

From: Prutzman, Kirk C
Sent: Friday, March 22, 2019 5:27 PM
To: 'Patrick.O'Neil@sanofi.com' <Patrick.O'Neil@sanofi.com>
Cc: Polo, Stephanie <Stephanie.Polo@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: RE: STN 125682 - Information Request

Dear Mr. O'Neil,

We have the following request for additional information regarding your request for “Deferral of Pediatric Studies” submitted in your amendment dated March 21, 2019, for STN 125682 (Dengue Tetravalent Vaccine, Live):

Please include the following dates (MM/DD/YYYY) for each study listed below which was identified in your request for deferral of pediatric studies:

1. Deferred study CYD 14 to evaluate the safety and effectiveness of Dengvaxia in children 2 through 8 years of age.

Final Protocol Submission: Please include the date the final protocol was submitted to the IND.

Study Completion Date: Please include the date study was completed.

Final Report Submission: Please include the date the Final Report will be submitted

2. Deferred study CYD 23/57 to evaluate the safety and effectiveness of Dengvaxia in children 4 through 8 years of age.

Final Protocol Submission: Please include the date the final protocol was submitted to the IND

Study Completion Date: Please include the date the study was completed.

Final Report Submission: Please include the date the Final Report will be submitted

3. Deferred study CYD XX (please provide the CYD number) to evaluate safety and effectiveness of Dengvaxia in infants and children 6 months to 2 years of age.

Final Protocol Submission: Please include the date the Final Protocol will be submitted

Study Completion Date: Please include the date the Study will be completed

Final Report Submission: Please include the date the Final Report will be submitted

Please submit a revised request for deferral of pediatric studies in an amendment to STN 125682 by March 25, 2019. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at 301-796-2640.

Regards,

Kirk Prutzman, PhD

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