

SENSORY STABILITY OF COPENHAGEN® SNUFF FINE CUT

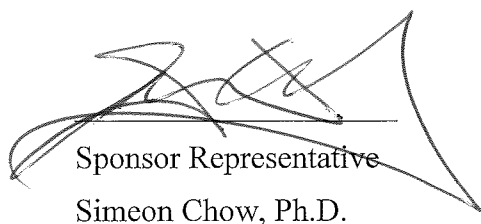
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Study Product: Copenhagen® Snuff Fine Cut¹

Study Conducted by: Consumer Opinion Center, Celerion Inc. Richmond, VA

Study Start Date: 27 March 2017
Study End Date: 5 July 2017

Sponsor:
Altria Client Services LLC
CMI-601 E. Jackson Street
Richmond, Virginia 23219
USA



Sponsor Representative
Simeon Chow, Ph.D.



Principal Investigator
Janine Fountain, MS

¹ Copenhagen® Fine Cut and variants thereof have been on the market since 1822. Since 2007, USSTC has made minor modifications to Copenhagen® Snuff Fine Cut, which are the subject of a separate pending Substantial Equivalence review. The candidate product subject to the MRTPA is the product for which FDA granted grandfathered status (Grandfather Number – GF1200194) on November 1, 2012. The product tested in this study was made according to the grandfather specifications.

3.1-19: SENSORY STABILITY OF THE CANDIDATE PRODUCT

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1. Summary:

Altria Client Services LLC (hereafter referred to as ALCS) on behalf of U.S. Smokeless Tobacco Company LLC (hereafter referred to as USSTC) designed and conducted a research project to study the sensory stability of Copenhagen® Snuff Fine Cut (candidate product¹). Sensory stability is defined as the duration of time during which an aged product maintains “desired sensory characteristics”, when stored under recommended conditions². Collectively, the desired sensory characteristics (also referred to as attributes) provide the sensory profile of the product that is described by “overall freshness” and fifteen (n=15) sensory attributes (b) (4)

Perception of “overall freshness” of moist smokeless tobacco (MST) products, like the candidate product, is an important component of consumer acceptability. Sensory stability is primarily determined by USSTC based on overall freshness and sensory attributes. Additionally, flavor descriptors are measured using a check all that apply (CATA) assessment as supportive diagnostic indicator to provide context to the potential changes in sensory attributes. The sensory stability of the candidate product was assessed using the method of descriptive analysis (Appendix 1). This method involves training consumers of a specific product category to evaluate objectively the desired sensory characteristics of that product category. The panelists who participated in this research were adult consumers of MST products who were trained to evaluate the sensory attributes and overall freshness of MST products. For every time period, a subset (N ~ 25) of a larger trained panel of adult MST consumers (N ~ 110) was randomly selected to evaluate the candidate product. A total of eight evaluations (time points 0 to 7), spaced at (b) (4) (Section 2.4), were conducted. The evaluation at time point 0 was conducted (b) (4) after the candidate product was finished and packed into the can since (b) (4) is the minimum amount of time required for a MST product to reach a retail shelf and be purchased by a consumer. This (b) (4) old candidate product is hereafter referred to as a “statistical control”³. Note that (b) (4) corresponds to time point 1, (b) (4) to time point 2 and so on, ending with (b) (4) corresponding to time point 7.

In order to observe a change in the sensory profile of the candidate product as it ages on the retail shelf, the sensory characteristics and overall freshness of candidate products at different time points in this study were compared to the (b) (4) candidate product (i.e. statistical control).

¹ Copenhagen® Fine Cut and variants thereof have been on the market since 1822. Since 2007, USSTC has made minor modifications to Candidate Product, which are the subject of a separate pending Substantial Equivalence review. The candidate product subject to the MRTPA is the product for which FDA granted grandfathered status (Grandfather Number – GF1200194) on November 1, 2012. The product tested in this study was made according to the grandfather specifications.

² ALCS internal definition developed from IFST definition of shelf life. Shelf life of foods: Guidelines for its determination and prediction Institute of Food Science and Technology, London (1993)

³ ASTM Standard E2425-05, 2005 (2011), “Standard Guide for Sensory Evaluation Methods to Determine the Sensory Shelf Life of Consumer Products” ASTM International, West Conshohocken, PA, 2011, DOI: 10.1520/E2425-05R11, www.astm.org

The sensory stability data for the candidate product is given in [Section 2.8](#).

1) [REDACTED] (b) (4)

2) The outcomes are summarized next in terms of attributes that were rated higher than the statistical control versus those that were rated lower than the statistical control during aging.

[REDACTED] (b) (4)

3) There were five attributes that showed significantly higher ratings at various time points during aging.

[REDACTED] (b) (4)

Additional analysis was conducted on CATA data collected from responses to flavor descriptors ([Section 2.8b](#)). [REDACTED] (b) (4)

[REDACTED]

[REDACTED] (b) (4)

2. Sensory Stability of Candidate Product

The objective of this research was to assess the sensory stability of the candidate product. The details of this research are given in the following sections (section 2.1 - 2.8).

2.1. Sensory Stability of Candidate Product – Methodology

The method of descriptive analysis ([Appendix 1](#)) was used to assess the sensory stability of the candidate product. Descriptive analysis is one of the primary sensory tools utilized for sensory stability testing³. The method requires consumers of a given product category who are trained to rate sensory characteristics of various products within that category⁴. A panel of adult MST consumers trained to evaluate various MST products participated in this research.

2.2. Sensory Stability of Candidate Product – Trained Panel

A trained panel of 8 to 12 individuals⁵ is often utilized in the method of descriptive analysis. In this research, approximately 25 trained panelists were selected randomly from a pool of approximately 110 trained panelists (b) (4). A total of 8 subpanels were utilized over the duration of the study. The use of a subpanel was deemed acceptable since the training process ([Appendix 1 Section E](#)) ensures consensus, consistency and accuracy ([Appendix 1 Section G](#)) amongst the trained panelists when evaluating product attributes. That is, the trained panelists are considered “calibrated instruments” with respect to the task of assessing the desired sensory characteristics of products⁴.

2.3. Sensory Stability of Candidate Product – Product Details

Sensory stability testing primarily involves comparing an aged product to a control, where the control is a specific product or a data set³. Three types of controls are recommended by ASTM E2454-05 when conducting sensory stability testing – a stable control, a statistical control or a fresh control. In order to use a stable control, storage conditions that minimize changes in the control product must be known³. (b) (4)

⁴ Lawless and Heymann. Sensory Evaluation of Food, 2nd Ed. Springer, 2010, Chapter 7, Page 150 and 160

⁵ Lawless and Heymann. Sensory Evaluation of Food, 2nd Ed. Springer, 2010, Chapter 10, Page 227

Therefore, as recommended by ASTM E2454-05, a statistical control was utilized in this research. An aged candidate product and the statistical control used in this research are described below:

Aged candidate product: A single lot of candidate product was produced at the beginning of this research and stored as loose cans at ambient conditions ($22 \pm 1^\circ\text{F}$ and $50 \pm 10\%$ relative humidity) for the duration of the research to represent typical conditions at retail.

Statistical control: Statistical control is a data set collected at time point 0³. Therefore, the sensory characteristics of candidate product estimated at (b) (4) time point 0 (Table 2.4a) were used as the statistical control.

2.4. Sensory Stability of Candidate Product - Study Design

The aged candidate product was evaluated by the trained panel (b) (4), as shown in Table 2.4a.

MST products offered by USSTC (b) (4) to reach retail shelf after their manufacturing. Therefore, the first evaluation session (time point 0) was conducted (b) (4). That is, the time at which the product reaches the retail shelf was considered as time point 0.

Table 2.4a Candidate Product Testing Session

| Session | Time point | Products |
|-----------|------------|----------|
| Session 1 | 0 | (b) (4) |
| Session 2 | 1 | |
| Session 3 | 2 | |
| Session 4 | 3 | |
| Session 5 | 4 | |
| Session 6 | 5 | |
| Session 7 | 6 | |
| Session 8 | 7 | |

2.5. Sensory Stability of Candidate Product - Evaluation Protocol

Candidate product was evaluated according to the protocol described in [Appendix 1 Section H](#). The ballot used to assess the sensory profile of candidate product is given in [Appendix 2](#).

2.6. Sensory Stability of Candidate Product - Statistical Analysis

2.6.1. Data Types

Two types of data were collected during sensory stability testing.

- Continuous data: collected from the responses to attribute intensity ratings on a (b) (4) (Appendix 1 Section E).
- Binary data: collected from the responses to overall freshness and flavor descriptors (CATA) questions (Appendix 1 Section E).

