

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Whatley, Angela](#); [Byrnes, Andrew](#); [Wang, Wei \(FDA\)](#); [Jarvis, Candace](#); [Glen, Jacqueline](#)
Subject: BLA 125694/0 | AveXis, Inc | Information Request 44 (Please Respond by March 22, 2019)
Date: Tuesday, March 19, 2019 3:26:12 AM **Attachments:** [image013.png](#)

Good morning Dr. L'Italien,

We have the following request for information regarding BLA 125694/0:

We note according to information provided in amendment 37 received on February 25 2019 the (b) (4) system was introduced after execution of the PPQ batches, however we do not have adequate information about how the (b) (4) systems compare. Please provide:

- a narrative comparing the (b) (4) systems, change
- control records for the introduction of the (b) (4) system
- process qualification for the new (b) (4) system equipment
- qualification for the (b) (4) system

Please provide this information by Friday March 22 2019. If you do not have any of this information or can note make the proposed deadline please let us know by Friday March 22 2019.

Regards,

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