

From: Do, Yu
To: ["James Maloney"](#)
Subject: Information Request (Response Due by Tuesday, March 19, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Friday, March 15, 2019 12:15:00 PM
Attachments: [image001.png](#)
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 determined that the following information is necessary to continue our review:

1. Please revise the "Post-Approval Stability Protocol and Stability Commitment" to indicate that the first batch manufactured each year will be placed on stability monitoring to ensure a random selection of annual stability lot.
2. Please verify if a correct unitage has been used for (b) (4) in your stability dataset. Please update the data accordingly if any correction needs to be made.

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 Tuesday, March 19, 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.
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