2.6.2. Analysis of Attribute Intensity Data

A one sample t-test³ was conducted to assess if an attribute intensity rating for the aged product from (b) (4) was significantly different from the statistical control.

The following test statistic was used:

$$t = \frac{\mu_a - \mu_{sc}}{S_a / \sqrt{n_a}}$$

where S_a , μ_a and n_a are the standard deviation, mean attribute intensity rating and sample size for the aged product respectively, and μ_{sc} is the mean attribute intensity rating for the aged product from (b) (4) (i.e. statistical control).

The aged product was considered to be significantly different from the statistical control if the test statistic, t was found to be less than $-t_{\alpha/2, n_a-1}$ or greater than $+t_{\alpha/2, n_a-1}$ where $t_{\alpha/2, n_a-1}$ represents a value from a t-distribution with n_a-1 degrees of freedom and $\alpha = 0.05$ for a 2-sided test.

2.6.3. Analysis of Overall Freshness and CATA Data:

The binary data from the responses to the overall freshness and flavor descriptors questions ([Appendix 1 Section E](#)) were analyzed as proportions (the proportion of panelists who

responded “yes” for overall freshness and a given flavor descriptor) and presented in percentages.

The following test statistic was used to determine whether the proportion of responses from the aged product was significantly different from the statistical control:

Test Statistic:

$$z = \frac{p_a - p_{sc}}{\sqrt{\frac{p_{sc}(1 - p_{sc})}{n_a}}}$$

where p_a and n_a is the proportion and sample size for the aged product respectively and p_{sc} is sample proportion for the aged product from (b) (4) (i.e. statistical control).

The aged product was considered to be significantly different from the statistical control for their CATA attributes if the test statistic (z-score) was found to be less than -1.96 or greater than $+1.96$ (2-sided test at $\alpha=0.05$).

Given the importance of overall freshness to the sensory stability of a product, a conservative confidence interval of 90% (i.e. z-score of ± 1.645) was used and the two proportions (aged product vs statistical control) were deemed to be significantly different from each other if the test statistic (z-score) was less than -1.645 or greater than $+1.645$ (2-sided test at $\alpha=0.10$).

2.7. Sensory Stability of Candidate Product – Outcomes of Sensory Stability Analyses

The sensory stability data for the candidate product is given in [Section 2.8](#). (b) (4)

The outcomes are summarized next in terms of attributes that were rated higher than the statistical control versus those that were rated lower than the statistical control during aging. (b) (4)

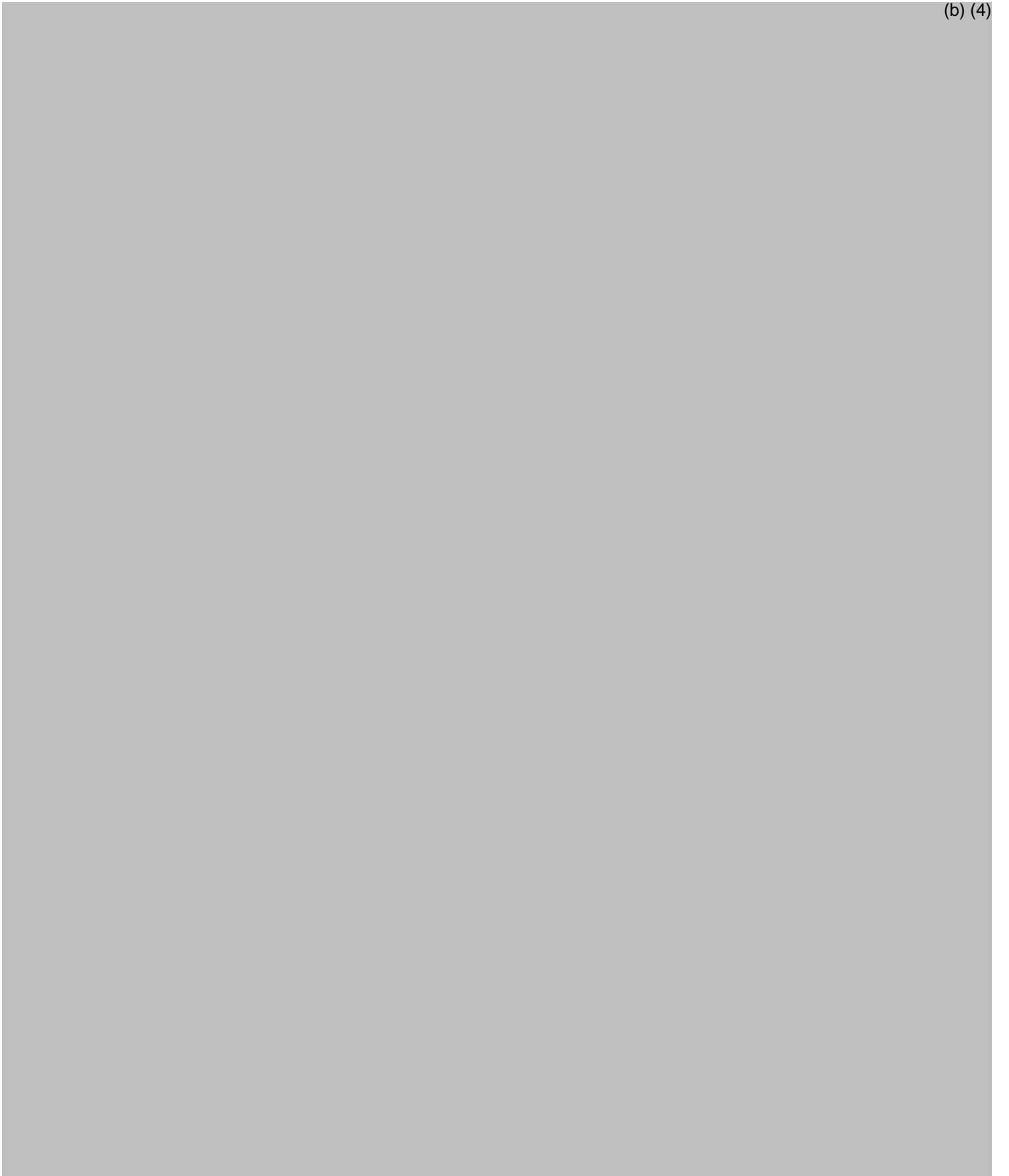
2.8. Sensory Stability Methodology of Candidate Product - Data Tables

(b) (4)



Table 2.8b CATA Percentages for Fresh Control and Candidate Product

(b) (4)



Appendix 1 Descriptive Analysis

A. Overview

Descriptive analysis involves the use of trained panelists to measure the perceived intensities of the sensory characteristics of an item^{6,7}. In this study, trained panelists were the adult consumers of MST products (also referred to as adult dippers) and the item being measured was moist smokeless tobacco. Adult dippers were trained over the course of 3 weeks for 90 minutes per session, followed by 6 weeks of panel validation and retraining as needed to be able to assess a range of smokeless tobacco products. This trained descriptive panel is termed the Total Smokeless Tobacco Panel (TSTP).

B. Total Smokeless Tobacco Panel - Introduction

The Total Smokeless Tobacco Panel was comprised of adult MST consumers who were recruited based on interest and product use, screened for sensory acuity, and finally trained in the method of descriptive analysis (b) (4) to assess MST products.

C. Total Smokeless Tobacco Panel – Panel Composition

Trained panelists are permitted to participate for a (b) (4)

Panelists who participated in the sensory stability assessment of candidate product were trained and validated in year (b) (4) or (b) (4) (b) (4)

A panel that participated in the candidate product sensory stability testing had the following demographic makeup:

- Mainly adult males and few adult females who use at least 1 can of MST per week (self-reported)
- Age distribution:
 - Age group 21-30: 17%
 - Age group 31-40: 34%
 - Age group 41-50: 30%
 - Age group 51-60: 19%
- Approximately 78% had some college education

⁶ Meilgaard, Civille, Carr. Sensory Evaluation Techniques, 4th Ed. CRC Press, 2006, section 10, Page 173

⁷ Lawless and Heymann. Sensory Evaluation of Food, 2nd Ed. Springer, 2010. Chapter 1, Page 6

- Approximately 85% were employed part or full time, with the remainder typically unemployed/retired
- Approximately 79% used long cut MST as their primary form and the remainder used either pouch or fine cut
- Approximately 56% used wintergreen MST as their regular variety. Another ~17% used mint MST while the remaining ~28% used other varieties.

