

From: Do, Yu
To: "[James Maloney](#)"
Subject: Information Request (Response Due by Wednesday, March 20, 2019): Class 2 Resubmission, BL 125590/0, Immune Globulin Intravenous (Human), 10% Liquid, ADMA Biologics, Inc.
Date: Friday, March 15, 2019 12:51:00 PM
Attachments: [image001.png](#)
[Nonproprietary Naming of Biological Products.pdf](#)
[Nonproprietary Naming of Biological Products March 2019.pdf](#)
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:

Your application falls within the scope of guidance for industry *Nonproprietary Naming of Biological Products* (January 2017), available at <https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>. This guidance describes FDA's current thinking on the need for biological products licensed under the Public Health Service Act to bear a nonproprietary name that includes an FDA-designated suffix.

You may submit up to 10 proposed suffixes in an order of your preference. The final determination on the acceptability of a proposed suffix is based on FDA's review of the information you submit using the criteria set forth in the attached copies of guidance for industry *Nonproprietary Naming of Biological Products*. Alternatively, if you choose not to submit suffixes for review, FDA will assign a randomly generated, pre-screened suffix for inclusion in the proper name designated in the license at the time FDA approves the application.

Please submit your proposed suffixes as an amendment to this file or inform us if you prefer to let FDA assign a suffix.

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 Wednesday, March 20, 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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