

From: Do, Yu
To: "[James Maloney](#)"
Subject: URGENT Information Request (Response Due by Thursday, March 28, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Wednesday, March 27, 2019 5:20:00 PM
Attachments: [image001.png](#)
[Annotated ADMA PI March 27 2019 BL 125590 ADMA FINAL.docx](#)
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:

Please revise the Prescribing Information according to the attached annotated version of the labeling and as follows. Please accept all those tracked changes with which you agree, but insert your own comments where further discussion is warranted. Please indicate clearly, point by point, whether you would accept each change or not. If not, please provide briefly your rationale or justification. Also, please be sure to submit in your response both clean and annotated versions of the revised labeling in Word and PDF files.

Our additional comments/recommendations are stated below, while more specific changes are proposed within the text of the Prescribing Information.

Additional Comments

- Please submit an updated SPL in XML format.
- Your product title and proper name are ASCENIV (immune globulin intravenous, human - slra), 10% Liquid and Immune Globulin Intravenous, Human – slra, respectively.
- Please ensure that term “humoral” is put back between primary and immunodeficiency throughout the PI: primary humoral immunodeficiency, as opposed to primary immunodeficiency.
- Please ensure that your draft labeling is 508-compliant and see the “Requirements Checklists for Section 508” at <https://www.fda.gov/aboutfda/aboutthiswebsite/accessibility/ucm209792.htm> for additional information.
- Please include the NDC number and revise the proper name in carton and container labels.

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 Thursday, March 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 FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."