

(b) (4)

November 2017

**ZYN<sup>®</sup> Likelihood of Use Survey  
Cognitive Testing Report**

Prepared for:

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## 2. BACKGROUND AND OVERVIEW

Swedish Match North America (SMNA) markets ZYN<sup>®</sup> as a nicotine delivery product and not as a smoking cessation product. SMNA will be filing a Premarket Tobacco Product Application (PMTA)<sup>1</sup> for ZYN<sup>®</sup> in 2018. A Likelihood of Use study<sup>2</sup> will be conducted and submitted to the FDA as part of the ZYN<sup>®</sup> PMTA.

The overarching question for the Likelihood of Use study can be stated as follows: How does exposure to a ZYN<sup>®</sup> description and package label affect intentions, behaviors, and perceptions among users of tobacco and/or nicotine products (TNP), when compared pre- to post-exposure? Additionally, does exposure to a ZYN<sup>®</sup> description and package label have a different impact on intentions, behaviors, and perceptions across TNP user groups? These questions will be studied among both TNP users and non-users.

User and non-user groups for this study include the following cohorts:

- Never tobacco users from legal age to 24 years of age,
- Never tobacco users older than 24 years of age,
- Former tobacco users from legal age and older,
- Current cigarette smokers with intent to quit from legal age to 24 years of age,
- Current cigarette smokers with intent to quit older than 24 years of age,
- Current cigarette smokers without intent to quit from legal age and older, and
- Current tobacco users (excluding cigarettes) from legal age and older.

Before executing the Likelihood of Use on-line surveys, cognitive interviews were conducted to assess how respondents understand, interpret, and answer each survey question. The cognitive testing research adhered to the Office of Management and Budget (OMB) Statistical Policy Directive No.2 Addendum: Standards and Guidelines for Cognitive Interviews<sup>3</sup>.

This report describes the cognitive interview research. All documents used in the research are contained in the Attachments ([Section 6](#)).

## 3. METHODS

### 3.1. Materials and Process

To ensure that the materials were appropriate and sufficiently clear to consumers, the Likelihood of Use online surveys were tested among 12 TNP users and 12 TNP non-users across two rounds of qualitative in-depth, in-person, cognitive interviews in two of the 11 states where ZYN<sup>®</sup> is available in retail outlets. Round 1 was conducted in Denver, CO and Round 2 in Seattle, WA. The second round of cognitive interviews was conducted a week after the initial round to allow for survey revisions between rounds. Cognitive interviews were up to 60 minutes in duration and each respondent received \$125 in a Visa Pre-Paid Card as compensation for the time spent.

(b) (4) developed the materials needed for the cognitive interviews; this included an informed consent form, recruitment screener, and cognitive interview guide (see [Attachments 1a, 1b, 2, and 3](#)). All materials were reviewed and approved by Sterling Institutional Review Board and SMNA in advance of recruiting and conducting interviews. Interviews across both markets were administered by the same interviewer who is certified to conduct cognitive interviews by the Odum Institute / University of Chapel Hill. Study team members from (b) (4) and the sponsor, SMNA, were present to observe the cognitive interviews and attended both rounds of research.

Interviews were conducted utilizing a concurrent interviewing methodology, where respondents were interviewed question by question rather than retrospectively after completion of the full survey. The interview was conducted using a programmed electronic survey that respondents completed on a laptop computer, while the interviewer, using a separate screen, monitored survey responses. The (b) (4) and SMNA study team viewed a separate screen in the observer room to track respondents' progress while completing the survey. Interviews in both rounds of research were audio recorded and a third-party vendor, MRT Babbletype, collated responses into a cognitive analysis grid to provide data for systematic analysis. This ensured that the findings represent the full range of responses to each question.

Interviews were conducted applying the “think aloud” technique whereby respondents stated their interpretation of the question and how they arrived at a response. Additional scripted probes were administered verbally, by the interviewer, to elicit desired comprehension information that was not anticipated to emerge from the “think aloud” approach (see red text for scripted probes in [Cognitive Interview Guide – Attachments 3](#)).

After Round 1, the interviewer, (b) (4) and SMNA observers participated in a cognitive interview debrief to develop recommendations for revisions to survey questions to implement in Round 2 testing. Questions where 30% or more of the sample in Round 1 could not demonstrate a logical thought process for arriving at their answer or misinterpreted the intent of the question and/or terminology were revised for greater clarification and to be tested in Round 2.

Round 2 interviews followed the same process utilizing the “think aloud” technique and additional scripted probes. Round 2 focused on ascertaining if survey question changes from Round 1 achieved universal understanding of the intent of each of the questions. Upon completion of Round 2, the same consensus process was used to determine if saturation was reached. Saturation was achieved of each question when 80% or more of the respondents in Round 2 verbalized a logical thought process when answering the question that fit with the intent of the question.

This report summarizes both the issues identified with comprehension, retrieval, decision-judgement, and response across all subjects<sup>4</sup> as well as the subsequent survey changes made to mitigate each issue.

### 3.2. Recruitment Procedures

Recruitment of respondents was a convenience sample. A qualification screener (see [Recruitment Screener – Attachment 2](#)) was developed by (b) (4) approved by the sponsor, and used by the research facility to select respondents representative of the population of interest

in the Likelihood Of Use research with respect to age, gender, race/ethnicity, and TNP use behavior. Fieldwork Research Denver and Fieldwork Research Seattle recruited respondents by screening their local databases of consumers.

