

From: Polo, Stephanie
Sent: Thursday, November 29, 2018 1:41 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]):

We have reviewed your November 20, 2018 submission (Amendment 12), which included your response to our October 23, 2018 information request regarding moisture assay method. We do not agree with your justification for not validating the entire method. In your method, residual water is (b) (4) from the lyophilized drug product and (b) (4). You stated that the matrix components do not interfere with the (b) (4), but you have not presented any data to substantiate your point. In addition, the sample (b) (4) step is an integral part of the method; therefore, the entire analytical procedure, including sample (b) (4), should be validated for the drug product. We suggest that you evaluate accuracy and linearity of the entire method by spiking water standard at different levels into the sample matrix. Please validate the entire method and provide the data, as previously requested, within 3 weeks. If you are not able to complete your validation within 3 weeks, please propose an alternate timeline.

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

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