

(b) (4)

November 2017

**ZYN[®] Patterns of Use: Retrospective and Prospective Survey
Cognitive Testing Report**

Prepared for:

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2. BACKGROUND AND OVERVIEW

Swedish Match North America (SMNA) markets ZYN® as a nicotine delivery product and not as a smoking cessation product. SMNA will be filing a Premarket Tobacco Product Application (PMTA)¹ for ZYN® in 2018. A Patterns of Use study² will be conducted and submitted to the FDA as part of the ZYN® PMTA.

The overarching research question for the Patterns of Use study can be stated as follows: *How do ZYN® users and ZYN® non-users use tobacco and/or nicotine products (TNP) and perceive health risks associated with TNP?* These questions will be studied by means of a retrospective assessment of TNP use among both ZYN® users and ZYN® non-users (all of whom are of legal age to use TNP in their residential geography). As a secondary objective, this study will evaluate TNP patterns of use over time among ZYN® users and ZYN® non-users by means of a prospective 10-week self-reported daily e-diary study.

Before executing the Patterns 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 Interviews³.

This report describes the cognitive interview research. All documents used in the research are contained in the Attachments (Section 5).

3. METHODS

3.1. Materials and Process

To ensure that the materials were appropriate and sufficiently clear to consumers, the Patterns of Use retrospective and prospective online surveys were tested among (b) (4) ZYN™ and (b) (4) non-ZYN™ users across two rounds of qualitative in-depth, in-person, cognitive interviews in two of the 11 states where ZYN® 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 (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 an informed consent forms, recruitment screener, and cognitive interview guide (see Attachments 1a, 1b, 2, 3a, and 3b). All materials were reviewed and approved by an Institutional Review Board (IRB) 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 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.

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 3a and 3b for retrospective and prospective studies, respectively).

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, 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 subjects⁴ 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, approved by the sponsor and used to select respondents representative of the population of interest in the Patterns Of Use research with respect to age, gender, race/ethnicity, and ZYN® users or ZYN™ non-users (who use other TNP). (b) (4) recruited respondents by screening their local databases of consumers. To enhance ability to recruit ZYN™ users, which is a relatively low incidence, SMNA sent an email to their database of ZYN® users in each city to inform them of the study and provide contact information to (b) (4) or (b) (4). If interested in participating, these consumers contacted (b) (4) in their respective city and were provided the electronic link to the screener for qualification.

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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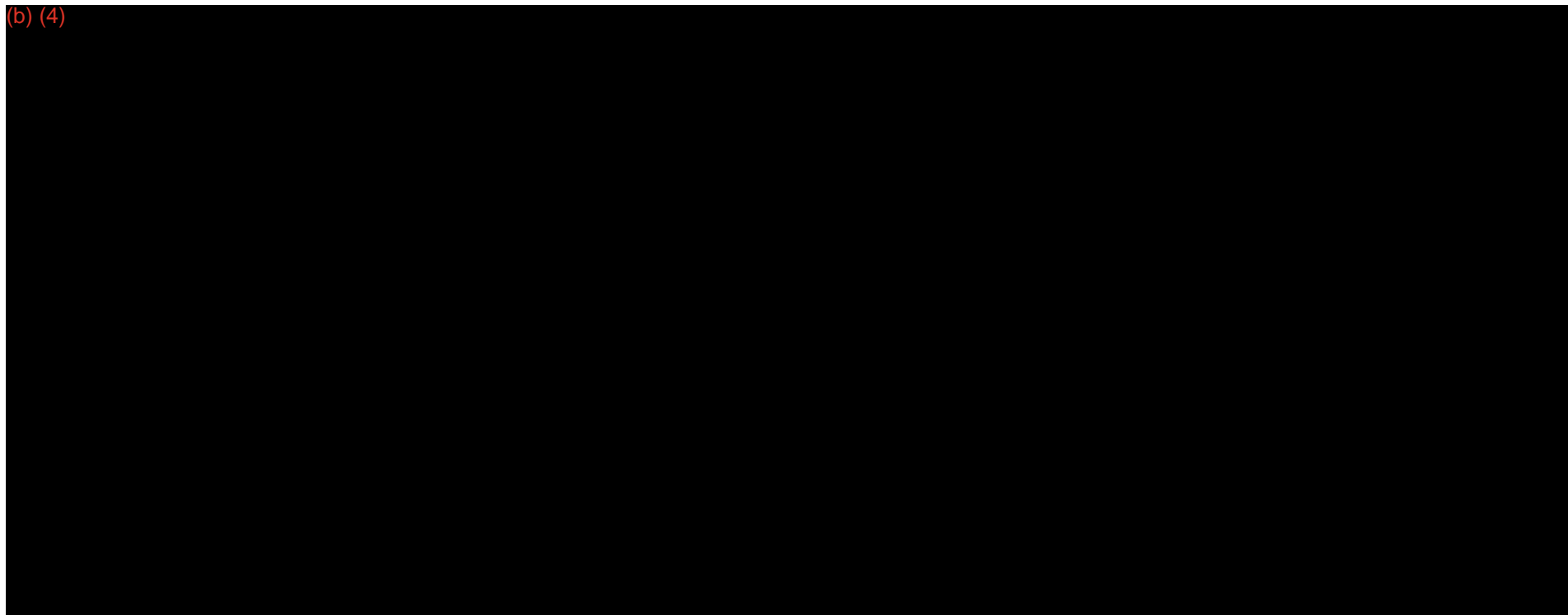


