



Our STN: BL 125426/0

Cangene Corporation
Attention: Mr. Steve McGregor
155 Innovation Drive
Winnipeg, Manitoba R3T 5Y3
Canada

Dear Mr. McGregor:

We have received your January 27, 2014 resubmission to your biologics license application for Coagulation Factor IX (Recombinant) on January 27, 2014.

The resubmission contains a complete response that you submitted in response to our February 1, 2013 complete response letter to Inspiration Biopharmaceuticals, Inc.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is July 29, 2014.

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

Sincerely yours,

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