**Tables 1 and 2** provide respondent demographic characteristics and TNP cohort classification for both rounds of cognitive interviews.

**Table 1: Round 1 Cognitive Interview Respondents**

(b) (4)

**Table 2: Round 2 Cognitive Interview Respondents**

(b) (4)

#### 4. FINDINGS

##### 4.1. Overall Findings – Round 1 Interviews

Issues identified in Round 1 cognitive interviews in Denver, October 16<sup>th</sup> - 18<sup>th</sup>, 2017 are listed in Table 3 below. Questions identified as having issues were revised for testing in Round 2.

**Table 3: Survey Changes after Round 1**

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#### 4.2. Overall Findings – Round 2 Interviews

Issues identified in Round 2 of cognitive interviews in Seattle, October 24<sup>th</sup> – 26<sup>th</sup>, 2017 are listed in [Table 5](#) below. Changes implemented after Round 1 improved comprehension and reduced response issues. There were no new substantive comprehension issues identified and thus saturation was achieved on the survey except for questions B6 and B6a which continued to have comprehension and fatigue issues. Further revisions were recommended. Since these two questions were also part of the Perceptions and Behavioral Intentions Study for *General Snus*® survey, revisions to these questions were tested in Philadelphia on Nov 7<sup>th</sup> and 8<sup>th</sup>, 2017 and comprehension was improved (see [General Snus® \*Cognitive Interview Report, Attachment 6\*\).](#)

**Table 4: Survey Changes after Round 2**

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#### 4.3. Conclusion

The design and execution of Round 1 identified questions not functioning as intended. Revisions tested in Round 2, using the same methodology as in Round 1, demonstrated improved comprehension of the questions. Saturation was achieved for all survey questions except B6 and B6a. Additional testing of the question during cognitive testing of the Perceptions and Behavioral Intentions Study for *General Snus*® survey showed that these questions as revised after Round 2 were adequately understood by respondents. Saturation has now been achieved on all questions. Changes made after the Perceptions and Behavioral Intentions Study for *General Snus*® cognitive interviews were completed were to simplify the user experience and reduce respondent fatigue and did not change the actual question which had demonstrated respondent comprehension.

The sample size was not designed to be projectable but was representative of the population that will be respondents in the quantitative phase in terms of age, gender, race/ethnicity, and TNP use behavior. No difference in understanding the intent of the questions was evident based on age, gender, race/ethnicity, TNP use behavior. No further testing is required.

## 5. REFERENCES

1. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Applications for Premarket Review of New Tobacco Products: Draft Guidance. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products; 2011
2. ZYN® Likelihood of Use. Protocol (b) (4) November 13, 2017.
3. OMB Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews. Accessed October 12, 2016.
4. Boeije, H., Willis, G. The Cognitive Interviewing Reporting Framework (CIRF): Towards the harmonization of cognitive testing reports. In Methodology: European Journal of Research Methods for the Behavioral and Social Sciences. 2013;9(3): 87 – 95.

## 6. ATTACHMENTS

**ATTACHMENT 1A – INFORMED CONSENT FORM – DENVER**

**ATTACHMENT 1B – INFORMED CONSENT FORM – SEATTLE**

**ATTACHMENT 2 – RECRUITMENT SCREENER**

**ATTACHMENT 3 – COGNITIVE INTERVIEW GUIDE**

**ATTACHMENT 4 – SURVEY WITH CHANGES AFTER ROUND 1**

**ATTACHMENT 5 – SURVEY WITH CHANGES AFTER ROUND 2**

**ATTACHMENT 6 - GENERAL SNUS® COGNITIVE INTERVIEW REPORT**



STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

## **PARTICIPANT INFORMED CONSENT FORM, CONFIDENTIALITY AGREEMENT AND RELEASE FOR AUDIO-VIDEO**

**STUDY TITLE:** Likelihood Of Use Study

**PROTOCOL NO:** (b) (4)

**STUDY SITE:** (b) (4)

**TELEPHONE:** (b) (4)

**SPONSOR:** Swedish Match

You are invited to participate in a research study. Before you decide if you want to participate in this study, this form will share some information about the study and your rights. The research study is conducted by (b) (4) a healthcare research company, on behalf of the sponsor.

Approximately (b) (4) men and women age 18 and older from the US will take part in this research study.

### Purpose of this Study:

The purpose of this study is to improve the content and wording of a survey about tobacco and nicotine products in order to ensure the understanding and answerability of the survey content before it is used in future research.

### Your Participation:

This study will include participation in an in-person interview which will last approximately 60 minutes. The questions will be provided by a (b) (4) moderator on an electronic device. The moderator will ask you follow up questions relating to the materials you review and will also be available in case you have any questions.

*Taking part in this study is voluntary.* You may decline to answer any specific questions. You may choose to leave the interview at any time before its completion.

*Your identity will be kept confidential.* The identifiable personal information you provide will be used only for the purposes of scheduling your interview and administering your honoraria check and will not be released to any other party. The sponsors of this research will not have access to your identifiable personal information.

*The answers you give and opinions that you express in this interview will contribute, with those of other participants, towards the sponsor's development of:*

STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

- marketing campaigns,
- educational materials
- the development of new commercial products

The results of this study will be shared with the sponsor and their agents engaged in the development of the materials listed above. Your individual answers will NOT be attributed to you and your identity will NOT be shared with the sponsor or their agents.