D. Total Smokeless Tobacco Panel - Prescreening Methodology

Recruiting of adult tobacco consumers for the TSTP was conducted via the Consumer Opinion Center Database and via radio advertising. The Consumer Opinion Center (COC) is a research facility owned by ALCS and operated by Celerion, Inc. Individuals who have already agreed to be contacted by the COC by becoming a member of their consumer database were contacted via telephone and/or email and invited to complete a screening questionnaire to gauge initial pre-qualification and interest in panel participation ([Appendices 3a-3b](#)). Additionally, the COC advertised on local radio stations. Interested individuals who called in response to these advertisements also completed the same screening questionnaire to gauge initial pre-qualification and interest in panel participation ([Appendices 3a-3b](#)).

Those adult dippers who completed the telephone screen without disqualification were invited to participate in an in-person pre-screening session aimed at assessing each individual's a) taste and odor acuity; and b) openness to using various forms and varieties of MST products and articulateness to describe them. These adult dippers were age verified, signed a voluntary participation statement ([Appendix 4](#)) and then completed a three-step in-person screening process aimed at assessing participants' taste and odor acuity as outlined below and in [Appendices 5](#) and [6](#):

(b) (4)

E. Total Smokeless Tobacco Panel - Training Methodology

(b) (4)



Additionally, panelists were provided a list of flavor descriptors. While no formal training was provided, references were available upon request to illustrate the nature of the flavor descriptors that were unclear to the panelists.

MST Flavor Descriptors:

(b) (4)

For each flavor descriptor, panelists indicated whether the flavor note was present in the MST product being evaluated (Yes/No) using a Check All That Apply (CATA) exercise ([Appendix 2](#)). Since no training is provided on flavor descriptors, the CATA data is used as a supportive diagnostic indicator to provide context to the potential changes in sensory attributes.

F. Total Smokeless Tobacco Panel - Data Collection

TSTP data, whether for panel training, validation or research studies, is collected using Compusense Cloud[®], a computerized data collection application administered by the Consumer Opinion Center (COC). The system houses the sensory ballots (questionnaires), a database of panelists, study design/sample rotation, sample identification and results. Ballots ([Appendix 2](#)) are drafted by the COC staff as directed by CMI-SPR team members. CMI-SPR is then responsible for verifying the ballot, study design and samples prior to data collection.

Panelists participated in an orientation to the computer software at the end of training and prior to data collection and panel validation.

G. Total Smokeless Tobacco Panel - Panel Validation

The goal of panel validation is to assess the performance of the newly trained panelists both as a group and as individuals. In this study, the panel performance was assessed for the elements of discrimination, agreement, consistency/repeatability and validity/accuracy.

- **DISCRIMINATION** – Are the panelists able to detect expected product differences based on the attribute intensities?
 - Mixed model ANOVA for each attribute
 - Product main effect indicates the discrimination ability of the panel
 - All effects were analyzed at 0.1 significance level ($\alpha = 0.1$)

- **CONSENSUS/AGREEMENT** – Is there a consensus amongst the panelists when rating products for a given attribute?
 - Product: Panelist interaction in a mixed ANOVA model indicates the agreement between panelists
 - Product: Panelist interaction plot - to see who's evaluating differently from the others.

OR

 - Compare the deviation of each panelist's average rating from the average rating on that product/attribute across all panelists with pooled variation across all panelists (#standard deviations away from the panel mean)

- **CONSISTENCY/REPEATABILITY** – Are the panelists able to rate the same product consistently from rep to rep for a given attribute?
 - Product:Session interaction in a mixed ANOVA model indicates the repeatability of the panelists
 - The variance of each panelist for a given attribute on a specific product was compared to the variance across all panelists (pooled variance) for that product. Scores were ranked to see whose scores were high. Panelist with lower score is more consistent.
 - Consistency/Repeatability = $s^2_{panelist} / s^2_{pooled}$

- **VALIDITY/ACCURACY** – Are panelists rating reference products where they should be?
 - Measure how accurate the rating is by comparing to the true measure (reference standard) using bar charts or scatter plots

Panel validation sessions were conducted two times per week for 6 weeks ([Appendix 8](#)) using the product evaluation protocol given in [Section H](#). For a select number of sessions, previously trained panelists who have been on the panel for a minimum of one year also completed the same product evaluations. This allowed for comparison of the performance of the newly trained panelists to the previously validated panel. The data for panel validation was collected through evaluation of selected market products ([Appendix 8](#)). On the first two days, the first product given to panelists was a reference product. This product was presented with the ratings, meaning that as the panelists navigated through the online data

collection system, the answers for this first product were provided on the screen. This allowed the panelists to orient themselves and to check their ratings initially and provide one additional layer of training prior to full validation.

Once data was collected, it was analyzed by an approved vendor to assess the above criteria and recommend next steps with regards to the following:

- Panelists who were performing well and may integrate into the existing panel pool;
- Panelists who require additional training prior to integration;
- Attributes which require additional training; and
- Product categories which require additional training.

H. Total Smokeless Tobacco Panel – Product Evaluation Protocol

During each evaluation session, no more than four products were evaluated in a sequential monadic fashion using either a williams square design (when evaluating 4 products) or a complete block design (when evaluating less than 4 products). Products were evaluated according to the following protocol which includes a 5 minute usage with a 10-minute wash-out period in between product evaluations. (b) (4) (Section E) for the relevant attributes.

Product Evaluation Protocol Example:

- Products:
 - Product #1 (A)
 - Product #2 (B)
 - Product #3 (C)
- Sample Rotation: ABC, ACB, BCA, BAC, CAB, CBA
- 5 minutes of product trial during which the product attributes from Section E were rated in a predetermined order, followed by a 10-minute wash out period

The computerized system prompted the panelists to rate each attribute in the predetermined order and included time-delays to ensure adherence to the 5 minute usage period, aftertaste metric of 30 seconds after product removal and 10 minute wash-out period.

Product Evaluation Flow

(b) (4)



I. Total Smokeless Tobacco Panel - Retraining

Panelists were retrained utilizing the same approach as outlined above in [Section E](#) and revalidated as in [Section G](#) prior to integrating with the panel. Panelists who did not benefit from retraining after two attempts were subsequently dismissed from the panel.

Appendix 2 Ballot used to assess the sensory profile of Candidate Product and Fresh Control

