

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Whatley, Angela](#); [Byrnes, Andrew](#)
Subject: 125694/0| AveXis, Inc | Information Request 49 (PLEASE RESPOND BY APRIL 15, 2019)
Date: Thursday, April 11, 2019 1:58:51 PM
Attachments: [image013.png](#)
[image014.jpg](#)
[image015.jpg](#)
[image016.jpg](#)
[image017.jpg](#)
[image018.jpg](#)
Importance: High

Hello Dr. L'Italien,,

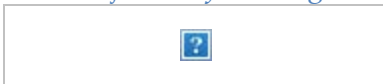
We have the following request for information regarding BLA 125694/0. Please respond by COB April 15, 2019.

We note in submission 58 received on April 8, 2019 you state that you will not release the (b) (4) without completing confirmatory testing. Then you also state that from time to time you will allow (b) (4) material forward for processing before full material release. We do not agree with conditional release. We also need clarity regarding your response: in that you state that you will require results for the (b) (4) lot for (b) (4) assays, plus the certificate of analysis to allow forward processing of (b) (4). The (b) (4) tests proposed are on the supplied COA from the (b) (4) supplier and it is not clear if you will conduct the confirmatory identity testing prior to conditional release of (b) (4). Please clarify how your proposed procedures for standard and conditional release compare. Additionally, please provide the proposed language for the updated SOP109, Raw Material Sampling, Testing and Release (step 8.7.1). Please provide this information by April 15, 2019.

Please acknowledge receipt.

Regards,

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