

From: [Do, Yu](#)
To: [James Maloney](#)
Subject: Information Request (Response Due by Noon on Tuesday, March 26, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Monday, March 25, 2019 10:24:00 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 have the following comment and request for additional information to continue our review:

The revised timeline for the PREA PMR pediatric study for 2 to 12 years of age is as follows:

Final Protocol Submission: December 31, 2019
Study Completion: December 31, 2022
Final Study Report Submission: June 30, 2023

Please inform us in writing, upon review and internal discussion, if you agree with the revised due dates. If not, please state accordingly and suggest alternative dates 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.
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