

APPENDIX D

Informed Consent Document

We are asking health care providers in the United States to participate in this voluntary research study. In the survey, you will be shown information about a drug and you will be asked questions about it. The survey will take approximately 20 minutes.

This research is being conducted by Fors Marsh Group (FMG) on behalf of the U.S. Food and Drug Administration (FDA). If you have questions about this survey, please contact Dr. Shane Mannis, Principal Investigator, by phone at 571-858-3757 or by email at pi@forsmarshgroup.com.

Possible Risks or Discomforts

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

Benefits

Your responses are very important because they will help researchers understand how health care providers make decisions about medications they might prescribe to patients. There is no direct benefit to you for your participation.

Incentive

In appreciation for your time, you will receive a \$46 honorarium for completing this survey.

Your Rights as a Participant

This study is voluntary. You can stop at any time. You also do not have to answer any questions that you do not want to. You will receive your honorarium for your time when you complete the survey even if you choose not to answer some questions.

The Institutional Review Board at the Food and Drug Administration has reviewed this research. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact the FDA IRB at 301-796-9605 or HSPPMS@fda.hhs.gov. The FDA IRB is an institutional review board, a group of people who are responsible for ensuring that the rights of participants in research are protected.

Privacy and Confidentiality

This survey will ask you for some general demographic information (e.g., age, gender, race/ethnicity). However, no personal information, such as 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 your responses, which will not be linked back to any personal information that can be used to identify you. Your information will be kept private to the extent allowed by law.

If you have read the previous screen and agree to participate, please select Yes below. If not, select No.

Value	Value Label
01	Yes, I agree to participate. [Go to next section]
00	No, I do not agree to participate. [Terminate]

-99	Refused [Terminate]
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