

From: Polo, Stephanie
Sent: Wednesday, December 12, 2018 4:34 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, Attenuated]):

1. Please identify the US states/territories where dengue is/was circulating, and Dengvaxia, if approved, is likely to be administered.
2. Please identify the regions in the US states/territories where cocirculation of dengue and other flaviviruses (especially, Yellow Fever, Japanese encephalitis, West Nile viruses and Zika virus) are likely present.
3. Please provide information/estimate on the seroprevalence of dengue and relevant cocirculating flavivirus in the identified regions in the US states/territories.
4. Please provide estimates of numbers of severe dengue cases prevented vs. severe dengue cases attributable to vaccinating individuals with false positive screening tests if the vaccine were to be used in endemic US territories while relying solely on currently available serological screening just prior to vaccination, without benefit of other clinical history, to identify individuals with prior dengue infection.

Please submit your response in an amendment to STN 125682 by January 18, 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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