#### Risk and Benefits of Participation:

There are no anticipated risks of this study outside of any unintentional breach of confidentiality. You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

#### Alternative to Participation:

There are no other alternatives to study participation. Your alternative is not to participate.

#### Costs and Compensation:

There is no cost to you for study participation. You will receive an honorarium in appreciation of your time for completing this interview in the form of a check for (b) (4).

#### Benefits

There are no benefits to you for your participation in this research.

#### Audio/Video Recording:

Under the relevant market research codes of practice, video or audio recordings may only be given by the research agency to the sponsor if the exact purpose to which the tapes will be put has been explained to all participants, and their explicit permission granted. This explanation must include the purpose to which the company wishes to put the tape, the identity of persons in the company to whom the tape will be shown and the identity of the person in the company who will be in charge of the tapes.

- The company sponsoring this research will be given a copy of the audio/video tape.
- Neither your name nor any other identifying information will be included in the audio/video tape.
- The purpose of the company having the tapes is to gain a better understanding of the interpretation of the survey questions and answers to ensure that the survey is easily understood once administered to other participants in the future.
- The audio/video tape will not be used for any other purposes or shared with any other 3<sup>rd</sup> party

STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

- The people in the company who will listen to/view the tape will be in the following functions/roles: Market Research Analyst, Market Research Manager, Market Research Director, Marketing Manager, Senior Marketing Manager and Marketing Director.
- No sales approaches will ever be made to you as a consequence of the sponsor having this tape.

Please initial below if you give your permission to be Audio/Video recorded.

\_\_\_\_\_ Participant Initials

The content of the discussion and the materials that you see today are confidential and must not be further discussed by you following the interview conducted today.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, or would like more information, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free). The Sterling IRB Reference ID is (b) (4).

*I acknowledge receipt of a copy of this agreement.*

By signing below, I indicate I have read the information above and agree to these uses. I agree to participate in this market research study.

I do not waive any of my legal rights by signing this form.

I will receive a signed copy of this consent form, which has 3 pages.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Printed Name

\_\_\_\_\_  
*Person Obtaining Consent*

\_\_\_\_\_  
*Person Obtaining Consent Signature*

\_\_\_\_\_  
*Date*

STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

## **PARTICIPANT INFORMED CONSENT FORM, CONFIDENTIALITY AGREEMENT AND RELEASE FOR AUDIO-VIDEO**

**STUDY TITLE:** Likelihood Of Use Study

**PROTOCOL NO:** (b) (4)

**STUDY SITE:** (b) (4)

**TELEPHONE:** (b) (4)

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*The answers you give and opinions that you express in this interview will contribute, with those of other participants, towards the sponsor's development of:*

STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

- marketing campaigns,
- educational materials
- the development of new commercial products

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#### Alternative to Participation:

There are no other alternatives to study participation. Your alternative is not to participate.

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STUDY: Likelihood to Use Study

(b) (4)

STERLING IRB ID: (b) (4)

DATE OF IRB REVIEW: 10/12/17

- The people in the company who will listen to/view the tape will be in the following functions/roles: Market Research Analyst, Market Research Manager, Market Research Director, Marketing Manager, Senior Marketing Manager and Marketing Director.
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\_\_\_\_\_ Participant Initials

The content of the discussion and the materials that you see today are confidential and must not be further discussed by you following the interview conducted today.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, or would like more information, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free). The Sterling IRB Reference ID is (b) (4).

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By signing below, I indicate I have read the information above and agree to these uses. I agree to participate in this market research study.

I do not waive any of my legal rights by signing this form.

I will receive a signed copy of this consent form, which has 3 pages.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Printed Name

\_\_\_\_\_  
*Person Obtaining Consent*

\_\_\_\_\_  
*Person Obtaining Consent Signature*

\_\_\_\_\_  
*Date*



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(b) (4)  
September 28, 2017

LIKELIHOOD OF USE  
Cognitive Interview Recruitment Screener

Updated 10/5 10/12

Quotas:

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(b) (4)

(b) (4)

September 28, 2017

(b) (4)



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September 28, 2017

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September 28, 2017

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Length of Cognitive Interview: **60 minutes** (Likelihood of Use)

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September 28, 2017

LIKELIHOOD TO USE  
SCREENER

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September 28, 2017

**RECRUITMENT TEAR OFF SHEET**

NAME: \_\_\_\_\_  
TEL: \_\_\_\_\_  
ALT TEL: \_\_\_\_\_  
FAX No. \_\_\_\_\_ EMAIL: \_\_\_\_\_  
POSTAL ADDRESS: \_\_\_\_\_  
CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ COUNTRY: \_\_\_\_\_  
ZIP CODE: \_\_\_\_\_  
\_\_\_\_\_  
APPT DATE: \_\_\_\_\_ APPT TIME: \_\_\_\_\_ am/pm.  
VENUE FOR INTERVIEW: \_\_\_\_\_  
RECRUITER: \_\_\_\_\_ DATE: \_\_\_\_\_  
**THANK AND REMIND RESPONDENT OF DAY/TIME OF APPOINTMENT.**

(b) (4)

(b) (4)  
October 13, 2017

LIKELIHOOD OF USE STUDY  
INTERVIEW GUIDE

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October 13, 2017

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October 13, 2017

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ELECTRONIC INFORMED CONSENT FORM

ASK EVERYONE

S32. Please read and indicate you have read the following information.