Table 2: Round 2 Cognitive Interview Respondents

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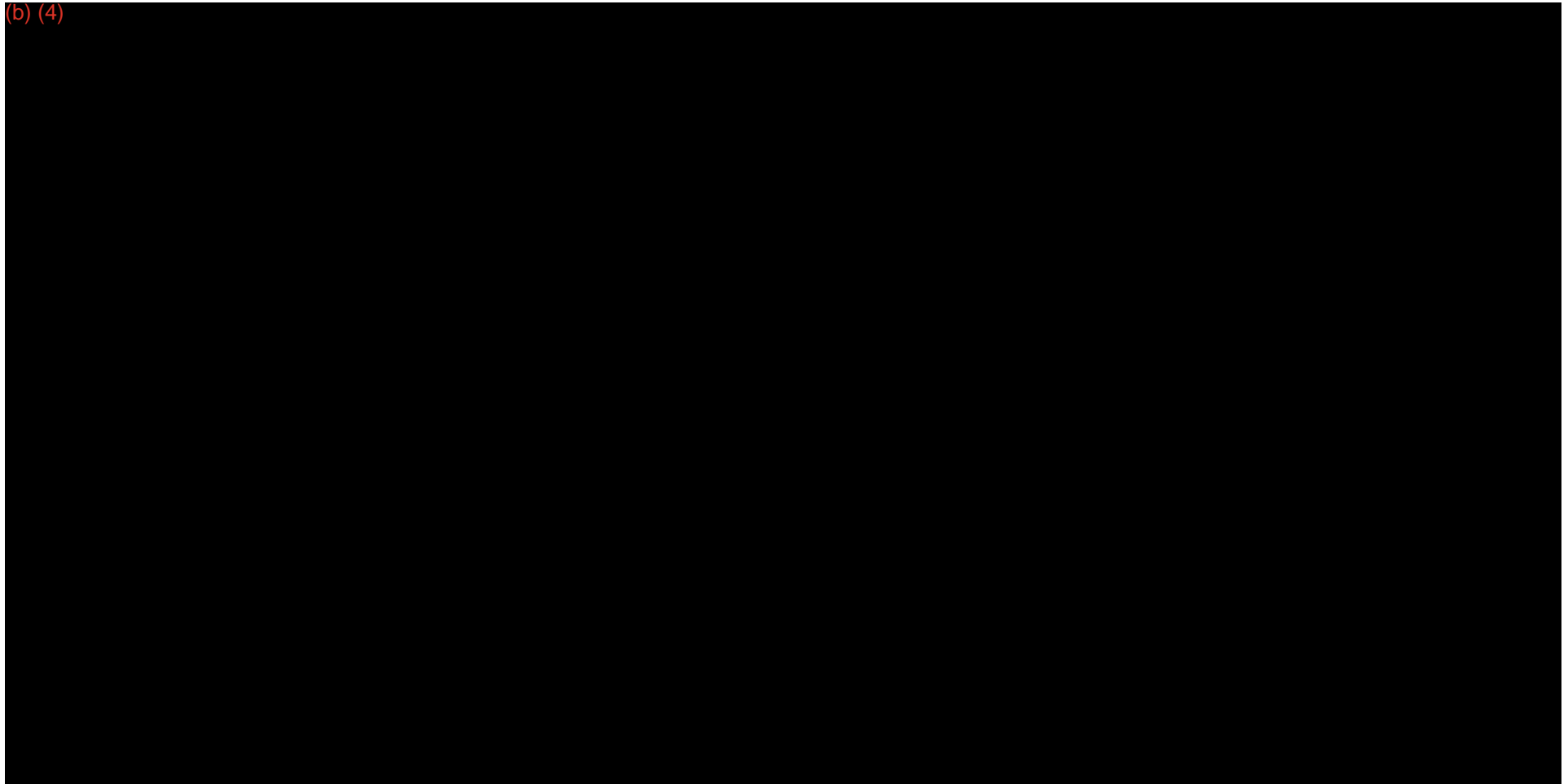
4. FINDINGS