Generated by Compusense Cloud



Total Smokeless Tobacco Panel

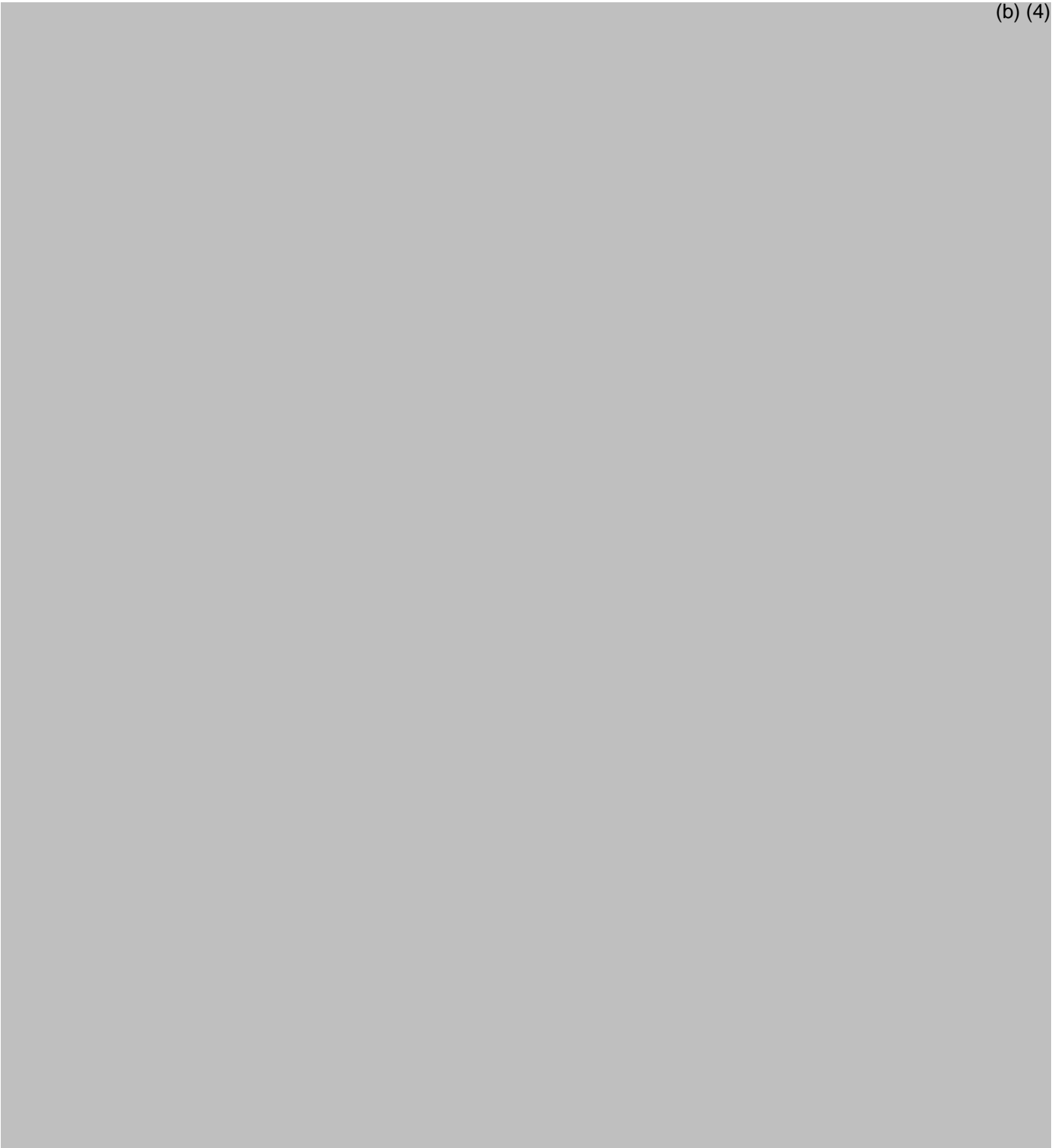
06/05/2017

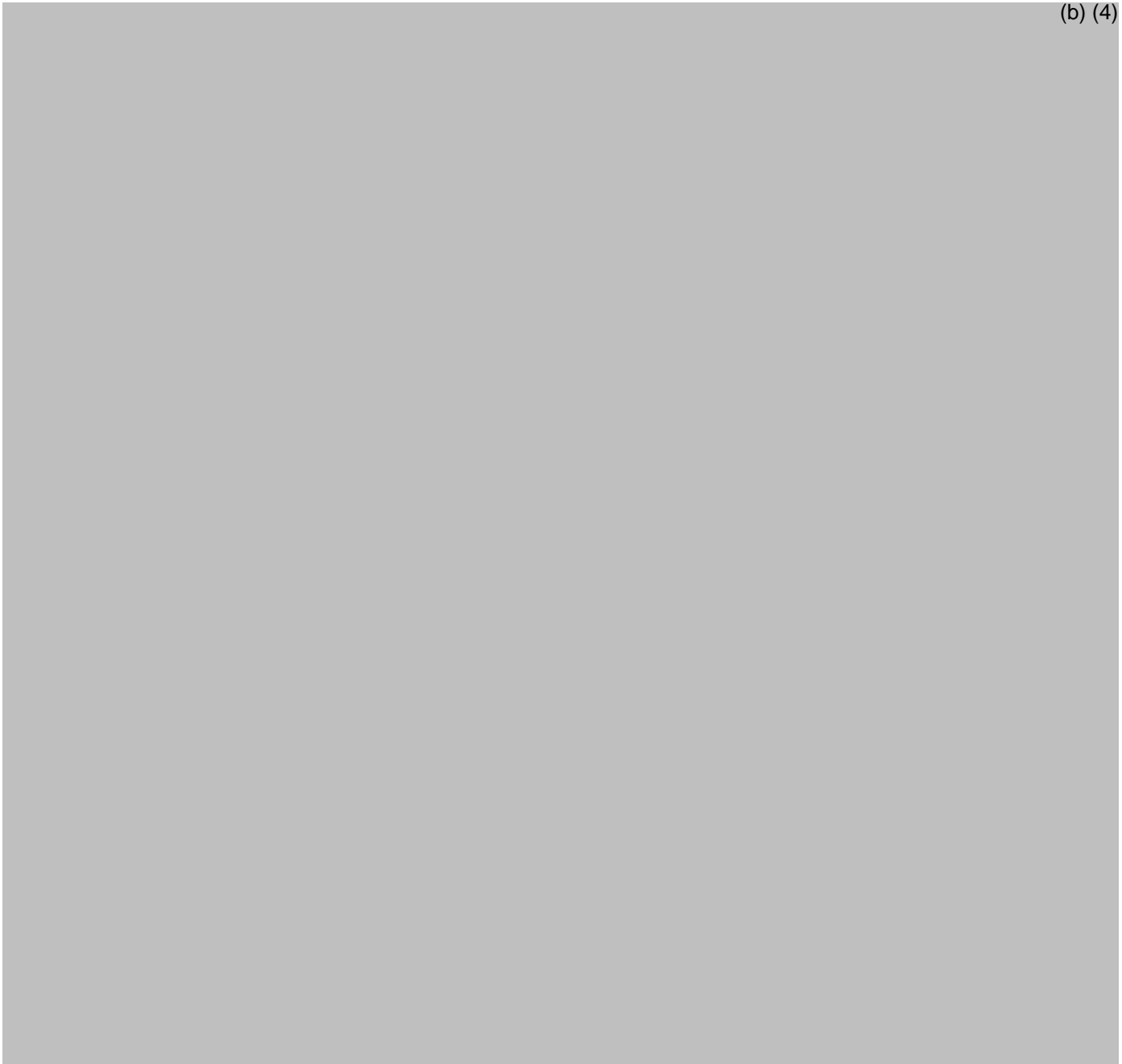
Welcome Panelist display name!
Thank you for participating in this important research!

Your participation on this panel is completely voluntary. You may discontinue participation at any time.

Click the **next** button to begin







Please wait 10 minutes in between sample evaluations.

When the timer reaches zero (0), Please get your next product from the COC study attendant.

Then click 'Next' to begin the evaluation.



Next

Back

Thank you for your participation at the



Please be sure that all products have been returned to the COC Study Attendant, and that your space has been cleared. You have completed your evaluation for today.

We look forward to seeing you for your next visit!

Finished

Appendix 3 Total Smokeless Panel Telephone Screener

Appendix 3a TSTP 2015

10/7/2014

Preview - CA15741 Total Smokeless Tobacco Panel Refresh

CA15741 Total Smokeless Tobacco Panel Refresh

[Print](#)

First I would like to give you some basic information about the study with respect to the dates and times when the study will take place. I WANT TO MAKE SURE YOU UNDERSTAND THAT THIS IS TOBACCO RELATED RESEARCH AND YOUR PARTICIPATION IS COMPLETELY VOLUNTARY.

This study is a long term study in which you will participate on a weekly panel for up to 2 years. Before participation on the weekly panel, you will be asked to participate in a pre-screening session and 12 training sessions. Selection for training will be based on your pre-screening visit; if qualified you will be asked to return for the training sessions. The pre-screening session will require a 1.5-hour visit to the COC facility and each of the 12 training sessions will require a 2.0 hour visit to the COC facility. Pre-screening sessions will occur on 30-Oct-2014, 06-Nov-2014, or 13-Nov-2014. The mandatory training sessions will take place Monday through Thursday the weeks of 01-Dec-2014, 08-Dec-2014, and 15-Dec-2014. Participants must be available to attend at least 11 training sessions prior to being placed on panel.

The COC compensates participants for full participation in our studies. If you participate in the prescreening session you will be compensated \$50 by check. If you participate in all 12 days of training you will be compensated \$500 by check. If you do not complete all 12 days of training you will be given a prorated stipend amount less than the total. You must complete the prescreening and training in full to be compensated in full.

All stipend checks for the prescreening portion will be provided to you on site unless you are recruited 48 hours prior to your prescreening appointment date. All stipend checks for the training portion will be mailed on Friday, 26-Dec-2014, to your home address.

In the event that a session time is cancelled we will communicate the cancellation to you by phone and/or e-mail.

In order to precede you will have to pass a qualifying questionnaire. This is much like a survey. The questionnaire will take about 5-10 minutes to complete. Please think carefully about your responses as I am obligated to take your first response only.

1. Is this an inbound call or an outbound call?

- ☐ Inbound
☐ Outbound

For Call Center Representatives

Enter your Celerion Initials

3. Are you interested in continuing?

- ☐ Yes
☐ No

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that may interest you. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page, or you can call our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you of the studies that are currently being recruited.

First Name as it appears on your government photo ID

Middle Initial/Name as it appears on your government photo ID

Last Name as it appears on your government photo ID

7. CALL CENTER: Did you verify the consumer's Full Name (First, Middle, Last), Address, Primary and Secondary phone numbers, and e-mail address?

☐ Yes

8. Record gender by observation:

☐ Female

☐ Male

Participant does not qualify because of gender.

9. What is your exact age?

Recruit 21 - 60

Participant does not qualify due to age.

