

From: Do, Yu
To: ["James Maloney"](#)
Subject: Information Request (Response Due by Friday, February 22, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Wednesday, February 13, 2019 3:23:00 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 provide an update on your ongoing stability studies and indicate when the 12 months stability data for Lot (b) (4) will become available.

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 February 22, 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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