



Our STN: BL 125590/0

PROPRIETARY NAME ACCEPTANCE

ADMA Biologics, Inc.
Attention: Ms. Diane P. Myers
Malvern Consulting Group, Inc.
490 Lapp Road
Malvern, PA 19355

Dear Ms. Myers:

We have reviewed your submission dated April 27, 2016, to your biologics license application (BLA) for Immune Globulin Intravenous (Human), requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, ASCENIV, is acceptable at this time.

If you have any questions, please contact Yu Do at (240) 402-8343.

Sincerely,

Howard Chazin, MD, MBA
Acting Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research