

**“Food and Drug Administration’s Evaluation of the Fresh Empire Campaign on Tobacco”
(OMB Control Number 0910-0788)**

Change Request

March 11, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to update the project schedule and revise the data collection documents for the first follow up data collection for EFECT.

In addition, the following is provided to explain the justification for this change request:

FDA’s *Fresh Empire* public education campaign aims to reduce tobacco use among multicultural youth aged 12 to 17 who affiliate with a Hip Hop peer crowd, and predominantly among African American, Hispanic, and Asian/ Pacific Islander youth.

The Evaluation of the Fresh Empire Campaign on Tobacco (EFECT) is designed to measure awareness of and exposure to the campaign and assess its impact on outcome variables of interest. Baseline data collection for EFECT was conducted between July 2015 and November 2015 in 15 campaign-targeted cities and 15 comparison cities through in-person and web-based surveys.

We request that the project schedule be updated as follows:

- 1) Begin the first follow-up data collection period six months after campaign launch (instead of three months), i.e., in April 2016.
- 2) Allow six months between follow-up data collection periods (rather than continuous data collection) with the second follow-up beginning in December 2016 and the third follow-up beginning in August 2017.



This population proved difficult to reach during baseline data collection through address-based-sampling, and we did not recruit as many participants as we expected to through social media. Therefore, continuous data collection is not feasible. These changes to the project schedule will allow us to retain as many baseline respondents as possible in follow-up survey rounds (the embedded longitudinal cohort), and as originally planned, we will recruit new respondents to account for attrition via mail and web-based screeners.









We request the following changes to the data collection documents:









- Create new consent process for youth in the embedded longitudinal cohort who are now 18 years old and therefore no longer require parental consent, and update related forms and reminders
- Revise the wording in multiple documents to reflect the new timeframe (first follow up) and update the number of participants to date








- Provide more detail for follow-up data collection for participants continuing in the embedded longitudinal cohort, including offering the option to take a web-based survey on a personal computer or mobile device, and update forms accordingly
- Edit and/or add items in the post-campaign instrument to:
 - o confirm respondent identity (for continued participation in longitudinal study)
 - o identify questions that do not have to be completed again by the embedded longitudinal cohort because baseline responses can be carried over
 - o add instructions and make edits based on mode (web vs. in-person)
 - o reflect EFECT messaging and campaign media, such as videos
 - o reflect best practices for item (i.e., question) development
- Delete questions from the post-campaign instrument for length
- Allow for social media recruitment through Instagram, in addition to Facebook and Twitter
- Revise multiple documents to more clearly explain study procedures and respondent rights
- Add items to collect baseline data on measures to be used for Wave 2 of the campaign
- Remove attachments #16 Verification form and #18 verification letter as the documents have not been used and will not be used.
- Re-arranged IC structure for clarity and to better reflect the study.

Contents of the OMB Package for the First EFECT Follow-up Survey:

Att #	Document	Edits
	Supporting Statement Part A  1. FE SS OMB_Part A TC.docx	<ul style="list-style-type: none"> - Updated to reflect the project schedule and provide more detail about the longitudinal cohort. - References to Attachment 5 have been changed to reference Attachments 5, 5a, 5b, 5c, 5d and 5e as appropriate, which is necessary to change the consenting process for longitudinal youth and youth who are now age 18 and 15 to 17 year-old cross-sectional youth recruited via social media. - Updated social media platforms.
	Supporting Statement Part B  2. FE SS OMB_Part B TC.docx	<ul style="list-style-type: none"> - Updated to reflect the project schedule and provide more detail about the longitudinal cohort. - References to Attachment 5 have been changed to reference Attachments 5, 5a, 5b, 5c, 5d and 5e as appropriate, which is necessary to change the consenting process for longitudinal youth and youth

