



Food and Drug Administration  
1401 Rockville Pike  
Rockville, MD 20852-1448

**October 17, 2012**

Our STN: BL 125446/0

Baxter Healthcare Corporation  
Attention: Mr. Kevin Smyth  
One Baxter Way  
Westlake Village, CA 91362

Dear Mr. Smyth:

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 August 28, 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 June 30, 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 May 31, 2013. If post marketing study commitments (506B) are required, we will contact you no later than May 31, 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, Edward M. Thompson, at (301) 827-9167.

Sincerely yours,

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