



Memorandum

Date January 10, 2011

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA Focus Group, "Consumer Perceptions Related to Harmful and Potentially Harmful Constituents in Tobacco Products"; OMB Control No. 0910-0674

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer _____

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is seeking OMB approval under the generic clearance 0910-0674 to conduct a set of focus groups, "Consumer Perceptions Related to Harmful and Potentially Harmful Constituents in Tobacco Products", to assess consumer perceptions and knowledge with respect to harmful and potentially harmful (H/PH) tobacco constituents, which will inform the Agency's efforts to implement the mandatory publicly available list of H-PH constituents required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

Section 904 (d)(1) of the Tobacco Control Act states "Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful and potentially harmful constituents] established under subsection (e)."

In order to develop information that is understandable and not misleading, FDA must conduct research to gain insight on consumer perceptions and knowledge with respect to harmful and potentially harmful (H-PH) tobacco constituents.

The first stage of the research will consist of 16 focus groups representing a diverse population. The focus groups will be conducted in areas of the United States with relatively high rates of smoking (Metropolitan D.C, Nashville, TN, Baton Rouge, LA, and Miami FL). At least eight of the groups will be comprised of young smokers: four groups between 13 and 17 years of age and four groups between 18 and 24 years of age. The remaining groups will consist of four groups between 25 and 34 years of age and four groups between 35 and 65 years of age. The groups will be separated by gender. Groups will also vary by race, income, and/or smoking status (e.g., regular users, occasional users, those planning to quit, etc.). At least half of the groups will be comprised of smokers with lower literacy levels.

The Contractor will recruit 12 individuals for each focus group discussion, with the expectation of having 8 to 10 participants per group. The Contractor will contact potential respondents by telephone and screen them for eligibility. Additionally, respondents will receive a reminder call and confirmation letter before the groups convene. Each respondent will also receive a \$75.00 cash incentive for their time and participation.

For studies employing similar respondent selection criteria, the incidence of a successful completed telephone screening has been found to be between 30-40%. The recruiter will require approximately five minutes to complete the screening interview for a selected participant, and will require less time to disqualify a potential respondent.

For the focus group with youth who are aged 13 to 17, the facility will first speak to an adult to determine if he or she is the parent or guardian of an adolescent aged 13 to 17 who lives in the household. If so, the recruiter will explain the study and ask permission to speak to the adolescent. If permission is given, the recruiter will explain the study to the adolescent and screen him/her for eligibility. The recruiter will speak to the parent/guardian again to tell him/her if the adolescent is eligible. If eligible, the recruiter will ask the parent/guardian if the adolescent would be interested in participating in the focus group. The recruiter will explain that the session will be videotaped and will ask if this is okay. If it is, the recruiter will explain that it is preferred that the parent/guardian accompanies his/her child to the session (a room for them to wait in will be provided) and will ask if the parent/guardian will do so. If the parent/guardian says no, the recruiter will confirm that the parent/guardian is giving permission for the adolescent to participate without their accompaniment.

A respondent screener, moderator’s guide, focus group packet, focus group stimuli (mock H-PH tobacco constituent lists) and consent forms are attached in Appendices I, II, III, IV, V. The contractor will recruit participants and facilitate discussions.

The time required for screening and participation will be 1.6 hours per participant. There will be a total of no more than 192 participants in 16 groups, producing a total estimated maximum respondent burden of 307.2 hours.

Table 1. Estimated Annual Reporting Burden for Selected Respondents^a

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
192	1	192	1.6	307.2

^aThere are no capital costs or operating and maintenance costs associated with this collection of information.

In order to meet the statutory deadline, FDA/CTP would like to begin the focus group research by January 2011 and have all groups completed by April 2011. The data collected in these focus groups will be used to inform the design of a follow-up qualitative-quantitative comprehension study and a quantitative experimental survey to assess the ability of consumers to use and understand the publicly available information on H-PH constituents. FDA/CTP plans to conduct the comprehension study in July 2011 and the experiment in March 2012.

If you have any questions, please contact Jonna Capezzuto on 301.796.3794.

Attachments:

Appendix 1

Respondent Screener: Consumer Knowledge and Perceptions of Harmful and Potentially Harmful Tobacco Constituents

Recruiting Goals

- Sixteen groups: (4) Washington DC, (4) Nashville, TN (4) Baton Rouge, LA, (4) Miami, FL
- The groups will be segmented by level of education (6- less than HS ed., 6-HS ed. and 4-post HS).
- Mix of races and ethnicities.
- All groups will be separated by gender.
- Each group should be comprised of participants who have similar socioeconomic backgrounds.
- Age profile for each group should be as follows:
 - 4 groups ages 13-17 (two group regular tobacco users, two occasional tobacco users); these groups should be separated into middle school attendees and high school attendees
 - 4 groups ages 18-24 years of age (two groups regular tobacco users, two groups occasional tobacco users)
 - 4 groups ages 25-34 years of age (two groups of tobacco users, two groups planning to quit tobacco use)
 - 4 groups between 35-65 years of age (two groups tobacco users, two groups planning to quit tobacco use)
- All participants must be able to read, understand, and speak English.
- Scientists, tobacco industry workers, and market researchers will be excluded.
- All participants who normally wear corrective lenses, contacts, or glasses to read must have them with them during the focus group.
- Participants cannot have participated in a focus group or a similar study in the past 6 months.
- 12 recruits per group in order to get 8-12 to participate.
- Participants will receive \$75 incentives.
- Each focus group will last approximately 90 minutes.
- Upon consent, groups will be audio- and video-taped.
- Obtain consent/assent.
- The identity of the participants will remain confidential.
- Groups at the Washington DC site will be observed by staff from the Food and Drug Administration (FDA). FDA will travel to other sites if funding permits.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate.

