



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

[DATE]

Dear \_\_\_\_\_,

A few weeks ago you were sent a letter from us regarding a survey that RTI is conducting on behalf of the Food and Drug Administration (FDA). The goal of this study is to determine what information should be provided with medical devices, and how that information should be organized and communicated. The findings from this study will help inform the FDA's approach to the development of medical device labeling.

We are writing you again because we have not yet received a response and the data collection time period is closing in the next few weeks. FDA needs the input of healthcare providers to ensure that the guidance it offers reflects your needs. Your participation in the survey is important to the success of this study, and is completely voluntary. To thank you for your time, you will be paid [FILL INCENTIVE]. The survey will take approximately 30 minutes to complete.

Your participation will be kept private to the fullest extent allowed by law. Refusal to participate will involve no penalty. There are no direct benefits to you for completing the survey, however, the results will be used to help inform FDA's approach to device labeling and better ensure that instructions for use communicate appropriate information.

If you would like to participate, we ask that you take a few minutes to print and review an example device 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).

Sincerely,

A handwritten signature in cursive script that reads "Michael F. Burke".

Michael F. Burke, PhD  
Study Director, RTI