DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BL 125426/0

Cangene Corporation
Attention: Mr. Steve McGregor
March 4, 2015
Sent by email

Dear Mr. McGregor:

We are reviewing your biologics license application (BLA) dated April 5, 2012 for Coagulation Factor IX (Recombinant). We request that you make the following postmarketing commitment (PMC):

1. Cangene Corporation commits to perform a field study to evaluate the ability of clinical laboratories to monitor recovery of your product in patient plasma (post-infusion monitoring) using their routine assays and reagents. The final report will be submitted to the FDA by (Month, Year).

2. Please propose a month and year to in the PMC agreement.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by March 18, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is April 29, 2015.

Please send an acknowledgement message for receipt of this request.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/RPMS

Number of pages (including cover sheet) _