

**From:** Polo, Stephanie  
**Sent:** Tuesday, March 26, 2019 5:40 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 STN 125682 (Dengue Tetravalent Vaccine, Live):

Please provide the following information regarding the Grade 3 Unsolicited Adverse Reactions included in your Prescribing Information (PI) label:

1. A table of each subject who had a Grade 3 unsolicited adverse reaction indicated in the PI that includes:
  - a. The subject's age;
  - b. Subject study ID number;
  - c. Dose of Dengvaxia or Placebo after which the Grade 3 Unsolicited AE was reported;
  - d. Time of Grade 3 Unsolicited AE in relation to administration of Dengvaxia or Placebo;
  - e. Study investigator assessment of relatedness of Grade 3 Unsolicited AE to Dengvaxia or Placebo administration;
  - f. The System Organ Class term and the MedDRA term for the Grade 3 Unsolicited AE.
2. Please provide your assessment of the imbalance in these Grade 3 Unsolicited AEs between Dengvaxia and Placebo groups.

Please submit your response as an amendment to STN 125682 by Friday, March 29, 2019.

If you have any questions about this communication, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at (301) 796-2640.

Best regards,

**Stephanie Polo**

*Primary Reviewer/Regulatory Project Manager*

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