

**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 47 (Please Respond by April 10, 2019)  
**Date:** Thursday, April 04, 2019 10:05:55 AM  
**Attachments:** [image002.png](#) **Importance:** High

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Good morning Dr L'Italien

We have the following CMC information request regarding BLA 125694/0. Please respond by April 10, 2019.

1. Please provide (b) (4).
2. The lower acceptance criterion for DS (b) (4) stability is (b) (4). We note that RPT-410 indicates that there have been excursions below this limit during stability studies. The justification of specifications (3.2.S.4.5) states only that this acceptance criterion is "sufficiently above the targeted AVXS-101 DP (b) (4)." Please provide further explanation for this acceptance criterion.
3. NCR-1352 describes stability data for lots (b) (4). The data for these lots were not included in RPT-411. Please explain.

Please acknowledge receipt.

*Regards,*

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