4.1. Overall Findings – Round 1 Interviews

Issues identified in Round 1 cognitive interviews in (b) (4), October 16th, 17th and 18th, 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: Retrospective Survey

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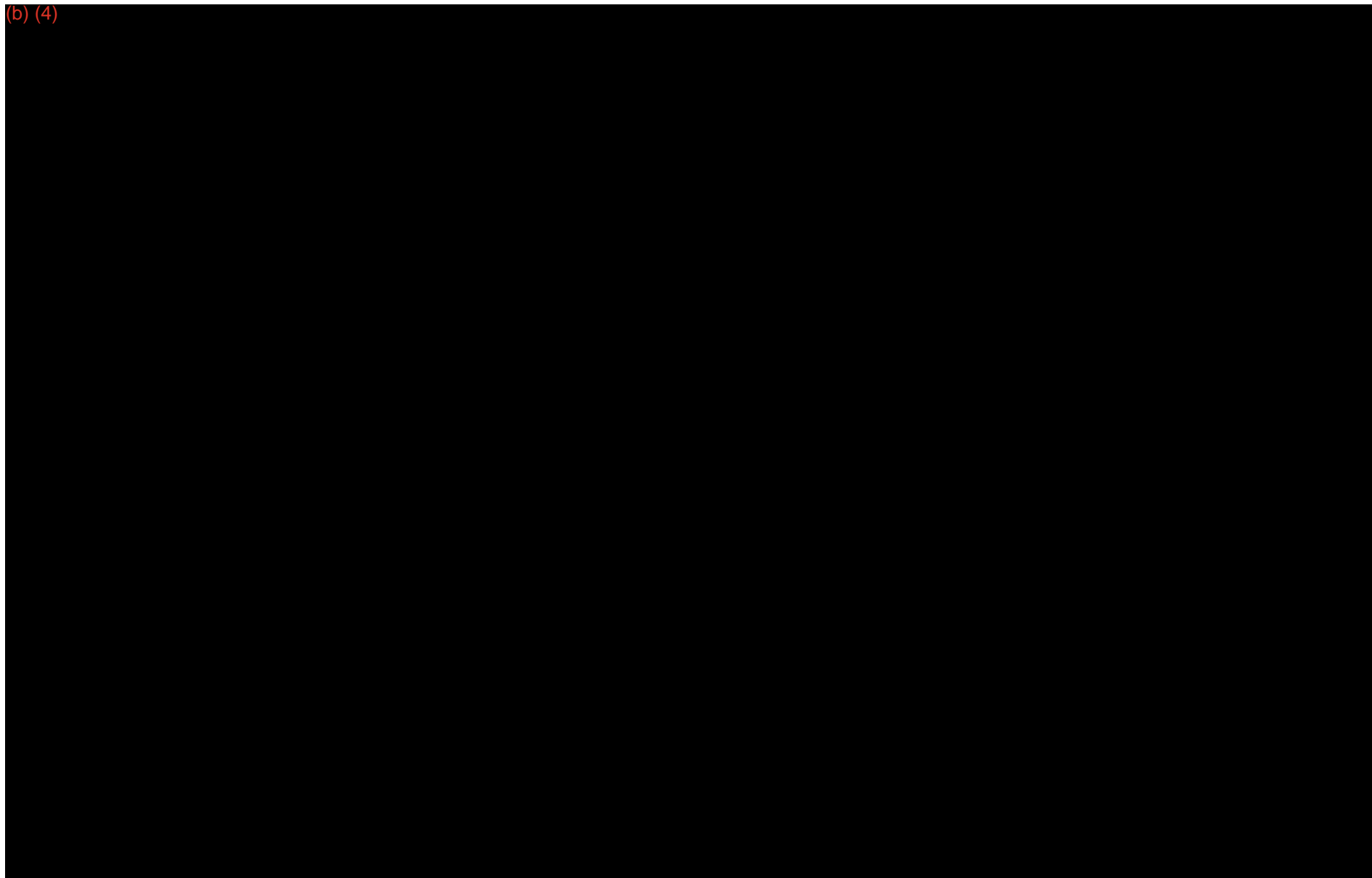
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Table 4: Survey Changes after Round 1: Prospective Daily Diary and Biweekly Survey

