

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: Friday, March 08, 2019 5:03:00 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:

Regarding the updated stability data submitted on February 22, 2019, please address the following issues and/or questions:

1. For the parameter "Particulate Matter by (b) (4) the unitage used for three conformance batches (particles/mL) is different from the one used in Batch Analysis (particles/container). Please verify which one is correct and update the data accordingly.
2. For the parameter (b) (4) there is a dramatic increase in the particulates levels at all different sizes for lot (b) (4) at the 9-month time point compared to other time points. Please explain and indicate if any investigation has been conducted. In addition, the results from "Particulate Matter by (b) (4) did not show any increase of the particulates, especially at (b) (4), which appears to be contradictory to the ones obtained from (b) (4)." Please explain.
3. Please provide a copy of the deviation investigation report for DEV 18065, regarding the foreign particle found in a single vial for Lot (b) (4) at the (b) (4) storage condition, 2-month time point. If it has been already submitted, please indicate its location in eCTD.

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 if you have any questions.

Sincerely,

Yu Do, M.S.
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