

14_BLA 125585 - Follow up comment_20150601_1415a.txt

From: Sista, Ramani V
Sent: Monday, June 01, 2015 2:08 PM
To: Dr. Rebecca Haley (BeckyH@BloodWorksNW.org)
Subject: BLA 125585 - Follow up comment

Importance: High

Hi Dr. Haley,
As a follow up to our telecon from May 22, Dr. Ghosh has the following comment:

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,
Ramani

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