- The purpose of this survey is to understand perceptions and reactions about some tobacco and/or nicotine product information from people who do not use tobacco or nicotine, as well as those who do use. This study is being conducted for research purposes.
- This survey will take approximately 15-20 minutes. About (b) (4) people will complete the survey.
- Assuming you complete all of the survey, you will receive the honoraria mentioned in the survey invitation for your time.
- There are no likely risks, discomforts or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- Your participation in this survey is strictly voluntary, and other information such as your identity, personal information and answers will be kept confidential.
- Everybody's survey answers will be merged, and results will be reported in combination. No answers will be attributable to you as an individual.
- You have the right to withdraw from the survey at any time, and if you do withdraw you will not receive the honorarium mentioned earlier.
- If you have questions or concerns about your rights as a research participant please contact Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).
- If you have questions or concerns about the survey, or compensation for participation please contact your panel care team.

Do you voluntarily agree to participate in this study? [SELECT ONE ONLY]

1	Yes	
2	No	

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October 13, 2017

LIKELIHOOD TO USE: MAIN SURVEY

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October 13, 2017

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October 13, 2017

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October 13, 2017

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INFORMATION SHEET (PROGRAMMER NOTE: THIS IS JUST AN EXAMPLE. USE HIGH-RES PDF PROVIDED)

**WARNING:** This product contains nicotine.  
Nicotine is an addictive chemical.

## ZYN NICOTINE POUCHES



SMOKE-FREE  
SPIT-FREE  
TOBACCO LEAF-FREE  
15 NICOTINE POUCHES

### What's in the pouch?

ZYN combines nicotine extracted from tobacco leaves, food-grade flavorings, and natural additives and sweeteners in a pouch that is completely tobacco leaf-free.

### How to use ZYN

1. Align arrows on either side of the child safety lid. Squeeze and lift.
2. Place a pouch under your upper lip.
3. Use for up to 60 minutes.
4. Discard the pouch when finished.

ZYN nicotine pouches come in six flavors,  
each offered at 3 mg or 6 mg of nicotine.

- |                     |                      |                   |
|---------------------|----------------------|-------------------|
| ● <i>Cool Mint</i>  | ● <i>Spearmint</i>   | ● <i>Cinnamon</i> |
| ● <i>Peppermint</i> | ● <i>Wintergreen</i> | ● <i>Coffee</i>   |



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October 13, 2017

**SHOW ON SAME SCREEN AS GRAPHIC:** Below is an example of the package label on one ZYN™ package. For purposes of illustration, this package label is for Cool Mint flavor and 3mg nicotine content. Aside from the flavor and strength, the information shown here would be shown on all packages.

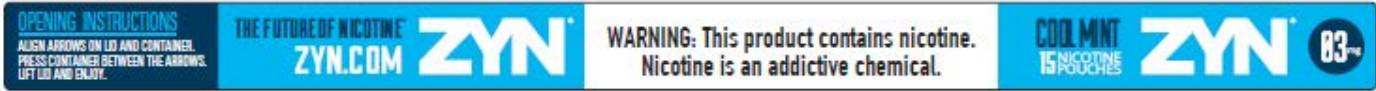
**(PROGRAMMER NOTE THIS IS JUST AN EXAMPLE. USE HIGH-RES PDF PROVIDED)**



Top Label



Bottom Label



Side Label

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October 13, 2017

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October 13, 2017

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October 13, 2017

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October 13, 2017

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FOR THE ONLINE VERSION, WE HAVE THE WORD "ZYN™" WITH A PIC, SHOULD BE THIS PIC:



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LIKELIHOOD OF USE STUDY  
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**ELECTRONIC INFORMED CONSENT FORM**

**ASK EVERYONE**

S32. Please read and indicate you have read the following information.

- The purpose of this survey is to understand perceptions and reactions about some tobacco and/or nicotine product information from people who do not use tobacco or nicotine, as well as those who do use. This study is being conducted for research purposes.
- This survey will take approximately 15-20 minutes. About (b) (4) people will complete the survey.
- Assuming you complete all of the survey, you will receive the honoraria mentioned in the survey invitation for your time.
- There are no likely risks, discomforts or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- Your participation in this survey is strictly voluntary, and other information such as your identity, personal information, and answers will be kept confidential.
- Everybody's survey answers will be merged, and results will be reported in combination. No answers will be attributable to you as an individual.
- You have the right to withdraw from the survey at any time, and if you do withdraw you will not receive the honorarium mentioned earlier.
- If you have questions or concerns about your rights as a research participant, please contact Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).
- If you have questions or concerns about the survey, or compensation for participation, please contact your panel care team.

Do you voluntarily agree to participate in this study? **[SELECT ONE ONLY]**

1	Yes	<b>CONTINUE</b>
2	No	<b>TERMINATE</b>

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October 21, 2017 - *Comparison doc from Cognitive Interviews Phase 1*

LIKELIHOOD TO USE: MAIN SURVEY

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INFORMATION SHEET (PROGRAMMER NOTE: THIS IS JUST AN EXAMPLE. USE HIGH-RES PDF PROVIDED)

**WARNING:** This product contains nicotine.  
Nicotine is an addictive chemical.

## ZYN NICOTINE POUCHES



**SMOKE-FREE**  
**SPIT-FREE**  
**TOBACCO LEAF-FREE**  
**15 NICOTINE POUCHES**

### What's in the pouch?

ZYN combines nicotine extracted from tobacco leaves, food-grade flavorings, and natural additives and sweeteners in a pouch that is completely tobacco leaf-free.

