

From: Do, Yu
To: "[James Maloney](#)"
Subject: Information Request (Response Due by Monday, March 18, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Wednesday, March 13, 2019 4:43:00 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:

1. Your Lot Release Protocol template (Amendment 54, received on March 12, 2019) does not include the CBER Lot 177 specifications for the Potency-Measles and Potency-Polio tests.

Please update your LRP template such that both CBER Lot 176 and CBER Lot 177 specifications are listed for these two potency tests.

2. Please delete from your Lot Release Protocol template the Potency-Polio specifications for anti-polio types 2 and 3. Your current Drug Product Release Specifications table only lists testing for anti-polio type 1. In addition, please take note that the World Health Organization (WHO) has a containment initiative to minimize the use of poliovirus type 2 in testing and research laboratories [refer to the WHO's Polio Eradication and Endgame Strategic Plan 2013-2018, WHO Global Action Plan (GAPIII)].

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 18, 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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Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco

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