10. Enter Birthday

11. Had you heard about this study prior to this phone call?

☐ Yes

☐ No

12. How did you hear about this study?

☐ COC Website

☐ Commonwealth Times

☐ Radio 102.1 FM

☐ Radio - K95FM

☐ Received An E-mail

☐ Facebook.com

☐ Richmond.com

☐ Beer, Bourbon, Barbecue

☐ New Kent/Charles City Chronicle

☐ Flyer

☐ Radio - 96.5 FM

☐ Radio Q94 FM

☐ Received A Text

☐ Returned Outbound Call

☐ timesdispatch.com

☐ Valpak

☐ Virginia Gazette

☐ Richmond Times-Dispatch Newspaper

☐ Radio - 92.1 FM

☐ Radio 106.5 FM

☐ Referred By Someone

☐ Yahoo.com

☐ commonwealthtimes.org

☐ Pandora

☐ Country Courier

<https://sandbox.clicktools.com/app/popups/Viewsurvey.jsp?assessmentid=214307165c1654&surveylanguage=en&language=en&version=&sbtok=5j5g...> 2/8

13. Are you allergic to menthol?

- ☐ Yes
☐ No

Participant does not qualify due to an allergy.

14. Do you have any food related allergies?

- ☐ Yes
☐ No

Participant does not qualify due to a food allergy.

15. Are you or is any member of your family, a friend or a relative living in your household employed by any of the following: market research firm, advertising or promotions agency, a TV or radio station, a manufacturer or distributor of cigarettes, or any other tobacco products, a magazine or newspaper, a government regulatory agency or a public policy advocacy group?

- ☐ Yes
☐ No

Participant does not qualify because he/she or a member of their current household works in the marketing and/or research industry.

16. CALL CENTER - Check consumer's account; did he/she COMPLETE one (1) study in the past three (3) months or two (2) studies in the past twelve (12) months?

- ☐ Yes
☐ No

Participant does not qualify due to prior participation.

17. Do you use cigarettes?

- ☐ Yes
☐ No

18. Do you use MST/Dip?

- ☐ Yes
☐ No

Participant does not qualify due to product usage.

19. Do you use dry snuff?

☐ Yes

☐ No

20. Do you use cigars?

☐ Yes

☐ No

21. Do you use SNUS?

☐ Yes

☐ No

22. Do you use Verve?

☐ Yes

☐ No

23. Do you use E-Vapor products?

☐ Yes

☐ No

24. What is your regular brand of MST/dip, that is the brand you purchase and use most often?

☐ Skoal ☐ Copenhagen

☐ Tahoe ☐ Timberwolf

☐ Grizzly ☐ Longhorn

☐ Husky ☐ Kayak

☐ Kodiak ☐ Other

Any brand qualifies.

Ensure that the participant's response matches what is indicated in the SFDC profile.

25. What is the cut of your regular brand of MST/Dip?

☐ Long Cut

☐ Fine Cut

☐ Pouches

Ensure that the participant's response matches what is indicated in the SFDC profile.

26. Would you be open to trying other cuts of MST/Dip on a regular basis, such as:

Yes No

Long Cut ☐ ☐

Fine Cut ☐ ☐

Pouch ☐ ☐

Participant does not qualify because they are not open to using other cuts of MST/dip.

27. What is the taste variety of your regular brand of MST/Dip?

- ☐ Wintergreen
☐ Straight
☐ Mint
☐ Natural/Original
☐ Apple Blend
☐ Berry Blend
☐ Peach Blend
☐ Citrus Blend
☐ Cherry

☐ Other - (Please Specify) :

Ensure that the participant's response matches what is indicated in the SFDC profile.

28. Would you be open to trying other varieties on a regular basis, such as:

| | Yes | No |
|---------------------------------------|-----------------------|-----------------------|
| Wintergreen | <input type="radio"/> | <input type="radio"/> |
| Mint | <input type="radio"/> | <input type="radio"/> |
| Natural | <input type="radio"/> | <input type="radio"/> |
| Other (ie. Crisp, Apply, Berry, etc.) | <input type="radio"/> | <input type="radio"/> |

The participant doesn't qualify because he is not open to using other taste varieties.

29. Please describe the appearance of your MST can.

Encourage the participant to use descriptive details such as shape, size, and colors, as well as describing brand and name of MST listed on can. Please verify against the MST Cheat Sheet.

30. How many cans of your regular brand of MST/Dip do you use per week?

- ☐ Less than 1 can/week
☐ 1 can/week
☐ 2 cans/week
☐ 3 cans/week
☐ 4 or more cans/week

Ensure that the participant's response matches what is indicated in the SFDC profile.

The participant doesn't qualify because he/she does not meet the required amount of Dip/MST used per week.

31. For this next question, I would like for you to use your imagination.

If you could meet a famous person from any time in history, who would you want to meet and why?

If respondent cannot clearly and coherently express themselves, or if the respondent speaks with a heavy accent, thank and terminate. Do not recruit respondents who are difficult to understand.

32. Is respondent articulate?

- ☐ Yes
☐ No

Participant does not qualify based on answers to articulation questions.

33. Are you currently employed.....

- ☐ Full time
☐ Part time
☐ Homemaker
☐ Not employed

Ensure that the participant's response matches what is indicated in the SFDC profile.

34. What is your annual household income?

- ☐ \$10,000 to \$15,000 ☐ \$15,000 to \$20,000 ☐ \$20,000 to \$30,000
☐ \$30,000 to \$40,000 ☐ \$40,000 to \$50,000 ☐ Over \$50,000

Ensure that the participant's response matches what is indicated in the SFDC profile.

35. Now I'm going to read a number of educational levels to you. Please stop me when I read the highest level of education you have completed.

- ☐ Did Not Graduate High School ☐ Graduated High School / Obtained GED
☐ Some College ☐ Graduated College
☐ Some Graduate School ☐ Graduate / Advanced Degree

Ensure that the participant's response matches what is indicated on the SFDC profile.

36. Did the participant pass the questionnaire?

- ☐ Yes
☐ No

Thank you \${question_4} for your time. You passed the qualifying questionnaire. Now I would like to give you more specific detail as to what you can expect while participating in the study.

Once you arrive at the facility, our Consumer Research Coordinator will check you into the building and escort you to our lobby. You will be checked in, consented, and required to complete an additional questionnaire. If you meet the requirements for the study after completing this additional questionnaire and you're selected, you will then be taken to the panel room where you will complete screening.

37. Are you interested in hearing the appointment times offered for this study?

- ☐ Yes
☐ No

Great! The appointment times being offered are as follows:

<https://sandbox.clicktools.com/app/popups/Viewsurvey.jsp?assessmentid=214307165c1654&surveylanguage=en&language=en&version=8&stok=5j5g...> 6/8

30-Oct-2014, 06-Nov-2014, 13-Nov-2014

09:00
11:00
13:00
15:00
17:00
19:00

38. Would you like for me to schedule you for an appointment time?

- ☐ Yes
☐ No

39. Select Group

- ☐ 1

Call Center Do Not Read

40. Select Appointment Date

- ☐ 30-Oct-2014
☐ 06-Nov-2014
☐ 13-Nov-2014
☐ Waitlist

41. Select Appointment Time

- ☐ 09:00
☐ 11:00
☐ 13:00
☐ 15:00
☐ 17:00
☐ 19:00

Enter SFID

Enter SFID

Call Center: Ensure study packet has been sent.

44. CALL CENTER: Please remember that a study packet needs to be sent to the participant.

- ☐ Noted

Unfortunately, I am unable to place you on this particular study. Our client is looking for very specific responses. This in no way prevents you from participating on future studies. Please check back with us in about a week and also check your e-mail for information regarding future opportunities. Another quick and easy way to check future study opportunities is to log onto www.consumeropinioncenter.com and click on the New Study Opportunities tab to see the full list of studies currently being recruited. Thank you for

your time and have a great day.

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that you may be interested in. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page or you can call into our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you on studies that are currently being recruited.

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that you may be interested in. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page or you can call into our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you on studies that are currently being recruited.

We currently have you on our waitlist for this study. Thank you for taking the time to go through this survey.

Great. You have been scheduled for \${question_40} at \${question_41}.

Checks for your pre-screening appointment will be provided to you on-site at the completion of your visit unless you are recruited 48 hours prior to your appointment date.

Lastly, if you have an e-mail address, we will e-mail you a study packet of information that includes the following:

- Calendar of important dates regarding your study*
- Driving directions to the COC*
- A list of frequently asked questions*
- A COC Referral Form*
- A Printable Parking Pass*

We are also capable of mailing you a study packet if no e-mail address is available. We will send you the study packet a few days prior to your appointment.

*You will need to bring a government issued Photo ID to your appointment such as a driver's license or a state ID that includes your date of birth. If you do not bring your government issued photo ID you will be dismissed from the study with NO COMPENSATION. **You will also need to bring your usual brand of MST/Dip with you to the facility as it will be required for the study.***

INDIVIDUALS NOT PARTICIPATING IN THE STUDY, INCLUDING CHILDREN, ARE NOT ALLOWED IN THE FACILITY.

