



Our STN: BL 125590/0

PROPRIETARY NAME NON-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 December 16, 2015, 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 name, (b) (4), is unacceptable.

The proposed proprietary name is considered misleading.

The basis for our decision is:

Your proposed name is considered false or misleading within the meaning of 21 U.S.C. 352(a) and 321(n). The requested proprietary name (b) (4) is misleading because the product can be thought to be an IgA product due to the ending of your proposed name, -IGA. Furthermore, the name has high similarity to that of another marketed product, INVEGA.

You may submit a new proprietary name for FDA consideration. Any alternate proprietary name(s) should comply with the regulations regarding false, misleading, or fanciful names and should not be confused with other medicinal products with orthographic or phonological similarities.

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