

From: Ramachandran, Girish
Sent: Wednesday, December 19, 2018 9:40 AM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: Information Request for BLA125563
Importance: High

Dear Ms. Mayer,

In regards to your BLA125563, we have the following comments for you:

1. As requested by CBER on November 01, 2018, MCM committed on November 19, 2018, to measure (b) (4) MCM committed to submit these data within one year after approval.
2. In response to CBER Information Request, dated, December 07, 2018, you mentioned in your submission on December 12, 2018 to BLA (STN 125563/0) that the D-Antigen (b) (4) test for poliovirus 1,2 and 3 transferred from the Marcy L'Etoile, France to the Toronto site, uses the same reference and critical reagents in both sites, and performance of the test is monitored using a shared positive control. The new reference lot was initially calibrated and qualified at the MLE site against the current reference standard (b) (4) . Per our request to demonstrate that implementation of the new reference would not impact the results of the (b) (4) you committed to perform (b) (4)

When you have fulfilled your commitment, submit your final report as Postmarketing Commitment – Final Study Report or Supplement contains Postmarketing Commitment – Final Study Report.

Please provide us with your concurrence to the above commitments by Thursday, December 20, 2018.

Thanks,

Girish

Girish Ramachandran, Ph.D.
Primary Regulatory Reviewer/Regulatory Project Manager
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave.
WO71
Silver Spring, MD 20993-0002