

FDA Approval Disclosure Consumer Focus Group Moderator Guide

Introduction and Ground Rules

MODERATOR: Welcome and thank you for participating in tonight's discussion. My name is _____ and I work for RTI International, a non-profit research organization.

We are conducting these groups on behalf of the Food and Drug Administration (FDA). FDA is interested in learning more about what people think about the process for approving prescription drugs and reviewing drug promotion. You have been asked to be part of this discussion because you may have seen this promotion, and you have valuable insight that can help FDA.

We're interested in hearing from you all today about your experiences and opinions. I'm not a medical professional or an expert on the topics we will discuss. My role is only to moderate today's focus group and ensure that everyone has the chance to express their ideas and opinions.

Before we begin, I want to go over a few ground rules for our discussion tonight, which will last about 90 minutes. Your participation is voluntary, and you have the right to not answer any question or withdraw from the study at any time.

- If at any time you are uncomfortable with my questions, you can choose not to answer.
- If you are unclear about what I am asking, please do not hesitate to ask me to repeat the question or provide clarification.
- Everything we discuss today will be kept confidential to the extent permitted by law. Use only your first name or a nickname in the group. Only the recruiters have your full name and contact information. It will not be given to anyone at RTI or to anyone at FDA, and no one will contact you about this study after the discussion is over.
- Our discussion will be audio-recorded. The recordings will be transcribed and will help me write the final report summarizing the feedback from the various focus groups being conducted. The recordings and transcripts will be stored on password-protected computers at RTI and FDA and then destroyed at the end of the study. No names or identifying information will be included in the transcripts or mentioned in the final report created from these focus group discussions.
- Behind me is a one-way mirror. Behind that are some of my colleagues. We are also video streaming for colleagues who could not travel to be here. They're watching to make sure that I ask you all the questions I have for you. Near the end of our conversation, I'm going to go into the back and see if they have any last-minute questions for you.
- Please try to speak one at a time. I may occasionally interrupt when two or more people are talking in order to be sure everyone gets a chance to talk and that responses are accurately recorded.
- Most importantly, there are no right or wrong answers. I want to know your opinions. I do not work for the people sponsoring this research, I'm not trying to sell anything, and I didn't write the questions we're going to look at, so don't hold back on giving me your honest opinions.
- Please silence your cell phones.
- Do you have any questions before we begin?

I. Warm Up

[**MODERATOR says:** First, I'd like to go around the room and introduce ourselves. When we get to you, please let us know your first name and share with us one place that you would like to travel.]

II. Understanding and Perceptions of Drug Approval Process

[**MODERATOR says:** Next, we are going to talk a little more about the process for approving prescription drugs. Please note that our discussion today is specific to prescription drugs, not drugs sold over the counter.]

1. When a prescription drug is "approved", what does this mean?
2. What do you know about the process for approving prescription drugs?
 - **Probe:** Who or what organization "approves" the drug?
 - **Probe:** What do you think happens before or after approval?

[**MODERATOR says:** For the rest of our discussion, we will be talking about the Food and Drug Administration, or FDA, as the organization that approves prescription drugs.]

3. If a drug has been approved, what does it mean about the drug's effectiveness or how well it works to treat an illness or condition?
 - **Probe:** What does drug approval indicate or suggest about how good the drug is?
 - **Probe:** What does drug approval indicate about how fast it works?
4. If a drug has been approved, what does that mean about the drug's safety and risks?
 - **Probe:** What does drug approval indicate about major risks?
 - **Probe:** What does drug approval indicate or suggest about side effects?
 - **Probe:** How do you feel differently about the drug risk and/or side effects if a drug is approved?
5. When you see a promotion or promotional material (like an advertisement) for a prescription drug, how do you know if *that drug* has been approved?
 - **Probe:** What words or pictures let you know it's approved?
 - **Probe:** Where are these words or pictures placed? Where should they be placed?

III. Exposure and impressions of DTC Prescription Drug Promotion

[**MODERATOR says:** We are going to spend the rest of our time together talking about types of prescription drug promotion. When people think of "promotion," they may think of different things.]

6. To start off, what do you think of when you think about prescription drug **promotion**?
 - **Probe:** What comes to mind when I say that phrase?
 - **Probe:** Do you think of advertising? What kinds of advertising?
 - **Probe:** Do you think of other promotion? How about websites, where a company shares information about a product or their brand? Any other promotion?
7. Where do you remember seeing promotion for prescription drugs?

- **Probe:** [IF NOT MENTIONED]: Have you seen drug advertisements in magazines? Have you seen them online (on a computer?) On a smartphone or other device? Anyplace else?
- **Probe:** [IF NOT MENTIONED]: Have you seen or visited websites for specific prescription drugs? Why did you visit these websites?

