

**Hair Smoothing Product Labeling Study
Moderator's Guide for Retail Consumers
June 2016**

Objective

The FDA Hair Smoothing Product Labeling Study is designed to help FDA better understand how salon stylists, salon clients and retail consumers of permanent hair smoothing products understand current and draft cautionary labels, developed by FDA, that appear on professional hair smoothing products that release formaldehyde. The findings from the research will provide background information to the FDA's Office of Cosmetics and Colors on certain professional hair smoothing products that may be hazardous when used improperly.

Specifically, this focus group research is to examine participant's reactions to proposed cautionary statements on professional hair-smoothing products that release formaldehyde. FDA notes that well-designed warning labels can be very effective in catching the attention of consumers and communicating precautions to be taken while using these products. Unless the message is clear and easily understood, the warning is likely to be ineffective. Critical design elements include: font size, color, and spacing, and location of warning message on the product. Pictorial images/symbols may also be critical in the warning statements in order to address users for whom English is a second language (while these focus groups will include participants with varied racial and ethnic backgrounds, English literacy will be a screening criterion. The purpose is to examine whether the FDA-proposed warning messages sufficiently inform consumers and salon workers about the potential health risks associated with formaldehyde-releasing cosmetics and provides adequate direction for safe use.

I. Introduction [3 minutes]

Thanks for joining us today. I'm _____, and I'm from Westat, a private research company based in Rockville, MD. My colleague, _____, is from the U.S. Food and Drug Administration (FDA). On behalf of FDA, Westat is conducting discussions with people who do hair smoothing and hair straightening outside of a hair salon, for example at home or another place. The purpose of our discussion today is to hear your views and opinions on the use of hair smoothing or straightening products and their labels. We will also ask for your reactions to different labeling options on hair smoothing products. Your insights are very important to us and your time today is appreciated. We will have about 90 minutes for our discussion.

[Moderator: Hand out consent forms as participants arrive. The consent form will be summarized by the moderator during introduction to ensure that all of the required consent points are covered. Any questions about the consent form will be answered at this point.]

Before we get started there are a few things I should mention to comply with the protocol for this study. We have provided a consent form for you all to sign. Please make sure you have read through the form. We would like to audio and video record this discussion. The audio recordings will be transcribed so that we don't miss the important things that you say. The recordings, transcripts, and any notes we have will be stored on Westat's and FDA's secure servers and will be destroyed after the project is complete. Your contribution to our discussion will be anonymous and your names or other personally identifying information will not appear in any report that we write. Your participation in this discussion is voluntary and you may stop participating at any time.

I should also tell you that other FDA staff involved in this project are observing the discussion remotely via the video cameras, but these are not yet turned on.

Do you have any questions? [ANSWER ALL QUESTIONS]

If you are happy to proceed I will start the recordings and turn on the video camera.

Please sign the consent form; my colleague XXX will collect the forms

II. Ground Rules [2 minutes]

Before we begin, I want to review a few ground rules for our discussion.

1. There are no right or wrong answers in today's discussion. We want to know your honest opinions and experiences.
2. Everyone's participation is important; we want to hear from everybody.
3. It is OK to disagree.
4. Please speak up (speak loudly).
5. Please speak one at the time so we can hear all the responses.
6. Please turn off your cell phones or anything else that may make it difficult to concentrate.
7. If at any point you feel uncomfortable with my questions, simply let me know that you prefer not to answer.
8. Do you have any questions before we begin?

III. Introductions of Participants [5 minutes]

I'm here to facilitate and guide our discussion but I mainly want to hear from you, about your experiences and opinions. [Moderator: have participants' introduction questions written up on a flip chart.]

1. Let's begin with introducing ourselves; please tell me:
 - your first name,
 - what is your favorite hair procedure to do by yourself,
 - do you have any formal training as a hair stylist,
 - how many hair smoothing or hair straightening treatments have you done at home either on yourself or on others? Since when have you been doing them?

[Moderator: the terms: "hair smoothing" and "hair straightening" will be used interchangeably during the discussion unless established that they have different meanings.]

