

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD](#) (jlitalien@avexis.com)
Cc: [Nancy Boman](#); [Whatley, Angela](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0| AveXis, Inc| Information request 46 (Please Respond by April 10, 2019)
Date: Monday, April 01, 2019 8:51:53 PM
Attachments: [image013.png](#) **Importance:** High

Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond by April 10, 2019.

1. We note in SN0028 received on January 25 you state: *At the time a new (b) (4) is needed, the technical specification referenced in PLAN-296 will be created to include the details for how the new (b) (4) will be manufactured and approved by AveXis prior to preparation of the new (b) (4).* We do not agree with this approach. Please submit a plan for how the new (b) (4) will be created and tested when needed. This plan should include a list of specifications for the (b) (4) including a specific identity test (such as (b) (4) of the (b) (4) capable of assessing (b) (4) in the (b) (4) .

Please confirm receipt.

Regards,

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