

**From:** Polo, Stephanie  
**Sent:** Tuesday, April 09, 2019 5:17 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):

1. We refer to your submission dated November 30, 2018 (Amendment 13), which included the summary report for the container closure integrity test for the (b) (4) 2 mL glass vials using a (b) (4) method. Please provide the following additional information:
  - a. The positive controls used for the container closure integrity test, including the types and sizes of defects in those controls, if available.
  - b. The determined sensitivity of the test.
  - c. Please clarify if the same diluent (same vial and content) is used for any other approved US product(s). Please provide the STN reference for those product(s), if available.

Please submit your response as an amendment to STN 125682 by Friday, April 12, 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*

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](mailto: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.**