Att #	Document	Edits
		<p>who are now age 18 and 15 to 17 year-old cross-sectional youth recruited via social media.</p> <ul style="list-style-type: none"> - Updated to describe snowball sampling approach. - Updated social media platforms.
1	<p>Pre and Post Campaign Instruments</p>  <p>Attachment 1_ Post Campaign Instrument</p>  <p>3. Summary of Changes to EFECT Pc</p>	<ul style="list-style-type: none"> - Baseline data collection is complete, so pre-campaign instrument has been deleted. - Items added, edited and deleted from post-campaign instrument. See details in “Summary of Changes to EFECT Post-Campaign Instrument.”
2	<p>Outcome Mail Screener</p>  <p>Attachment 2_Outcome Mail Scre</p>	<ul style="list-style-type: none"> - Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
3	<p>Outcome Web Screener</p>  <p>Attachment 3_Outcome Web Scre</p>	<ul style="list-style-type: none"> - Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
3a	<p>Social Media Ad</p>  <p>Attachment 3a_Social_Media_Ad.</p>	<ul style="list-style-type: none"> - Updated to reflect new images and advertisements.
5	<p>Informed Consent and Assent</p>  <p>Attachment 5_Informed Consent</p>	<ul style="list-style-type: none"> - Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
5a	<p>Longitudinal Informed Consent and Assent</p>  <p>Attachment 5a_Longitudinal Infor</p>	<ul style="list-style-type: none"> - NEW FORM for youth who completed baseline survey
5b	<p>Longitudinal Informed Consent 18+ Year Old Youth</p>  <p>Attachment 5b_Longitudinal Infor</p>	<ul style="list-style-type: none"> - NEW FORM for youth age 18 and older

Att #	Document	Edits
5c	<p>Longitudinal Web Consent and Assent</p>  <p>Attachment 5c_Longitudinal Web</p>	- NEW FORM for longitudinal youth opting to take web survey
5d	<p>Longitudinal Web Consent 18+ Year Old Youth</p>  <p>Attachment 5d_Longitudinal Web</p>	- NEW FORM for youth age 18 and older for web survey
5e	<p>Cross-Sectional Social Media/Snowball 15+ Youth</p>  <p>Attachment 5e_Cross Sectional Sr</p>	- NEW FORM for youth 15+ who are recruited via social media
6	<p>Study Description</p>  <p>Attachment 6_Study Description TC.docx</p>	- Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
8	<p>Outcome Parent Lead Letter</p>  <p>Attachment 8_Outcome Parent Le</p>	- Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
8a	<p>Outcome Parent Lead Letter Wave 2</p>  <p>Attachment 8a_Outcome Parent l</p>	- Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording.
9	<p>Reminder Postcard</p>  <p>Attachment 9_Reminder Postcard TC</p>	- Minor edits to wording.
10	<p>Parent Second Mailing</p>  <p>Attachment 10_Parent Second M</p>	- Revised to more clearly explain respondent rights. Some other minor edits to wording.
11	<p>Welcome to the Study Letter</p>	- Revised to more clearly explain study procedures and respondent rights. Some other minor edits to wording

Att #	Document	Edits
	 Attachment 11_ Welcome to the S	
12	Sorry I Missed You Card  Attachment 12 _ Sorry I Missed You C	- Minor edits to wording.
13	Unable to Contact Letters  Attachment 13_ Unable to Contac	- Minor edits to wording.
14a	Questions and Answers Fact Sheet  Attachment 14a_ Questions and A	- Revised to more clearly explain study procedures. Some other minor edits to wording.
14b	Questions and Answers Fact Sheet  Attachment 14b_ Questions and A	- Revised to more clearly explain respondent rights. Some other minor edits to wording.
15	Interview Incentive Receipt  Attachment 15_ Interview Incenti	- Minor edits to formatting.
17	Verification Call Script  Attachment 17_ Verification Call Sc	- Revised to more clearly elicit verification information. Some other minor wording and skip pattern changes.