

15b_BLA 125585 Sterility Test Validation 20160601_15b.txt

From: Ghosh, Joydeep
Sent: Monday, June 01, 2015 1:34 PM
To: Sista, Ramani V
Cc: Benton, Kimberly; Gavin, Denise K; Niland, Brian
Subject: BLA 125585 Sterility Test Validation

Hi Ramani,

When you get a chance could you please send the following comment (this is in addition to what we told during our T-con on May 22, 2015) to Dr. Haley. Please make sure she confirms receiving it.

"We note that the Inhibition data submitted in BLA 125585 for (b) (4) are more than two years old. Please note that if you have made any changes/upgrades to your (b) (4) test equipment (either for the hardware or the software) during this period, you will need to revalidate the (b) (4) using (b) (4)."

Thanks,

Joy

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