

Dear Ms. Mayer,

With regard to BLA 125563, we have the following request for additional information:

In amendment 0.33 to your application STN # 125563 you cite approval of a comparability protocol (SOP Q_0235230) under STN # 1033666/5157 as support for the implementation of the new lot of reference standard used in the in vitro portion of the acellular pertussis mouse immunogenicity assay. However the approved SOP appears to be SOP A004335. Please provide the SOP number of the appropriate approved comparability protocol used to evaluate reference standard lot (b) (4) describe any changes to the protocol since approval, and clarify any discrepancies.

Thank you,

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

Phone- 301-796-2640

FAX-301-595-1124

Girish.Ramachandran@fda.hhs.gov

