

From: Do, Yu
To: ["James Maloney"](#)
Subject: Information Request (Response Due by Thursday, February 28, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Friday, February 22, 2019 5:21:00 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. In your response to CR Question 2, you mentioned a “potential alternate lab for the concentration of diphtheria antitoxin antibodies in the RI-002 drug product using antibody (b) (4) method based on (b) (4) for diphtheria antitoxin (b) (4)

If this lab was qualified, please add to the Form FDA 356h.

2. In your response to CR Question 8, you reference a memorandum dated August 10, 2016, from (b) (4). Please provide that memorandum, specifically Attachment T – Biological Indicator Results.

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 28, 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.
Regulatory Project Manager
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Office of Medical Products and Tobacco
Food and Drug Administration
(240) 402-8343
Yu.Do@fda.hhs.gov



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED