

From: Do, Yu
Sent: Tuesday, January 19, 2016 11:25 AM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Tuesday, February 02, 2016):
Postmarketing Commitment - 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). We are providing the following comments and request additional information to continue our review:

1. The single-arm, pre-licensure clinical trial, ADMA-003, was limited in size and scope to assess the potential risks of hypotension and hepatic toxicity in subjects treated with RI-002. A postmarketing study (i.e., postmarketing commitment) could be conducted to adequately address the safety concerns of hypotension and hepatic toxicity associated with excipient polysorbate 80.

Please submit the proposed postmarketing study with the following information: study design, sample size, statistical analysis plan, information to be collected at baseline, frequency and methods for follow-up data collection, information to be collected in follow-up, study timeline, and milestone dates.

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 February 02, 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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