

From: Ramachandran, Girish
Sent: Wednesday, November 14, 2018 11:47 AM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: Information Request for BLA125563

Dear Ms. Mayer,

With regards to your BLA 125563, could you please submit the latest and most updated Stability study data for all your clinical and commercial lots of VAXELIS along with the shelf-life of the filled product you are seeking? Could you please submit this information by Monday November 19th?

Thanks,
Girish

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