

ATTACHMENT B: Cover Letter

FDA Medical Device Labeling
Draft Cover Letter

Dear _____,

RTI International is conducting this survey in conjunction with the Food and Drug Administration (FDA) to determine what information should be provided with medical devices, and how that information should be organized and communicated. We are asking health care professionals to assess whether the format and content of example device labeling is clear, understandable, useful, and user-friendly. The project findings will help inform FDA's approach to standardizing device labeling.

We would like you to participate in our online survey. Your participation in this survey is voluntary. To compensate you for your time, you will be paid [FILL]. The survey will take approximately 30 minutes to complete. You will receive a check to thank you for participating. Your participation in this research will be kept private to the fullest extent allowed by law and your name will never be reported with the information you provide. Refusal to participate will involve no penalty. There are no direct benefits to you for completing the survey, however, the data will be used to review how device instructions for use communicate appropriate information.

If you have any questions about the study, please feel free to call us at [FILL 800 #]. 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,
