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Expiration

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Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

This study is being conducted on behalf of the U.S. Food and Drug Administration by the University of Maryland.

Questionnaire for the Proposed Focus Group on Improving FDA Health Communications with Older Women Regarding FDA-Regulated Products

1. When you had a question about a drug or vaccine, did you try to find information to answer your question? You don't need to talk about any particular health concern, but just whether you tried to find information about this concern.

Probe:

- If no, why not? (e.g., fears, time, not sure where to find information)
- If yes, why? (e.g., motivations; health-related goals; discussion with provider, family, friends)
- Would your responses differ depending on whether your question is about prescription drugs, over-the-counter drugs, or vaccines? If yes, please explain how it differs.

2. If you looked for information to answer your question, what sources did you check for information?

Probe:

- Sources of information: family, friends; physicians, pharmacists, other healthcare providers; pharmaceutical industries; patient support groups; medical societies; ministers, communities, senior centers; product website, the internet (if so, what site?), social media; journal articles; news; drug inserts; pamphlets/newsletters.
- Would your responses differ depending on if it is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.

- What sources of information do you trust or rely on the most? What makes them your trusted sources of information? What sources do you not trust and why?
- How often do you look for information on the FDA website? If you use the FDA website, do you find the information useful and easy to access? If not, why not?

3. Thinking about the types of information that you found on the FDA website, was this information useful (e.g., testimonials, data, where or who was providing the information (peer, provider, etc.))?

Probe:

- If yes, what made this information useful to you?
- If no, what could make this information more helpful?
- Would your responses differ depending on if it is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.

4. Assuming that you've learned about the different choices you can make to improve your health, what source of information is most helpful or influential to you in making a health-related decision among the following sources:

family, friends, physicians, pharmacists, other healthcare providers, pharmaceutical industries, patient support groups, medical societies, ministers, communities, senior centers, FDA website, product website, the internet, social media, journal articles, and news

Probe:

- What source(s) do you find most helpful?
- Would your responses differ depending on if the information is for prescription drugs? Over-the-counter drugs? Vaccines?

5. Have you ever looked for answers to a health question, but couldn't find enough information about the topic or what you found didn't really help you?

Probe:

- If yes, what was the reason for this? (e.g., information lacking or needed improvement, overwhelmed with too much information, don't know where and how to find this information)
- Did you end up making a decision about your health even though you wanted more information about the topic? If so, why or why not? If yes, how?

6. Have you ever looked for answers to a health question, and you found information that was too confusing to understand?

- If yes, what made you confused? (e.g., difficult to understand terms, overwhelmed with too much information,...etc.)

7. What are your thoughts about receiving health information in this [*type of communication*] format?

Probe:

- Does this [*type of communication*] appeal to you as a way to receive health information? If so, what makes it appealing? If not, what are the reasons (e.g., can't read well, need help to understand)?
- What would make [*type of communication*] more helpful when you are looking for health information (e.g., time, access to technology, balanced information on both benefits and risks, large font size, short, comprehensive, patient experience data, up-to-date)?
- Is this type of communication the best way to receive information about prescription drugs? Over-the-counter drugs? Vaccines? None of them? Why or why not?

8. Thinking about [*type of communication*] as a way to receive health information, would you recommend [*type of communication*] to others?

Probe:

- Whom would you recommend this to (e.g., age, gender, cultural groups)?
- What are some reasons why you would recommend this type of communication to others?
- What are the reasons why you would not recommend to this type of communication to others?

Repeat questions #7 and #8 for each type of communication.

9. Do you have a preference for one type of communication format over the others when you think of...

- Prescription drugs?
- Over-the-counter drugs?
- Vaccines?

10. What do you think about receiving FDA newsletters at regular intervals containing messages about drug- or vaccine-related health information?

Probe:

- Does a newsletter appeal to you as a way to receive health information? If so, what makes it appealing? If not, what are the reasons (e.g. annoying)?
- If it is appealing, how often do you like to receive these newsletters (e.g. weekly, monthly, custom?)
- Would your responses differ depending on if the information is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.

11. Now, I'd like you to think about the papers that come packaged with a prescription or over-the-counter drug. These papers have information about the drug, how to use the drug safely, potential benefits and risks, and a phone number to report side effects. What are your thoughts about these papers?

Probe:

- Do you find these papers helpful?
- How would you improve on the design of these papers to make them more user-friendly? (e.g., language, format, content).

12. Please share your experience, if any, in finding health information on vaccines.

Probe:

- What are your feelings about this experience?

- What could have improved this experience for you?

13. Is there any other type of communication that you would prefer to receive from the FDA that we did not discuss today?