

From: Sista, Ramani V
Sent: Thursday, January 22, 2015 11:12 AM
To: Heather Pratt (heather@macopharmausa.com)
Subject: NDA125552, amendment 2 clarification

Importance: High

Hi Heather,
Regarding some of the information requested in our September 22 telecon and subsequent email exchanges, Macopharma indicated in amendment 2, dated October 9, 2014, that the following information would be sent following additional testing:

* Response to Question 3 states "The report for the minimum load validation will be completed in during the week of 03 November 2014 (week 45). A copy of the report will be submitted to FDA at the time of completion.

* Response to Question 4 stated "The report with the results for the retesting of the sensors will be completed during the week of 27 October 2014 (week 44). A copy of the report will be submitted to FDA at the time of completion."

Please confirm if this information has been submitted, and if so, where in the submission can we find it.

Thanks,
Ramani

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