

[FDA LOGO]

[To appear on paper and web versions though the placement might vary based on formatting for the web versus paper]

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Paperwork Reduction Act Statement: The Paperwork Reduction Act of 1995 provides that an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0929. The time required to complete this information collection is estimated to average 30 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.

National Survey on Numerical Claims in Prescription Drug Advertising

Information on Participating: Consent Form

We request that an adult household member with the next birthday and who is at least 18 years of age or older participate in this survey sponsored by the U.S. Food and Drug Administration.

Purpose:

- Westat is conducting this study on behalf of the FDA to understand how people interpret different claims used in prescription drug advertising.

What is involved:

- You are being asked to complete a survey, which will take approximately 30 minutes.
- You are one of about 4,500 people from around the United States being asked to participate in this survey. Your participation is voluntary, and you don't have to answer any questions you are not comfortable answering. You can also stop participating at any time.
- You will read some claims used in prescription drug advertising and respond to multiple choice questions as well as a few open-ended questions for additional input.

Confidentiality:

- Your responses collected through this survey will be kept secure and private to the full extent of the law.
- We will report our results in a summary aggregate report.

Risks:

- There are minimal psychological, social, or legal risks to participating in this study. The survey questions are not sensitive in nature.

Benefits:

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research study to help improve claims made in prescription drug advertising.

Cost and Incentive:

- There are no costs to you for completing the survey.
- We included \$5 cash in your initial invitation letter to thank you for your consideration for completing the survey. **[Included in the post-paid condition:** After you have completed and submitted the survey, you will receive an additional \$10 as a token of appreciation.]

Questions:

- If you have questions about the study, you may contact the Westat Project Director, Naomi Yount, at [toll-free number] or [study email address].
- If you have any questions or complaints about your rights as a research participant, please contact Westat's Human Subject Protections Office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (National Survey on Numerical Claims in Prescription Drug Advertising), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Consent [Web Survey]:

I have read the consent form. Completing this survey means that I understand the information and I consent to participate in this study.

Consent [Paper Survey]:

By completing the survey you are indicating that you are at least 18 years old, have read and understood this consent form and agree to participate in this study. Please DO NOT write your name on the survey.