



Our STN: 125506/0

Bio Products Laboratory

Attention: (b) (4)

Dear (b) (4) :

We have reviewed your submission dated July 25, 2013 to your biologics license application (BLA) for Coagulation Factor X (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, REPLAFACTEN, is acceptable at this time.

We will perform another proprietary name review of REPLAFACTEN 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 Pratibha Rana at (301) 827-6124.

Sincerely yours,

Basil Golding, MD
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research