

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

Change Request (83-C)

July 14, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to extend the dates of data collection and increase the designated market areas (DMA). In the original design, control data for a case-control evaluation design were to be constructed from ExPECTT data (the evaluation of the national general market campaign, *The Real Cost*). Using that design, we would have compared effect estimates from the 21 Rural Smokeless markets (DMAs) in aggregate to data constructed from ExPECTT data collected in DMAs not included in the Rural Smokeless Campaign. In the revised design, we will compare effect estimates from 15 Rural Smokeless campaign-targeted market (cases) in aggregate to data from 15 non-campaign markets (controls) that are similar demographically. This modification will allow for an improvement in the alignment of data collection instruments and measures, thereby yielding more precise estimates of effect.

Dates:

Supporting Statement Part A states that the original smokeless campaign baseline information collection would take place between August and October 2014. We would like to revise it to have baseline data collection take place between January 2016 and July 2016. The first follow-up wave would then begin 4 months after campaign launch and be followed by 2 waves in 8 month intervals after that. Changes appear on pages 3 and 22.



Supporting_Statment
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DMAs:

Supporting Statement Part B states that we will draw our sample from 21 DMAs. We would like to increase the number of DMAs from which the statement would be drawn to 30 DMAs (15 campaign-targeted DMAs and 15 comparison DMAs). The number of participants and total burden hours would not change. The change appears on page 1

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



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