

From: [Do, Yu](#)
To: [James Maloney](#)
Subject: Information Request (Response Due by Monday, February 25, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Wednesday, February 20, 2019 12:33:00 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 your response to Question 1 of FDA's Information Request dated February 8, 2019, we disagree with your proposed verbiage "Essentially free of visible particles" in the Drug Product Appearance specification.

Please revise the wording of the Appearance specification to "Clear to slightly opalescent. Colorless to pale yellow. Free of turbidity. Free of visible particles."

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 25, 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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