

From: Ramachandran, Girish
Sent: Thursday, November 29, 2018 12:57 PM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: Information Request for BLA125563

Dear Ms. Mayer,

In regard to your BLA STN 125563, we have the following comment for you:

The specification for IPV monovalents presented in Table 1 in section 1.1 Release Specification [module 3.2.S.2.4 Controls of Critical Steps and Intermediates, section Controls of Monovalents (Types 1, 2 and 3)] lists (b) (4) in the test for effective inactivation. Please update the specifications to align with the proposed analytical procedure that currently uses (b) (4) .

Could you please send us your comments by Tuesday December 4th? If you have any questions, please feel free to contact me.

Thanks,
Girish

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