



Our STN: BL 125596/0

PROPRIETARY NAME ACCEPTANCE

Baxalta US Inc.
Attention: Ms. Ade Denloye
One Baxter Way
Westlake Village, CA 91362

Dear Ms. Denloye:

We have reviewed your submission dated November 13, 2015, to your biologics license application (BLA) for Immune Globulin Subcutaneous (Human), 20% Solution, 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, CUVITRU, is acceptable at this time.

We will perform another proprietary name review of CUVITRU closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

If you have any questions, please contact LT Thomas J. Maruna, USPHS, MSc, MLS(ASCP), CPH at (240) 402-8454 or thomas.maruna@fda.hhs.gov.

Sincerely,

Paul D. Mintz
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research