### How to use ZYN

1. Align arrows on either side of the child safety lid. Squeeze and lift.
2. Place a pouch under your upper lip.
3. Use for up to 60 minutes.
4. Discard the pouch when finished.

**ZYN nicotine pouches come in six flavors,  
each offered at 3 mg or 6 mg of nicotine.**

- |   |  |   |
|---|--|---|
|  <b>Cool Mint</b>  |  <b>Spearmint</b>   |  <b>Cinnamon</b> |
|  <b>Peppermint</b> |  <b>Wintergreen</b> |  <b>Coffee</b>   |

October 21, 2017 – *Comparison doc from Cognitive Interviews Phase 1*

**SHOW ON SAME SCREEN AS GRAPHIC:** Below is an example of the package label on one ZYN™ package. For purposes of illustration, this package label is for Cool Mint flavor and 3mg nicotine content. Aside from the flavor and strength, the information shown here would be shown on all packages.

**(PROGRAMMER NOTE THIS IS JUST AN EXAMPLE. USE HIGH-RES PDF PROVIDED October 18)**

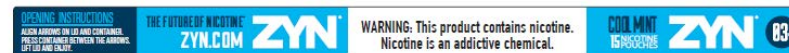
**[ADD 5 SECOND DELAY ON CONTINUE BUTTON]**



Top Label



Bottom Label



Side Label

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October 21, 2017 – *Comparison doc from Cognitive Interviews Phase 1*

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FOR THE ONLINE VERSION, WE HAVE THE WORD “ZYN™” WITH A PIC, SHOULD BE THIS PIC:





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LIKELIHOOD OF USE STUDY  
SCREENER

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**ELECTRONIC INFORMED CONSENT FORM**

**ASK EVERYONE**

S32. Please read and indicate you have read the following information. **You may need to scroll to see all the information and to continue.**

- The purpose of this survey is to understand perceptions and reactions about some tobacco and/or nicotine product information from people who do not use tobacco or nicotine, as well as those who do use. This study is being conducted for research purposes.
- This survey will take approximately 15-20 minutes. About (b) (4) people will complete the survey.
- Assuming you complete all of the survey, you will be **compensated for your time and opinions, as** mentioned in the survey invitation.
- There are no likely risks, discomforts, or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- Your participation in this survey is strictly voluntary, and other information such as your identity, personal information, and answers will be kept confidential.
- Everybody's survey answers will be merged, and results will be reported in combination. No answers will be attributable to you as an individual.
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- If you have questions or concerns about the survey, or compensation for participation, please contact your panel care team.

Do you voluntarily agree to participate in this study? **[SELECT ONE ONLY]**

1	Yes	<b>CONTINUE</b>
2	No	<b>TERMINATE</b>

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October 30, 2017 - *Comparison doc – post-Seattle*

LIKELIHOOD TO USE: MAIN SURVEY

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INFORMATION SHEET (PROGRAMMER NOTE: THIS IS JUST AN EXAMPLE. USE HIGH-RES PDF PROVIDED)

**WARNING:** This product contains nicotine.  
Nicotine is an addictive chemical.

## ZYN NICOTINE POUCHES



**SMOKE-FREE**  
**SPIT-FREE**  
**TOBACCO LEAF-FREE**  
**15 NICOTINE POUCHES**

### What's in the pouch?

ZYN combines nicotine extracted from tobacco leaves, food-grade flavorings, and natural additives and sweeteners in a pouch that is completely tobacco leaf-free.

### How to use ZYN

1. Align arrows on either side of the child safety lid. Squeeze and lift.
2. Place a pouch under your upper lip.
3. Use for up to 60 minutes.
4. Discard the pouch when finished.

**ZYN nicotine pouches come in six flavors,  
each offered at 3 mg or 6 mg of nicotine.**

- |   |  |   |
|---|--|---|
|  <i>Cool Mint</i>  |  <i>Spearmint</i>   |  <i>Cinnamon</i> |
|  <i>Peppermint</i> |  <i>Wintergreen</i> |  <i>Coffee</i>   |

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October 30, 2017 – Comparison doc – post-Seattle

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Top Label



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FOR THE ONLINE VERSION, WE HAVE THE WORD “ZYN™” WITH A PIC, SHOULD BE THIS PIC:



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December 2017

**Perceptions and Behavioral Intentions Study for *General Snus*<sup>®</sup>  
Cognitive Testing Report**

Prepared for:

(b) (4), (b) (6)

Swedish Match, US Division  
Two James Center  
1021 East Cary Street, Suite 1600  
Richmond, VA 23219

Prepared by:

(b) (4), (b) (6)



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## 2. BACKGROUND AND OVERVIEW

In November 2015, Swedish Match North America, Inc. (SMNA) received U.S. market authorization for *General Snus*<sup>®</sup>. In June 2014 SMNA submitted modified risk tobacco product applications (MRTPAs) for *General Snus*<sup>®</sup> smokeless tobacco products. SMNA has elected to submit an amended MRTPA for its *General Snus*<sup>®</sup> product line. A Perceptions and Behavioral Intentions Study for *General Snus*<sup>®</sup> will be conducted to determine how proposed modified risk claims impact various cohorts of adult consumers' perceptions of health risks of using *General Snus*<sup>®</sup> and their behavior intentions regarding tobacco use. This study will be submitted to the FDA as part of the *General Snus*<sup>®</sup> MRTPA amendment.

