

**From:** Houck, Christina M  
**Sent:** Wednesday, February 17, 2016 9:13 AM  
**To:** KSmyth@paxvax.com  
**Subject:** STN 125597 Advice/Information Request

Dear Mr. Smyth,

We have the following advice/request for additional information for STN 125597:

1. In Sections 3.2.P.5.6 Justification of Specifications [Buffer] and 3.2.P.8 Stability [Buffer] of your BLA, we note that you do not include a test for Moisture Content. Please include Moisture Content in your release tests and stability tests (first and last time points) for the buffer. Please submit your response as an amendment to your BLA STN 125597/0. Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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