

From: Trayer, Amanda

Sent: Tuesday, May 7, 2019 7:50 AM

To: Jlitalien@avexis.com

Cc: Wang, Wei (FDA); Trout, Deborah; Jarvis, Candace; Byrnes, Andrew

Subject: Information and Teleconference Request for BLA 125694/0

Importance: High

Dr. L'Italien-

Below is an additional Information Request in support of the review of BLA 125694/0. In addition, we would like to set up a teleconference to discuss these items as soon as possible. Please let me know when you are available today or tomorrow to discuss this IR.

1. During the pre-license inspection (PLI), we audited the summary report of

(b) (4) run (b) (4) performed (b) (4). Please provide a summary report of the most recent (b) (4) run (performed around (b) (4) along with any associated Non-Conformance reports.

2. You indicated that the sterile filtered Drug Product (FDP) may be hold for ?

(b) (4) to filling. Please provide justifications why your (b) (4) study did not include the (b) (4) hold time.

3. During the PLI, you indicated that you follow the SOP-170 to clean (b) (4) with (b) (4). Per SOP-170, the minimum contact time for

(b) (4) for (b) (4) cleaning of equipment surfaces. Your disinfectant effectiveness study indicated that the disinfectant and sporicidal minimum contact times (i.e., (b) (4) were documented.

* Please describe the procedures for cleaning and sanitizing of (b) (4)

Please note that sanitization/disinfection is performed after cleaning.

* Please provide validation data for the (b) (4) sanitization/disinfection.

If validation has not been completed, please provide your plans, including dates for completing this study.

Please submit the response in an Information Amendment to the submission through the Gateway by Monday, May 13, 2019. To expedite review, you may submit the responses directly to me (cc Wei Wang) via email in addition to submitting through the Gateway. Please confirm that you received this email, and contact me via phone or email with any questions or concerns regarding this submission.

Thank you-

Amanda

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