The overarching research question for the Perceptions and Behavioral Intentions Study for *General Snus*<sup>®</sup> can be stated as follows: How does the presence of a statement claiming benefits of *General Snus*<sup>®</sup> usage over cigarette smoking (the MRTP claim) affect intentions and behaviors of tobacco/nicotine product (TNP) use, when compared to the absence of that same claim? The question will be studied among both TNP users and non-users (all of whom are of legal age to use TNP in their residential geography). The effectiveness of the three proposed MRTP claims will be studied in the context of a single exposure to a *General Snus*<sup>®</sup> description provided in a video advertisement, each with one of the three proposed claims or absence of a claim.

User and non-user groups for this study include the following cohorts:

- Never users of TNP from legal age to 24 years of age
- Never users of TNP older than 24 years of age
- Former cigarette smokers from legal age and older
- Current cigarette smokers from legal age to 24 years of age
- Current cigarette smokers older than 24 years of age
- Current smokeless tobacco users from legal age and older

Before executing the Perceptions and Behavioral Intentions Study for *General Snus*<sup>®</sup> on-line survey, cognitive interviews were conducted to assess how respondents understand, interpret, and answer each survey question. The cognitive testing research<sup>3</sup> adhered to the Office of Management and Budget (OMB) Statistical Policy Directive No.2 Addendum: Standards and Guidelines for Cognitive Interviews<sup>1</sup>.

This report describes the cognitive interview research. All documents used in the research are contained in the Attachments (Section 6).

### 3. METHODS

#### 3.1. Materials and Process

To ensure that the materials were appropriate and sufficiently clear to consumers, the Perceptions and Behavioral Intentions Study online survey was tested among (b) (4) respondents across two rounds of qualitative in-depth, in-person, cognitive interviews. Round 1 was conducted in Seattle, WA and Round 2 in Philadelphia, PA. The second round of cognitive interviews was conducted two weeks after the initial round to allow for survey revisions between rounds. Cognitive interviews were up to 60 minutes in duration and each respondent received (b) (4) in a Visa Pre-Paid Card as compensation for the time spent.

(b) (4) developed the materials needed for the cognitive interviews; this included informed consent forms, recruitment screener, and cognitive interview guide (see Attachments 1a, 1b, 2, and 3). All materials were reviewed and approved by Sterling Institutional Review Board and SMNA in advance of recruiting and conducting interviews. Interviews across both markets were administered by the same interviewer who was trained by (b) (4) VP and Lead of Qualitative Services who is certified to conduct cognitive interviews by the Odum Institute / University of Chapel Hill. Study team members from (b) (4) and the sponsor, SMNA, were present to observe the cognitive interviews and attended both rounds of research.

Interviews were conducted utilizing a concurrent interviewing methodology, where respondents were interviewed question by question rather than retrospectively after completion of the full survey. The interview was conducted using a programmed electronic survey that respondents completed on a laptop computer, while the interviewer, using a separate screen, monitored survey responses. The (b) (4) and SMNA study team viewed a separate screen in the observer room to track the respondents' progress while completing the survey. Interviews in both rounds of research were audio recorded and a third-party vendor, (b) (4), collated responses into a cognitive analysis grid to provide data for systematic analysis. This ensured that the findings represent the full range of responses to each question.

During the cognitive interview respondents viewed a video advertisement (video) for *General Snus*®. The videos were created such that each showed only one of 3 test claims or was absent any modified risk claim, thus serving as the control. Each video also showed one of 4 warning statements and one of 2 flavors of *General Snus*® on the product package shown in the video. The video shown to each respondent was randomly selected. (See SMNA 17-01GEN Perceptions and Behavioral Intentions Protocol – Attachment 6 for Claims, Warnings, and flavors<sup>2</sup>).

Interviews were conducted applying the “think aloud” technique whereby respondents stated their interpretation of the question and how they arrived at a response. Additional scripted probes were administered verbally, by the interviewer, to elicit desired comprehension information that was not anticipated to emerge from the “think aloud” approach (see red text for scripted probes in Cognitive Interview Guide – Attachment 3).

After Round 1, the interviewer, (b) (4) and SMNA observers participated in a cognitive interview debrief to develop recommendations for revisions to survey questions to implement in Round 2 testing. Questions where 30% or more of the sample in Round 1 could not

demonstrate a logical thought process for arriving at their answer or misinterpreted the intent of the question and/or terminology were revised for greater clarification and to be tested in Round 2.

Round 2 interviews followed the same process utilizing the “think aloud” technique and additional scripted probes. Round 2 focused on ascertaining if survey question changes from Round 1 achieved universal understanding of the intent of each of the questions. Upon completion of Round 2, the same consensus process was used to determine if saturation was reached. Saturation was achieved, when for each question 80% or more of the respondents in Round 2 verbalized a logical thought process when answering the question that fit with the intent of the question.

This report summarizes both the issues identified with “comprehension, retrieval, decision-judgement, and response across all subjects”<sup>3</sup> as well as the subsequent survey changes made to mitigate each issue.

### 3.2. Recruitment Procedures

Recruitment of respondents was a convenience sample. A qualification screener (see Recruitment Screener – Attachment 2) was developed by (b) (4) approved by SMNA and used to select respondents representative of the population of interest in the Perceptions and Behavioral Intentions research with respect to age, gender, race/ethnicity, and TNP use or non-use. (b) (4) and (b) (4) recruited respondents by screening their local databases of consumers.

