

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Jarvis, Candace](#); [Byrnes, Andrew](#); [Whatley, Angela](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 13 (Please Respond by November 30, 2018)
Date: Thursday, November 15, 2018 4:34:09 PM
Attachments: [image013.png](#) **Importance:** High

Good afternoon Dr. L'Italien,

We have the following request for information regarding BLA 125694.

Your BLA does not contain sufficient information about (b) (4) manufacturing at the (b) (4) manufacturing site. Please clarify how you ensure the purity of your (b) (4) manufactured at (b) (4) and assess plasmids for cross contamination from other (b) (4) manufactured at the same facility. This information should include evidence such as:

- a. A description of the quality unit at (b) (4)
 - b. A list of all raw materials and manufacturing equipment used to make the (b) (4) and denote the materials and equipment that are single use or (b) (4)
 - c. Cleaning validation studies for equipment or raw materials which are (b) (4).
- Please respond to this request by November 30, 2018.

Please confirm receipt.

Regards,

Candace N. Jarvis
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