

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Jarvis, Candace](#); [Byrnes, Andrew](#)
Subject: BLA 125694/0| AveXis, Inc | Information Request 7 (Please Respond by October 31, 2018)
Date: Tuesday, October 23, 2018 9:40:26 PM
Attachments: [image013.png](#) **Importance:** High

Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond to this request by October 31, 2019 by COB.

1. Please provide the study reports that generated the data for section 3.2.P.2.6 (DP compatibility)
2. Please provide RPT-779
3. Please provide NCR-673 and any associated change control reports
4. Please provide the (b) (4) [REDACTED] qualification reports for the (b) (4) [REDACTED]
5. Section 3.2.P.8.1.6.1 states that additional long-term stability data will be communicated to the Agency as it becomes available during the review period. Please provide a schedule indicating when these updates will be provided and how many months of stability data each update will cover.

Please confirm receipt of the email.

Regards,

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