



Review Memorandum

Date: December 20, 2018
To: The file STN 125563
From: Girish Ramachandran, OVRR/DVRPA, RPM
Through: Jon Daugherty, OVRR/DVRPA
Rana Chattopadhyay, OVRR/DVRPA, RPM
Copy: Rana Chattopadhyay, OVRR/DVRPA, RPM
Applicant name: SANOFI PASTEUR SA
STN: 125563/0.59
Product: VAXELIS
Subject: Response to IR from December 19th 2018, requesting concurrence to the 2 D-antigen (b) (4) assay commitments
Action due date: December 29, 2018

Recommendation: Approval

Summary

In this amendment, the sponsor submitted a response to the Information Request received by email from CBER (Dr. Girish Ramachandran) on 19 December 2018, requesting concurrence to the 2 D-antigen (b) (4) assay commitments. The sponsor provided a written commitment to the two items requested (below).

Summary of Changes

In regards to the BLA 125563, CBER has the following comments: When you have fulfilled your commitment, submit your final report as Post-marketing Commitment – Final Study Report or Supplement contains Post-marketing Commitment – Final Study Report.

Question 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.

Response 1

We concur with the above commitment.

Question 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)

Response 2

We concur with the above commitment.

Reviewer's Conclusion:

I find the sponsor's response acceptable.