

**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 53 (PLEASE RESPOND BY APRIL 30, 2019)  
**Date:** Tuesday, April 23, 2019 5:47:16 PM  
**Attachments:** [image013.png](#) **Importance:** High

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Good afternoon Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond no later than April 30, 2019.

During the April 16, 2019 telecon, AveXis stated that there were (b) (4) lots of DS that were stored for approximately (b) (4) before being forward processed to DP. Please provide information for these DS lots and the associated DP lots, including the dates of manufacture, the DP yield, the lot release data, and any relevant in-process data from the manufacturing of these DP lots.

Please confirm receipt.

*Regards,*

**Candace N. Jarvis**  
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*Center for Biologics Evaluation and Research*  
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