IV. Warm-up [5 minutes]

I would like to talk briefly about hair care in general. What do you like most about doing hair straightening treatments?

V. Hair Smoothing/Straightening Practices and Habits [25 minutes]

Many of you mentioned during your qualifying interview you do hair smoothing/straightening at home. I would like to ask you a few questions about that.

1. What types of hair smoothing/straightening treatments do you do? [Probe for: Brazilian blowout, keratin, treatment, relaxer, other?] What are the differences between the various types of hair smoothing treatments you mentioned? [Probe for: how effective, how many months do the effects last?] Are there any differences between the terms “hair smoothing” and “hair straightening”?
2. Now, I would like us to concentrate on hair smoothing procedures that are most often called Brazilian blowout or keratin treatments. How often do you do Brazilian blowouts/keratin treatments? Do you do it on your own hair? What about doing it on other people's hair?
3. What type of products do you use for these hair smoothing procedures? What are some of the names of the products you use? [Moderator: please write down responses on a flip chart.]
4. Where do you buy the products you use for hair straightening? [Probe: from a salon stylist, beauty supply store, internet, other?] Are they easy or difficult to purchase? How expensive are they?
5. What information, if any, about the safety of smoothing products do you have? Where did you learn about it?
6. When you do perform the hair straightening procedure on someone, is there anything you talk to them about ahead of time? What about during and after the procedure?
7. Is there anything about these products people who have their hair straightened should be concerned by?
8. What are the pros and cons of having a hair smoothing procedure done? [Probe for: amazing results vs. emitting irritating gasses; a risk of hair breakage or hair falling out, etc.]
9. [If this did not come up in the discussion so far, ask:] Do you know the ingredients in the hair smoothing products you use? Do any of these ingredients concern you?

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10. Do products that you use contain formaldehyde or formaldehyde-releasing agents? If so, how did you learn about it? Do you know how much of the formaldehyde or formaldehyde-releasing agents they contain? Would it be useful to have that information? Why/why not?
11. What possible negative side effects could you experience from using hair smoothing products containing formaldehyde? What about the persons who have it done on their hair? Are they exposed to the same risks as you? [Probe: eye/skin irritation, coughing, hair breakage, hair loss, etc.]
12. How do you protect yourself from the product's side effects? What about the person who has it done on their hair?
13. What precautions do you currently take, if any? [Probe for use of masks, protective glasses, gloves; differentiate between what is used by the participants and what is used to protect the person they are doing it on.]
14. Are there any circumstances under which you would not do a hair smoothing treatment? Would you perform this treatment if you were pregnant? What about the person who has it done on them?
15. What challenges are there to doing hair straightening at home vs. at a hair salon? How safe is it to do hair straightening at home compared to a hair salon?
16. What kind of training, if any, have you had with regard to hair smoothing treatments?

VI. Evaluation of Labeling Statements [40 minutes]

1. Have you seen any warning labels for hair smoothing products that contain formaldehyde or formaldehyde-releasing agents? Were they located on the bottle itself or elsewhere? What do they say?
2. How often do you read/review them, if at all?
3. What kinds of information do you think should be included in the warning labels for hair smoothing products that contain formaldehyde, or formaldehyde-releasing agents?

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[Moderator: please pass around booklets with labeling statements. Ask respondents not to look at all labels, only one at the time as directed by the moderator. Each labeling statement will be presented on an image of a hair smoothing product and as an enlarged text.]

Now, I would like to show you several different warning labels and ask for your reactions. Please look at the first one – Example A – and take a couple of minutes to read it; in the follow-up discussion, I would like to hear your overall impressions. Also, please circle anything you think is critically important, underline anything confusing, cross-out anything you think is not needed, and write down anything you think should be added.

[Moderator: write up instructions on flip chart: 1. CIRCLE what is critically important; 2. Underline anything confusing; 3. Cross-out anything that is not needed; 4. Write down anything that should be added.]

