OMB No. 0910-XXXX
Exp. Date:

NAME
STREET ADDRESS
CITY, STATE, ZIP

DATE

Dear _____,

The U.S. Food and Drug Administration (FDA) is conducting a research study that will provide us with information needed to guide our thinking on the content and format of labeling for medical devices. We would like to gain insight from health care professionals (HCPs) on what is considered important and useful information for prescribing and using medical devices. FDA has contracted with RTI International (RTI) to conduct a survey as part of this research study; RTI is not a representative of the FDA or of the federal government.

As you may know, at the present time, there are few regulations that define and describe requirements for medical device labeling, including the instructions for use. FDA would like to examine what information should be provided with medical devices, and how that information should be organized and communicated. In an effort to provide guidance on this issue, RTI is asking HCPs to assess whether the proposed format and content of an example of an abbreviated version of medical device labeling is useful, clear, understandable, and user-friendly. The example medical device and abbreviated labeling have been created for survey purposes only. This is not a marketed product. The study findings will help FDA develop a standard for the content and format of medical device labeling.

Please consider participating in this survey. The information provided by you and other HCPs is important to FDA's understanding of what is needed in labeling for the safe and effective use of medical devices.

In the accompanying letter from RTI, you will find all the information you need to complete the survey online. The survey will take approximately 30 minutes and is completely voluntary and will be kept private to the fullest extent allowed by law.

We value your opinion on this matter and hope that you will take part in the survey. If you have any questions, please contact RTI using the contact information in the accompanying letter.

Sincerely,

Mary Weick-Brady, MSN, RN
Senior Policy Analyst
Office of the Center Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration