

**From:** [Jarvis, Candace](#)  
**To:** [James L'Italien, PhD](#)  
**Cc:** [Nancy Boman](#); [Byrnes, Andrew](#); [McDowell, Erin](#); [Cato, Dennis](#); [Jarvis, Candace](#); [Glen, Jacqueline](#)  
**Subject:** BLA 125694/0 | AveXis, Inc | Information Request 43 (Please Respond by March 21, 21019)  
**Date:** Thursday, March 14, 2019 9:41:07 PM **Attachments:**  
[image013.png](#)

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Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694.0. Respond by no later than March 21, 2019.

Study AVXS-101-CL-303 has the incorrect dose route of (b) (4) listed in the exposure SDTM data line listings. The protocol and source documents from the FDA inspected sites show the subjects received AVXS-101 by intravenous infusion. Please confirm that all subjects enrolled in this study were intravenously dosed and update the dataset to accurately reflect the correct method of administration.

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)



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