

**“Evaluation of the Food and Drug Administration's General Market Youth
Tobacco Prevention Campaign”
(OMB Control Number 0910-0753)**

Change Request

February 9, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate minor edits to the youth follow-up instrument (attachment 2), Media Tracking Screener (attachment 4), permission letters (attachment 6), Panel Maintenance Letter (attachment 10), and supporting statements part A and B. Additionally, FDA is requesting that some burden hours assigned to the longitudinal study component be moved to the media tracking study component.

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

The ICR includes several study components, including a longitudinal study with a baseline and three follow-up surveys, and a media tracking survey.

The longitudinal baseline and first follow-up samples were smaller than originally planned, as shown in Table 1, resulting in our use of 1,009 (336 annually) fewer burden hours than expected.

The media tracking survey has proven useful in terms of understanding youth reactions to campaign advertising. For this reason, we would like to collect a greater number of interviews than originally planned.

Currently OMB has approved a total of 12,000 (1,333 annually) per questionnaire type 30-minute media tracking respondent interviews. To date, we have utilized 9,178 (1,020 annually) respondents' media tracking interviews. This leaves 2,822 (941 annually) OMB-approved media tracking interviews.

FDA would like to shift unused respondent burden hours 1,009 (336 annually), from the longitudinal study to the media tracking study. We could then field three media tracking surveys, each to be administered over a six-week period, with 250 interviews per week, for a total of 4,500 (1,500 annually) interviews, as shown in Table 2.

In annual terms, 314 respondents per questionnaire type are remaining. An additional 559 respondents (186 per questionnaire) are desired for a new total of 500 respondents per questionnaire type. A total of 280 annualized burden hours require transferring.

The burden figures listed in Table 1 and 2 of this memo have been divided by 3 to represent the one time nature of this burden and to avoid double counting in the ROCIS system. These figures are listed in parentheses as “annualized” burden.

Table 1. Projected and Actual Sample Sizes and Respondent Burden Hours for Components of the Longitudinal Survey

Study Component	Projected Sample Size (approved by OMB)	Actual Sample Size	Difference in Sample Size	Average Burden per Response (in hours)	Burden Hours Unused
Baseline	8,057 (2686)	6,864 (2288)	1,193 (398)	.50	596.5(199)
1 st Follow-up	6,445 (2148)	5,895 (1965)	550 (183)	.75	412.5 (137)
Total to Date			1,743(581)		1,009(336)

Table 2. Number of Burden Hours Needed to Field Three 6-Week media Tracking Surveys, Each n=1500

Study Component	Remaining (Respondents) Interviews Approved by OMB	Desired Number of Interviews for 2015	Difference in Sample Size	Average Burden per Response (in hours)	Burden Hours Shifted
Media Tracking Surveys 1, 2, and 3	2,822 (941) 314 per type	4,500 (1500)	1,678 (559) 186 per type	.50	839 (280)

In addition, the following documents are provided in track change to explain the justification for this change request:

1. Supporting Statement Part A - Edits on pages 6, 14, 15, regarding media tracking data being housed on GMIs server rather than RTIs server. Edits on page 13, on dates of data collection. Updates to table 1 Estimated Annual Reporting Burden on page 19.



1. Supporting Statment Part A 091C

2. Supporting Statement Part B - Edits on pages 5 and 9 related to media tracking data storage server.



2. Supporting
Statment Part B 0910

3. Lead Letter (Attachment 10) - Updated language from previously approved lead letter



3. Attachment 10.
Lead Letter 0910-075

4. Survey Invitation Email - Dates of study changed



4.
Survey_invitation_en

5. Email reminder #1 - New document, but almost entirely based on the lead letter



5. Email_reminder1_
0910-0753.doc

6. Email reminder #2 - New document, but almost entirely based on the lead letter



6. Email_reminder2_
0910-0753.doc

7. Email reminder #3 - New document, but almost entirely based on the lead letter



7. Email_reminder3_
0910-0753.doc

8. Parent Permission form (Attachment 6) - Dates of study changed



8. Attachment
6_Parent Permission

9. Youth Assent form (Attachment 6) - Dates of study changed



9. Attachment
6_Youth Assent 0910

10. Second Follow-up Instrument - Items added, removed and edited



10. Attachment
2_Youth Follow-up In

11. Rationale Document outlining all changes and rationale to the Second Follow-up Instrument – (New document)



11. Rationale for
ItemChanges to the

12. Media Tracking Instrument (Attachment 4) - Items added, removed and edited



12. Attachment
4_Media Tracking Scri

13. Rationale Document outlining all changes and rationale to the Media Tracking
Instrument - New Document



13. Rationale for
ItemChanges to the

In conversations with OMB in the past, we noted that we expected to have non-substantive changes to our instruments based on the development/changes to the campaign creative.