

[NAME] [STREET ADDRESS] [CITY], [STATE] [ZIP]

[DATE]

Dear _____,

RTI International is conducting a survey on behalf of the Food and Drug Administration (FDA) to examine what information should be provided with medical devices, and how that information should be organized and communicated. We would like to invite you to participate in our online survey. The information you provide will help the FDA implement guidelines for future medical device labels.

Your participation in the study is voluntary and the survey will take approximately 30 minutes to complete. Any information you provide will be kept private to the fullest extent of the law. There are no direct benefits to you for completing the survey and refusal to participate will involve no penalty. However, to thank you for your time, you will receive a check in the amount of [FILL INCENTIVE] for participating.

To participate in the study, you will need to print a copy of the example device label we would like for you to evaluate. We ask that you take a few minutes to review the label prior to completing your survey.

You can access both the example label and the survey at this web address: [FILL WEB ADDRESS]

In order to complete the survey, you will need to enter the following information:

Username: [FILL USERNAME] Password: [FILL PASSWORD]

If you have any questions about the study, please feel free to call Stacey Weger at 1-800-334-8571 ext. 26902. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

Thank you,

Michael Buch

Michael F. Burke, PhD Study Director, RTI