

**From:** Do, Yu  
**To:** ["James Maloney"](#)  
**Subject:** Information Request (Response Due by Monday, March 25, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.  
**Date:** Friday, March 22, 2019 4:08:00 PM  
**Attachments:** [image001.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 have the following comment and request for additional information to continue our review:

Your proposed timeline for the PREA PMR pediatric study for 2 to 12 years of age, included in your agreed initial Pediatric Study Plan, is as follows:

Final Protocol Submission: December 31, 2015  
Study Completion: December 31, 2018  
Final Study Report Submission: June 30, 2019

Please propose new milestone dates for the timeline of your pediatric study 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 Monday, March 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](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  
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