

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 51 (PLEASE PROVIDE BY APRIL 22, 2019)
Date: Monday, April 15, 2019 10:32:38 AM **Attachments:** [image013.png](#)

Good morning Dr. L'Italien,

We have the following information request regarding BLA 125694/0. Please respond by April 22, 2019.

We note in submission 58 received on April 10, 2019 that you provided an updated Plan-296, which lists the minimal testing required of a (b) (4), which includes (b) (4) with an acceptance criteria to confirm (b) (4). While we agree that confirmation of the (b) (4) is essential to confirm the (b) (4) alone is not sufficient to confirm the (b) (4) of the (b) (4). Please update Plan 296 to specify that the (b) (4) include methods capable of (b) (4), and that your acceptance criteria include justifying any unexpected (b) (4) identified. Please provide this information by April 22, 2019. Please acknowledge receipt.

Regards,

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