



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.