

From: Do, Yu  
Sent: Friday, January 15, 2016 3:21 PM  
To: dmyers@malvernconsultinggroup.com  
Subject: Information Request (Response Due by Friday, January 29, 2016): Process Validation - 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. Please provide rationale for the following alcohol range settings for RI-002, which are different from those of Bivigam and of the robustness study results:

Critical parameters: alcohol  
concentration and pH

RI-002

Tested by

robustness studies

Optimal by

robustness studies

Bivigam

(b) (4)

[Redacted content]

16-18%

2. (b) (4)

7. Please provide bioburden measurements for the shelf life of (b) (4).

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 January 29, 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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