

**From:** Hoffman, Kelsy  
**Sent:** Wednesday, November 28, 2018 11:04 AM  
**To:** 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>  
**Cc:** Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>; Chattopadhyay, Rana <Rana.Chattopadhyay@fda.hhs.gov>  
**Subject:** RE: Information Request for BLA125563

Dear Ms. Mayer,

Yes, submission of your response on Monday, December 3<sup>rd</sup> is acceptable.

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  
Tel: 301-796-2640  
[Kelsy.Hoffman@fda.hhs.gov](mailto:Kelsy.Hoffman@fda.hhs.gov)



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**From:** [Kristen.Mayer@sanofi.com](mailto:Kristen.Mayer@sanofi.com) <[Kristen.Mayer@sanofi.com](mailto:Kristen.Mayer@sanofi.com)>  
**Sent:** Wednesday, November 28, 2018 10:11 AM  
**To:** Hoffman, Kelsy <[Kelsy.Hoffman@fda.hhs.gov](mailto:Kelsy.Hoffman@fda.hhs.gov)>  
**Cc:** Ramachandran, Girish <[Girish.Ramachandran@fda.hhs.gov](mailto:Girish.Ramachandran@fda.hhs.gov)>; Chattopadhyay, Rana <[Rana.Chattopadhyay@fda.hhs.gov](mailto:Rana.Chattopadhyay@fda.hhs.gov)>  
**Subject:** RE: Information Request for BLA125563

Dear Dr Hoffman,

Our publishing group has indicated that they can provide this submission on Monday Dec 3. It's too large for me to email to you, so will that date be acceptable?

Thanks,  
Kristen

**From:** Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]  
**Sent:** Monday, November 26, 2018 4:45 PM  
**To:** Mayer, Kristen /US <[Kristen.Mayer@sanofi.com](mailto:Kristen.Mayer@sanofi.com)>  
**Cc:** Ramachandran, Girish <[Girish.Ramachandran@fda.hhs.gov](mailto:Girish.Ramachandran@fda.hhs.gov)>; Chattopadhyay, Rana <[Rana.Chattopadhyay@fda.hhs.gov](mailto:Rana.Chattopadhyay@fda.hhs.gov)>  
**Subject:** [EXTERNAL] Information Request for BLA125563  
**Importance:** High

Dear Ms. Mayer,

We have the following information request for your BLA125563:

We acknowledge your submission of the Vaxelis PSUR for the reporting interval of February 16, 2018 to August 15, 2018. Please submit all additional PSURs (or other periodic safety reports) from the Vaxelis International Birthdate, February 15, 2016, to the present date. Please also submit any late-breaking postmarketing safety information since the end of the reporting interval for the most recent PSUR, August 15, 2018, to the present date.

Please submit your response by Friday, November 30<sup>th</sup>. Also, please let me know if you have any questions.

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  
Tel: 301-796-2640  
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