



BLA 125514/S-98

APPROVAL LETTER

Merck Sharp and Dohme Corp
Attention: Anne Marie O'Connell, MS
Senior Director, Global Regulatory Affairs
1180 Church Road
Suite 1
Lansdale, PA 19446

Dear Anne Marie O'Connell:

Please refer to your supplemental biologics license application dated and received October 16, 2020, and your amendment, submitted under section 351(a) of the Public Health Service Act for Keytruda (pembrolizumab) Injection.

This Prior Approval supplemental biologics license application provides for the alignment of the (b) (4) description and protocols across all of the approved pembrolizumab drug substance manufacturing sites (b) (4) (b) (4) and allows (b) (4) (b) (4) during pembrolizumab drug substance manufacturing.

APPROVAL

We have completed our review of this supplemental biologics license application, as amended. This supplement is approved.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated October 16, 2020, containing the final report for the following post-marketing commitment listed in the June 23, 2020 approval letter for BLA (b) (4)

(b) (4)

We have reviewed your submission and conclude that the above commitment was fulfilled.

This information will be included in your biologics license application file.

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



Kathleen
Clouse Strebel

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