Recruitment Script for Adults

Hello Mr. /Ms. _____, my name is _____ and I would like to talk to you about a focus group study we plan to conduct for the U.S. Department of Health and Human Services. We are recruiting people for an upcoming focus group in which participants will be asked to share their thoughts and feelings about information regarding tobacco products. Would you mind answering a few questions to see if you are able to participate in the study?

Screening Questions

Q1. Before I start, are you at least 18 years old?

[YES] Continue

[NO]

If no: Can I speak with someone at least 18 years old?

If no, when would be a good time to call back and speak with someone at least 18 years old? SET UP CALL BACK TIME

Or, is there no one over 18 in the household? TERMINATE IF NO ONE OVER 18

Q2. Have you participated in a focus group within the past 6 months?

[YES] TERMINATE

[NO] Continue

Q3. Do you currently smoke cigarettes?

[YES]

Do you smoke everyday or occasionally? ___everyday ___occasionally

[For those who smoke everyday] How many cigarettes do you smoke each day?

[NO] Continue

Q4. Do you use other tobacco products such as chewing tobacco, snuff, dip or snus?

[YES]

Do you use **[state the tobacco product mentioned]** every day or occasionally?
___everyday ___occasionally

[For those who use a tobacco product everyday] How many times a day do you use **[state the tobacco product mentioned]**? _____

[NO] Continue

[If answers **NO** to both Q3 and Q4, **TERMINATE**]

Q5. How long have you been using tobacco products?

- Less than 2 years
- 2-5 years
- 6-10 years
- 11-20 years
- More than 20 years

Q6. Which of the following best describes your thinking about quitting tobacco use?

- Planning to quit within the next month *[assign to planning to quit group]*
- Thinking about quitting within the next 12 months *[assign to planning to quit group]*
- I will quit someday but not within the next 12 months *[assign to not planning to quit group]*
- I'm not interested in quitting *[assign to not planning to quit group]*

Demographic Questions

Q7. Are you male or female?

- Male
- Female

Q8. How old are you? _____

If the person refuses to report age, then say "I understand you don't want to tell me your age. Which of the following category of age are you in?"

- 18-24
- 25-34
- 35-49
- 50-65

Q9. What is the highest level of education you have completed?

- Less than high school
- High school (including GED)
- Some college
- College
- Post graduate

Q10. What is your profession? _____

[TERMINATE if market researcher, scientist, or employed by the tobacco industry. Ask directly if unsure based on response above.]

Q11. Are you of Hispanic or Latino origin?

- Yes
- No

Q12. What is your race? I am going to read several categories of race. You may choose one or more categories as they apply. Are you...

- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- Other

Q13. On a scale of 1-5, how comfortable are you understanding and speaking English? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. _____

[TERMINATE if 3 or lower]

Q14. On a scale of 1-5, how comfortable are you participating in a group discussion with approximately 8-10 other adults? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. _____

[TERMINATE if 3 or lower]

Q15. Which of the following groups includes your total annual household income?

- Under \$20,000
- \$20,000-34,999
- \$35,000-59,999
- \$60,000-99,999
- \$100,000 or more

[Optional, participant may refuse to provide]

From what you told me it looks like you are eligible to participate in the study therefore we invite you to meet with a group to discuss issues related to tobacco products with about 10 other people who use tobacco products. The discussion will last no more than two hours, will be video- and audio-taped, and observed by the focus group staff. Your participation and everything you say during the discussion will remain confidential. You will receive \$75 for participating. Additionally, we will serve you snacks and beverages before the group discussion starts. Are you interested in participating in this focus group?

- [YES] Continue
- [NO] TERMINATE

I'm glad that you will be able to join us! The focus group will take place on **[Day], [Date], at [6:00 or 8:00 p.m.] at [site location]**. If you normally wear corrective lenses, contacts, or glasses to read please remember to have them with you during the focus group.

Will you be available to participate at this time?

[YES] Continue
[NO] TERMINATE

I would like to send you a confirmation letter and directions to the facility. In order to do so, could you please tell me your mailing address (or fax number, e-mail address) and a phone number where you can be reached:

Name: _____
Address: _____
City: _____ State: _____ Zip: _____
Phone: _____
Email: _____
Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call **[recruiter]** at **[telephone number]** if this should happen. We look forward to seeing you on **[date]** at **[time]**.

Recruitment Script for Adolescents

Parent Introduction:

Hello Mr. /Ms. _____, my name is _____ and I would like to talk to you about a focus group study we plan to conduct for the U.S. Department of Health and Human Services. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about information regarding tobacco products. We believe it is particularly important to talk with teens about this issue. Can we speak to _____ **[teen's name]** to see if they are able to participate in the study? If he/she is able to participate, we will need you to sign a consent form and have him/her bring it to the focus group.

Adolescent Introduction:

Hello _____, my name is _____. I'm with XXX and we're interested in talking to teens about tobacco products. We are planning to conduct discussion groups with teens for the U.S. Department of Health and Human Services. Everything you share in the group will be confidential—which means it will not be shared with anyone outside of the group, including your parents. Would you mind answering a few questions to see if you are able to participate in the study?

