Appendix D --

Healthcare Provider Perception of Boxed Warning Information Survey

Consent form: OB/GYN/Geriatrician: Vulvar and Vaginal Atrophy Scenario

Appendix D

Consent Form—OB/Gyn and Geriatrician sub-set for Vulvar and Vaginal Atrophy Scenario

Thank you for completing the screening questionnaire. Your opinions are very important to us. Please read this information carefully. If there is anything you do not understand, please <u>click here</u> to email us. The research team will be happy to answer your questions.

[Programmer: Link 'click here' to the email address pi@forsmarshgroup.com]

INFORMED CONSENT FORM

Thank you for your participation in our online survey. Your opinions are very important to us. Your personal information will not be linked to your answers or used in any report. You are being asked to take part in this study because you are a healthcare professional who writes prescriptions. During the survey, you will be shown prescription drug information and you will be asked your opinions about it. The survey will take approximately 20 minutes.

This survey is being conducted by Fors Marsh Group on behalf of the U.S. Food and Drug Administration (FDA). If you have questions about this survey, please contact Dr. Elise Bui, Principal Investigator, by phone at 571-444-1131 or by email at <u>pi@forsmarshgroup.com</u>.

After reading this form, which explains the research, you may decide if you would like to participate in the study or not. Your participation is completely voluntary. If you decide to start the study and then change your mind, you can withdraw at any time by exiting the survey. You may skip any questions you do not want to answer.

You must complete and submit this form before you can take part in the study. If you would like a copy for your records, you can <u>print a</u> <u>copy now</u>.

[Programmer: Link 'print a copy now' to the browser's printer options]

About this Study:

Fors Marsh Group is a research company partnering with the FDA to investigate healthcare professionals' reactions to and understanding of information in prescription drug labeling through an online survey.

Possible Risks or Discomforts:

We do not expect that any of the survey questions will make you uncomfortable or upset you; however, if they do, you can refuse to answer any question. If you skip a question, you can continue with the rest of the survey.

Study Benefits:

There is no direct benefit to you. However, your feedback will help us decide how professional prescription drug labeling can be improved.

Honorarium:

You will receive an honorarium of [\$40] as a token of appreciation for your participation. SurveyHealthcare Globus will issue payment to you upon completion of the survey. You will receive the honorarium for your time even if you choose not to answer some questions during the survey.

Privacy:

Some demographic information, like your age, gender, and race/ethnicity, has been gathered for the study, but no personal information, like your name, will be collected. Your identity will not be linked to your responses. We will be very careful to only let people working on the study see the responses you provide, which will not be linked back to any personal information that can be used to identify you. Your personal information will be kept private to the extent allowed by law. In the case of a breach of information security, appropriate steps will be taken to notify participants.

If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact Fors Marsh Group at researchinfo@forsmarshgroup.com or call 571-366-3266.

Please read the statement below. Then, please click on the statement that describes whether you want to participate in this study and complete the

survey. After checking the box that best represents your willingness to participate, please click "Submit."

By checking "yes" below, you are consenting to participate. If you check "no" below, you are not consenting to participate, and will exit out of this study.

Consent. Do you agree to participate in the study? [SINGLE PUNCH]

Yes, I agree to participate in this study.01No, I do not wish to participate in this study.02

[SUBMIT BUTTON]