If you need to cancel your appointment we ask that you give us as much notice as possible but we require at least 48 hours notice.

Appendix 3b TSTP 2017

9/9/2016

Preview - CA20852 TSTP Refresh

CA20852 TSTP Refresh

Print

First I would like to give you some basic information about the study with respect to the dates and times when the study will take place. I WANT TO MAKE SURE YOU UNDERSTAND THAT THIS IS TOBACCO RELATED RESEARCH AND YOUR PARTICIPATION IS COMPLETELY VOLUNTARY.

This study is a long term study in which you will participate on a weekly panel for up to 3 years. Before participation on the weekly panel, you will be asked to participate in a pre-screening session and 11 training sessions. Selection for training will be based on your pre-screening visit; if qualified you will be asked to return for the training sessions. The pre-screening session will require a 1.5-hour visit to the COC facility and each of the 11 training sessions will require a 2.0 hour visit to the COC facility. Pre-screening sessions will occur on 12-Oct, 13-Oct, 14-Oct, 17-Oct, 19-Oct or 20-Oct-2016. The mandatory training sessions will take place Monday through Thursday the weeks of 31-Oct-2016, 07-Nov-2016, and 14-Nov-2016. Participants must be available to attend all the training sessions prior to being placed on panel.

The COC compensates participants for full participation in our studies. If you participate in the prescreening session you will be compensated \$75 by check. If you participate in all 11 days of training you will be compensated \$590 by check. If you do not complete all 11 days of training you will be given a prorated stipend amount less than the total. You must complete the prescreening and training in full to be compensated in full.

All stipend checks for the prescreening portion will be mailed on Friday 28-Oct-2016 to your home address.

In the event that a session time is cancelled we will communicate the cancellation to you by phone and/or e-mail.

In order to proceed you will have to pass a qualifying questionnaire. This is much like a survey. The questionnaire will take about 5-10 minutes to complete. Please think carefully about your responses as I am obligated to take your first response only.

1. Is this an inbound call or an outbound call?

- ☐ Inbound
☐ Outbound

For Call Center Representatives

Enter your Celerion Initials

3. Are you interested in continuing?

- ☐ Yes
☐ No

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that may interest you. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page, or you can call our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you of the studies that are currently being recruited.

First Name as it appears on your government photo ID

Middle Initial/Name as it appears on your government photo ID

Last Name as it appears on your government photo ID

7. CALL CENTER: Did you verify the consumer's Full Name (First, Middle, Last), Address, Primary and Secondary phone numbers, and e-mail address?

☐ Yes

8. Record gender by observation:

☐ Female

☐ Male

9. If Female Ask: Are you pregnant, planning to become pregnant, or currently nursing?

☐ Yes

☐ No

Participant does not qualify because she is currently pregnant and/or nursing.

10. What is your exact age?

Recruit 21 - 60

Participant does not qualify due to age.

11. Enter Birthday

12. Had you heard about this study prior to this phone call?

☐ Yes

☐ No

13. How did you hear about this study?

☐ COC Website

☐ Flyer

☐ Radio - 96.5 FM

☐ Radio - 92.1 FM

☐ Radio 102.1 FM

☐ Radio Q94 FM

☐ Radio 106.5 FM

☐ Radio - K95FM

☐ Received A Text

☐ Referred By Someone

☐ Received An E-mail

☐ Returned Outbound Call

☐ Facebook

☐ Valpak

☐ Pandora

☐ Text Message

☐ Online Ad

Call Center -

If it is the participant's first time participating and they were referred by someone, confirm the name of the person who

referred them to us. Please advise the caller that if that person's name is not on their profile by the time we make confirmation calls, there will be no referral stipend paid.

14. Do you have any drug allergies?

- ☐ Yes
☐ No

Participant does not qualify due to an allergy.

15. Are you allergic to menthol?

- ☐ Yes
☐ No

Participant does not qualify due to an allergy.

16. Do you have any food related allergies?

- ☐ Yes
☐ No

Participant does not qualify due to a food allergy.

17. Are you or is any member of your family, a friend or a relative living in your household employed by any of the following: market research firm, advertising or promotions agency, a TV or radio station, a manufacturer or distributor of cigarettes, or any other tobacco products, a magazine or newspaper, a government regulatory agency or a public policy advocacy group?

- ☐ Yes
☐ No

Participant does not qualify because he/she or a member of their current household works in the marketing and/or research industry.

18. CALL CENTER - Check consumer's account; did he/she COMPLETE AA86005, AA91614, AA96303, AA93703, AA96272, AA97283?

Prior participation in the above studies does not necessarily prohibit them from participating on this panel.

- ☐ Yes
☐ No

19. CALL CENTER - Check consumer's account; did he/she COMPLETE one (1) study in the past three (3) months or two (2) studies in the past twelve (12) months?

- ☐ Yes
☐ No

Participant does not qualify due to prior participation.

20. Do you use cigarettes?

- ☐ Yes
☐ No

21. Do you use MST/Dip?

- ☐ Yes
☐ No

Participant does not qualify due to product usage.

22. Do you use dry snuff?

- ☐ Yes
☐ No

23. Do you use cigars?

- ☐ Yes
☐ No

24. Do you use SNUS?

- ☐ Yes
☐ No

25. Do you use Verve?

- ☐ Yes
☐ No

26. Do you use E-Vapor products?

- ☐ Yes
☐ No

27. What is your regular brand of MST/dip, that is the brand you purchase and use most often?

- ☐ Skoal ☐ Copenhagen
☐ Tahoe ☐ Timberwolf
☐ Grizzly ☐ Longhorn
☐ Husky ☐ Kayak
☐ Kodiak ☐ Other

Any brand qualifies.

Ensure that the participant's response matches what is indicated in the SFDC profile.

28. What is the cut of your regular brand of MST/Dip?

- ☐ Long Cut
☐ Fine Cut
☐ Pouches
☐ Wide Cut
☐ Extra Long Cut

Ensure that the participant's response matches what is indicated in the SFDC profile.

29. Would you be open to trying other cuts of MST/Dip on a regular basis, such as:

- | | Yes | No |
|----------|-----------------------|-----------------------|
| Long Cut | <input type="radio"/> | <input type="radio"/> |
| Fine Cut | <input type="radio"/> | <input type="radio"/> |
| Pouch | <input type="radio"/> | <input type="radio"/> |

Participant does not qualify because they are not open to using other cuts of MST/dip.

30. What is the taste variety of your regular brand of MST/Dip?

- ☐ Wintergreen
☐ Straight
☐ Mint
☐ Natural/Original
☐ Apple Blend
☐ Berry Blend
☐ Peach Blend
☐ Citrus Blend
☐ Cherry

☐ Other - (Please Specify) :

Ensure that the participant's response matches what is indicated in the SFDC profile.

31. Would you be open to trying other varieties on a regular basis, such as:

- | | Yes | No |
|---|-----------------------|-----------------------|
| Wintergreen | <input type="radio"/> | <input type="radio"/> |
| Mint | <input type="radio"/> | <input type="radio"/> |
| Natural | <input type="radio"/> | <input type="radio"/> |
| Other (ie. Crisp Blend, Apple Blend, Berry Blend, etc.) | <input type="radio"/> | <input type="radio"/> |

The participant doesn't qualify because he is not open to using other taste varieties.

32. Please describe the appearance of your MST can.

Encourage the participant to use descriptive details such as shape, size, and colors, as well as describing brand and name of MST listed on can. Please verify against the MST Cheat Sheet.

33. How many cans of your regular brand of MST/Dip do you use per week?

- ☐ Less than 1 can/week
☐ 1 can/week
☐ 2 cans/week
☐ 3 cans/week
☐ 4 or more cans/week

Ensure that the participant's response matches what is indicated in the SFDC profile.

The participant doesn't qualify because he/she does not meet the required amount of Dip/MST used per week.

34. For this next question, I would like for you to use your imagination. Imagine you are a celebrity spokesperson for the regular MST/Dip brand you smoke. How would you pitch your MST/Dip brand in a commercial? Do your best to describe how it tastes, looks, etc.

If respondent cannot clearly and coherently express themselves, or if the respondent speaks with a heavy accent, thank and terminate. Do not recruit respondents who are difficult to understand or who are not articulate.

35. Is respondent articulate?

- ☐ Yes
☐ No

Participant does not qualify based on answers to articulation questions.

36. Are you currently employed.....

- ☐ Full time
☐ Part time
☐ Homemaker
☐ Not employed

Ensure that the participant's response matches what is indicated in the SFDC profile.

