

From: Do, Yu  
Sent: Thursday, March 03, 2016 11:44 AM  
To: 'Diane Myers'  
Subject: RE: Information Request (Response Due by Tuesday, March 08, 2016):  
Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.

Importance: High

Dear Diane:

I hereby inform you that ADMA Biologics should not submit, until further notified, their response to Information Request dated February 16, 2016, regarding the Lot Release Protocol template.

Please accept my apology for the confusion and stay tuned for a further update.

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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From: Diane Myers [mailto:dmyers@malvernconsultinggroup.com]  
Sent: Wednesday, March 02, 2016 12:31 PM  
To: Do, Yu  
Subject: RE: Information Request (Response Due by Tuesday, March 08, 2016): Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.

Dear Yu,  
Thank you for the reply. Sorry to be a pest but please note that ADMA was hoping to provide the response document to the eCTD partner by tomorrow for filing on 3/8 in order to avoid expedited fees. The response document is complete with the exception of the (b) (4) Item#2.

We would appreciate it if you could advise whether we should proceed with a "pending" response until the (b) (4) issue is resolved.

Thank you,  
Diane

Diane P. Myers

SVP, Regulatory & Quality  
484-395-2407 (desk)

(b) (6)

From: Do, Yu [mailto:Yu.Do@fda.hhs.gov]  
Sent: Wednesday, March 02, 2016 10:05 AM  
To: Diane Myers <dmyers@malvernconsultinggroup.com>  
Subject: RE: Information Request (Response Due by Tuesday, March 08, 2016): Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.

Dear Diane:

I am still waiting and will get back in touch with you as soon as I have more information regarding the matter. Thanks in advance for your patience.

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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From: Diane Myers [mailto:dmyers@malvernconsultinggroup.com]  
Sent: Tuesday, March 01, 2016 3:01 PM  
To: Do, Yu  
Subject: RE: Information Request (Response Due by Tuesday, March 08, 2016): Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.  
Importance: High

Dear Yu,  
The sponsor is asking how to manage responding to item #2 below. Do you still expect to have resolution to the (b) (4) issue in the next couple of days or should the response be sent back with that response stating that the requested change is pending until final resolution of the (b) (4) in the PI and specifications is provided?

Thanks for your help.

Diane

Diane P. Myers  
SVP, Regulatory & Quality  
484-395-2407 (desk)  
(b) (6)

From: Do, Yu [mailto:Yu.Do@fda.hhs.gov]  
Sent: Tuesday, February 16, 2016 12:39 PM  
To: Diane Myers <dmyers@malvernconsultinggroup.com>  
Subject: Information Request (Response Due by Tuesday, March 08, 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:

Comments for Lot Release Protocol Template submitted on September 25, 2015

1. Throughout the document, please add an additional column to each of the tables 1-5, 7, and 9 to indicate Test Date for each test.
2. On page 3 of 4 with reference to Table 5. Potency, please remove the entire row regarding Test for (b) (4).
3. On page 3 of 4 with reference to Table 6. Sterility, please add Specification and Result to the table.
4. On page 4 of 4 with reference to Table 8. (b) (4) Pyrogen, please add Specification to the table.

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 March 08, 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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