

**From:** Hoffman, Kelsy  
**Sent:** Friday, October 12, 2018 11:57 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 the most recent Periodic Benefit-Risk Evaluation Report (PBRER) for Vaxelis as an amendment to your BLA 125563/0 by October 19, 2018.

Thank you,

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