

From: Do, Yu
Sent: Tuesday, March 08, 2016 12:13 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Tuesday, March 22, 2016):
Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.

Importance: High

Dear Ms. Myers:

We are reviewing your original July 31, 2015, submission to BLA 125590 for Immune Globulin Intravenous (Human). We are providing the following comments and request additional information to continue our review:

Assay for (b) (4)

1. You indicated that the Working Reference Standard used in (b) (4) assay (in TM-10011 and validation reports AMVR-20121022-01 and AMVR-20121022-02) was calibrated against the (b) (4) reference material (b) (4).

Please provide the qualification report for this standard.

2. In AMVR-20121022-02, you indicated, "As a consequence of the Analytical Laboratory Investigation Report (ALIR-2014-006), the activity of the (b) (4) reference standard changed from (b) (4)

Please provide details of this investigation, including its background and results.

3. You have presented the results of the intermediate precision study as evidence of robustness for the (b) (4) Assay Test Method for IVIG Drug Product. This data, however, is insufficient to demonstrate method robustness.

Please provide data to evaluate the effect of small deliberate changes of critical method parameters, such as reagent concentration, incubation time, etc., in order to demonstrate method robustness.

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 March 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.

Regulatory Project Manager

FDA/OMPT/CBER/OBRR/PPMS

(240) 402-8343

yu.do@fda.hhs.gov

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."