37. What is your annual household income?

- ☐ \$10,000 to \$15,000 ☐ \$15,000 to \$20,000 ☐ \$20,000 to \$30,000
☐ \$30,000 to \$40,000 ☐ \$40,000 to \$50,000 ☐ Over \$50,000

Ensure that the participant's response matches what is indicated in the SFDC profile.

38. Now I'm going to read a number of educational levels to you. Please stop me when I read the highest level of education you have completed.

- ☐ Did Not Graduate High School ☐ Graduated High School / Obtained GED
☐ Some College ☐ Graduated College
☐ Some Graduate School ☐ Graduate / Advanced Degree

Ensure that the participant's response matches what is indicated on the SFDC profile.

39. Did the participant pass the questionnaire?

- ☐ Yes
☐ No

Thank you \${question_4} for your time. You passed the qualifying questionnaire. Now I would like to give you more specific detail as to what you can expect while participating in the study.

Once you arrive at the facility, our Consumer Research Coordinator will check you into the building and escort you to our lobby. You will be checked in, consented, and required to complete an additional questionnaire. If you meet the requirements for the study after completing this additional questionnaire and you're selected, you will then be taken to the panel room where you will complete screening.

40. Are you interested in hearing the appointment times offered for this study?

- ☐ Yes

☐ No

Great! The appointment times being offered are as follows:

12-Oct-2016
09:00 (09:00 AM)
11:00 (11:00 AM)
13:00 (01:00 PM)

13-Oct-2016
13:00 (01:00 PM)
17:00 (05:00 PM)
19:00 (07:00 PM)

14-Oct-2016
11:00 (11:00 AM)
15:00 (03:00 PM)
17:00 (05:00 PM)

17-Oct-2016
13:00 (01:00 PM)
17:00 (05:00 PM)
19:00 (07:00 PM)

19-Oct-2016
11:00 (11:00 AM)
17:00 (05:00 PM)
19:00 (07:00 PM)

20-Oct-2016
13:00 (01:00 PM)
17:00 (05:00 PM)
19:00 (07:00 PM)

41. Would you like for me to schedule you for an appointment time?

☐ Yes
☐ No

42. Select Group

☐ 1

Call Center Do Not Read

43. Select Appointment Date

☐ 12-Oct-2016
☐ 13-Oct-2016
☐ 14-Oct-2016
☐ 17-Oct-2016
☐ 19-Oct-2016
☐ 20-Oct-2016
☐ Waitlist

44. Select Appointment Time

☐ 09:00 (09:00 AM)

- ☐ 11:00 (11:00 AM)
☐ 13:00 (01:00 PM)

45. Select Appointment Time

- ☐ 13:00 (01:00 PM)
☐ 17:00 (05:00 PM)
☐ 19:00 (07:00 PM)

46. Select Appointment Time

- ☐ 11:00 (11:00 AM)
☐ 15:00 (03:00 PM)
☐ 17:00 (05:00 PM)

47. Select Appointment Time

- ☐ 11:00 (11:00 AM)
☐ 17:00 (05:00 PM)
☐ 19:00 (07:00 PM)

Enter SFID

Enter SFID

Call Center: Ensure study packet has been sent.

50. CALL CENTER: Please remember that a study packet needs to be sent to the participant.

☐ Noted

Unfortunately, I am unable to place you on this particular study. Our client is looking for very specific responses. This in no way prevents you from participating on future studies. Please check back with us in about a week and also check your e-mail for information regarding future opportunities. Another quick and easy way to check future study opportunities is to log onto www.consumeropinioncenter.com and click on the New Study Opportunities tab to see the full list of studies currently being recruited. Thank you for your time and have a great day.

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that you may be interested in. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page or you can call into our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you on studies that are currently being recruited.

Participant is not interested in registering for this study.

I understand. I want to thank you for your time and interest in the Consumer Opinion Center. The Consumer Opinion Center is constantly offering study opportunities that you may be interested in. To stay current on studies being recruited you can log onto our website at www.consumeropinioncenter.com and check the Study Opportunities page or you can call into our call center periodically at 800-926-7262 and one of our Study Participant Representatives can inform you on studies that are currently being recruited.

We currently have you on our waitlist for this study. Thank you for taking the time to go through this survey.

Great. You have been scheduled for \${question_43} at \${question_44} \${question_45} \${question_46} \${question_47}.

Checks for prescreening will be mailed to your home address on Friday, 28-Oct-2016.

You will receive an additional \$50.00 for every new person you refer to the Consumer Opinion Center when they participate on a study or are selected as an alternate on a study. If you have any friends that are adult tobacco consumers, between the ages of 21 to 64 years old, that you think may be interested in this study or tobacco related research, please have them contact us right away as our studies can fill up quickly. Our number is 1-800-926-7262 and we are open Monday through Friday, from 8am to 8pm. Or they can visit us on the web at www.consumeropinioncenter.com for more information.

Lastly, if you have an e-mail address, we will e-mail you a study packet of information that includes the following:

- Calendar of important dates regarding your study*
- Driving directions to the COC*
- A list of frequently asked questions*
- A Printable Parking Pass*

We are also capable of mailing you a study packet if no e-mail address is available. We will send you the study packet a few days prior to your appointment.

*You will need to bring a government issued Photo ID to your appointment such as a driver's license or a state ID that includes your date of birth. If you do not bring your government issued photo ID you will be dismissed from the study with NO COMPENSATION. **You will also need to bring your usual brand of MST/Dip with you to the facility as it will be required for the study.***

INDIVIDUALS NOT PARTICIPATING IN THE STUDY, INCLUDING CHILDREN, ARE NOT ALLOWED IN THE FACILITY.

If you need to cancel your appointment we ask that you give us as much notice as possible but we require at least 48 hours notice.

Appendix 4 Statement of Voluntary Participation

CONFIDENTIALITY AGREEMENT AND STATEMENT OF VOLUNTARY PARTICIPATION IN SMOKELESS TOBACCO PRODUCT RESEARCH

Thank you for agreeing to participate in smokeless tobacco product consumer research. This statement contains important information about your participation in this research and the products you may use and evaluate. Please read this statement carefully.

The products you may use and evaluate in this research are smokeless tobacco products. These products may include prototype smokeless tobacco products not commercially available in the United States, smokeless tobacco products that are commercially available in the United States, or smokeless tobacco products available in limited test market in the United States.

The packaging for the smokeless tobacco products used in this research carries or would carry one of the following rotating warning labels:

WARNING: THIS PRODUCT CAN CAUSE MOUTH CANCER.

WARNING: THIS PRODUCT CAN CAUSE GUM DISEASE AND TOOTH LOSS.

WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

WARNING: SMOKELESS TOBACCO IS ADDICTIVE.

Do not participate in any use or evaluation of any of these products if you are pregnant or planning to become pregnant during your participation, are nursing, have any allergies, have any other health restrictions, or have other reasons not to participate.

Your participation is completely voluntary. You may discontinue participation at any time for any reason.

If you have any questions about your participation, please contact:

Consumer Opinion Center at (800) 926-7262

Contact Name at Research Supplier

Facility Contact Number

If you experience any undesirable physical effect from the use of study product that causes you concern, please call 800-559-9675.

CONFIDENTIALITY AND INTELLECTUAL PROPERTY AGREEMENT AND ACKNOWLEDGEMENT

I agree that any prototype products and other research materials used in this study are of a proprietary nature.

I agree not to disassemble, photograph, record, discuss or disclose any aspect of this research, including any prototype product or research materials, with others (including, but not limited to, family, friends, and employers).

I certify that I will use the products provided to me for the sole purpose of consumer testing and evaluation by me, and that I will not distribute, sell, transfer or offer any of these products to any person.

As a participant in this consumer research, I understand I may make statements and provide suggestions and/or ideas. The research sponsor may use these statements, suggestions and ideas and may potentially incorporate them into one or more of its products, promotional materials, or other materials or services. I understand and agree that the research sponsor shall own all intellectual property rights in and to these statements, suggestions and ideas. Additionally, I agree that the research sponsor may use any of my statements, suggestions, or ideas in any manner either with or without attributing them to me. The research sponsor shall have no further obligation (beyond the compensation provided to me for my participation in the current research) to compensate me for the intellectual property rights in my statements, suggestions, or ideas, or to use such statements, suggestions, or ideas with or without attribution, or to inform me of such use.

I understand that my personal information will be kept confidential and retained in Celerion's secure database. Celerion will not share my information with third parties except as permitted by law. For the purposes of study reporting, I will be identified by my initials and participant ID only. The results of this study may be used or disclosed for the purposes of future data analysis without identifying me as a participant in the study.

I have read and understand this statement. I have been given the opportunity to discuss it and ask questions. I agree voluntarily to participate in this consumer research and understand I may discontinue or limit my participation at any time and for whatever reason.

