

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 54 (Please Respond By May 1, 2019)
Date: Thursday, April 25, 2019 10:43:02 PM
Attachments: [image013.png](#) **Importance:** High

Good evening Dr L'Italien,

We have the following request for information concerning BLA 125694/0. Please respond no later than May 1, 2019.

Our review of the updated specifications is still ongoing, but we tentatively agree to all specifications for (b) (4) in 3.2.S.4.1. We also tentatively agree to all DP specifications in 3.2.P.5.1 except the following:

- Please change the DP Total protein by (b) (4) acceptance criteria to (b) (4) . Our analysis of the (b) (4) tolerance limits does not support wider limits.
- Please change the DP (b) (4) by (b) (4) acceptance criteria to (b) (4) . It is necessary to raise the lower limit to (b) (4) to ensure that the DP strength remains within an appropriate range through the full DP shelf life. The lower limit for stability studies can remain at (b) (4)

Please update section 3.2.P.5.1 in the BLA to revise these DP lot release specifications.

Please acknowledge receipt.

Regards,

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