

From: [Do, Yu](#)
To: [James Maloney](#)
Subject: Information Request (Response Due by Thursday, February 14, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Friday, February 08, 2019 7:08:00 AM
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. We noted several discrepancies in your wording of the Drug Product specification for Appearance after comparing the following eCTD section files:
 - eCTD Section 2.3.R Method Validation Package: “Clear to slightly opalescent. Colorless to pale yellow. Free of turbidity”
 - eCTD Section 2.3.P Control of Drug Product: “Clear or slightly opalescent. Colorless or pale yellow. Free of turbidity. Essentially Free of visible particles.”
 - eCTD Section 3.2.P.5.1 Specifications: “Clear or slightly opalescent. Colorless or pale yellow. Free of turbidity. Essentially free of visible particles.”
 - eCTD Section 3.2.P.5.4 Batch Analyses: “Slightly opalescent; clear. Colorless to pale yellow. Free of turbidity. Free of visible particles.”
 - eCTD Section 3.2.P.8.1 Stability Summary and Conclusion: “Clear to opalescent. Colorless to pale yellow. Free of turbidity. Free of visible particles.”
 - eCTD Section 3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment: “Clear to Slightly Opalescent. Colorless to Pale Yellow. Free of Turbidity. Free of Visible Particles.”

Please revise the wording of the Appearance specification in the above-mentioned eCTD section files so that they all consistently state: “Clear to slightly opalescent. Colorless to pale yellow. Free of turbidity. Free of visible particles.”

2. You have submitted SOP QC3230, which is an integral part of the Appearance assay; however, SOP QC3230 is not referenced in the Visual Evaluation SOP QC2130, Rev. 10. Please update SOP QC2130, such that SOP QC3230 is included in Section 5 References. Please also indicate which version of QC2130 was used for testing RI-002 conformance lots.

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 14, 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,

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