U.S. Food and Drug Administration
Center for Tobacco Products
Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications
OMB Control Number 0910-0810
"FDA Tobacco Prevention Broad Quantitative Research Package"

Change Request October 2022

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to account for the misuse of a previously approved individual generic request under control number (0910-0810). The individual Gen IC titled "FDA Tobacco Prevention Broad Quantitative Research Package" utilized by the Office of Health Communication and Education (OHCE) in the Center for Tobacco Products (CTP) operated inconsistently within the spirit and guidance covering generic clearances**.** The individual Gen IC was approved (hereafter, referred to as the "approved Gen IC") to enable OHCE to pursue a quantitative data collection to assess consumer reactions to tobacco prevention messaging advertisements (called "copy testing"). OHCE CTP conducted two copy testing studies that relied on similar methodology and study approaches as found in the approved Gen IC for a copy testing data collection. However, the study materials and participant samples in the two completed copy testing studies deviated from what was described in the approved Gen IC. As such, instead of utilizing the burden from the approved Gen IC, OHCE CTP should have sought OMB review and approval of the two copy testing studies (hereafter, referred to as the "two unapproved studies"). Collectively, the two unapproved studies used 898 burden hours (Study 1: 449 hours and Study 2: 449 hours) out of 5,596 stated in the approved Gen IC.

This memo describes the two copy testing studies that were improperly conducted under the approved Gen IC for copy testing data collections. While we are not submitting these collections for approval or review as part of new Gen ICs, we are submitting updated materials to ensure that the administrative record is clear as to what occurred and ensure that the appropriate burden hours are accounted for.

Overview of the Original Collection in the Approved Gen IC

The Gen IC ("FDA Tobacco Prevention Broad Quantitative Research Package") collection, was approved in March of 2020 with approval through March of 2023. OMB approved 5,500 youth (13-17) respondents and 5,500 adult respondents (18-54) who were susceptible to, or users of, tobacco products. To achieve this number, we anticipated needing to screen 8,250 youth and 8,250 adults.

Under the approved Gen IC for copy testing data collection, respondents are to be recruited through an online self-administered survey through a web-based panel. The data collection under the approved Gen IC is intended to measure youth and adult perceptions of various tobacco-related facts and messages to learn about opinions of tobacco product education messaging, tobacco-related facts and tobacco related knowledge, attitudes, and beliefs (KABs) in copy testing.

Updates Made to Study Materials, Relevant Documents, and Supporting Statements associated with the previously approved Gen IC to Account for Two Copy Testing Studies

The two copy testing studies (described in subsequent sections in the memo) have study aims and protocols that are similar to the approved Gen IC. We are submitting supporting statements for each

of the two unapproved studies. The submitted documents in the current memo also contain all study materials and the study protocols for both unapproved studies.

The total amount of burden in the two unapproved studies (449 hours for Copy Testing Study 1; 449 hours for Copy Testing Study 2) did not exceed the 5,596 approved burden hours for the approved Gen IC (See Tables 1 and 2).

Copy Testing Study 1: "The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use"

This research assessed the performance of ads developed to prevent initiation and reduce use of e-cigarettes and cigarettes among at-risk youth and assess potential adverse or unintended consequences of viewing these ads. To address these objectives, researchers conducted online copy testing (survey) research with youth. Qualified youth were invited to complete the full Questionnaire. Participants were randomly assigned to either an ad-viewing group or a non-ad viewing (control) group. All participants answered a series of questions about tobacco use and exposure as well as general questions about their attitudes and beliefs about the harms of tobacco use. The questions that target general attitudes and beliefs about the harms of tobacco use were used to assess message efficacy and potential unintended consequences by comparing responses between the ad-viewing and control groups. Participants randomly assigned to the ad-viewing group completed additional questions designed to assess whether the advertisements provide an understandable and engaging message about the harms of e-cigarette or cigarette use. See Appendix A for the study materials, study protocol, and IRB approval document for Copy Testing Study 1.

