



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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.

Sincerely,

For

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