



CMC Review Memorandum

Date: November 30, 2018
To: The file STN 125563
From: Diana Kouivaskaia, OVRD/DVP, Product reviewer
Through: Steven Rubin, OVRD/DVP
Sara Gagneten, OVRD/DVP
Robin Levis, OVRD/DVP
Copy: Rana Chattopadhyay, OVRD/DVRPA, RPM
Applicant name: SANOFI PASTEUR
STN: 125563/0.48 (Sequence Number 50)
Product: PR5I (Vaxelis)
Subject: Quality amendment submitted in response to CBER Information Requests of
11/14/2018
Action due date: December 29, 2018
Recommendation: **Approval**

Summary

In response to the Information Request communicated on November 14, 2018, the company submitted updated stability data for Vaxelis along with the proposed 48 month shelf-life of the filled product.

Review of the amendment

The following question was emailed to the company on November 14, 2018:

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?

Response:

Complete (48 months) stability data for clinical lots C3145A, C3146B, C3147A, and (b) (4) were submitted in amendment 0.33 (3.2.P.8.3_Stability data_Long term stability study). All four lots met potency specifications for the poliovirus component when stored for up to 48 months at 2-8°C in 2 mL glass vials as proposed for licensure in the U.S. Based on these updated stability data, the company requested a 48-month shelf life for the product.

In the present amendment, the company provided additional, supportive stability data for (b) (4) PR5I commercial lots (b) (4) presentation distributed outside the U.S. Results of D-antigen (b) (4) for these lots are available for times (b) (4) lots), and 24 months (lot (b) (4) only). All results were within the acceptance limits. PR5I lots (b) (4) (vial presentation) and (b) (4) presentation) were placed on stability in 2017. Only results of tests performed at Time 0 are available at this time. Data for the 12-month time point are pending.

Recommendation:

Based on the stability data for four PR5I clinical lots (C3145A, C3146B, C3147A, and (b) (4) IPV potency appears to be stable over a 48-month period from the time of Final (b) (4) formulation. Approval of a 48-month shelf life for PR5I (Vaxelis) is recommended.