I certify that I am an adult tobacco consumer who is 21 years of age or older. I certify that I have provided a copy of a valid government-issued ID. I certify that I do not have any allergies or any other

health restrictions. If female, I certify that I am not pregnant, nursing or planning to become pregnant during my participation in the research.

Participant Name (please print)

Participant Date of Birth (month, day, year)

Participant Signature

Today's Date (month, day, year)

Participant Location (City)

COC – Richmond, VA

Facility Name and Location

Participant ID

Celerion – CAXXXXXX

Research Supplier Name & Study Number

Witness Signature

Today's Date (month, day, year)

Appendix 5 Total Smokeless Panel Pre-Screening Ballot

Name: _____

Panelist ID: _____

Today you will participate in a total of 3 mini-tests to assess your ability to taste and discriminate.

Please focus on each individual task and read all instructions in their entirety before moving on to the next test. If you have questions at any time, the test proctor will be able to help you. After you have completed each screening test, please raise your hand and the proctor will bring you the next screening test.

Screening Test 1: Basic Tastes

As you probably remember from school, there are 4 basic tastes – sweet, sour, salty and bitter. For this task, you will taste each of the solutions and determine which basic taste or combinations of basic tastes are present.

In between solutions, please rinse your mouth with water.

(b) (4)



Screening Test 2: Sniff Book

Please complete the scratch and sniff book.

Screening Test 3: Product Trial Interview #1

Circle One:

ML

PW

SR

NS

(b) (4)

Other comments about the product.

Screening Test 3: Product Trial Interview #2

Circle One:

ML

PW

SR

NS

(b) (4)

Other comments about the product.

Appendix 6 Total Smokeless Tobacco Panel Pre-Screening Protocol

1. Pre-Screening Flow

- Basic taste identification (10 minutes)
 - 4 solutions (b) (4)
- Sniff book – aroma identification (10 minutes)
 - One complete book procured from Sensonics, Inc.
- Interview and Product Screening (no more than 30 min)
 - Brief interview to assess adult dippers' articulation and ability to describe sensory characteristics of the products and assess rejection of key varieties/forms
 - During interview, adult dipper will have opportunity to taste and describe no more than 2 of the products below: no more than 5 minute evaluation with 15 min wait in between
 - Training years (b) (4)
(b) (4)
 - Training years (b) (4)
(b) (4)

2. Tasting Protocol

- **Objective:** to screen interested adult MST consumers based on their ability to accurately describe basic tastes (Step 1), taste/aroma identification (step 2), and to describe the sensory experience during product use (step 3) in order to be qualified for further MST panel training
- **Participants:** N = ~180 (2015 Panel); ~120 (2017 Panel), Adult dippers age 21-60 who use at least 1 can of MST per week.

- **Method: Step 1**

- Taste 1mL of 4 different basic taste solutions/products by swishing the product in the mouth and then expectorating
- Rinse with water and/or unsalted cracker in between solutions
- On the answer sheet provided (Appendix 2), circle the basic taste(s) that you taste in each solution

(b) (4)

- **Method: Step 2**

- On each page of the Smell Identification Test, scratch the identified spot and sniff the aroma generated by scratching.
- Of the multiple choice answers, circle the descriptor that best matches your impression of the aroma.
- Must get at least 70% correct to be considered for panel admission

- **Method: Step 3**

- Participants discuss current product and other products ever tried – as per screener – to understand whether they have experience with the key flavors (b) (4)
- Participants will be given the forms/ flavors that they are less familiar with to ensure openness to future trial as a member of the panel and to assess ability to describe sensory experience of this product.

- Tasting of 1-2 different products within a 30 minute interview session. Product options below:

- Training years (b) (4)

(b) (4)

- Training years (b) (4)

(b) (4)

- Rinse with water and unsalted cracker in between product trials
- Evaluate each of 1-2 products product for no more than 5 minutes with a 15 minute break in between
 - During the 5-minute taste period, complete the taste trial worksheet (Appendix 3) and then participate in the interview.
- **Timing & Location:** (b) (4)
(b) (4) at the Consumer Opinion Center in Richmond, VA

Appendix 7 Total Smokeless Tobacco Panel Training Details

Appendix 7a TSTP (b) (4)

| Training Day | Objective |
|--------------|-----------|
|--------------|-----------|

(b) (4)

(b) (4)



(b) (4)

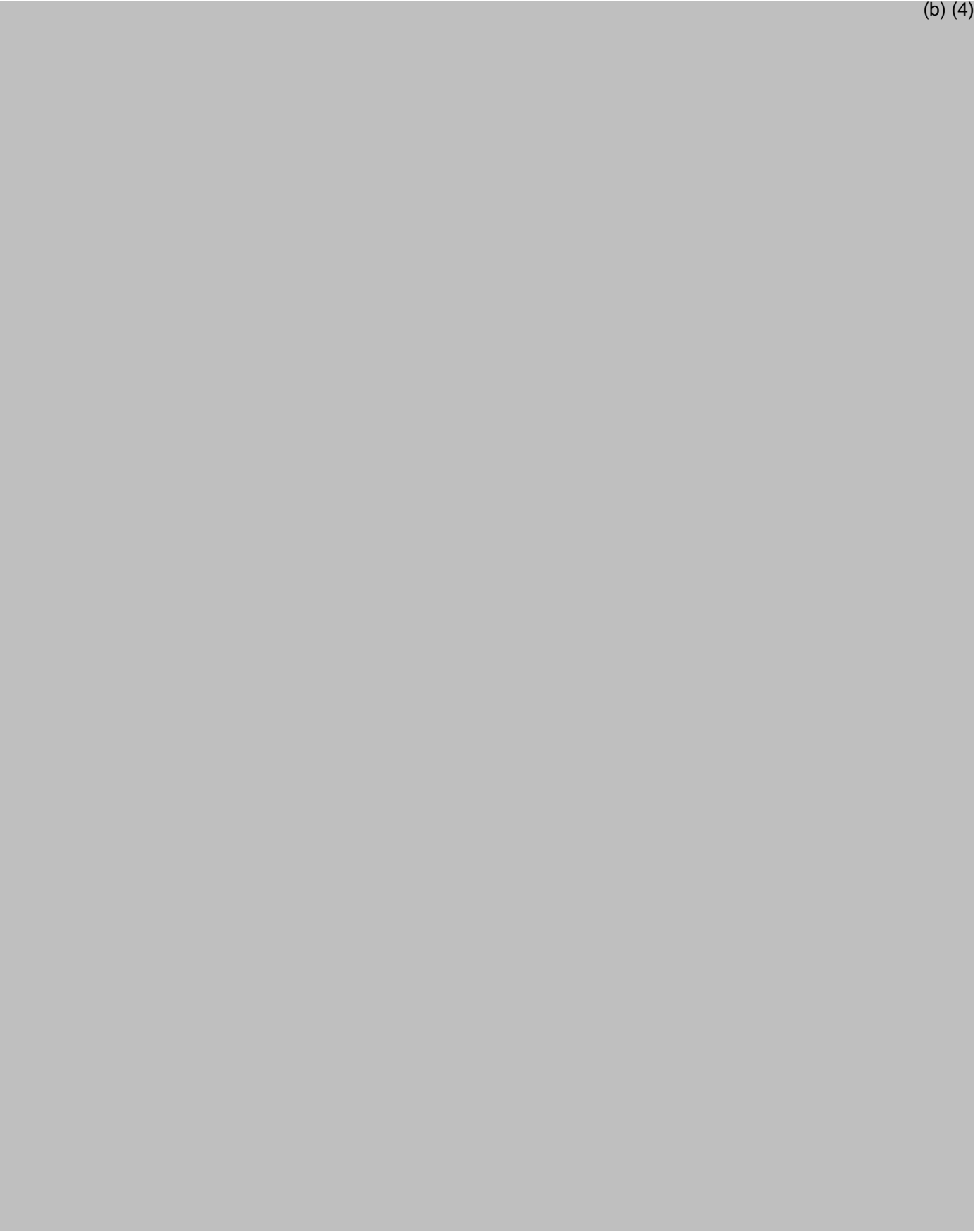


CRT: Center for research and technology, testing facility.

Appendix 7b TSTP (b) (4)

| Training Day | Objective |
|--------------|--|
| 1 | Overview of Panel, Introduction to basic taste, scale and Snus |
| (b) (4) | |
| 9 | Computer Practice Day |
| (b) (4) | |
| 11 | Refresh |

| Day | In Class Products (BC = Blinding Code) | Homework Products |
|---------|--|-------------------|
| (b) (4) | | |



Appendix 8 Total Smokeless Tobacco Panel Validation Schedule

(b) (4)

