

**From:** [Jarvis, Candace](#) **To:** [Jarvis, Candace](#)  
**Subject:** FW: BLA 125694/0 | AveXis, Inc. | Information Request 26 (PLEASE RESPOND BY JANUARY 15, 2019)  
**Date:** Thursday, January 10, 2019 1:36:22 PM  
**Attachments:** [image013.png](#) **Importance:** High

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*Regards,*

*Candace*

*Tel: 240-402-8315*

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**From:** Jarvis, Candace  
**Sent:** Thursday, January 10, 2019 1:36 PM  
**To:** James L'Italien, PhD (jlitalien@avexis.com) <jlitalien@avexis.com>  
**Cc:** Nancy Boman <NBoman796@avexis.com>; Byrnes, Andrew <Andrew.Byrnes@fda.hhs.gov>; Whatley, Angela <Angela.Whatley@fda.hhs.gov>  
**Subject:** BLA 125694/0 | AveXis, Inc. | Information Request 26 (PLEASE RESPOND BY JANUARY 15, 2019)  
**Importance:** High

Good afternoon Dr. L'Italien,

We have the following CMC request for information regarding BLA 125694/0. Please respond to this request by 5 PM, Tuesday, January 15, 2019.

Your process parameter classification and operating ranges are not adequately justified, and the PPQ studies did not vary the process parameters sufficiently to justify the operating ranges. Please submit all documents related to process risk assessment, process parameter classification, and process operating ranges, including the following:

1. DVP-007, "AVXS-101 (b) (4) Process Parameter Evaluation"
2. RA-010, "AVXS-101 (b) (4) Process Risk Assessment"
3. DVP-006, "AVXS-101 Downstream Process Parameter Classifications"
4. DVP-012, "AVXS-101 Downstream Process Parameter Trending Report"
5. DVP-009, "AVXS-101 (b) (4) Process Parameter Evaluation Report"
6. DVP-005, "AVXS-101 Downstream Process Parameter Classifications"
7. DVP-014, "AVXS-101 Drug Product Process Parameter Evaluation Report" 8.  
RA-016, "AVXS-101 Drug Product Process Parameter Risk Assessment"

*Regards,*

*Candace N. Jarvis*  
*Regulatory Project Manager*  
*Center for Biologics Evaluation and Research*  
**Office of Tissues and Advanced Therapies**  
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