



Our STN: BL 125426/0

Inspiration Biopharmaceuticals, Inc.  
Attention: Bonnie Mills, Ph.D.  
One Kendall Square  
Bldg 1400E, 5th Floor  
Cambridge, MA 02139

Dear Dr. Mills:

We have reviewed your submission to your biologics license application (BLA) for Coagulation Factor IX (Recombinant), dated April 23, 2012, 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, IXINITY is acceptable at this time.

We will perform another proprietary name review of IXINITY 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 Leigh Pracht at (301) 827-6116.

Sincerely yours,

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