Table 1. Estimated Annual Reporting Burden for Copy Testing Study 1

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Screened Youth	*Screener completion*	*2,008*	*1*	*2,008*	*0.083 (5 min)*	*167*
Parents of Invited Youth	*Email invite and Parental notification and opt-out process*	*2,008*	*1*	*2,008*	*0.033 (2 min)*	*66*
Youth Respondents	*Youth assent*	*2,008*	*1*	*2,008*	*0.033 (2 min)*	*66*
	Questionnaire completion	*450*	*1*	*450*	*0.333 (20 min)*	*150*
Total Annualized Hours						***449 hours permitted***

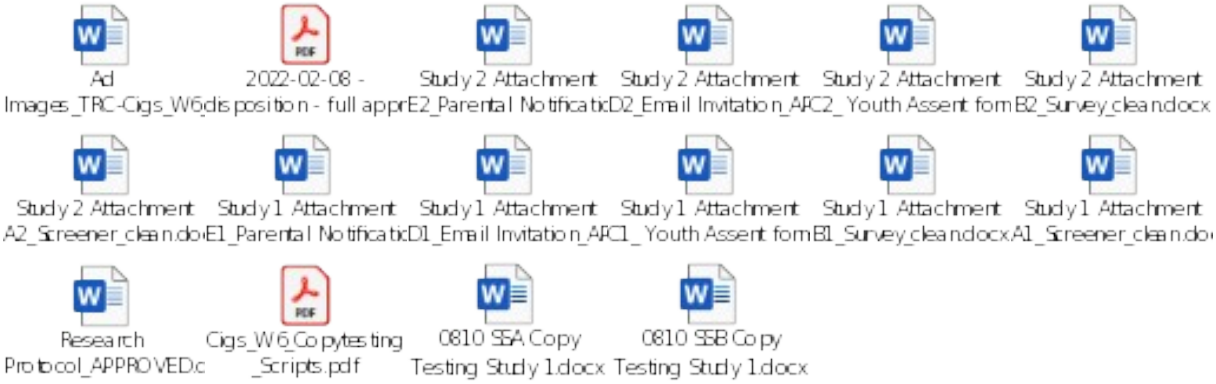
Copy Testing Study 2: "Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use"

The goal of this study was to help CTP refine the messaging strategies for its Multicultural Campaigns by assessing reactions of the campaign target audience to video advertisements designed to prevent tobacco use among multicultural youth. Research was conducted online, through a web panel, with US youth ages 13 to 17 who either are tobacco users or are non-users who are susceptible to using tobacco (susceptible non-users). Participants were recruited using online research panels and completed an online screener survey to determine eligibility (ages 13-17, tobacco user or susceptible non-user, residing in the US). Qualified youth were invited to complete the full questionnaire, where they were randomly assigned to either the ad-viewing condition or the control condition where they did not view an ad. Study aims were: (1) to assess if the ads provide an understanding and engaging message, as measured via perceived effectiveness score, open-ended feedback, and attitudinal responses to the ads; and (2) to ensure no potential unintended adverse or counterproductive effects within the target audience from viewing the ads, as measured via comparison of ad-viewing and control participants' responses to a series of tobacco knowledge, attitude, and belief items. See Appendix B for the study materials, study protocol, and IRB approval document for Copy Testing Study 2.

Table 2. Estimated Annual Reporting Burden for Copy Testing Study 2

Type of Respondent	**Activity**	**Number of Respondents**	**Number of Responses per Respondent**	**Total Responses**	**Average Burden per Response (in hours)**	**Total Hours**
Screened Youth	*Screener completion*	*1,198*	*1*	*1,198*	*0.116 (7 min)*	*140*
Parents of Invited Youth	*Email invite and Parental notification and opt-out process*	*1,198*	*1*	*1,198*	*0.083 (5 min)*	*100*
Youth Respondents	*Youth assent*	*1,198*	*1*	*1,198*	*0.083 (5 min)*	*100*
	Questionnaire completion	*261*	*1*	*261*	*0.417 (25 min)*	*109*
Total Annualized Hours						***449 hours permitted***

APPENDIX A: Copy Testing Study 1 Study Materials, Study Protocol, and Supporting Statements



APPENDIX B: Copy Testing Study 2 Study Materials, Study Protocol, and Supporting Statements