

From: Do, Yu
Sent: Sunday, March 06, 2016 8:11 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, March 18, 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:

1. In response to item 2a of the Information Request dated November 09, 2015, you have provided summaries of the equipment/instrument qualification. Your response, however, has not addressed our request for verification of suitability of the Test for Particulate Matter to include repeatability and intermediate precision for the RI-002 Injection, Sterile Solution.

Please submit the requested information.

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 18, 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/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

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