

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Jarvis, Candace](#); [Whatley, Angela](#); [Byrnes, Andrew](#); [Nancy Roman](#)
Subject: BLA 125694/0| AveXis, Inc. | Information Request 11 (PLEASE RESPOND by November 20, 2018)
Date: Tuesday, November 13, 2018 9:55:25 AM
Attachments: [image013.png](#) **Importance:** High

Good morning Dr. L'Italien,

With regard to the your submitted BLA 125694, we have the following request for information

Please direct us to which section in the BLA contains the **prospective** Process Validation Plans referenced in section 3.2.S.2.5 of your BLA. If the prospective plans are not in the BLA please submit them as an amendment by 5:00 PM Tuesday November 20, 2018.

Please confirm receipt.

Regards,

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