

10/31/2020

Cosmetic Allergens: Focus Groups with People without Allergies Final Moderator Guide (02/09/18)

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I. Introduction—Welcome Group (5 minutes)

1. Hello. My name is ..., and I work for a not-for-profit research organization called RTI International. I will be leading tonight's discussion. On behalf of the U.S. Food and Drug Administration (often called FDA), RTI is conducting discussions with individuals like you around the country regarding allergies to cosmetics in the United States. Your insights are very important to us, and your time today is appreciated. We will have about 105 minutes for our discussion.
2. You have been asked to participate because...
 - a. You are consumers who use the products we will talk about this evening
 - b. Your experiences as consumers are important
 - c. You have opinions and ideas that we'd like to know about
3. How the discussion will work
 - a. Session will last about 1.75 hours
 - b. So I can give you my full attention, tonight's session will be audio- and video-recorded, which will let me listen to you more intently instead of spending my time taking notes. I will use the recordings to write a summary report, but I will not use names in any report.
 - c. Study team members have come tonight to hear your opinions firsthand. They'll be listening from behind the one-way mirror.
 - d. We would like the discussion to be open and informal and encourage interaction
 - e. We would like to hear from everyone in the group
 - f. One person talks at a time
 - g. No right or wrong answers or ideas—we want YOUR opinions
 - h. Silence or turn off cell phones
 - i. I am not an expert on the topics that we will be discussing tonight, so I may not be able to answer all of your questions.

4. Participant introductions
 - a. First name and what you like to do on the weekends

II. Cosmetic Knowledge (5 minutes)

1. Tonight, we will be talking about cosmetics. When you hear the word cosmetics, what kind of products come to mind? *[Record responses on flipchart.]*
2. *[Pass out and refer to handout.]* Looking at these examples, you can see that by cosmetics we mean hair and body products as well as products you apply to your face, like toners, moisturizers, facial masks, and of course make-up.

III. Cosmetic Purchasing Behaviors (25 minutes)

1. Think about the hair, body, and face products you buy. When you buy a hair, body, or face product for the first time, what type of things do you consider before buying? *[Probe: labelling information, presence or absence of ingredient(s), brand, doctor recommendation]*
 - a. *[If mentioned]* Why do you trust a particular brand? *[Probe: advertising, reputation, recommendations, personal experience]*
2. When purchasing a hair, body, or face product for the first time, how often do you read the labelling information? Would you say never, rarely, sometimes, often, or all the time?
 - a. Do you look on all products or just specific products? Which ones?
3. What information do you typically look for on a hair, body, or face product label? *[Probe: ingredient list, drug fact panel, warnings, directions, claims, expiration dates, or whether the product is hypoallergenic, natural, organic, or paraben- or gluten-free].* Why?
4. Does any information on the label affect whether you purchase a hair, body, or face product? If yes, please explain.
5. What other product characteristics, if any, influence your decision to purchase a hair, body, or face product? Please explain. *[Probe: scent, texture, amount/type of packaging material]*
6. Between labelling information and advertisements, which one do you think has a greater effect on your decision to buy a hair, body, or face product?

IV. Cosmetic Use (35 minutes)

1. Think about the hair, body, and face products you use at home. How often do you try new products or switch brands? Would you say never, rarely, often, or all the time? Why?
 - a. Is this true for all products? Why or why not?
 - b. What usually prompts you to try new products or switch brands? *[Probe: advertising, recommendations, word of mouth, personal experience]*

