

From: Do, Yu
Sent: Wednesday, August 05, 2015 11:07 AM
To: 'dmyers@malvernconsultinggroup.com'
Subject: Information Request: Original BLA, BL 125590/0, Immune Globulin Intravenous (RI-002), ADMA Biologics, Inc.

Importance: High

Dear Ms. Myers:

We are reviewing your original July 31, 2015 submission to BLA 125590/0 for Immune Globulin Intravenous (Human) and will be issuing an Acknowledgement Letter in the near future. In the meantime, we determined that the following information is necessary to continue our review:

1. Please submit the form FDA 3674 (for clinical trials) with authorized signature. Also, please ensure that the form contains the NCT Numbers.

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 August 7, 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 29, 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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