

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 Vixelis as an amendment to your BLA 125563/0 by October 19, 2018.

Thank you,

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