

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Jarvis, Candace](#); [Byrnes, Andrew](#); [Nancy Boman](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 15 (Please RESPOND by December 28, 2018)
Date: Wednesday, December 12, 2018 10:48:43 AM
Attachments: [image013.png](#) **Importance:** High

Good morning Dr. L'Italien,

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

1. Please provide PRO-417.
2. For the (b) (4) method (SOP-190), what is the length of the (b) (4) [REDACTED]
3. The (b) (4) method for quantitation of (b) (4) (SOP-186) states that the (b) (4) target a (b) (4) in (b) (4). Please clarify what this (b) (4) is and whether this sequence is present in all of the (b) (4) that are used to manufacture AVXS-101.
4. Section 3.2.P.5.2 contains two protocols for detection of (b) (4) (SOP-191 and SOP-340), performed by (b) (4) different CTOs. Please clarify why the BLA contains (b) (4) protocols for detection of (b) (4).
5. Please provide CCR-260.
6. Please provide data regarding the compatibility of DP with polycarbonate syringes.
7. We are unable to evaluate the method validation report for the (b) (4) potency (b) (4) (RPT-863) because it does not include any of the documents in section 7 (References). Please provide the documents referenced in 7.2 through 7.8 of RPT-863.

Please RESPOND by December 28, 2018.

Please confirm receipt of this email.

Regards,

Candace N. Jarvis
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