

From: Do, Yu
To: ["James Maloney"](#)
Subject: Information Request (Response Due by Tuesday, March 26, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Monday, March 25, 2019 3:25:00 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 have the following comment and request for additional information to continue our review:

ADMA commits to resetting the lot release specification for (b) (4) using the approved manufacturing process. The final study report will be submitted as a CBE-30 by December 31, 2020.

Final Study Report Submission: December 31, 2020

Please inform us in writing, upon review and internal discussion, if you agree with our proposed language and due date. If not, please state accordingly and suggest alternative language and date 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 noon on Tuesday, March 26, 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
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