

# **“Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications”**

**(OMB Control Number 0910-0810)**

## **Change Request**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to account for changes for previously approved individual generic requests.

The first IC is The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use. The current collection is already in the field collecting.

Minor changes are being requested due to an adjustment in campaign priorities. We must now copy test an additional concept that focuses on electronic nicotine delivery systems (ENDS). ENDS concepts are being tested among both youth and adults. This has resulted in a need to expand the adult cohort.

The following modifications will allow us to expand the adult sample size and test additional stimuli with minimal impact to previously requested burden hours:

Modify sample size as follows:

1. Reduce the sample size of youth participants from up to 3,000 to up to 2,500
2. Increase the sample size of adult participants from up to 1,000 to up to 1,500
3. Decrease number of respondents from 17,000 to 16,500
4. Decrease amount of burden hours from 1,732 to 1,720
5. Update stimuli to include an additional item
6. Extend timeline of the study from approximately ending in March 2019 to ending in August of 2019

## **Tracked Documents**

1. SS Part A



TRC Copy Testing  
Part A.docx

2. SS Part B



TRC Copy Testing  
Part B.docx

3. Stimuli



H TRC Copy Testing  
Stimuli.docx

#### 4. Adult Consent Form



G TRC Copy Testing  
Adult Participant Co

#### 5. Notification opt-out



E TRC Copy Testing  
Parental Notificatio

#### 6. Youth assent



F TRC Copy Testing  
Youth Assent Form

The second IC is the Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use. The study has not yet gone in the field for data collection.

Minor changes are being requested to account for changes to the study timeline, IRB requests and to capture information based on current e-cigarettes trends. We are requesting updates to the study documents for the following reasons:

1. The study has not launched as projected. Our approximate timeline has changed from 2018 to 2019.
2. FDA's IRB has requested that we incorporate a way for participants to give assent before the screener.
3. Update the example product listing according to new trends in new ENDS (e-cigarette) sales.
4. Test for unintended consequences in all related products. To accomplish this, we needed to add measures about ENDS in the survey to investigate if the ads have any effects on e-cigarette knowledge, attitudes, and beliefs.

### **Tracked documents**

#### 1. SS Part A



FE CTW ave 3\_OMB  
SS Part A.docx

#### 2. Questionnaire



Questionnaire\_TC.d  
ocx

### 3. Screener



Screener\_TC.docx