

From: Hoffman, Kelsy
Sent: Friday, December 14, 2018 6:29 PM
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: Vixelis revised PI

Dear Ms. Mayer,

I have attached our additional proposed revisions to the Package Insert for Vixelis to this email. Please respond by **Monday, December 17, 2018**.

Also, please submit for our review, as an amendment to your BLA, updated Cartons and Containers reflecting the new proper name.

Thank you,

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