

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 3rd 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



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From: Kristen.Mayer@sanofi.com <Kristen.Mayer@sanofi.com>
Sent: Wednesday, November 28, 2018 10:11 AM
To: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Cc: Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>; Chattopadhyay, Rana <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>
Cc: Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>; Chattopadhyay, Rana <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 30th. 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
Kelsy.Hoffman@fda.hhs.gov



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