

**From:** Steele, Matthew  
**Sent:** Friday, May 20, 2016 1:02 PM  
**To:** 'nadine\_margaretten@merck.com'  
**Cc:** Sweeney, Colleen; Khurana, Taruna  
**Subject:** BLA 125592 Information Request

Dear Dr. Margaretten,

Please note that Ms. Katie Rivers has taken a position elsewhere in the Agency and is no longer chair of this submission. CAPT Colleen Sweeny is the new chair, and myself and Dr. Taruna Khurana are the co-RPMs. Please include all three of us on all correspondence regarding this BLA

Additionally, we have the following Information request for this BLA:

We note that the endpoint data you provided in your BLA from the P001 pivotal trial appears to be computed using data from subjects ages 12 through 85. Please provide these data using subjects ages 18 through 65, which is the age range for which you are seeking licensure.

Please let us know if you have any questions.

Matthew Steele, PhD  
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Primary Reviewer and RPM  
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