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Table 5: Survey Changes after Round 2: Retrospective Survey

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Survey Changes after Round 2: Prospective Daily Diary and Biweekly Survey

No further substantive findings occurred with the Prospective Daily Diary and Biweekly Prospective survey.

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 E4 and E4a. Additional testing of the question during cognitive testing of the Perceptions and Behavioral Intentions Study for *General Snus*TM 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*TM 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 ZYN® usage or non-usage. No difference in understanding the intent of the questions was evident based on age, gender, race/ethnicity, ZYN® usage or non-usage. No further testing is required.

(b) (4)

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™ Patterns of Use Study. 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 3A – COGNITIVE INTERVIEW GUIDE – RETROSPECTIVE

ATTACHMENT 3B – COGNITIVE INTERVIEW GUIDE – PROSPECTIVE

ATTACHMENT 4A – SURVEY WITH CHANGES AFTER ROUND 1 – RETROSPECTIVE

ATTACHMENT 4B – SURVEY WITH CHANGES AFTER ROUND 1 – PROSPECTIVE

ATTACHMENT 5A – SURVEY WITH CHANGES AFTER ROUND 2 – RETROSPECTIVE

ATTACHMENT 5B – SURVEY WITH CHANGES AFTER ROUND 2 - PROSPECTIVE

STUDY: Patterns of 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: Patterns of Use Study

PROTOCOL NO: (b) (4)

STUDY SITE: (b) (4)

TELEPHONE: (b) (4)

SPONSOR: Swedish Match North America

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: Patterns of 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 3rd party

STUDY: Patterns of 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: Patterns of 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: Patterns of Use Study

PROTOCOL NO: (b) (4)

STUDY SITE: (b) (4)

TELEPHONE: (b) (4)

SPONSOR: Swedish Match North America

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.

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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: Patterns of 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.

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- 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 3rd party

STUDY: Patterns of Use Study

(b) (4)

STERLING IRB ID: 6007-001

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

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September 28, 2017

PATTERNS OF USE
Cognitive Interview Recruitment Screener


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PATTERNS OF USE
SCREENER

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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.

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October 13, 2017

**RETROSPECTIVE PATTERNS OF USE SURVEY
INTERVIEW GUIDE**

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PATTERNS OF USE - RETROSPECTIVE STUDY
SCREENER

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ELECTRONIC INFORMED CONSENT FORM**ASK EVERYONE**

S19_ICF.

Please read and indicate you have read the following information.

- The purpose of this study is to learn about consumer usage of tobacco and nicotine. The study is being conducted for research purposes
- This survey will take approximately 15-20 minutes. About (b) (4) people will complete the survey.
- **[SHOW IF PANEL:** Assuming you complete all of the survey, you will receive the honoraria mentioned in the survey invitation for your time. **[SHOW IF NON-PANEL:** Assuming you complete all of the survey, you will receive (b) (4) 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. **[SHOW IF NON-PANEL:** Your name and address will be requested and will only be used to provide you your compensation.]
- 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 compensation mentioned earlier.
- Only one person per household may participate in this survey.
- 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 **[SHOW IF PANEL: INSERT SURVEY CONTACT PER PANEL PARTNER] [SHOW IF NON-PANEL: INSERT HOTLINE NUMBER (TBD FROM KH)].**

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

1	Yes	CONTINUE
2	No	TERMINATE

Moderator:

In your own words, how would you summarize what this is saying?

ASK EVERYONE**SHOW ON OWN SCREEN:**

After taking this survey, you will receive information and an invitation about another research study on this same topic. That study occurs over 10 weeks and also offers financial compensation.

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PATTERNS OF USE - RETROSPECTIVE SURVEY

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PROSPECTIVE 10-WEEK PATTERNS OF USE SURVEY

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ASK EVERYONE ON DAY 1

ICF.

PLEASE READ AND RESPOND TO THE QUESTION BELOW

- The purpose of this survey is to learn about tobacco and nicotine usage among the general public and to understand if there are any differences in product use. This survey is being conducted for research purposes.
- Your participation includes completing 1 brief survey every day for 10 straight weeks.
- The daily survey will take approximately 5 minutes to complete. Every two weeks the survey will include a few additional questions, and on those occasions the survey may take approximately 10 minutes to complete.
- You may receive up to (b) (4) for your participation if you participate for the full 10 weeks as requested. You will receive (b) (4) for each week (7 days) that you complete the daily surveys and an additional (b) (4) if you provide completed surveys every day for the full 10 weeks, which includes the 10-minute survey asked every two weeks (14 days). You will receive compensation following the completion of each week (7 days). The (b) (4) for completing all 10 weeks will be paid to you at the end of the 10-week data collection period.
- If you miss 3 surveys or more within 1 week (7 days) you will not receive compensation for that week, and you will be disqualified from continuing to the remaining daily surveys left in the 10 week period.
- If you miss one of the daily surveys in a one week period (7 days), a representative will call you using the phone number you provide to remind you to complete the next survey to ensure that you continue to qualify to participate and receive compensation for your time.
- Each day the survey will ask you about your tobacco and/or nicotine use from the day before. For this reason, we recommend answering the survey early in the day so that you may recall your activities from the day before more easily. Daily or continued use of tobacco and/or nicotine products is not required in order to continue to be qualified for this study.
- Your participation in this survey is strictly voluntary, and information such as your identity, personal information and answers will be kept confidential. Your name and address will be requested and will only be used to provide you your compensation. We will also ask for your email address and phone number which will be used only for the purpose of sending you survey reminders through the duration of this study.
- There are no likely risks, discomforts or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- 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 compensation 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 **[INSERT HOTLINE CONTACT INFORMATION]**

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

1	Yes	
2	No	

Moderator:

In your own words, how would you summarize what this is saying?

Is anything confusing or hard to understand?

Do you have any concerns?

