

From: Polo, Stephanie
Sent: Wednesday, March 20, 2019 10:47 AM
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 Section 8 of the Prescribing Information label for STN 125682 (Dengue Tetravalent Vaccine, Live):

1. Please complete the table in the attached document which summarizes the outcomes of each pregnancy in which females were administered Dengvaxia in your clinical trials as well as any data from spontaneous postmarketing reports. Please do not include pregnancies in which females were administered placebo.
2. Please provide the subject identification number for each subject whose pregnancy is included in the table and who was enrolled in a clinical trial.
3. Please provide any available follow-up information for each female whose pregnancy was identified from spontaneous postmarketing reports and whose information is included in the attached table.

Please submit your response in an amendment to STN 125682 by March 27, 2019. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps to organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at 301-796-2460.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

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