

**From:** [Jarvis, Candace](#)  
**To:** James L'Italien, PhD ([jlitalien@avexis.com](mailto:jlitalien@avexis.com))  
**Cc:** [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)  
**Subject:** BLA 125694/0| AveXis, Inc| Information Request 55 (PLEASE RESPOND BY MAY 3, 2019)  
**Date:** Monday, April 29, 2019 11:35:37 AM  
**Attachments:** [image013.png](#)  
**Importance:** High

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Good morning Dr. L'Italien,

We have the following request for information concerning BLA 125694/0 and request that you please respond by May 3, 2019.

1. The vial and carton do not appear to be compliant with the labeling standards in 21 CFR 610.62, please revise as follows:
  - a. The point size of the proper name should be no smaller than the point size of the trade name.
  - b. All items required to be on the labels should be easily readable (type with sufficient point size).
2. The label artwork provided in submission number 66 on April 17<sup>th</sup> had poor resolution. Please provide high-resolution images of the vial labels, the carton, and the variable carton label.
3. Please also provide high-resolution sample images of the vial labels and variable carton label with all variable text filled in (e.g. expiration dates, lot numbers, etc.).

Please acknowledge Receipt.

*Regards,*

**Candace N. Jarvis**  
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