

From: Sista, Ramani V
Sent: Thursday, November 12, 2015 5:17 PM
To: 'Dr. Rebecca Haley'
Subject: BLA 125585

Importance: High

Hi Dr. Haley,
Please provide the following information by COB Monday, November 16th or earlier.
Initial response can be via email followed by submission to file via immediate amendment.

1. Reference - Sections 3.2.S.4.3.2.2 (b)(4) Validation Addendum.pdf and 3.2.S.4.3.2.1B (b)(4) Addendum Narrative.pdf:
 - a) Please clarify the (b)(4) temperature used for the validation studies.
 - b) Please confirm that you will be using the same temperature settings for your product sterility test.
 - c) Validation of Assay Ruggedness: Please clarify if you have used at least (b)(4) different lots of media (both aerobic and anaerobic) for each of the microorganisms tested and provide the respective information.
 - d) Validation of Assay Robustness: Please clarify how you have validated the robustness of your assay. If you have not, please provide information on how you monitor the (b)(4) temperature of your (b)(4) system and the temperature of the room where the respective instrument is located.
2. Reference CBP 6400: Please update the SOP for the following information and submit both the clean and track-changed version of the SOP.
 - a) Page 2 (Equipment and Supplies): Please specify the type of (b)(4) used and the number of CFUs expected from each (b)(4).
 - b) Page 6 (Load the (b)(4)): Please specify the (b)(4) temperature.
 - c) Page 7 (Review Results): Please change the acceptance criterion for the anaerobic (b)(4).
3. Reference CBP 6410: Please update the SOP for the following information and submit both the clean and track-changed version of the SOP.
 - a) Page 1 (Sample Requirements): Please update the test sample size to (b)(4) for both aerobic and anaerobic (b)(4).
 - b) Page 7 (Post-inoculation instruction): Please specify the (b)(4) temperature.
4. Reference CBP 6420: Please update the SOP for the following information and submit both the clean and track-changed version of the SOP.
 - a) Page 1 (Policies): Please specify the (b)(4) temperature.

Please confirm receipt and let me know if you have questions.

Thanks,
Ramani

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