**Tables 1 and 2** provide respondent demographic characteristics and TNP quota group classification for both rounds of cognitive interviews.

**Table 1: Round 1 Cognitive Interview Respondents**



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**Table 2: Round 2 Cognitive Interview Respondents**

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#### 4. FINDINGS

##### 4.1. Overall Findings – Round 1 Interviews

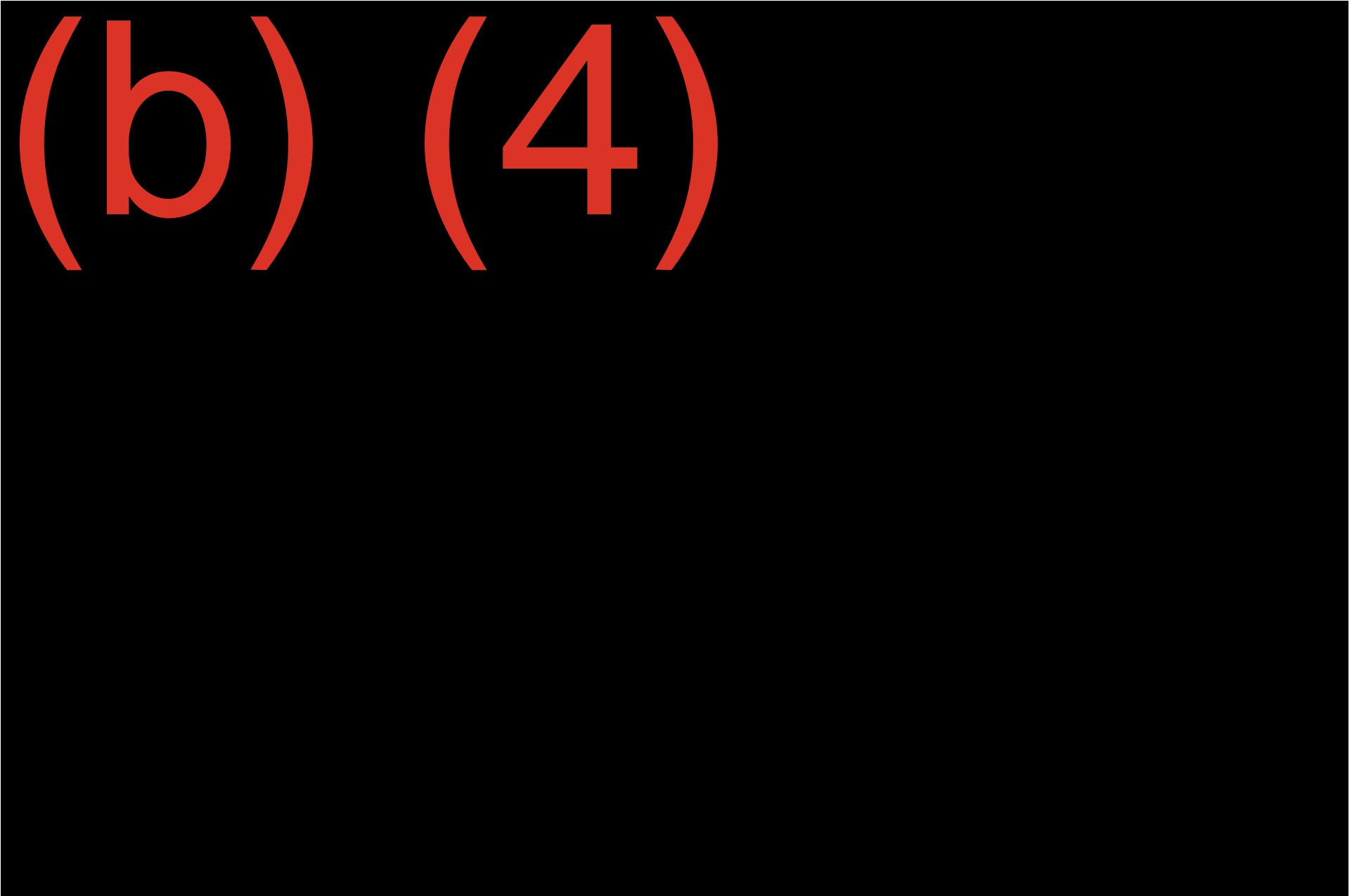
Issues identified in Round 1 cognitive interviews in (b) (4), October 25<sup>th</sup> and 26<sup>th</sup>, 2017 are listed in Table 3 below. Questions identified as having issues were revised for testing in Round 2.

