

**From:** [Jarvis, Candace](#)  
**To:** [James L'Italien, PhD \(jlitalien@avexis.com\)](#)  
**Cc:** [Nancy Boman](#); [Garnepudi, Varsha](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)  
**Subject:** BLA 125694/0| AveXis, Inc |Information Request 58 (PLEASE RESPOND BY MAY 7,2019)  
**Date:** Wednesday, May 01, 2019 3:07:04 PM  
**Attachments:** [IR LRP template BLA 125694-0.24 final 3.docx](#)  
[image002.png](#)  
[image004.jpg](#)  
[image006.jpg](#)  
[image008.jpg](#)  
[image010.jpg](#)  
[image012.jpg](#)

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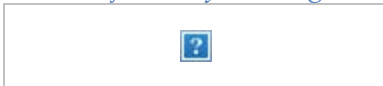
Hi Dr L'Italien,

Please find attached an information request we'd like for you to respond to by COB May 7, 2019.

Please acknowledge receipt.

*Regards,*

***Candace N. Jarvis***  
*Regulatory Project Manager*  
*Center for Biologics Evaluation and Research*  
**Office of Tissues and Advanced Therapies**  
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Comments on LRP template submitted to BLA 125694/0.24 on 8<sup>th</sup> Jan 2019

Please make the following modifications to the Lot Release protocol (LRP):

1. On each page of the LRP template please update the cc: line to STN/License No/FC (Final Container or Bulk).
2. On page 1 of 11, please correct the non-proprietary name to include the suffix -xioi.
3. On page 2 to 3 of 11, under Drug Substance table please update the specifications (see amendment 125694/0.60) for:

a. (b) (4)

[Redacted]

4. On page 8 of 11, please update:

a. (b) (4)

[Redacted]

5. On page 9 of 11, in Final container table please update the specifications (see amendment 125694/0.60) for:

a. (b) (4)

[Redacted]

b. Total protein by (b) (4)

c. Identity (protein) by (b) (4)

[Redacted]

6. On page 11 of 11, Sterility - please remove the (b) (4) test results. Instead of this, for the (b) (4), please add the test result and date tested under Safety section of the (b) (4) table (page 2).

7. Please add the following additional information for the following DS assays: (Use a separate table, to report the test for (b) (4) (remove it from the table 2 under Drug Substance)

a. (b) (4)


[Redacted]:

(b) (4)

8. Please add the following additional information for the following DP assays:

a. (b) (4) (Use a separate table for In (b) (4) test page 10 of 11 and remove the test from Final Container table):

i. (b) (4)




(b) (4)

b. (b) (4) : (Use a separate table for (b) (4) and remove the test from page 10 of 11 of the Final Container table):

- i. For each of the (b) (4) independent valid assay results, provide:
1. The lot number of the assay reference standard:
  2. The slope of the assay reference standard:
  3. The lot number of the assay control:
  4. The relative potency of the assay control:
  5. The relative potency of the test sample:


(b) (4)

c. (b) (4)



(b) (4)

d. (b) (4)



9. Please update the numbering of the Tables