

From: Prutzman, Kirk C
Sent: Tuesday, March 19, 2019 5:36 PM
To: Patrick.O'Neil@sanofi.com
Cc: Polo, Stephanie <Stephanie.Polo@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: 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 18, 2019, for STN 125682 (Dengue Tetravalent Vaccine, Live):

1. For the pediatric age group 6 months to 2 years of age you state: "If the benefit-risk assessment is favorable in seropositive subjects aged 2 to 8 years, additional immune-bridging to children 6 months to 2 years of age would be proposed based on existing or future clinical data." CBER does not agree that immuno-bridging to children 6 months to 2 years of age at this time. Please propose a study of safety and effectiveness for infants and children 6 months through 2 years of age.
2. Please include the following information for each study identified in your request for deferral of pediatric studies:

[Study Title]

Final Protocol Submission: [INSERT DATE]

Study Completion: [INSERT DATE]

Final Report Submission: [INSERT DATE THAT THE DEFERRAL PMR IS DUE]

Please submit a revised request for deferral of pediatric studies in an amendment to STN 125682 by March 21, 2019. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at 301-796-2460.

Regards,

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