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To: [Kim M. Sullivan \(SULLIVAN@smarthealth.com\)](#)
Cc: [Houck, Christina M](#); [Valenti, Elizabeth](#)
Subject: STN 125579/0, Rubber Panel T.R.U.E. TEST, Missing Goal Date
Date: Friday, February 26, 2016 3:45:45 PM

Dear Kim,

This is to follow-up on our phone conversation. As discussed, CBER is missing the goal date, today, February 26, 2016, for STN 125579/0, Rubber Panel T.R.U.E. TEST. We received your revisions to the PI; therefore, there are no outstanding items for you to address at this time. However, we need additional time to review your responses to our information requests and to finalize labeling. We will contact you if we have additional information requests or labeling revisions. At this time, we do not intend to issue a Complete Response (CR) Letter.

Please let me or Christina know if you have any questions.

Thank you, Betsy

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