

**From:** [Jarvis, Candace](#)  
**To:** [James L'Italien, PhD \(jlitalien@avexis.com\)](#)  
**Cc:** [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)  
**Subject:** BLA 125694/0| AveXis, Inc| Information Request 57 (PLEASE RESPOND BY MAY 3, 2019)  
**Date:** Monday, April 29, 2019 1:58:40 PM  
**Attachments:** [image002.png](#) **Importance:** High

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Good afternoon Dr L'Italien,

We have the following PMC information request for BLA 125694/0 and ask that you please respond no later than May 3, 2019.

The following draft PMCs are provided for your review and comment. If acceptable, please submit these commitments in an amendment to the BLA.

1. AveXis, Inc. commits to develop and qualify a suitable method for quantifying (b) (4) and to subsequently provide the method, the method qualification report and an additional process validation report for (b) (4) by December 31, 2019.
2. AveXis, Inc. commits to validate the robustness of the (b) (4) assay by carrying out the study in protocol REC-2566, and to provide the supplemental validation report by December 31, 2019.
3. AveXis, Inc. commits to update the (b) (4) assay to include an assay validity criterion for the reference standard, and to provide a supplemental validation report evaluating the robustness of the (b) (4) assay by December 31, 2019.

Please acknowledge receipt.

*Regards,*

**Candace N. Jarvis**  
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