Screening Questions

Q1. Before I start, are you between ages 13 and 17?

[YES] Continue
[NO] TERMINATE

Q2. Have you participated in a focus group within the past 6 months?

[YES] TERMINATE
[NO] Continue

Q3. Do you currently smoke cigarettes?

[YES]

How many days in the past 30 days have you smoked? ____

[For those who smoke 20 or more days, assign to regular user group]

[NO] Continue

Q4. Do you use other tobacco products such as chewing tobacco, snuff, dip or snus?

[YES]

How many days in the past 30 days did you use a smokeless tobacco product? _____

[For those who used a smokeless tobacco product for 20 or more days, assign to regular user group]

[If total days of tobacco use is 20 or more with combined cigarettes and smokeless tobacco use, assign to regular user group]

[NO] Continue

[If answers NO to both Q3 and Q4, TERMINATE]

Q5. How long have you been using tobacco products?

- Less than 1 year
- 1-2 years
- 3 or more years

Demographic Questions

Q6. Are you male or female?

- Male
- Female

Q7. How old are you? _____

Q8. What grade are you in?

- 7th grade
- 8th grade
- 9th grade
- 10th grade
- 11th grade
- 12th grade
- No longer attending school
- Other _____

Q10. [*For those who report being in school*] Are you in middle school or high school?

- Middle School
- High School

Q9. Are you of Hispanic or Latino origin?

- Yes
- No

Q10. What is your race? I am going to read several categories of race. You may choose one or more categories as they apply. Are you...

- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- Other

Q11. On a scale of 1-5, how comfortable are you understanding and speaking English? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. _____

[TERMINATE if 3 or lower]

Q12. On a scale of 1-5, how comfortable are you participating in a group discussion with approximately 8-10 other people around your age? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. _____

[TERMINATE if 3 or lower]

From what you told me it looks like you are eligible to participate in the study. I would like to invite you to join about 10 other teens who also use tobacco products in a group discussion. The discussion will last no more than two hours, will be video- and audio-taped, and observed by the focus group staff. As I said earlier, your participation and everything you say during the discussion will remain confidential. You will receive \$75 for participating. Additionally, we will serve you snacks and beverages before the group discussion starts. Are you interested in participating in this focus group?

- [YES] Continue
- [NO] TERMINATE

Because you are under age 18, we will need a parent or guardian's permission for you to be in the focus group. Will you be able to have a parent or a guardian sign a form giving you permission to attend?

- [YES] Continue
- [NO] TERMINATE

You will need to bring the consent form I will send you with your parent or guardian's signature when you come to the focus group. If you don't have this consent form, you won't be able to participate.

I'm glad that you will be able to join us! The focus group will take place on **[Day], [Date], at [6:00 or 8:00 p.m.] at [site location]**. If you normally wear corrective lenses, contacts, or glasses to read please remember to have them with you during the focus group.

Will you be available to participate at this time?

[YES] Continue
[NO] TERMINATE

Because you are under 18, you will need to get written permission from a parent or guardian in order to participate in the focus group. I would also like to send you a confirmation letter and directions to the facility. In order to do so, could you please tell me your mailing address (or fax number, e-mail address) and a phone number where you can be reached:

Name: _____
Address: _____
City: _____ State: _____ Zip: _____
Phone: _____
Email: _____
Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call **[recruiter]** at **[telephone number]** if this should happen. We look forward to seeing you on **[date]** at **[time]**. If you use reading glasses, please bring them with you to the focus group.

Informed Consent for Participation in a Discussion Group

ICF Macro is conducting discussion groups on behalf of the U.S. Department of Health and Human Services to better understand consumers' thoughts and knowledge about tobacco products. We have invited you to participate in a discussion with other consumers to share your thoughts and knowledge about these products.

If you consent to participate in the discussion, here are some things you should know:

- Your participation is totally voluntary.
- Your name will not be used in any reports about this discussion group. We will be taking notes during the discussion about what was said, but we will not record who made the comments.
- The discussion will be audio- and video-taped so that when we write our report we can make sure we understand everything that was said.
- There will be observers from the Food and Drug Administration and ICF Macro in another room taking notes during this discussion.
- Anything discussed during the group will be confidential
- You will receive \$75 for participating in the group.
- You may discontinue participation at any time, either by leaving the discussion group or not answering a question, without penalty or loss of benefits.
- The discussion group will last approximately 90 minutes.
- Any questions you have about the discussion groups will be answered before we begin our discussion. Contact information is provided below for any questions that arise after the discussion.
- You will be provided with a copy of this form to take with you.

Contact information: If you have any concerns about your participation in this discussion group or have any further questions about the project, contact Ms. Edith Stevens at ICF Macro, telephone number (301) 572-0534.

Your signature below indicates that you understand the above and agree to participate in this group.

Print your name: _____ Date: _____

Signature: _____ Witness: _____

Informed Consent for Participation in a Discussion Group

ADOLESCENT FOCUS GROUP

Please read this assent form carefully. Take time to ask as many questions as you want. If there are any words or information you do not clearly understand, study personnel will be happy to explain them to you. This assent form must be signed before you can participate in the focus group. **Your parent/guardian must also sign this form before you can participate.**

INTRODUCTION

ICF Macro is conducting discussion groups on behalf of the U.S. Department of Health and Human Services to better understand adolescents' thoughts and knowledge about tobacco products. We have invited you to participate in a discussion with other adolescents to share your thoughts and knowledge about these products. Your part in this study involves being in a focus group (discussion group). The focus group will be guided by an adult who is trained to get your opinion and encourage everyone to take part.