**Table 3: Survey Changes after Round 1**





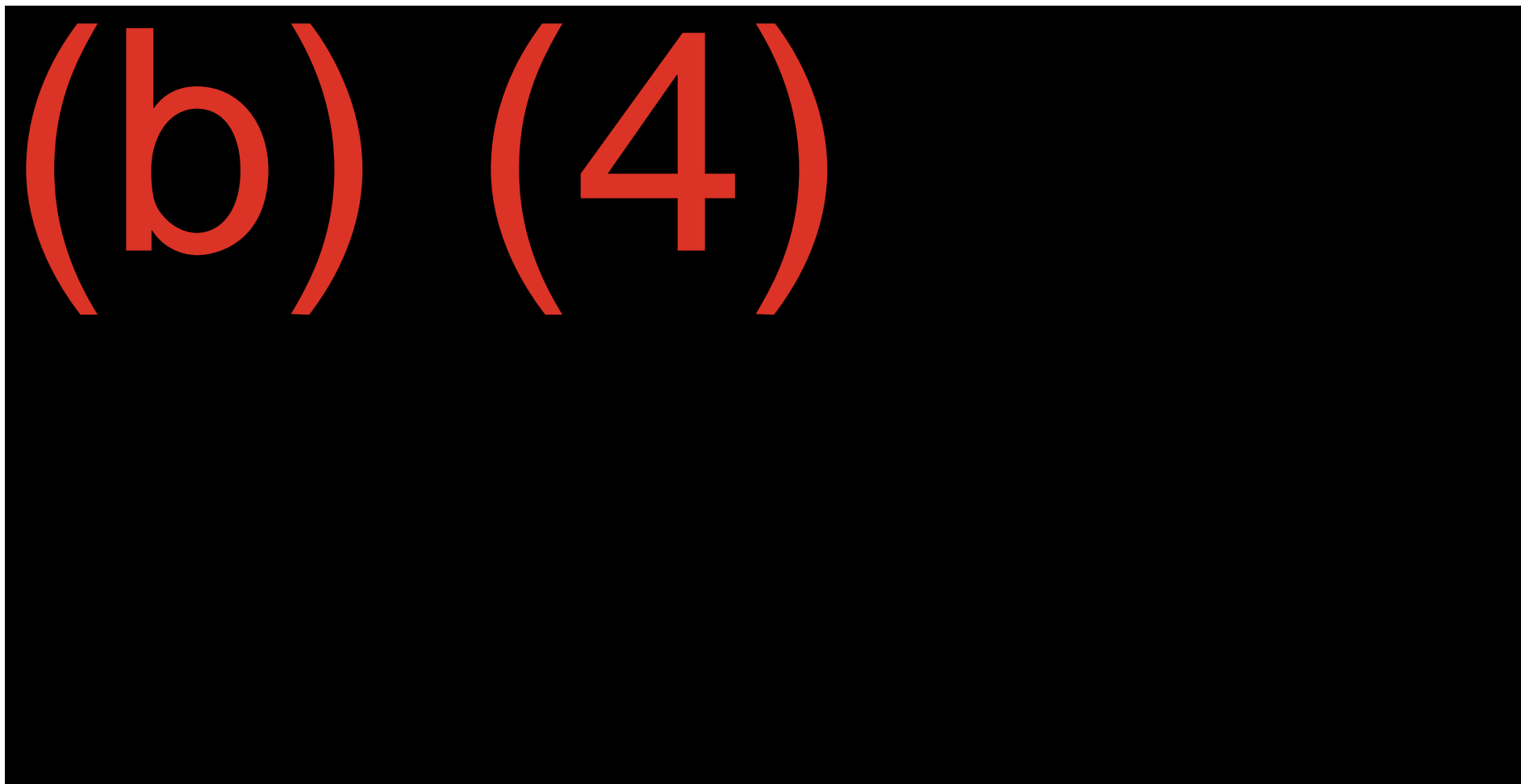
(b) (4)



### Overall Findings – Round 2 Interviews

A minor issue identified in Round 2 of cognitive interviews in (b) (4), November 7<sup>th</sup> and 8<sup>th</sup>, 2017 is listed in Table 4 below. There were no new substantive comprehension issues.

**Table 4: Survey Changes after Round 2**



(b) (4)

## 4.2. Conclusion

The design and execution of Round 1 identified questions not functioning as intended. Revisions tested in Round 2, using the same methodology as in Round 1, demonstrated improved comprehension of the questions. Saturation was achieved for all survey questions in Round 2. Simplifying question C42a-h by adding the one-time upfront instruction page improves readability but does not represent a comprehension issue that requires further testing.

The sample size was not designed to be projectable but was representative of the population that will be respondents in the quantitative phase in terms of age, gender, race/ethnicity, and TNP usage or non-usage. No difference in understanding the intent of the questions was evident based on age, gender, race/ethnicity, TNP usage or non-usage. No further testing is required.

## 5. REFERENCES

1. OMB Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews. Accessed October 12, 2016.
2. Perceptions and Behavioral Intentions Study for General Snus. Protocol SMNA 17-01GEN. November 27, 2017
3. Boeije, H., Willis, G. The Cognitive Interviewing Reporting Framework (CIRF): Towards the harmonization of cognitive testing reports. In *Methodology: European Journal of Research Methods for the Behavioral and Social Sciences*. 2013;9(3): 87 – 95.

**6. ATTACHMENTS**

**ATTACHMENT 1A – INFORMED CONSENT FORM – SEATTLE**

**ATTACHMENT 1B – INFORMED CONSENT FORM – PHILADELPHIA**

**ATTACHMENT 2 – RECRUITMENT SCREENER**

**ATTACHMENT 3 – COGNITIVE INTERVIEW GUIDE**

**ATTACHMENT 4 – SURVEY WITH CHANGES AFTER ROUND 1**

**ATTACHMENT 5 – SURVEY WITH CHANGES AFTER ROUND 2**

**ATTACHMENT 6 - SMNA 17-01GEN PERCEPTION AND BEHAVIORAL INTENTIONS PROTOCOL, VERSION 1 (AMENDMENT 1). NOVEMBER 27, 2017.**