

**From:** [Jarvis, Candace](#)  
**To:** [James L'Italien, PhD \(jlitalien@avexis.com\)](#)  
**Cc:** [Nancy Boman](#); [Jarvis, Candace](#); [Whatley, Angela](#); [Byrnes, Andrew](#)  
**Subject:** 125694/0| AveXis, Inc.| information Request 12 (PLEASE RESPOND BY NOVEMBER 20, 2018)  
**Date:** Tuesday, November 13, 2018 12:00:13 PM  
**Attachments:** [image013.png](#) **Importance:** High

---

Good afternoon Dr. L'Italien,

We have the following information request regarding BLA 125694.

Please direct us to which section in the BLA that contains the list of additional QC testing performed by AveXis on incoming lots of (b) (4) entering your facility. If this information is not in the BLA please submit it as an amendment by 5:00 PM Tuesday November 20, 2018.

Please confirm receipt

*Regards,*

*Candace N. Jarvis*

*Regulatory Project Manager*

*Center for Biologics Evaluation and Research*

**Office of Tissues and Advanced Therapies**

**U.S. Food and Drug Administration**

Tel: 240-402-8315

[candace.jarvis@fda.hhs.gov](mailto:candace.jarvis@fda.hhs.gov)



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.