APPENDIX B

FDA Device Labeling Study
Health Care Practitioner Moderator's Guide
DRAFT 10.25.10

[NOTE: Participants will be given written consents to sign in the waiting area. They will keep a copy of the consent]

Thank you for coming this evening. I'm ____ and I'm from RTI, a non-profit research organization. I am conducting these interviews for the U.S. Food and Drug Administration (the FDA). The purpose of our discussion tonight is to hear your opinions about the current labeling or instructions for use of medical devices particularly those medical devices healthcare practitioners would use in the areas of: [insert (1) respiratory therapy or anesthesia, (2) infusion therapy or (3) wound care].

The results of these focus group discussions will be used to help FDA improve the content and format of medical device labeling and instructions for use. Your insights are very important to us in this process, and your time this evening is appreciated. Our discussion will last about 90 minutes.

Before we begin, I want to review a few things:

- Your participation is voluntary and you have the right to not answer any question or withdraw from the discussion at any time.
- Everything we discuss today will be kept private to the extent allowable by law. Your name and contact information, which only the study staff knows, will not be given to anyone else and no one will contact you after this group is over.
- We will be video and audio recording our conversation today. The recordings will be used to help RTI write the final report and will be kept in a secure location then destroyed at the conclusion of the study. No names will be mentioned in the final report created from these focus groups.
- I have colleagues behind the one way mirror. They are watching our discussion tonight and are making sure that I get through all the questions I have here. Before we end our discussion, I will be going into the back to ask them if they have any further questions for you.
- If at any time you are uncomfortable with my questions, you can choose not to answer. Just let me know that you prefer not to answer.
- Most importantly, there is no right or wrong answers. I want to know your opinions. I do not work for medical device manufacturers, the government, or health care industry, so don't hold back on giving me your honest opinions.
- Do you have any questions before we begin?

I. Warm-Up

I'd like to go around the room and have each of you please

- state your first name,
- what type of setting you primarily work in, and
- give an example of a medical device you use.

You don't have to mention the name of where you work; I'm interested in whether you work in a hospital, private practice, clinic, nursing home, etc. [PROBE: Do you read the labeling for these?]

II. General Discussion – (30 minutes)

[Where appropriate for each question, insert the specialty of the group - (1) respiratory therapy or anesthesia, (2) infusion therapy or (3) wound care]

1. When you think about the term "medical device labeling", what do you think of? Do you have other names to refer to medical device labeling? [moderator start list on easel]

When we talk about labeling, we mean things such as instruction booklets or manuals that are written specifically for use by practitioners, not patients. Labeling provides end users, in this case health care professionals, with the information they need to use or operate a medical device safely and effectively.

2. How do you and your colleagues use medical device labeling? Can you walk me through the steps?

3. What factors influence the likelihood that you refer to medical device labeling? **[**Probes: first time use, familiarity with the device type, need for risk information such as contraindications or warnings and precautions, instructions for use, cleaning, troubleshooting]

4. What are some barriers to reading the medical device labeling? Why might a colleague not read the labeling?

5. When you want to read the medical device labeling, where do you look? Where would you find it?

6. When you need the medical device labeling, can you easily access it? If not, why not?

7. What sections of medical device labeling do you usually read? [moderator start list on easel]

8. What sections of medical device labeling are most important or useful to you? [moderator continue list on easel] How about least important or useful?

9. Is there anything missing in medical device labeling that would be important or useful to you? (probe: e.g., "proper disposal of disposables")

10. How would you change medical device labeling to make it a appealing or that would make healthcare practitioners want to use the labeling? [RTI working on probes that would get HCPs thinking out of the box]

III. Content Topics based on SPL (20 minutes)

Each of you has a handout that has 13 different topic areas that can be on medical device labeling. I'd like to ask some questions now about these topic areas.

11. Looking at this list of possible topics for medical device labeling, what are the most important or useful for you and your colleagues in similar specialties to know when you use a medical device?

12. In what order would you like to see these topics in medical device labeling? [moderator start list on easel] [Probe: focus on most important/first and least important/last]

IV. Formatting opinions on presentation and methods to provide labeling/instructions for use (10 minutes)

13. What are some ways that you'd like to see labeling presented? [Probes: all on packaging, all on insert, highlights on packaging, etc.]
14. Are there cases where it would be helpful to have certain information on the device itself? Why?
15. If so, what? And how much information ?
16. What are your thoughts about having a shortened version of medical device labeling that would provide a synopsis of the instructions for use (just enough information about the device to operate it)?

17. What are some of the ways that you would like labeling made available to you? [Probe: online, PDA, trainings, written]

18. Would it be helpful for you to have the device labeling information available electronically on the FDA website? Why or why not?

19. How do you and your colleagues currently know if there have been changes to specific medical device labeling?

20. How would you and your colleagues like to know if there have been changes to particular medical device labeling? [Probes: How would that information get to you? Should that be a separate section on the label?]

21. What are your recommendations for changes to the format of medical device labeling in order to improve it?

I'm going to go into the back now to see if my colleagues have any further questions for you. While I'm there, we have a short questionnaire for you to fill out to help us learn more about you and the patient population you serve. The questionnaire will also help us understand the various contexts in which health care providers work. ,

[Moderator passes out questionnaires and pens then goes into back to check with observers for any follow-up questions]

V. Conclusion (5 minutes)

22. Is there anything else you would like to say about medical device labeling?

I would like to thank you for your time and opinions this evening. Your feedback was very useful and will be very helpful to FDA as they move forward with their changes to medical device labeling.