[**MODERATOR says:** Thanks for sharing those. As we've discussed, there are a wide variety of promotion types for prescription drugs (and other products). Today, we are going to focus on two specific kinds of promotion: 1) websites for prescription drugs and 2) mobile based advertisements. We're going to show you mockups of a website and mobile ad. The web site and mobile ad aren't real, but we're using them to help with the discussion.]

[**MODERATOR shows displays of blown-up promotion: consumer-targeted website and mobile reminder ad.**]

[**MODERATOR says:** A prescription drug website (or homepage), like this one (**INDICATE EXAMPLE**) is a website created, owned, and managed by the pharmaceutical company who produces the drug and is geared towards the general public. You could see this promotion if you clicked on an advertisement for this drug or perhaps if you searched for more information about this drug.

A mobile ad, like this one (**INDICATE EXAMPLE**) is an advertisement for a drug that you may see on a smartphone or tablet as you browse websites or use apps. These are ads that you can click on to be directed to a website for additional information (like the one we just showed you). For our discussion, we aren't going to focus on other types of promotion, like advertisements on television or radio, or in print materials like magazines. The samples we are using here are made-up to help us with our discussion; they are not for real prescription drugs.]

8. How often do you see *websites* for prescription drugs (like the one we just looked at)?
 - **Probe:** Would you say very often? Somewhat often? Never?
9. What do you remember about seeing *websites* like the one we looked at?
 - **Probe:** How did seeing the website impact your view of the drug? What kind of follow-up information did you look for about the drug? Where did you look for that information?
10. How often do you see *mobile advertisements* for prescription drugs?
 - **Probe:** Would you say very often? Somewhat often? Never?
 - **Probe:** Have you ever seen this type of ad outside of a mobile device, such as on a computer?
11. What do you remember about seeing *mobile advertisements* for prescription drug?
 - **Probe:** How did seeing the promotion impact your view of the drug? What kind of follow-up information did you look for about the drug? Where did you look for that information?

IV. Understanding and Perceptions of Drug Promotion Review Process

[MODERATOR says: Next, we are going to talk a little bit about the specific information that is included in prescription drug promotion. Remember, there are no right or wrong answers; we want you to share what you know, what you think, or your gut instinct.]

12. What do you know about the process for reviewing prescription drug *promotion*, including websites and advertisements, **before** they are “live,” or in a place where they can be seen by the public?
 - **Probe:** What do you know about the **requirements or regulations** for reviewing promotional materials?
 - **Probe:** Who, if anyone, reviews the content and design of prescription drug promotions **before** they are live? Who, if anyone *approves* them?
 - **Probe [IF PARTICIPANTS SAY “I don’t know”]:** If you are unsure, what would you imagine the process may be for reviewing prescription drug promotions before they are “live”?
 - **Probe:** How is the process similar or different for websites and ads (like mobile ads)?

13. [IF NOT MENTIONED ABOVE]: What do you think FDA’s role is in reviewing the content for prescription drug *websites*?
 - **Probe:** What kind of content do they review? What portion of the website do they review? All of it? Some of it? Do they look at it before or after it goes “live?”

14. When you see a prescription drug *website* how do you know if it has been reviewed beforehand?
 - **Probe:** What might be on the website itself (for example, words or pictures) to let you know it has been reviewed?

15. [IF NOT MENTIONED]: What do you think FDA’s role is in reviewing the content for prescription drug *advertisements* like mobile ads?
 - **Probe:** What kind of content do they review? What portion of the advertisement do they review? All of it? Some of it? Do they look at it before or after it goes “live?”

16. When you see an *advertisement* for a prescription drug, how do you know if the promotional material has been reviewed beforehand?
 - **Probe:** What might be on the promotion itself (for example, words or pictures) to let you know it has been reviewed?

17. If a prescription drug promotion such as *websites* or *mobile ads* has been reviewed, what does that mean about the [safety/effectiveness/risks] claims shown in the promotion?
 - **Probe:** What does promotion review indicate about major risks?
 - **Probe:** What does promotion review indicate or suggest about side effects? Anything?
 - **Probe:** What does promotion review indicate about how well a drug works?

V. Feedback on Drug Approval and Ad Review Signals

[MODERATOR displays sample **consumer-targeted website** and **mobile reminder ad** and directs attention back to them. In the following questions, MODERATOR will rotate the order of the signals (**FDA Review**, **FDA Approve**). MODERATOR will also rotate *versions* of **FDA Review** signal as necessary.]