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PATTERNS OF USE
DAILY DIARY SURVEY

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BIWEEKLY PROSPECTIVE
PATTERNS OF USE SURVEY

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October 21, 2017 – Comparison document post Cognitive Interviews Phase 1

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PROSPECTIVE 10-WEEK PATTERNS OF USE SURVEY

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ASK EVERYONE ON DAY 1

ICF.

PLEASE READ AND RESPOND TO THE QUESTION BELOW

- The purpose of this survey is to learn about tobacco and nicotine usage among the general public and to understand if there are any differences in product use. This survey is being conducted for research purposes.
- Your participation includes completing 1 brief survey every day for 10 straight weeks.
- The daily survey will take approximately 5 minutes to complete. Every two weeks the survey will include a few additional questions, and on those occasions the survey may take approximately 10 minutes to complete.
- You may receive up to (b) (4) for your participation if you participate for the full 10 weeks as requested. You will receive (b) (4) for each week (7 days) that you complete the daily surveys and an additional (b) (4) if you provide completed surveys every day for the full 10 weeks, which includes the 10-minute survey asked every two weeks (14 days). You will receive compensation following the completion of each week (7 days). The (b) (4) for completing all 10 weeks will be paid to you at the end of the 10-week data collection period.
- If you miss 3 surveys or more within 1 week (7 days) you will not receive compensation for that week, and you will be disqualified from continuing to the remaining daily surveys left in the 10 week period.
- If you miss one of the daily surveys in a one week period (7 days), a representative will call you using the phone number you provide to remind you to complete the next survey to ensure that you continue to qualify to participate and receive compensation for your time.
- Each day the survey will ask you about your tobacco and/or nicotine use from the day before. For this reason, we recommend answering the survey early in the day so that you may recall your activities from the day before more easily. Daily or continued use of tobacco and/or nicotine products is not required in order to continue to be qualified for this study.
- Your participation in this survey is strictly voluntary, and information such as your identity, personal information and answers will be kept confidential. Your name and address will be requested and will only be used to provide you your compensation. We will also ask for your email address and phone number which will be used only for the purpose of sending you survey reminders through the duration of this study.
- There are no likely risks, discomforts or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- 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 compensation 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 **[INSERT HOTLINE CONTACT INFORMATION]**

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

1	Yes	CONTINUE
2	No	TERMINATE

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**PATTERNS OF USE
DAILY DIARY SURVEY**

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BIWEEKLY PROSPECTIVE
PATTERNS OF USE SURVEY

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RETROSPECTIVE PATTERNS OF USE SURVEY

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**PATTERNS OF USE - RETROSPECTIVE STUDY
SCREENER**

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ELECTRONIC INFORMED CONSENT FORM**ASK EVERYONE**

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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 study is to learn about consumer usage of tobacco and nicotine. The study is being conducted for research purposes.
- This survey will take approximately 15-20 minutes. About 1,600 people will complete the survey.
- **[SHOW IF PANEL:** Assuming you complete all of the survey, you will **be compensated for your time and opinions**, as mentioned in the survey invitation. **[SHOW IF NON-PANEL:** Assuming you complete all of the survey, you will receive **(b) (4)** 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. **[SHOW IF NON-PANEL:** Your name and address will be requested and will only be used to provide you your compensation.]
- 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**. If you do withdraw, you will not receive the compensation mentioned earlier.
- Only one person per household may participate in this survey.
- 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 **[SHOW IF PANEL: INSERT SURVEY CONTACT PER PANEL PARTNER] [SHOW IF NON-PANEL: INSERT HOTLINE NUMBER (TBD FROM KH)]**.

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

1	Yes	CONTINUE
2	No	TERMINATE

ASK EVERYONE**SHOW ON OWN SCREEN:**

After taking this survey, you will receive information and an invitation about another research study on this same topic. That study occurs over 10 weeks and also offers financial compensation.

