

From: [Do, Yu](#)
To: [James Maloney](#)
Subject: REVISED: Information Request (Response Due by Thursday, March 21, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Thursday, March 21, 2019 1:48:00 PM
Attachments: [image039.png](#)
[image007.png](#)
[image020.png](#)
Importance: High

Dear Mr. Maloney:

You are right. This is our oversight. Please accept our sincere apology and see below for the corrected version of our proposed PMC language:

ADMA commits to submitting information on the ongoing stability study, SP-DF-3093, annually as a "Postmarketing Commitment – Status Update." The final stability report will be submitted as a "Postmarketing Commitment – Final Study Report" by June 30, 2020. ADMA will also report any confirmed out-of-specification results at the recommended storage condition from the stability monitoring to the Agency within 45 days of the event(s).

Final Report Submission Date: June 30, 2020

Thanks for bringing this to my attention.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco
Food and Drug Administration
(240) 402-8343
Yu.Do@fda.hhs.gov



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From: Do, Yu

Sent: Thursday, March 21, 2019 12:54 PM

To: 'James Maloney' <jmaloney@admabio.com>

Subject: RE: Information Request (Response Due by Thursday, March 21, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.

Let me check with the appropriate reviewers and get back to you. Please stay tuned.

Sincerely,

Yu Do, M.S.

Regulatory Project Manager

Office of Tissues and Advanced Therapies

Center for Biologics Evaluation and Research

Office of Medical Products and Tobacco

Food and Drug Administration

(240) 402-8343

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From: James Maloney <jmaloney@admabio.com>

Sent: Thursday, March 21, 2019 12:35 PM

To: Do, Yu <Yu.Do@fda.hhs.gov>

Subject: RE: Information Request (Response Due by Thursday, March 21, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.

Importance: High

Dear Mr. Do,

Would you please confirm that Agency is requesting information on stability study SP-BK-3092 (Bulk Drug Substance) rather than SP-DF-3093 (Drug Product)? Please note that study SP-BK-3092 is now complete and the attached Final Report, SP-FR-3092 was submitted on February 22, 2019 in sequence 0051.

Best Regards,

Jim

James Maloney
Senior Director, Regulatory Affairs



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Boca Raton, FL 33487
Phone 561-989-5745
Fax 561-989-5898
jmaloney@admabio.com

From: Do, Yu [<mailto:Yu.Do@fda.hhs.gov>]
Sent: Wednesday, March 20, 2019 10:00 PM
To: James Maloney
Subject: Information Request (Response Due by Thursday, March 21, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Importance: High

Dear Mr. Maloney:

We are reviewing your resubmission of September 28, 2018, to BL 125590/0 for Immune Globulin Intravenous (Human), 10% Liquid. We have the following comment and request for additional information to continue our review:

The following is our proposed language drafted for a Postmarketing Commitment with regard to BL 125590/0:

ADMA commits to submitting information on the ongoing stability study, SP-BK-3092, annually as a “Postmarketing Commitment – Status Update.” The final stability report will be submitted as a “Postmarketing Commitment – Final Study Report” by June 30, 2020. ADMA will also report any confirmed out-of-specification results at the recommended storage condition from the stability monitoring to the Agency within 45 days of the event(s).

Final Report Submission Date: June 30, 2020

Please inform us in writing, upon review and internal discussion, if you agree with the proposed due date. If not, please state accordingly and suggest alternative date(s) for our consideration.

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 (BL 125590/0) by Thursday, March 21, 2019, 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 April 2, 2019.

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
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco
Food and Drug Administration
(240) 402-8343
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