[MODERATOR says: So now we are going to back to these made-up promotional materials for the rest of our discussion. As you see right now, they don't include any specific language, logo, or cue that clearly shows whether FDA has: 1) approved the drug or 2) reviewed the material.

We are going to work with that and look at some options for adding pieces to the promotion that will "cue" the reader. I am going to walk through some scenarios of adding a cue or not adding a cue. I want all of you to share your impressions of what each would mean. Remember, there are no wrong or right answers.]

[MODERATOR adhere the first signal (**FDA Approve** or **FDA Review**) to **consumer-targeted website** and **mobile reminder ad**. Note which was discussed first.]

[MODERATOR says: So now I have added a cue on the advertisement. (MODERATOR read content of signal) Let's walk through your thoughts.]

18. What are your first impressions of this addition/this cue?
 - **Probe:** How does including this on the website or mobile ad make you feel about the advertisement? How does it affect your opinion?
 - **Probe:** How has it changed your thoughts about the website or mobile ad?
19. In your own words, what does this cue mean, or what is it trying to say?
 - **Probe:** How would you describe what this cue is intended to do?
20. How does this cue affect your trust in the information *about the drug* that is included in the promotion?
 - **Probe:** How believable is the information? How does including this cue affect your thoughts?
21. How does this cue affect what would you think about the advertiser, or the pharmaceutical company who makes the drug?
 - **Probe:** How much do you trust the drug company? How does including this cue affect your thoughts?
22. If this cue was added, what would that make you think about claims in the promotion?
 - **Probe:** What would that make you think about the drugs effectiveness or how well it works to treat the condition?
 - **Probe:** What would that make you think about the drug's risks and side effects?

[MODERATOR take off the first signal and add **the second signal** (**FDA Approve** or **FDA Review**) to **consumer-targeted website** and **mobile reminder ad**. Note which was discussed second.]

[MODERATOR says: I have removed the cue we just talked about and added a new one. (MODERATOR: Read content of signal.) Let's walk through your impressions.]

23. What are your first impressions of this addition/this cue?
 - **Probe:** How does including this on the website or mobile ad make you feel about the advertisement?
 - **Probe:** How has it changed your thoughts about the website or mobile ad?
24. In your own words, what does this cue mean, or what is it trying to say?
 - **Probe:** How would you describe what this cue is intended to do?
25. How does this cue affect your trust in the information *about the drug* that is included in the promotion?
 - **Probe:** How believable is the information? How does including this cue affect your thoughts?
26. How does this cue affect what would you think about the advertiser, or the pharmaceutical company who makes the drug?
 - **Probe:** How much do you trust the drug company? How does including this cue affect your thoughts?
27. If this cue was added, what would that make you think about the claims in the promotion?
 - **Probe:** What would that make you think about the drug's effectiveness or how well it works to treat the condition?
 - **Probe:** What would that make you think about the drug's risks and side effects?
28. If [FDA Approve signal] was on the advertisement, but not [FDA Review signal], what would that mean to you?
 - **Probe:** Are there particular issues or concerns you would have with the drug or advertisement?

[MODERATOR add both FDA Approve and FDA Review signals to consumer-targeted website and mobile reminder ad.]

[MODERATOR says: So now I have added both of these cues on the promotional material. Let's walk through your impressions.]

29. What are your first impressions of having these cues together?
 - **Probe:** How does including these on the website or mobile ad make you feel about the advertisement? How do they affect your opinion?
 - **Probe:** How has it changed your thoughts about the website or mobile ad?
30. In your own words, what do these cues mean, or what are they trying to say?
 - **Probe:** How would you describe what these cues are intended to do?
31. How do these cues affect your trust in the information *about the drug* that is included in the promotion?

- **Probe:** How believable is the information? How does including these cues affect your thoughts?
32. How do these cues affect what you think about the advertiser, or the pharmaceutical company who makes the drug?
- **Probe:** How much do you trust the drug company? How does including these cues affect your thoughts?
33. If these cues were added, what would that make you think about the promotional claims?
- **Probe:** What would that make you think about the drug's effectiveness or how well it works to treat the condition?
 - **Probe:** What would that make you think about the drug's risks and side effects?

[MODERATOR RETURNS TO BACK ROOM TO SEE IF THERE ARE ADDITIONAL QUESTIONS FROM FDA.]

[IF ANY, MODERATOR ASKS ADDITIONAL QUESTIONS FROM FDA.]

Closing

[MODERATOR says: I would like to thank you for coming here today and participating in this discussion. This research was sponsored by the Food and Drug Administration also known as the FDA. FDA would like to thank you for sharing your opinions as they will be very useful in helping them to understand people's reactions and thoughts about the types of promotion we have talked about.]