of feeling anxious after using tobacco, and other key predictors of tobacco use that campaign messages aim to change.	1,078
Testing Message Evaluation Measures Using Youth-focused Vaping Prevention Messages	September 16, 2022 – October 24 2022	2,147	The objective of the study was to determine valid measures to use in evaluating youth-targeted anti-tobacco messaging. The results of this study have been used to inform the selection of optimal message evaluation measures for evaluating the relative potential effectiveness of campaign messages prior to tobacco public education campaigns launch.	816
Promising Themes Study	October 18, 2022 –	1,665	This study collected primary data to assess agreement with specific	920

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
	February 1, 2023		beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), marijuana, and smokeless tobacco. Information obtained through this study has informed FDA’s public education programs to reduce tobacco-related death and disease, and helped to develop new media campaign messages related to tobacco products that resonate with youth and young adults ages 15 to 30 years old in the United States.	
The Real Cost Campaign (W3): Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use	October 18, 2022 – November 3, 2022	304	The objective of the study was to develop appropriate messaging to inform youth about the risks of using tobacco products and to gain insight into youth perceptions of (electronic nicotine delivery systems) ENDS and cigarettes and reactions to draft advertising concepts. Information obtained through this study has been used to develop and refine messaging related to preventing ENDS use among youth aged 13 to 17 who are at risk of initiating or who have experimented with ENDS products.	142
Monthly Monitoring Study: Little Cigar, Cigarillo, and Blunt Use Audience Insights Survey	March 1, 2023 – June 2, 2023	1,501	This study collected primary data to better understand use and perceptions of blunt and little cigars and cigarillos (LCCs) among youth and young adults ages 15-24 in the United States. The results of this study has helped FDA develop new public education programs that	854

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
			resonate with youth and young adults who are most at risk for use.	
Survey of Risk Factors of Lithium-Ion Batteries used in ENDS	January 3 - 26, 2023	6,010	This study collected information from current adult users of electronic nicotine delivery systems (ENDS) to better understand the products, user characteristics, circumstances, and outcomes associated with incidents of overheating, fire, and explosion (O/F/E) related to the use of lithium-ion batteries in ENDS. Results from this study have supported FDA’s efforts to understand the causes of ENDS-related O/F/E incidents and identified ways in which FDA may decrease the frequency of ENDS-related O/F/E incidents.	1,718
Hispanic/Latino Youth and Young Adult Tobacco Use Online Survey Study	March 27, 2023 – April 10, 2023	1,758	Results informed FDA’s understanding of the Hispanic youth and young adults who may be at higher risk of Electronic Nicotine Delivery Systems (ENDS) and other tobacco use. The results of this study has 1) informed efforts to develop communication strategies and messaging among Hispanic youth/young adults in the United States who are susceptible non-triers and experimenters of ENDS products as well as dual or poly tobacco users; 2) examined risk and protective factors for ENDS use across different segments of the Hispanic population; and 3) explored how intersections between Hispanic identity and key	932

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
			demographics affect risk/susceptibility and use of ENDS and other tobacco products.	
Increasing Understanding of Digital Advertising: Hookah Beliefs Survey	April 20, 2023 – May 10, 2023	1,200	This study assessed current knowledge, attitudes, and beliefs (KABs) about hookah use and identified KABs that could be targeted in a digital campaign. Results of the survey helped FDA to better understand: 1) the level of agreement with hookah-related beliefs among young adults ages 18-24 years old in the United States, and 2) whether hookah-related beliefs are likely to change as a result of exposure to a future digital media campaign among young adults ages 18-24 years old in the United States.	488
Increasing Understanding of Digital Advertising: Awareness, Receptivity, and Comprehension (ARC) Experiment	Did not field	0	In response to shifting priorities, FDA redirected resources to other initiatives. As a result, the study was put on hold until further notice. FDA will reassess the situation to determine if it is still a priority and if it can be accomplished with the available resources. The outcome of the study would have assessed the influence of hookah public education video advertisements delivered through digital media channels on knowledge, attitudes, and beliefs (KABs) about hookah use among young adults aged 18 to 24-years and would have supported the implementation of tobacco public education campaigns for	0

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
			youth and young adults that rely on digital media channels.	
Copy Testing of Tobacco Prevention and Cessation Advertisements Research Study	August 16, 2023 – September 12, 2023	804	Results informed FDA’s formative approach to ad development. An online survey was conducted among youth aged 13-17 who have used or are susceptible to use of electronic nicotine delivery systems (ENDS) or cigarettes to understand the extent to which reactions to tobacco prevention messaging and patterns of ad reaction scores vary between pre- and post-production ad versions.	612
Gathering Consumer Feedback on the Real Cost Campaign (Cigarette Ad Focus)	March 5, 2024 – April 8, 2024	900	Results provided to valuable insights into youth awareness and receptivity to the FDA’s The Real Cost campaign. Information obtained through this study has helped to develop and refine messaging related to preventing cigarette use among youth aged 13 to 17 who are at risk of initiating or who have experimented with cigarettes.	543
Menthol User Audience Research	October 26, 2023 – December 29, 2023	1,004	Results provided FDA with insights on audience segments of adult menthol smokers. Results of the survey has helped FDA build upon its knowledge base about the demographic, behavioral, psychographic, and sociocultural characteristics of people who smoke menthol cigarettes which has led to the development of data-driven profiles of adult menthol cigarette smokers.	700

Title of Gen IC	Date(s) Conducted	Number of Participants	How the Information Was Used	Hours Used
Gathering Consumer Feedback on the Real Cost Campaign (ENDS Ad Focus)	August 2, 2024 – September 17, 2024	5,442	Results of the study will provide FDA with valuable insights into youth awareness and receptivity to the FDA’s The Real Cost campaign. Information obtained through this study will help to develop and refine messaging related to preventing ENDS use among teens aged 13 to 17 who are at risk of initiating or who have experimented with ENDS.	1,077
Kantar Media Study: The Effect of FDA Messaging on Tobacco Product Risks on Attention, Perceptions, and Behaviors among Young People	Anticipated to start late September 2024	0	Results will provide FDA with information to assess exposure to FDA messages developed to prevent initiation and reduce use of ENDS among young people. Information obtained through this study will be used to understand the impact of exposure to the campaign’s digital messaging; to optimize media frequency and placement; and to inform future media planning.	0
Think Out Loud" Post-Market Research on the Effectiveness of the "Next Legends" Campaign	Anticipated to start October 2024	0	Results will provide FDA with insights into FDA’s efforts to implement a campaign educating American Indian and Alaska Native teens about tobacco use.	0