

From: Do, Yu
Sent: Tuesday, September 15, 2015 12:52 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Tuesday, September 29, 2015):
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 submit a lot release protocol template. Please include the specifications and the name of the method used to perform the analysis.

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 September 29, 2015, 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/IOD/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

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