

UNITED STATES FOOD & DRUG ADMINISTRATION

National Panel of Tobacco Consumer Studies OMB Control Number 0910-0815

Change Request

April 27, 2020

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to update the incentive delivery mode. Due to the coronavirus (COVID-19) pandemic, and the resulting reduction in contractor capacity for on-site research operations including respondent incentive mailings, FDA seeks OMB concurrence of a change for incentive payments. We plan to modify our research protocol to allow for an additional mode of delivery for the \$15 incentive for completion of TCS topical studies. The change would allow for the provision of a \$15 digital gift card, delivered via email, while retaining the flexibility to support cash incentive payments, if possible, during study data collection. There is no change to the amount of the incentive, only to the delivery mode.

We are requesting OMB approval of this change request by May 8, 2020 to maintain the topical study web and mail data collection schedule.

Overview of the Change Request

- Develop a brief message for web-mode panelists *who have not yet completed the study*, that will be deployed at the beginning of the topical surveys (Studies B and C) to inform them of the option to select either a cash incentive or digital VISA card due to the COVID-19 situation, noting that the option is intended to provide respondents with their incentive quickly. Panel members will be required to provide a current email address through which they will receive instructions and a link to access and redeem their online card.
- Revise the closing script in the topical survey instruments (Studies B and C) to reflect both the digital and cash incentive options.
- For respondents who choose the digital incentive option, script an email message thanking the panel member for their survey participation and providing the necessary information to access/redeem their digital VISA gift card, including the value and expiration date. Use currently approved language from the incentive/thank you letter as appropriate.
- Panel members who opt to receive a cash incentive will receive the approved incentive letter with their incentive payment.
- Update several web nonresponse follow-up letters/postcards to remove the word “cash” when referring to the \$15 incentive.

Change Documentation

Tracked versions of the Supporting Statements, English- and Spanish-language questionnaires and respondent materials are provided as attachments below.



Table 1 summarizes the revisions to the Study B and Study C questionnaires. The same changes have been made in each questionnaire. The respondent materials revisions are detailed in **Table 2**. **Table 3** summarizes the changes made to the Supporting Statement Part A and B.

Table 1. Summary of Changes or Additions to Questionnaires, Attachments 1 and 2

Questionnaire	Item number ¹	Page Number ²	Type of Change	Change	Rationale
Study B <i>Attachments 1-18, 2-18</i>	Web Survey Consent	76 (79)	Edit	Revised skip instruction for “Yes” responses.	Revised to route respondents to the new digital incentive choice items.
	SB_INCENTIVE	76 (79)	Addition	Added new incentive choice item and associated programming instructions.	Explain digital gift card and cash incentive options to web respondents and ask them to indicate their choice of incentive.
	SB_EMAIL1	77 (80)	Addition	Added new item to collect respondent's email address and associated programming instructions.	Collect email address where the respondent would like to receive the instructions for redeeming his/her digital gift card incentive.
	SB_EMAIL2	77 (80)	Addition	Added new item to confirm respondent's email address and associated programming instructions.	Confirm email address where the respondent would like to receive the instructions for redeeming his/her digital gift card incentive.
	WEB MODE END	120 (124)	Edit	Revised closing script to reference both incentive options.	Incorporated “fill” text to tailor the web survey closing script based on the respondent's choice of incentive.
Study C <i>Attachments 1-19, 2-19</i>	Web Survey Consent	121 (125)	Edit	Revised skip instruction for “Yes” responses.	Revised to route respondents to the new digital incentive choice items.
	SC_INCENTIVE	121 (125)	Addition	Added new incentive choice item and associated programming instructions.	Explain digital gift card and cash incentive options to web respondents and ask them to indicate their choice of incentive.
	SC_EMAIL1	122 (126)	Addition	Added new item to collect respondent's email address and associated programming instructions.	Collect email address where the respondent would like to receive the instructions for redeeming his/her digital gift card incentive.
	SC_EMAIL2	122 (126)	Addition	Added new item to confirm respondent's email address and associated programming instructions.	Confirm email address where the respondent would like to receive the instructions for redeeming his/her digital gift card incentive.
	WEB MODE END	141 (146)	Edit	Revised closing script to reference both incentive options.	Incorporated “fill” text to tailor the web survey closing script based on the respondent's choice of incentive.

¹ Current question number; original question number provided in italics for items that have been deleted or renumbered.

² Page number for Spanish-language instrument presented in parentheses if different from English instrument.

Table 2. Summary of Changes to Respondent Materials, Attachments 3 and 4

Material	Attachment Number	Page Number³	Type of Change	Change	Rationale
Web Topical Survey Nonresponse Letter	3-24, 4-24	24	Edit	Removed reference to \$15 “cash” incentive.	Allows the letter to be used for all web panel members, regardless of type of incentive.
Incentive Thank You Letter	3-32, 4-32	36-37	Edit	Added an email version of the incentive thank you script.	Provides an email version of the approved incentive thank you script that incorporates instructions for redeeming the digital gift card.
Topical Web Reminder Postcard	3-39, 4-39	43 (44)	Edit	Removed reference to \$15 “cash” incentive.	Allows the postcard to be used for all web panel members, regardless of type of incentive.
Topical Study Nonresponse Follow-up Letter	3-52, 4-52	73	Edit	Removed reference to \$15 “cash” incentive.	Allows the letter to be used for all panel members, regardless of type of incentive.
Web/Mail Topical Study Consent Script	3-53, 4-53	74-75	Edit	Revised skip instruction for “Yes” responses to Web Survey Consent item. Added new incentive choice and email address items and associated programming instructions.	Mirrors revisions made to the Study B and Study C introductory scripts. Routes respondents to the new digital incentive items, explains digital gift card and cash incentive options to web respondents, and asks them to indicate their choice of incentive.

Table 3. Summary of Changes to Supporting Statement

³ Page number for Spanish-language materials presented in parentheses if different from English materials.

Page Number	Change	Rationale
Part A, page 17	Updated type of incentive specified for experimental and observational studies in Exhibits A.9-1.	For Exhibit A.9-1, the description of the experimental and observational survey incentive was revised to reflect both the \$15 digital gift card and cash incentive options.
Part B, page 27	Revised text in Section B.3-1 to reference both digital gift card and cash incentive options. Also revised language specific to “mailing” the incentive.	In Section B.3-1, the text was revised to reference both the \$15 digital gift card and cash incentive options for panel members who complete the experimental and observational studies. Reference to “mailing” the incentive was revised to allow for both payment options.