

**From:** Smith, Michael (CBER)  
**Sent:** Thursday, July 15, 2021 1:47 PM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>  
**Cc:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>  
**Subject:** STN 125742.0: IR RE Study C4591007

Elisa,

The review team has the question below for you regarding Study C4591007. The review team has requested that a response be submitted to the BLA by July 21, 2021.

We note that the goal dates provided for Study C4591007 final protocol submission reflect the date of the first version of the protocol, which did not include all children 11 years of age and younger. Please provide updated goal dates for final protocol submission (that will include participants down to birth), study completion and report submission for Study C4591007.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

**Mike Smith, Ph.D.**  
**Captain, USPHS**

**Senior Regulatory Review Officer**  
**Food and Drug Administration**  
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