

**From:** Sweeney, Colleen [<mailto:Colleen.Sweeney@fda.hhs.gov>]  
**Sent:** Monday, August 23, 2016 7:49 PM  
**To:** Margaretten, Nadine  
**Subject:** RE: STN: 125592/0 Clarification of August 22, 2016, Information Request item 2(d)

Dear Dr. Margaretten,

This correspondence is in request for clarification regarding item 2 (d) of the August 22, 2016, IR. We confirm the following request:

1. We request the following additional analyses of the P001 study results:

Please provide the 95% confidence intervals of the treatment differences relative to placebo for all of your secondary endpoints by age subgroups listed above.

Please submit the above information as an amendment to STN 125592/0.

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