

**From:** Do, Yu  
**To:** ["James Maloney"](#)  
**Subject:** Information Request (Response Due by Noon on Tuesday, March 12, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.  
**Date:** Thursday, March 07, 2019 3:32:00 PM  
**Attachments:** [image002.png](#)  
**Importance:** High

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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:

Please provide the following items:

1. A complete deviation list and details regarding each deviation in the batch records.
2. All batch record comment forms related to the batch records.
3. Please clarify if samples taken for bioburden testing are (b) (4) prior to testing.
4. QA/QC reports related to batch record.

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 March 12, 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](mailto: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  
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