2. How often do you look for expiration dates on hair, body, and face products? Would you say never, rarely, often, or all the time? Why?
 - a. Do you look for expiration dates on all types of products or just specific ones? Which ones? Why only these types of products?
 - b. Do you usually look for expiration dates on hair, body, and face products at the store, at home, or both? Why?
 - i. If at the store, does the presence or absence of an expiration date affect your decision to purchase a hair, body, or face product? Why?
 - c. What do you do with hair, body, or face products after their expiration dates? [Probe: continue using or dispose of]
 - d. How do you determine if or when to dispose of a product?
3. Let's discuss any problems or reactions you may have had from using a hair, body, or face product. First, have you ever had a problem or a reaction from using a hair, body, or face product? If yes, please explain.
 - a. What was the product?
 - b. How long after you applied the product did you experience the problem/reaction? [Probe: minutes, hours, days]
 - c. How long did the problem/reaction last?
 - d. Do you think you had an allergic reaction? Why or why not?
 - e. What did you do?
 - i. Did you stop using the product? Why or why not? If yes, for how long?
 - ii. Did you make any changes? Why or why not? If yes, what kind of changes did you make? [Probe: read labels, avoid ingredient or product]
 - iii. Did you contact the company or manufacturer? Why or why not?
 - iv. Did you contact anyone else about the problem/reaction? If yes, please explain.

V. Response to Adverse Events (20 minutes)

1. We are almost done. I just have two more topics I'd like you to discuss. First, how safe do you think hair, body, and face products are in the United States? Would you not very safe, somewhat safe, or very safe? Why?
2. Who do you think is responsible for the safety of hair, body, and face products in the United States? Why? [Probe: manufactures, government, consumer organizations]
 - a. [If not mentioned] Do you think the government has a role in ensuring the safety of hair, body, and face products in the United States?

- b. If yes, what do you think that role is?
 - i. *[If not mentioned]* Do you think the government approves hair, body, and face products before they are available for sale? Why or why not?
 - ii. *[If not mentioned]* Do you think the government does specific tests or inspections to ensure the safety of hair, body, and face products? Why or why not?
3. The Food and Drug Administration, or FDA, wants to be informed if a consumer has an adverse event related to cosmetics, which brings me to my last set of questions.
 - a. First, what do you think FDA means by adverse event?
 - b. To help identify problems with cosmetics, FDA wants to know if you experienced a rash, redness, itchiness, burning, swelling, blistering, allergic reaction, and temporary or permanent hair loss after using a hair, body, or face product.
4. Before today, did you know that you can report adverse events to FDA?
 - a. If yes, have you ever reported an adverse event to FDA? Why or why not? If yes, please tell me about your experience.
 - b. If no, would you report an adverse event to FDA? Why or why not?
 - i. What types of adverse events would you be more likely to report to FDA?
 - ii. What types of adverse events would you be least likely to report to FDA?
 - iii. How do you think you would go about reporting an adverse event to FDA?
5. You can report adverse events related to hair, body, and face products by calling an FDA Consumer Complaint Coordinator, or CCCC, in your local area or by completing what is called a MedWatch form and submitting it online or by mail.
6. What approaches do you think FDA should use to inform consumers about reporting adverse events related to hair, body, and face products?
7. How do you think FDA could encourage consumers to report adverse events related to hair, body, and face products?
8. If you experienced an adverse event related to a hair, body, or face product, would you allow your doctor to share your health data with FDA? What about photos of your adverse event?

VI. Wrap Up (15 minutes)

1. Any other comments or questions before we wrap up?
2. Tonight's discussion was sponsored by FDA. Your responses will help FDA better understand how consumers use cosmetics.

3. Thank you for sharing your thoughts and opinions tonight.
4. Please pick up your incentive on your way out.

Draft Participant Handout 1

The federal Food, Drug, and Cosmetic Act defines “cosmetics” as products that are intended to be applied to the body “for cleansing, beautifying, promoting attractiveness, or altering the appearance.” But the legal definition includes items that most Americans might not ordinarily think of as cosmetics, including:

- Baby products, such as baby shampoos, conditioners, and other baby cleansing products, baby oil, diapers, and baby wipes
- Bath additives, such as bubble bath, bombs, oil, and salts
- Fragrance products, such as perfumes and cologne
- Hair products, such as shampoos, gels, hairspray, and hair coloring and straightening products)
- Hair removal products, such as waxes and shaving creams
- Make up, including makeup removers
- Nail polishes and other manicuring products
- Oral hygiene products, such as mouthwash, toothpaste, and tooth whitener
- Cleansing products for the face and body, such as soap, shower gels, and other cleansers and deodorants
- Other face and body products, such as toners, moisturizers, exfoliants, and masks
- Suntan products, such as self-tanning products