Example A

WARNING: This product contains methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

1. What are your overall impressions? [Probe for: what makes the concept appealing or unappealing, what feels most inspiring or motivating for you personally?]
2. What is the main message and for whom is it intended?
3. What did you focus on in the label/what caught your attention?
4. What new facts, if any, did you learn from this statement? [Probe for facts that they did not know before participating in this discussion.]
5. How clear and understandable is this warning? Is it too technical or not technical enough?

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6. What is this warning asking you to do? What might you do after seeing this? [Probe: which actions would be easy or hard to do and why, what information or tools that would help people implement the actions suggested in the messages]
7. Using your own words can you explain what the following terms mean to you: 'well ventilated', 'prolonged or repeated exposure', 'ingestion', 'suitable eye and skin protection'. [Moderator: this would allow the opportunity to follow up with asking respondents about their own experiences with respect to ventilation and any adverse effects from using the product to themselves or their clients (if not covered earlier in focus group).]
8. What does this statement make you think of in relation to the safety of this product? Does it provide adequate direction for safe use?
9. What could be done to make it more persuasive?
10. What additional information would you include in the warning statement?
11. What do you think of the way the text is presented? [Probe for: font size, location on the bottle, spacing, symbols, etc.]

Example B

WARNING: This product contains **the chemical** methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. **Use suitable eye and skin protection when applying and rinsing product to avoid skin and scalp irritation and eye injury.** Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. If ingestion or eye contact occurs, call a physician immediately. In the event of illness or medical emergency seek medical attention immediately.

Example B is very similar to Example A; the only difference between them is the added words/sentences highlighted in yellow. Please take a moment and look at the added text.

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1. What do you think about adding the word “the chemical” before methylene glycol? Does it make a difference? Does it make the statement more or less clear?
2. What about adding the sentence “Use suitable eye and skin protection when applying and rinsing product to avoid skin and scalp irritation and eye injury”? How important is it to add this information?
3. What about adding the sentence “If ingestion or eye contact occurs, call a physician immediately.”? How important is it to add this information?

Example C



WARNING: This product contains methylene glycol and should only be used in a **WELL- VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

Example C is exactly the same as Example A, except for the symbol that has been added.

[Moderator: This is a universally used symbol signifying hot surface; formaldehyde is released upon the contact of hair smoothing product with hot flat iron.]

1. What do you think about placing a symbol along with a warning statement?
2. What does the symbol bring to mind? In what way, if any, does it change your overall impression of the warning?

Symbols

This is a sheet of different symbols that could be used along with a warning statement.

1. What idea does each of these symbols bring to mind? How understandable would each of them would be to users of hair smoothing products? Why/why not? [Moderator: please elicit responses on each and every symbol on the page.]
2. Which of these symbols would be most appropriate to accompany a warning statement? Why this one? Why not the others?

Example D

WARNING: This product contains methylene glycol and should only be used in a WELL-VENTILATED area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product SHOULD NOT be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

Example D is also exactly the same as Example A, except the text at the bottom is placed in a box.

1. What is your impression of placing this text in a box?
2. Would you rather put different information in the box? Why/why not?

Example E

WARNING: This product contains methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

➤ **AVOID PROLONGED OR REPEATED EXPOSURE TO THIS PRODUCT.**

- **More than one procedure should not be performed at a time.**
- **Avoid direct contact with eyes, skin, and mouth.**
- **Do not use on hair that is breaking, splitting, shedding, or damaged.**
- **If skin contact occurs, wash immediately.**

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

IF YOU ARE NURSING OR PREGNANT, DO NOT USE THIS PRODUCT WITHOUT FIRST CONSULTING YOUR DOCTOR.

In the event of illness or medical emergency, SEEK MEDICAL ATTENTION IMMEDIATELY.

Example E is also very similar to Example A, but some text was bulleted and the sentence at the bottom has been added.

1. What impression do you get from formatting this text in bullet points?
2. How important, if at all, is it to add this last sentence to the warning statement? Why?

Example F

Caution: This product contains methylene glycol and should only be used in a WELL- VENTILATED area

- **AVOID REPEATED EXPOSURE TO THE PRODUCT**
- **Avoid touching this product or breathing its fumes**
- **Don't do more than one of these treatments at the same time in the same place.**
- **Avoid direct contact with eyes, skin, and mouth. If contact occurs, wash immediately**
- **Do not use on hair that is breaking, splitting, shedding, or damaged.**

Product **SHOULD NOT** be used on people who are sensitive to formaldehyde or have pre-existing medical conditions, such as asthma. If skin or scalp irritation occurs, rinse the product out immediately.

IF YOU ARE NURSING OR PREGNANT, DO NOT USE THIS PRODUCT. DO NOT USE THIS PRODUCT WITHOUT FIRST CONSULTING YOUR DOCTOR.

If you get sick or have a medical emergency when you use this product, get medical attention immediately.

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1. What are your overall impressions?
2. What caught your attention?
3. How does it compare to Example A?
4. What are the advantages and disadvantage of this shortened Example F as compared to example A?

Example G

WARNING: This product contains methylene glycol and should only be used in a WELL- VENTILATED area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

In Example G, the frame around the text of the warning has been removed.

1. How does it impact the overall impression of the warning text on the bottle?
2. Does it make the warning stand out more, or does it make it less noticeable?

Example H

WARNING: Product releases formaldehyde gas when treated hair is heated, which may cause short-term and long-term health effects, such as eye, skin, and throat irritation, headache, dizziness, burning sensations, breathing problems, and certain cancers, particularly for those who are sensitive to formaldehyde. This product must be applied by hair professionals only and in conditions that provide adequate ventilation. Concurrent use in the same facility may increase concentration of formaldehyde in the air, which could increase the risk of adverse effects. Avoid unnecessary repeated use.

If you are nursing or pregnant do not use the product without first consulting your physician. If skin contact occurs, wash immediately. If ingestion or eye contact occurs, call a physician immediately. Information on the physical and health hazards, and the safety data sheet, may be obtained from the company.

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1. What are your overall impressions?
2. What caught your attention?
3. What new facts, if any, did you learn from this statement?
4. How clear and understandable is this warning? Is it too technical or not technical enough?
5. Does it provide adequate direction for safe use?
6. What could be done to make it more persuasive? [Probe: what catches your attention, what makes the concept appealing or unappealing, what feels most inspiring or motivating for you personally]
7. What additional information would you include in the labeling statement?
8. How does it compare to Example A?

[Moderator: Ask the following questions after participants have seen and evaluated all warning statements.]

1. Which of these warning statements do you think would be most effective for hair stylist like you? Why?
2. Which of these warning statements do you think would be least effective? Why?
3. How does this label compare to what you currently see?

VII. Evaluation of FDA Web information [10 minute]

Hair-Smoothing Products That Release Formaldehyde When Heated

<http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm228898.htm>

[Moderator: pass around printed Web reading material on Formaldehyde, ask respondents to read it swiftly in no more than 5 minutes and ask the questions. Please keep this section brief, it's not a main focus of this discussion.]

1. What is the take away message from this information on Formaldehyde?
2. Who is this information intended for?

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3. What is unclear or not understandable?
4. What specific actions, if any, does this information call for?
5. Would you change/add anything?

[Additional questions from OCAC (3 minutes); will be printed on a sheet of paper to be filled out by the respondents individually.]

1. How important do you consider information about bad reactions and other risks associated with the use of a product? Please mark your response on the scale below where 1 is “not at all important” and 10 is “very important”.

Not important at all										Very important
1	2	3	4	5	6	7	8	9	10	

2. How important is it to include such information on a product label?

Not important at all										Very important
1	2	3	4	5	6	7	8	9	10	

3. How likely would you be to buy /use the product if information about bad reactions and risks associated with the use of the product was declared on a product label?

I would definitely NOT use/buy the product										I would definitely use/buy the product
1	2	3	4	5	6	7	8	9	10	

False Close [5 minutes]

That’s all the questions I have. Do you have any questions for me or any additional feedback that you’d like to provide?

Thank you!

Thank you very much for your time today. Your feedback is very much appreciated.

[Moderator: Stop recording. Administer incentives and obtain receipts.]