

From: Polo, Stephanie
Sent: Friday, February 01, 2019 5:45 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 comments and request for additional information regarding STN 125682 (Dengue Tetravalent Vaccine [Live, Attenuated]):

We refer to your response in your submission dated January 28, 2019 (Sequence 0020) addressing our information request of January 11, 2019; specifically, to your response to Item 8 pertaining to the test for Virus Identification in the Finished Product (i.e., labeled and packaged DP). Because an identity test is required prior to release of each vaccine lot after all labeling operations have been completed (21 CFR 610.14), your commitment to submit the assay method and validation information for a simplified identity test to be performed at the Swiftwater, U.S. site as a CBE-30 before release of the first DENGVAXIA vaccine lot in the U.S. market is not acceptable. If you are unable to submit the SOP and validation report for the simplified identity test by March 1, 2019, we recommend that you consider performing the test at the (b) (4) site using the validated test described in SOP Q_0144050 (i.e., by sending samples of Finished Product lots from Swiftwater to (b) (4)). In addition, please update the affected modules (e.g., revise modules 3.2.P.3.1, Table 2 and 3.2.P.5.2, section 3.8, to include a reference to the appropriate laboratory site and assay method Q_0144050), if applicable.

Please submit your response in an amendment to STN 125682. 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



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.