**National Panel of Tobacco Consumer Studies (OMB Control Number 0910-0815)**

**Change Request (83-C)**

**August 10, 2016**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate several non-substantive changes to the questionnaires.

**Overview of the Change Request for OMB Control No. 0910-0815**

Based on final review, programming, and testing of the questionnaires, several non-substantive changes are needed in advance of the initial implementation phase of the panel. No changes to other study materials are requested. Additionally, there is no change in the burden estimate included in the original clearance request. All changes described in this memorandum and reflected in the attachments have been approved by the Institutional Review Board at RTI International (RTI).

Questionnaire Changes

Questionnaire changes are focused on assuring the correct question wording and routing for each item, ensuring consistency across panel questionnaires, and improving alignment with the National Health Interview Survey (NHIS). In addition, several typographical errors and fonts have also been corrected in the questionnaire specifications. Minor changes in several questionnaire instructions are designed to improve the readability of mail survey responses during optical scanning and simplify administration of the item by an interviewer.

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| **Att #** | **Type** | **Attachment Title** | **Tracked Versions** |
| 1 | Revised | Questionnaire English |  |
| 2 | Revised | Questionnaire Spanish |  |

Table 1 provides a summary of the non-substantive changes that have been made to four panel questionnaires: Mail Screener (Attachments 1-1, 2-1), Field Screener (Attachments 1-2, 2-2), Enrollment Survey (Attachments 1-3, 2-3), and Baseline Survey (1-4, 2-4). This memo also includes tracked and clean versions of the English- and Spanish-language questionnaires that have been modified.

**Table 1. Summary of Changes to Panel Questionnaires**

| **Questionnaire** | **Item Number** | **Page Number\*** | **Addition** | **Deletion** | **Edit** | **Change and Rationale** | **Prior Approval Given by OMB** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Mail Screener  (Attachments 1-1, 2-1) | “Start Here” | 2 |  |  | X | Inserted instruction to complete form using blue or black ink  RATIONALE: Improve scanning performance. | Base item approved by OMB on 6/8/16 |
| Field Screening Instrument  (Attachments 1-2, 2-2) | SCD1 | 10 |  |  | X | Inserted skip instruction for “no” response; underlined ”cigarettes” for emphasis  RATIONALE: Align with NHIS screening of cigarette users; ensure consistency with other items in screener. | Base item approved by OMB on 6/8/16 |
| SCD3 | 10 (11) |  |  | X | Inserted “regular” in on-screen banner and question text  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| Enrollment Survey (Attachments 1-3, 2-3) | ESA3 | 16 (17) |  |  | X | Inserted skip instruction for “no” response; underlined “cigarettes” for emphasis  RATIONALE: Align with NHIS screening of cigarette users; ensure consistency with other items in questionnaire. | Base item approved by OMB on 6/8/16 |
| ESA4 | 16 (17) |  |  | X | Underlined “cigarettes” for emphasis  RATIONALE: Ensure consistency with other items in questionnaire. | Base item approved by OMB on 6/8/16 |
| ESB9 | 21 (23) |  |  | X | Revised wording of interviewer instruction; created separate interviewer instruction screen at ESB9CHK  RATIONALE: Improve item administration for interviewers. | Base item approved by OMB on 6/8/16 |
| CHECK BOX 4 | 21 (23) |  |  | X | Updated skip logic  RATIONALE: Update programming instructions to improve exit script transition for potential tablet candidates | Base item approved by OMB on 6/8/16 |
| Baseline Survey (Attachments 1-4, 2-4) | PBB1 | 39 (43) |  |  | X | Moved location of “a day” to end of question  RATIONALE: Align with wording of other items in baseline questionnaire and NHIS. | Base item approved by OMB on 6/8/16 |
| PBB2 | 40 (43) |  |  | X | Removed date fill text, “that is, since [FILL DATE]”  RATIONALE: Align with NHIS. | Base item approved by OMB on 6/8/16 |
| PBB3 | 40 (43) |  |  | X | Inserted “the” and moved location and underlined “cigarettes” in question text  RATIONALE: Align with parallel items on cigar and smokeless tobacco in baseline questionnaire. | Base item approved by OMB on 6/8/16 |
| PBB7 | 42 (45) |  |  | X | Added “regular” to question wording and on-screen banner  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB8 | 42 (45) |  |  | X | Inserted “the” and moved location of “a day” to end of question; also added “regular” to question wording  RATIONALE: Align with wording of other items in baseline questionnaire and NHIS, and for consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB9 | 43 (45) |  |  | X | Added “regular” to question wording; also removed date fill text, “that is, since [FILL DATE]”  RATIONALE: Align with NHIS, and for consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB10 | 43 (46) |  |  | X | Added “the” and “regular” to question wording  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB10a | 43 (46) |  |  | X | Added “regular” to question wording  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB11 | 43 (46) |  |  | X | Added “regular” to question wording; also included “cigarillos, or little filtered cigars” in question text  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires, and wording of other cigar items in baseline questionnaire. | Base item approved by OMB on 6/8/16 |
| CHECK BOX 5 | 44 (47) |  |  | X | Updated skip pattern  RATIONALE: Ensure proper routing for new item PBB12a | Base item approved by OMB on 6/8/16 |
| PBB12a | 44 (47) | X |  |  | Inserted new item on number of times panel member now uses smokeless tobacco a day  RATIONALE: Consistency with parallel intensity question for cigarettes and cigars. | Item not previously approved |
| PBB13 | 44 (47) |  |  | X | Removed date fill text, “that is, since [FILL DATE]”  RATIONALE: Align with NHIS. | Base item approved by OMB on 6/8/16 |
| PBB14 | 45 (47) |  |  | X | Inserted “the” and changed item from a categorical to open-ended response; also revised skip patterns to ensure item only asked of “some days” smokeless users  RATIONALE: Consistency with parallel cigarette and cigar items. | Base item approved by OMB on 6/8/16 |
| PBB17 | 46 (48) |  | X |  | Deleted item on number of containers of smokeless tobacco used per week; replaced with PBB12a (number of times panel member now uses smokeless tobacco a day)  RATIONALE: Consistency with parallel intensity question for cigarettes and cigars. | Base item approved by OMB on 6/8/16 |
| PBB20I2 | 47 |  |  | X | Changed “some day” to “some days” in question text  RATIONALE: Correct typographical error in English questionnaire. | Base item approved by OMB on 6/8/16 |
| PBB20I3 | 47 (50) |  |  | X | Removed date fill text, “that is, since [FILL DATE]”; also updated question wording to “did you use e-cigarettes”  RATIONALE: Align with NHIS; correct typographical error. | Base item approved by OMB on 6/8/16 |
| PBB21 | 47 (50) |  |  | X | Added “regular” to question wording  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |
| PBB22 | 48 (50) |  |  | X | Added “regular” to question wording  RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires. | Base item approved by OMB on 6/8/16 |

\*Page numbers in parentheses show the location of the changes in the corresponding Spanish questionnaires.