

**From:** Polo, Stephanie  
**Sent:** Wednesday, February 27, 2019 5:29 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. In relation to the exogenous particles found in drug product batch (b) (4) (Section 3.2.P.5.4, page 13 of 18), please provide the investigation report conducted to examine the detection of exogenous particles.

Please submit the requested information in an amendment to STN 125682 by Wednesday, March 13, 2019. 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*

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)



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