

**From:** Hoffman, Kelsy  
**Sent:** Thursday, August 30, 2018 8:15 AM  
**To:** 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>  
**Cc:** Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>  
**Subject:** STN 125563 Information Request

Dear Ms. Mayer,

With regard to BLA 125563, we have the following request for additional information:

Please submit a revised, redlined Lot Release Protocol (LRP) template that includes a table of the changes made which address the issues mentioned in the IR dated June 19, 2015. Also, please submit the LRP template for the poliovirus (IPV) trivalent concentrate.

Thank you,

**Kelsy F. Hoffman, Ph.D.**  
**LCDR, USPHS**  
Center for Biologics Evaluation and Research  
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U.S. Food and Drug Administration  
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