

From: Polo, Stephanie
Sent: Friday, April 26, 2019 4:50 PM
To: 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 reviewed your April 26, 2019 submission to STN 125682 (Amendment 52), and we have the following comment:

Please confirm the information below regarding your proposed pregnancy registry and the indicated dates:

To establish a pregnancy registry for DENG VAXIA in the United States to prospectively collect data on spontaneously reported exposures to DENG VAXIA at any time during pregnancy. You will submit annual reports as well as a 5-year summary report, after which you will continue enrolling patients in the registry and submitting annual reports pending CBER review of the reports and determination that the registry can be discontinued.

Final protocol submission: December 31, 2019 [Please confirm]

Study/Clinical trial completion: December 31, 2024 [Please confirm]

Final Report Submission: December 31, 2025 [Please confirm]

Please submit your response in an amendment to STN 125682 by Monday, April 29, 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

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