







U.S Food and Drug Administration
Change Request (83-C)











**Evaluation of the FDA's General Market Youth Tobacco Prevention Campaigns
(OMB Control No. 0910-0753)**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to update materials related to the Public Education on Teen Tobacco (ExPECTT) for the final (follow-up 5) wave of data collection. Some of our study participants have now aged up and require consent rather than parental consent and assent. Additionally, due to the COVID-19 pandemic, in person data collection has been suspended. The communication materials have been changed to reflect that in person data collection will not occur. FDA has added burden for the fifth follow-up. This resulted in an increase of 2,090 responses and 1,568 hours. The new estimated burden for this collection is 10,462 hours.












The study materials listed below have been updated to reflect changes for follow-up 5:

Tracked Changes Document		Modification
Attachment 2. ExPECTT II Youth Instrument_5th FU_3_17_2022	 Attachment 2. ExPECTT II Youth Ins	<ul style="list-style-type: none"> Updated to reflect changes in new advertising Updated to reflect changes in terminology for tobacco products
Attachment 06b. Parent Guardian Permission ExPECTT II 5th FU	 Attachment 06b. Parent Guardian Per	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 06c. Youth Assent under 18 ExPECTT II 5th FU	 Attachment 06c. Youth Assent under	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 06d. Youth Consent 18 and up ExPECTT II 5th FU	 Attachment 06d. Youth Consent 18 and	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 10. Lead Letter ExPECTT II 5th FU	 Attachment 10. Lead Letter ExPECTT	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to inform participants that this is the final wave of data collection Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 10b. Lead Letter_Young Adult_ExPECTT II 5th FU	 Attachment 10b. Lead Letter_Young A	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to inform participants that this is the final wave of data collection Updated to reflect new delivery of incentive payment (mail instead of email)


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Attachment 11. Q&As about ExPECTT II 5th FU	 Attachment 11. Q&As about ExPECT	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 11b. Q&As_Young Adult_ExPECTT II 5th FU	 Attachment 11b. Q&As_Young Adult_	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 13. Notifications ExPECTT II 5th FU	 Attachment 13. Notifications ExPEC	<ul style="list-style-type: none"> Updated to reflect addition of reminder text messages Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 13b. Notifications_Yo ung Adult_ExPECTT II 5th FU	 Attachment 13b. Notifications_Young	<ul style="list-style-type: none"> Updated to reflect addition of reminder text messages Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 15. Panel Maintenance Letter ExPECTT II 5th FU	 Attachment 15. Panel Maintenance	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to inform participants that this is the final wave of data collection
Attachment 15b. Panel Maintenance Letter_Young Adult_ExPECTT II 5th FU	 Attachment 15b. Panel Maintenance	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to inform participants that this is the final wave of data collection
Attachment 18. Survey Invitation Email ExPECTT II 5th FU	 Attachment 18. Survey Invitation Err	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 18b. Survey Invitation Email_Young Adult_ExPECTT II 5th FU	 Attachment 18b. Survey Invitation Err	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 19. Email_reminder1 _ExPECTT II 5th FU	 Attachment 19. Email_reminder1_Exl	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 19b. Email_reminder1 _Young Adult_ExPECTT II 5th FU	 Attachment 19b. Email_reminder1_Yo	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)

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Attachment 20. Email_reminder2 ExPECTT II 5th FU	 Attachment 20. Email_reminder2 Exf	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 20b. Email_reminder2 _Young Adult_ExPECTT II 5th FU	 Attachment 20b. Email_reminder2 _Yc	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 21. Email_reminder3 ExPECTT II 5th FU	 Attachment 21. Email_reminder3 Exf	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 21b. Email_reminder3 _Young Adult_ExPECTT II 5th FU	 Attachment 21b. Email_reminder3 _Yc	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 22. Reminder Letter ExPECTT II 5th FU	 Attachment 22. Reminder Letter Exp	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 22b. Reminder Letter_Young Adult_ExPECTT II 5th FU	 Attachment 22b. Reminder Letter _You	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 23. Email_reminder4 ExPECTT II 5th FU	 Attachment 23. Email_reminder4 Exf	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 23b. Email_reminder4 _Young Adult_ExPECTT II 5th FU	 Attachment 23b. Email_reminder4 _Yc	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 24. Reminder Letter ExPECTT II 5th FU	 Attachment 24. Reminder Letter Exp	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
Attachment 24b. Reminder Letter_Young Adult_ExPECTT II 5th FU	 Attachment 24b. Reminder Letter _You	<ul style="list-style-type: none"> Updated to reflect changes to online only data collection due to coronavirus Updated to reflect new delivery of incentive payment (mail instead of email)
1.Part A ExPECTT_FU5 3_4_2022	 1. Part A ExPECTT_FU5_3-4-22	<ul style="list-style-type: none"> Updated for fifth wave of data collection

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<p>2. Part B EXPECTT_FU5_3 _4_2022</p>	 <p>2. Part B EXPECTT_FU5_3-4-22</p>	<ul style="list-style-type: none">• Updated for fifth wave of data collection
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