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PATTERNS OF USE - RETROSPECTIVE SURVEY

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October 21, 2017 – *COMPARISON DOC TO COGNITIVE INTERVIEWS PHASE 1*

RETROSPECTIVE PATTERNS OF USE SURVEY

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October 21, 2017 – *COMPARISON DOC TO COGNITIVE INTERVIEWS PHASE 1*

**PATTERNS OF USE - RETROSPECTIVE STUDY
SCREENER**

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ELECTRONIC INFORMED CONSENT FORM**ASK EVERYONE**

S19_ICF.

Please read and indicate you have read the following information.

- The purpose of this study is to learn about consumer usage of tobacco and nicotine. The study is being conducted for research purposes.
- This survey will take approximately 15-20 minutes. About (b) (4) people will complete the survey.
- **[SHOW IF PANEL:** Assuming you complete all of the survey, you will receive the honoraria mentioned in the survey invitation for your time. **[SHOW IF NON-PANEL:** Assuming you complete all of the survey, you will receive (b) (4) 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. **[SHOW IF NON-PANEL:** Your name and address will be requested and will only be used to provide you your compensation.]
- 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 compensation mentioned earlier.
- Only one person per household may participate in this survey.
- 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 **[SHOW IF PANEL: INSERT SURVEY CONTACT PER PANEL PARTNER] [SHOW IF NON-PANEL: INSERT HOTLINE NUMBER (TBD FROM KH)].**

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

1	Yes	CONTINUE
2	No	TERMINATE

ASK EVERYONE**SHOW ON OWN SCREEN:**

After taking this survey, you will receive information and an invitation about another research study on this same topic. That study occurs over 10 weeks and also offers financial compensation.

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PATTERNS OF USE - RETROSPECTIVE SURVEY

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October 30, 2017 – Comparison document – post-Seattle

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PROSPECTIVE 10-WEEK PATTERNS OF USE SURVEY

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ASK EVERYONE ON DAY 1
ICF.

PLEASE READ AND RESPOND TO THE QUESTION BELOW

You may need to scroll to see all options and to continue

- The purpose of this survey is to learn about tobacco and nicotine usage among the general public and to understand if there are any differences in product use. This survey is being conducted for research purposes.
- Your participation includes completing 1 brief survey every day for 10 straight weeks.
- The daily survey will take approximately 5 minutes to complete. Every two weeks the survey will include a few additional questions, and on those occasions the survey may take approximately 10 minutes to complete.
- You may receive up to (b) (4) for your participation if you participate for the full 10 weeks as requested. You will receive (b) (4) for each week (7 days) that you complete the daily surveys and an additional (b) (4) if you provide completed surveys every day for the full 10 weeks, which includes the 10-minute survey asked every two weeks (14 days). You will receive compensation following the completion of each week (7 days). The (b) (4) bonus for completing all 10 weeks will be paid to you at the end of the 10-week data collection period.
- If you miss 3 surveys or more within 1 week (7 days) you will not receive compensation for that week, and you will be disqualified from continuing to the remaining daily surveys left in the 10 week period.
- If you miss one of the daily surveys in a one week period (7 days), a representative will call you using the phone number you provide to remind you to complete the next survey to ensure that you continue to qualify to participate and receive compensation for your time.
- Each day the survey will ask you about your tobacco and/or nicotine use from the day before. For this reason, we recommend answering the survey early in the day so that you may recall your activities from the day before more easily. Daily or continued use of tobacco and/or nicotine products is not required in order to continue to be qualified for this study.
- Your participation in this survey is strictly voluntary, and information such as your identity, personal information and answers will be kept confidential. Your name and address will be requested and will only be used to provide you your compensation. We will also ask for your email address and phone number which will be used only for the purpose of sending you survey reminders through the duration of this study.
- There are no likely risks, discomforts or inconveniences to taking this survey. You will not receive any benefits from taking the survey.
- 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. If you do withdraw, you will not receive the compensation 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 **[INSERT HOTLINE CONTACT INFORMATION]**

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

1	Yes	CONTINUE
2	No	TERMINATE

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PATTERNS OF USE
DAILY DIARY SURVEY

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BIWEEKLY PROSPECTIVE
PATTERNS OF USE SURVEY

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