

From: Do, Yu
To: ["James Maloney"](#)
Subject: URGENT Information Request (Response Due by COB Today, March 29, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Friday, March 29, 2019 9:30:00 AM
Attachments: [FDA Annotated ADMA PI March 29 2019 BL 125590.docx](#)
[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 comments and requests for additional information to continue our review:

Please revise the Prescribing Information according to the attached annotated version of the labeling and the carton and container labels 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 comments/recommendations for the carton and container labels are stated below, while specific changes for the Prescribing Information are proposed within the attached text.

Carton and Container Labels [As Per 21 CFR §610.61, § 610.62, and §610.62(b)]

1. The proper name of the product on the package label should be placed above any trademark or trade name identifying the product and symmetrically arranged, not across the top, with respect to other printing on the label. For example, in the case of the proposed draft vial (container) label, one would have to turn the label around merely to see the concentration. Please revise accordingly.
2. There should be no “intervening matter” between the proper and proprietary names. There is a line between the two names that points to, or potentially obstructs, the letter V in the name ASCENIV (which makes representation to the intravenous dosage form). Please revise accordingly.
3. The point size and typeface of the proper name should be at least as prominent as the point size and typeface used in designating the trademark and trade name. We interpret “at least as prominent as the point size” to mean *no less than half the height*. Also, the contrast in color value between the proper name and the background should be at least as great as the color value between the trademark and trade name and the background. The color and typography in these labels are adversely affecting prominence. Please revise accordingly.
4. Please replace “Preservative Free” with “No Preservative,” as per 21 CFR §610.61. The term “Preservative Free” is promotional in tone.

5. Currently, your NDC numbers (69800-0250-1) for carton and container are the same. They need to be differentiated between the two package types by the third segment of the NDC number (e.g., 69800-0250-1 for carton and 69800-0250-2 for container). Please revise accordingly.

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 close of business today, March 29, 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



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