Your participation is entirely voluntary.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to better understand adolescents' thoughts and knowledge about tobacco products.

INFORMATION ABOUT THE STUDY

This research involves 4 focus groups of about 6-10 adolescents each. If you agree, you will participate in one focus group. This meeting will last about 2 hours. Group conversations will be recorded, and notes will be taken. Only first names will be used to help protect your privacy.

YOUR ROLE IN THE STUDY

Participating in a research study can be an inconvenience to daily life. Please consider the study time commitments and responsibilities when you are deciding whether or not you should participate. These include:

- Coming to the study site for the focus group at the planned time;
- Providing truthful information about what you think about the usefulness of the materials for yourself and other adolescents.

REIMBURSEMENT FOR STUDY PARTICIPATION

You will receive \$75.00 in cash for your participation in the study. This will be given to you at the end of the focus group session.

CONFIDENTIALITY

As part of this study, the study staff may record personal information about you that contains your name and other personal identifiers. Transcripts of focus groups will only include your first name.

Subject's Initials_____

The collection and submission of the information will be accomplished with strict adherence to professional standards of confidentiality. Information from this study may be published in professional journals or at scientific conferences, but your confidentiality will be respected and no names will be used in any report or presentation.

RESEARCH QUESTIONS AND CONTACTS

You may freely ask questions about this assent form or the study now or at any time during the study. If you have any questions about the research, or compensation, during this study you may contact the study staff.

VOLUNTARY NATURE OF STUDY

Entering a research study is voluntary. Anyone who is asked to be in a research study may so no. No one has to become a research subject. If you start a research study, you may stop at any time. You do not need to give a reason. No health care professional can discriminate against you or treat you differently if you choose not to be in a research study or later decide not to participate.

ASSENT STATEMENT BY PARTICIPANT 17 AND UNDER

I have read this assent form. I understand what I am being asked to do. My questions have been answered and any words I did not understand have been explained to me. I agree to be in this research study for the purposes listed above. I will receive a copy of this assent form for my records.

Print your name here if you want to be in this study

Sign your name here if you want to
be in this study

Signature

Date

CONSENT STATEMENT BY PARENT OR GUARDIAN

I have read this consent form. My questions have been answered. I agree to allow my child to be in this research study for the purposes listed above. I will receive a copy of this consent form for my records.

By signing this consent form I am not giving up any of my or my child’s legal rights. I also understand that nothing in this consent is intended to change any applicable federal, state or local laws regarding informed consent.

Printed Name of Minor Research Subject (Child)

Name of Guardian (Print) Signature Date

Name of Person Obtaining Informed Consent Signature Date

Name of Person Obtaining Informed Consent Signature Date

Moderator's Guide: Consumer Knowledge and Perceptions about Harmful and Potentially Harmful Tobacco Constituents

Opening Remarks – Introductions and Rules (5 minutes)

- Welcome and thank you for participating
 - Conducting focus group on behalf of the U.S. Department of Health and Human Services
 - Would like to learn more about what you know and want to know about tobacco products
 - Speak freely and openly—no right or wrong answers
 - Encourage everyone to participate but you do not have to answer any questions you don't want to
 - Ok to disagree with each other, but must remain respectful
 - Try to speak one at a time
 - Everything said is completely confidential and will not be reported in connection with names or other identifying information
 - Will begin audio recording after introductions
 - Audio recordings will be transcribed for analysis purposes but will not include names or other identifying information
 - Please do not look through or write on packets in front of you until instructed to do so; do not write your name on the packet
 - Group will last no more than two hours
 - For the purposes of time, may need to end parts of the discussion before everyone has had a chance to speak—will allow time at the end for final thoughts and questions
 - Please silence cell phones; if you must take a call, please step out of the room
 - Restrooms are located XX
 - Questions?
-

Ice Breaker (5 minutes)

Let's go around the room and introduce ourselves. Please tell me your first name, and a little bit about yourself, like what you would be doing right now if you weren't here with us.

1. Tobacco products introduction (15 minutes)

As you may know, we brought you here tonight because you use tobacco products. We would like to hear your thoughts about these products. Let's start by going around the room and having everyone tell us how long you have been using tobacco. Keep in mind that when we talk about tobacco products tonight, we are referring to cigarettes, chewing tobacco, snuff, dip, snus.

How many of you know that the Food and Drug Administration (FDA) regulates tobacco products? *[Get a tally of number of hands that go up]*

What comes to mind when you hear that the FDA regulates tobacco? What do you think this means?

What do you think this means FDA will be doing to regulate tobacco products?

Do you think FDA regulating tobacco products will affect you? If so, how?

How important do you think it is for the FDA to regulate tobacco products? Why?

As of June 2009, the FDA was given authority to regulate tobacco products. This includes developing new health warnings and providing people with information on the chemicals found in tobacco products.

2. General knowledge about H-PH constituents found in tobacco products (15 minutes)

What do you know about the tobacco product you use? Do you think about what may be in your tobacco products? Or do you think about what gets inside your body when you use your tobacco product?

[Allow for discussion. If needed prompt group to discuss the chemicals that may be in their products]

In front of you is a packet. This packet is something that we will be using during this group to let you write down some of the thoughts you might have tonight. Please do not write your name on the packets. I will let you know when to open them and when you should turn to the next page.

Go ahead and open to the first page. As you can see this first page asks you the question “How important do you think it is for you to know about the chemicals that are in your tobacco product(s)?” Please mark the response that matches how you feel. *[Likert scale of 1-5 (1=not at all important, 5=very important)]*

Ask participants to discuss their answers and why they chose them.

Now turn to page 2 in your packet and mark your response to the question “How important do you think it is for you to know how each of these chemicals affects your body?” *[Likert scale of 1-5 (1=not at all important, 5=very important)]*

Ask participants to discuss their answers and why they chose them.

How many of you know or have heard something about chemicals in tobacco products and smoke? *[Get a tally of number of hands that go up]*

What comes to mind when you think about these chemicals?

What are these chemicals? *[Record on board]*

Are there any others you can think of?

How many do you think there are in one cigarette?

What do you think these chemicals do to your body? *[Ask about the specific chemicals the participants mentioned]*

Where did you learn about the chemicals in tobacco products? How about their effect on the body?

3. Use of Information (10 minutes)

Some of you said it was important for you to know what chemicals are in your tobacco products.

If you wanted to know more about what is in your tobacco products, where would you look? Why?

Have you ever searched for this type of information before?

If so...

- Where did you look?
- What made you search for this information?
- How did you know where to look for the information?
- What did you do with the information? [*PROBE: decision-making, behavior change*]

If not...

- If you knew this information was available, would you be interested in looking at it?
- What would prompt you to look for this information?
- Where do you think this information would be found?
- What do you think you would do with the information? [*PROBE: decision-making, behavior change*]

4. Test HPHC list (20 minutes)

Now we're going to take some time to look at a list of some of the chemicals found in tobacco products. As you are looking at this list, please write down any thoughts that come to mind on page 3 in your packet.

[Pass out a copy of the list created for testing purposes only. Give participants a few minutes to review and record.]

Does anyone want to share what they wrote down? What does this list make you think? How does it make you feel? Does it make you want to do anything with it?

What do you think the purpose of this list is?

Does this list mean anything to you? What does this information mean to you?

What do you notice as you look at this list? [*PROBE: order, headers, numbers listed below*]

Order:

Do you think the chemicals are listed in any particular order? Why do you think this?

Do you think the health conditions along the top are listed in any particular order? Why do you think this?

How should a list like this to be ordered?

Headers:

What do the headers mean?

Do you find the headers useful?

Is this the type of information you expected to see?

What other headers or types of information would you find useful?

What do the health condition headers mean to you (cancer, lung...)?

What does the header “amount per cigarette” mean to you?

Numbers:

What do the numbers on this list tell you?

Are the numbers meaningful?

Are the numbers useful?

Why do you think that there is often two numbers listed?

Why do you think some chemicals may only have one number?

What comes to mind when you see a high number versus a low number?

Do the symbols (mg, μ g, ng) after the number tell you anything?

Do you think listing the amount in the chemical is necessary? Why? Why not?

General:

What types of chemicals do you think are on this list and why?

What information do you find the most useful on this list? Why?

What information do you find the least useful on this list? Why?

Is there anything about this list that surprises you? What and Why?

What would help you understand this list better? [PROBE: instructions]

If you could change the way the list looks or the information it shows, how would you change it?
[PROBE: reasons why participants would make the changes they suggest]

If there was a list like this for your tobacco product, how likely is it that you would look for it?
Turn to page 4 in your packet and mark your response *[Likert scale of 1-5]*

Ask participants to discuss their answers and why they chose them.

Imagine this is a list for your brand of cigarettes or smokeless tobacco. What does this make you think about...

- 1) your brand?
- 2) your smoking?
- 3) other brands of tobacco products?

5. Multiple HPHC test lists of tobacco products (15 minutes)

Now we're going to take a look at lists for a few different tobacco products--we'll refer to them as Brand X, Brand Y, and Brand Z. We want to know what you are thinking about when you look at a list of chemicals from different tobacco products. I want you to look at these lists and hear your reactions. Flip to page 5 in your packet and write down words or phrases that come to mind.

[Pass out a copy of the three lists created for testing purposes only. Give participants a few minutes to review.]

What comes to mind when you look at these lists?

How are these lists similar and how are they different?

What do these similarities and differences mean to you?

If Brand X was your brand, would having these other lists make you think differently about your brand? How so? What does this make you think of the other two brands?

What if I tell you Brand Z is a type of chewing tobacco? Now what do you think about these products? *[PROBE: impact on tobacco use, impression of brands, product safety]*

Impression of brands:

How do you think Brand Z compares to the other two brands?

If you do not use chewing tobacco, does seeing this list make you think differently about your own brand? Why or why not?

If you use chewing tobacco, what does this make you think about your brand?

Impact on tobacco use:

If you do not use chewing tobacco, does seeing this list make you think differently about the type of tobacco product you use?

If you use chewing tobacco, what does seeing this list make you think about your own tobacco use?

Product safety:

Does one brand appear to be safer than another? If so, what makes you think this?

Do you think you would look at lists of different tobacco products other than your own brand? Why?

6. Publication and Dissemination (10 minutes)

Now that you've had a chance to look at examples of these lists of chemicals...

Who would you expect to put these lists out? Why?

Where would you expect to see lists like these? [*PROBE: website*]

What would come to mind if you saw these lists posted on an FDA website?

7. Debrief/Closing (5 minutes)

Under the Family Smoking Prevention and Tobacco Control Act, the FDA is required to develop a list of "harmful and potentially harmful constituents" found in tobacco products by brand and sub-brand. For example, consumers will be able to find a list of these chemicals for every brand of cigarette and smokeless tobacco.

Tobacco companies will be responsible for providing the list to FDA, who will then make it available to consumers.

FDA is making this list available to let consumers know which harmful chemicals are in their tobacco products.

Knowing this, is there anything else you would like FDA to keep in mind as they develop this list and make it available to the public?

Do you have any questions before we conclude?

FDA wants to remind you that all tobacco is harmful and encourages you to consider quitting. For more information, there are brochures available as you leave.

Thank you for participating in today's discussion. As a token of our appreciation for your time, you will each receive \$75. Please pick up your incentive from XX as you leave.

DO NOT OPEN UNTIL INSTRUCTED

Please do not write your name on this packet.

How important do you think it is for you to know which chemicals are in your tobacco products?

1 _____ 2 _____ 3 _____ 4 _____ 5
Not at all important Neutral Very important

Please do not write your name on this packet.

How important do you think it is for you to know how each of these chemicals affects your body?

1 _____ 2 _____ 3 _____ 4 _____ 5 _____
Not at all important Neutral Very important

Warning: Tobacco smoke and smokeless tobacco products contain over 7,000 chemicals that can harm tobacco users and non-users. Tar in cigarettes comes from 1000s of these chemicals. The following is a list of some of the chemicals in this product that may harm you or others when used. The list also includes examples of the types of cancer and damage these chemicals can cause.

Brand Q: Toxic Chemicals

Chemical	Cancer	Lungs	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per Cigarette Standard puffing Intense puffing
	-Lung -Throat -Bladder -Cervical -Stomach -Kidney -Pancreas	-Asthma -COPD -Cough -Shortness of breath	-Heart disease -Heart attack -Stroke -Hardening of the arteries	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
Acetaldehyde	•	•	•	•	•	0.2 - 3.74 mg
Acetamide	•					44.3 - 62.2 µg
Acetone		•				52.0 - 923 µg
Acrolein		•	•	•		74.0 - 122.3 µg
Acrylamide	•					Less than 10.0 µg
Acrylonitrile	•	•				1.8 - 23.3 µg
Aflatoxin B1	•			•		12.5 ng
4-Aminobiphenyl	•					1.8 - 4.9 ng
1-Aminonaphthalene	•					31.3 - 103.6 ng
2-Aminonaphthalene	•					17.3 - 212.0 ng
Ammonia		•				14.7 - 210.0 µg
Anabasine		•				7.3 µg
o-Anisidine	•			•	•	22.5 - 91.4 µg
Arsenic	•	•				32.0 - 181.0 ng
A-α-C (2-Amino-9H-pyrido[2,3-b]indole)	•					19.9 - 377.0 ng
Benz[a]anthracene	•					71.0 ng
Benz[j]aceanthrylene	•		•			7.4 - 63.9 ng
Benzene	•					55.3 µg
Benzo[b]fluoranthene	•		•	•		11.6 - 29.4 ng
Benzo[k]fluoranthene	•			•		17.8 - 19.7 ng
Benzo[b]furan	•			•		Less than 35.0 µg
Benzo[a]pyrene	•		•	•		16.7 - 51.1 ng
Benzo[c]phenanthrene	•					Less than 15.0 µg
Beryllium	•			•		0.5 ng
1,3-Butadiene		•	•			12.9 - 96.5 µg
Cadmium	•	•	•	•		13.0 - 402.0 ng
Caffeic acid	•					8.6 µg
Carbon monoxide			•	•		9.0 - 35.0 mg
Catechol	•			•		0.1 - 3.3 mg
Chlorinated dioxins/furans	•			•		0.0001 - 0.0003 ng
Chromium	•	•		•		3.2 - 62.9 ng
Chrysene	•		•	•		64.1 - 117.5 ng
Cobalt	•		•	•		0.1 - 0.3 ng
Coumarin				•		2.9 - 5.6 ng

Chemical	Cancer	Lungs	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per Cigarette Standard puffing — Intense puffing
	-Lung -Throat -Bladder -Cervical -Stomach -Kidney -Pancreas	-Asthma -COPD -Cough -Shortness of breath	-Heart disease -Heart attack -Stroke -Hardening of the arteries	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
Cresols (o-, m-, and p-cresol)	•	•				34.0 - 187.5 µg
Crotonaldehyde	•	•	•			8.7 - 61.1 µg
Cyclopenta[<i>c,d</i>]pyrene	•					4.2 - 31.1 ng
Dibenz[<i>a,h</i>]acridine	•					Not detected
Dibenz[<i>a,i</i>]acridine	•					3.4 - 16.4 ng
Dibenz[<i>a,h</i>]anthracene	•					3.5 - 3.2 ng
Dibenzo[<i>c,g</i>]carbazole	•					0.9 - 1.0 ng
Dibenzo[<i>a,e</i>]pyrene	•					4.3 - 9.8 ng
Dibenzo[<i>a,h</i>]pyrene	•					4.3 - 9.8 ng
Dibenzo[<i>a,i</i>]pyrene	•	•				5.2 - 22.8 ng
Dibenzo[<i>a,j</i>]pyrene	•					1.9 - 4.7 ng
2,6-Dimethylaniline	•					4.8 - 33.1 ng
Ethyl carbamate (urethane)	•			•		3.2 - 54.67 µg
Ethylbenzene	•			•		1.3 - 9.6 µg
Ethylene oxide	•	•		•		6.2 µg
Formaldehyde	•	•	•			54.0 - 113.4 µg
Furan	•					9.3 - 66.6 µg
Glu-P-1 (2-Amino-6-methylpyrido[1,2- <i>a</i> :3',2'- <i>d</i>]imidazole)	•					0.8 - 0.9 ng
Glu-P-2 (2-Aminopyrido[1,2- <i>a</i> :3',2'- <i>d</i>]imidazole)	•					0.5 - 1.2 ng
Hydrazine	•	•		•		24.6 - 37.4 ng
Hydrogen cyanide		•	•			300.0 – 600.0 µg
Indeno[1,2,3- <i>cd</i>]pyrene	•					13.5 - 16.1 ng
IQ (2-Amino-3-methylimidazo[4,5- <i>f</i>]quinoline)	•					0.4 ng
Isoprene	•					0.9 - 2.2 mg
Lead	•		•	•		17.2 - 96.7 ng
MeA- <i>a</i> -C (2-Amino-3-methyl)-9 <i>H</i> -pyrido[2,3- <i>b</i>]indole)	•					2.2 - 39.0 ng
Mercury	•			•		5.3 - 44.5 ng
Methyl ethyl ketone		•		•		12.1 - 90.2 µg
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	•					52.4 - 201.0 ng
Naphthalene	•	•		•		1.1 - 5.7 µg
Nickel	•	•		•		Less than 5.2 - 512.0 ng
5-Methylchrysene	•					0.4 - 0.94ng
Nicotine			•	•	•	0.5 - 3.7 mg
Nitrobenzene	•	•		•		37.5 µg
Nitromethane		•		•		414.0 - 881.0 ng
2-Nitropropane	•	•		•		0.5 - 1.8 µg

Chemical	Cancer	Lungs	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per Cigarette Standard puffing — Intense puffing
	-Lung -Throat -Bladder -Cervical -Stomach -Kidney -Pancreas	-Asthma -COPD -Cough -Shortness of breath	-Heart disease -Heart attack -Stroke -Hardening of the arteries	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
<i>N</i> -Nitrosodiethanolamine (NDELA)	•					Less than 15.0-77.5 ng
<i>N</i> -Nitrosodiethylamine (NDEA)	•					Less than 12.2-3.3 ng
<i>N</i> -Nitrosodimethylamine (NDMA)	•					0.1 - 1.4 µg
<i>N</i> -Nitrosomethylethylamine	•					3.9 - 14.3 ng
<i>N</i> -Nitrosomorpholine (NMOR)	•					Less than 4.0-9.6 ng
<i>N</i> -Nitrosonornicotine (NNN)	•					96.5 - 263.0 ng
<i>N</i> -Nitrosopiperidine (NPIP)	•					Less than 3.7-9.2 ng
<i>N</i> -Nitrosopyrrolidine (NPYR)	•					2.2 - 144.3 ng
<i>N</i> -Nitrososarcosine (NSAR)	•					8.3 ng
Nornicotine	•				•	12.0 - 199.5 µg
Phenol	•	•	•	•		75.0 - 160.0 µg
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5- <i>b</i>]pyridine)	•					8.3 - 39.4 ng
Polonium-210	•					0.1 - 1.2 pCi
Propionaldehyde		•	•			18.0 - 109.8 µg
Propylene oxide	•	•				Less than 9.0 - 142.3 ng
Quinoline	•					0.9 - 2.5 µg
Selenium		•				18.6 - 32.8 ng
Styrene	•					2.4 - 14.7 µg
<i>o</i> -Toluidine	•					27.3 - 650.0 ng
Toluene	•		•			8.2 - 90.0 µg
Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3- <i>b</i>]indole)	•					0.3 - 0.5 ng
Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3- <i>b</i>]indole)	•					1.3 - 1.9 ng
Uranium-235	•	•		•		Not tested
Uranium-238	•	•		•		0.1 - 1.5 pCi
Vinyl acetate	•	•		•		4.6 - 68.6 µg
Vinyl chloride	•					5.5 - 19.3 µg

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Brand X: Toxic Chemicals

Chemical	Cancer	Lungs	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per Cigarette Standard puffing Intense puffing
	-Lung -Throat -Bladder -Cervical -Stomach -Kidney -Pancreas	-Asthma -COPD -Cough -Shortness of breath	-Heart disease -Heart attack -Stroke -Hardening of the arteries	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
Acetaldehyde	•	•	•	•	•	0.2 - 3.74 mg
Acetone		•				52.0 - 923 µg
Acrolein		•	•	•		74.0 - 122.3 µg
Acrylonitrile	•	•				1.8 - 23.3 µg
Ammonia		•				14.7 - 210.0 µg
Arsenic	•	•				32.0 - 181.0 ng
Benzo[<i>a</i>]pyrene	•		•	•		16.7 - 51.1 ng
Beryllium	•			•		0.5 ng
1,3-Butadiene		•	•	•		12.9 - 96.5 µg
Carbon monoxide			•	•		9.0 - 35.0 mg
Cobalt	•		•	•		0.1 - 0.3 ng
Dibenz[<i>a,h</i>]acridine	•					Not detected
Ethylene oxide	•	•		•		6.2 µg
Formaldehyde	•	•	•			54.0 - 113.4 µg
Furan	•					9.3 - 66.6 µg
Glu-P-2 (2-Aminodipyrido[1,2- <i>a:3'</i> ,2'- <i>d</i>]imidazole)	•					0.5 - 1.2 ng
Hydrazine	•	•		•		24.6 - 37.4 ng
Hydrogen cyanide		•	•			300.0 - 600.0 µg
Lead	•		•	•		17.2 - 96.7 ng
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	•					52.4 - 201.0 ng
Naphthalene	•	•		•		1.1 - 5.7 µg
Nickel	•	•		•		Less than 5.2 - 512.0 ng
Nicotine			•	•	•	0.5 - 3.7 mg
<i>N</i> -Nitrosodimethylamine (NDMA)	•					0.1 - 1.4 µg
Quinoline	•					0.9 - 2.5 µg
Selenium		•				18.6 - 32.8 ng
Styrene	•					2.4 - 14.7 µg
Toluene	•		•			8.2 - 90.0 µg
Uranium-235	•	•		•		Not tested
Vinyl acetate	•	•		•		4.6 - 68.6 µg

