

From: Polo, Stephanie
Sent: Friday, March 29, 2019 5:18 PM
To: 'Patrick.O'Neil@sanofi.com' <Patrick.O'Neil@sanofi.com>
Cc: Prutzman, Kirk C <Kirk.Prutzman@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” for STN 125682 (Dengue Tetravalent Vaccine, Live), sent in your email dated March 28, 2019, to Kirk Prutzman, PhD:

1. Please include the following dates (MM/DD/YYYY) for each study listed below which was identified in your request for deferral of pediatric studies:
 - a. 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 initial version of the final protocol (version 1.0) was submitted to the IND.
 - b. Deferred study CYD 23 to evaluate the safety and effectiveness of Dengvaxia in children 4 through 8 years of age.

Final Protocol Submission: Please include the date the initial version of the final protocol was submitted to the IND.
Study Completion Date: Please include the date the study ended (i.e., 09/10/2013).
 - c. Deferred study CYD 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 initial version of the final protocol was submitted to the IND.
2. Please include the rationale for why the time needed to prepare and submit the final reports for CYD 14, 23 and 57 is estimated to take more than 1 year (i.e., beyond 04/01/2020). Also, please note that the projected date for final report submission corresponds to the date the reports would be submitted to the BLA, either as a clinical efficacy sBLA or initially as a final study report. The postmarketing requirement would not be fulfilled until the pediatric assessment is complete (i.e., approval of clinical efficacy sBLA).

Please submit a revised request for deferral of pediatric studies which includes the information requested above in an amendment to STN 125682 by April 1, 2019. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at 301-796-2640.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
stephanie.polo@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.