

From: Do, Yu  
Sent: Friday, April 15, 2016 9:25 AM  
To: dmyers@malvernconsultinggroup.com  
Subject: Information Request (Response Due by Wednesday, April 20, 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. ADMA Biologics mentioned in Table 6 on page 13 ("Summary of Efficacy Results in Subjects with PI") of the draft labeling:

Hospitalization due to infection	
Number of subjects (%)	1 (3.3%)
Number of Days	5

To obtain 3.3%, there needs to be a population of at least 30 subjects with infection. Please advise where in the submission this number 30 may be found.

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 April 20, 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  
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