Warning: Tobacco smoke and smokeless tobacco products contain over 7,000 chemicals that can harm tobacco users and non-users. Tar in cigarettes comes from 1000s of these chemicals. The following is a list of some of the chemicals in this product that may harm you or others when used. The list also includes examples of the types of cancer and damage these chemicals can cause.

Brand Y: Toxic Chemicals

Chemical	Cancer	Lungs	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per Cigarette Standard puffing Intense puffing
	-Lung -Throat -Bladder -Cervical -Stomach -Kidney -Pancreas	-Asthma -COPD -Cough -Shortness of breath	-Heart disease -Heart attack -Stroke -Hardening of the arteries	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
Acetaldehyde	•	•	•	•	•	0.5 - 6.80 mg
Acetone		•				51.0 - 887 µg
Acrolein		•	•	•		80.0 - 130.8 µg
Acrylonitrile	•	•				2.9 - 31.0 µg
Ammonia		•				10.7 - 178.0 µg
Arsenic	•	•				30.0 - 180.0 ng
Benzo[<i>a</i>]pyrene	•		•	•		18.9 - 58.7 ng
Beryllium	•			•		1.2 ng
1,3-Butadiene		•	•	•		10.9 - 92.5 µg
Carbon monoxide			•	•		12.0 - 33.0 mg
Cobalt	•		•	•		0.8 - 1.2 ng
Dibenz[<i>a,h</i>]acridine	•					Not detected
Ethylene oxide	•	•		•		5.4 µg
Formaldehyde	•	•	•			60.0 - 123.8 µg
Furan	•					8.7 - 58.9 µg
Glu-P-2 (2-Aminodipyrido[1,2- <i>a:3'</i> ,2'- <i>d</i>]imidazole)	•					0.3 - 1.0 ng
Hydrazine	•	•		•		31.1 - 40.3 ng
Hydrogen cyanide		•	•			286.1 - 581.0 µg
Lead	•		•	•		19.0 - 101.3 ng
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	•					48.6 - 182.7 ng
Naphthalene	•	•		•		1.9 - 8.8 µg
Nickel	•	•		•		Less than 2.2 - 412.5 ng
Nicotine			•	•	•	2.1 - 4.3 mg
<i>N</i> -Nitrosodimethylamine (NDMA)	•					1.3 - 2.1 µg
Quinoline	•					0.3 - 1.8 µg
Selenium		•				23.4 - 41.7 ng
Styrene	•					1.8 - 13.6 µg
Toluene	•		•			7.6 - 84.3 µg
Uranium-235	•	•		•		Not tested
Vinyl acetate	•	•		•		4.0 - 71.9 µg

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Brand Z: Toxic Chemicals

Chemical	Cancer	Heart and Blood Flow	Fetal Development and Fertility	Addiction	Amount Per gram of tobacco
	-Oral: cheek gums, throat -Pancreas	-Increased blood pressure -Increased heart rate	-Trouble getting pregnant -Early births -Low birth weight -Pregnancy complications	-Difficulty quitting -Strong desire to use -Withdrawal symptoms	
Acetaldehyde	•	•	•	•	0.3 - 3.61 mg
Aflatoxin B-1	•		•		32.6 ng
Arsenic	•				112.4 – 115.6 ng
Benzo[a]pyrene	•	•	•		21.3 – 24.2 ng
Beryllium	•		•		0.8 ng
Cadmium	•	•	•		213.6 – 218.1 ng
Chromium	•		•		36.3 - 38.8 ng
Chrysene	•	•	•		69.8 - 77.4 ng
Coumarin			•		6.3 – 8.1 ng
Crotonaldehyde	•	•			8.2 - 60.1 µg
Dibenzo[a,h]anthracene	•				2.4 – 3.1 ng
Formaldehyde	•	•			84.1 - 86.4 µg
Indeno[1,2,3-cd]pyrene	•				13.5 - 16.1 ng
Lead	•	•	•		43.8 - 46.9 ng
Mercury	•		•		22.7- 29.9 ng
Naphthalene	•		•		0.3 – 4.1 µg
Nickel	•		•		Less than 6.4 -678.3 ng
Nicotine		•	•	•	0.8 – 4.2 mg
N-nitrosodimethylamine (NDMA)	•		•		1.2 – 2.8 µg
Nornicotine	•			•	0.52 – 1.9 pCi/cig