

From: Do, Yu
To: ["James Maloney"](#)
Subject: Information Request regarding Suffix Review (Response Due by March 26, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Monday, March 25, 2019 3:04:00 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 have the following comment and request for additional information to continue our review:

Your first two proposed suffixes are unacceptable because they connote a high-affinity chromatography method used to separate out specific antibodies in plasma.

We find the proper name, immune globulin intravenous, human – slra, is conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, immune globulin intravenous, human - slra, will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a Complete Response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.

Please inform us in writing, upon review and internal discussion, if you agree with our selection of suffix and proper name for your product. If not, please state accordingly and provide rationale 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 Tuesday, March 26, 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

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