

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

[DATE]

Dear _____,

Two weeks ago we sent you an email about a study the Food and Drug Administration (FDA) is conducting. The goal of this study is to compare the labeling for medical devices as it currently exists with labeling for the same medical device prepared using a format we are considering to standardize medical device labeling. The study's results will help inform the FDA's approach to standardizing content found in medical device labeling so that it communicates most effectively the critical information users need and want to know.

We are writing you again because we have not yet heard from you and we are completing the study in the next few weeks. FDA needs the input of healthcare providers to ensure that FDA guidance reflects **your** needs. Although it is completely voluntary, your participation in the survey is extremely important to the success of this study. To thank you for your time, we will pay you [FILL: INCENTIVE AMOUNT] via check. The study will take approximately 90 minutes.

We will keep your participation private to the fullest extent allowed by law. There is no penalty if you decide not to participate. However, while you will receive no direct benefits beyond the incentive, your participation is very important to provide good representation of the range of users of medical devices.

If you would like to participate, we ask that you please contact Mary Brady at mary.brady@fda.hhs.gov.

If you have any questions about the study, please feel free to call Mary Brady at 1-301-796-6089.

Sincerely,

Mary Weick-Brady, MSN, RN
Senior Policy Advisor
Office of the Center Director
Center for Devices and Radiological Health
US Food and Drug Administration
301-796-6089

OMB No. 0910-XXXX, expires xx/xx/yyyy

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8455 Colesville Rd., COLE-14526,

Silver Spring, MD 20993-0002,

PRAStaff@fda.hhs.gov