

From: Do, Yu
Sent: Tuesday, January 05, 2016 12:56 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, January 22, 2016): Original BLA, BL 125590/0, Immune Globulin Intravenous (RI-002), ADMA Biologics, Inc.

Dear Ms. Myers:

We are reviewing your original July 31, 2015 submission to BLA 125590/0 for Immune Globulin Intravenous (Human). We determined that the following information is necessary to continue our review:

1. Please provide a summary report to better explain what was submitted regarding the most recent (b) (4) depyrogenation oven requalification.
2. Provide a summary report to better explain what was submitted regarding the most recent (b) (4) autoclave requalification for the (b) (4).
3. Provide a complete description of all defects categories found in the visual inspection defect test kit, their overall composition, and number. Include the categories broken down into critical, major, and minor sub-groupings, as appropriate for RI-002.
4. Provide a complete description of the 100% visual inspect training and qualification program.
5. Confirm if a more current media fill with the 50 mL vial configuration has been performed. Provide the requalification data if this information is available.
6. Regarding the Biotest equipment cleaning process, it appears the equipment cleaning capabilities can meet (b) (4) specification for (b) (4). Please clarify if Biotest is using alert limits when the final (b) (4) rinse results are higher than (b) (4).
7. Clarify if the (b) (4) filling Suite (b) (4) will be the only filling suite used to manufacture RI-002. The submitted facility diagram indicates (b) (4) filling rooms are located in the same area.
8. Regarding the drug substance shipping validation, please provide a shipping validation summary with data that supports the bulk drug substance transfer from Biotest to (b) (4).
9. Provide a summary of the shipping validation that supports the movement of the final drug product manufactured at (b) (4) to the distribution center.

The review of this submission is ongoing and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by January 22, 2016, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is July 30, 2016.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.

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