



**August 11, 2014**

Our STN: BL 125506/0

**PROPRIETARY NAME ACCEPTANCE**

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, COAGADEX, is acceptable at this time.

We will perform another proprietary name review of COAGADEX 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 (240) 402-8433 or [pratibha.rana@fda.hhs.gov](mailto:pratibha.rana@fda.hhs.gov).

Sincerely,

For

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