



Our STN: BL 125426/0

Inspiration Biopharmaceuticals, Inc.  
Attention: Bonnie J Mills, Ph.D.  
28202 Cabot Road, Suite 300  
Laguna Niguel, CA 92677

Dear Dr. Mills:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated April 5, 2012 for Coagulation Factor IX (Recombinant) to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review goal date is February 4, 2013. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We will contact you regarding your proposed labeling no later than January 5, 2013. If postmarketing study commitments (506B) are required, we will contact you no later than January 5, 2013.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Leigh Pracht, at (301) 827-6116.

Sincerely yours,

Iliana Valencia  
Chief, Regulatory Project  
Management Branch  
Office of Blood Research and Review  
Center for Biologics  
Evaluation and Research