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
February 24, 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 determined that the following information is necessary to continue our review:

For subjects who have received modified IB1001 in Trials IB1001-01 and IB1001-02, please provide the most current data for:

1. Exposure figures to modified IB1001.

2. Recovery data for modified IB1001. Please present this similarly to that presented in the Supplemental Report in Amendment 23, Sections 11.4.1 and 14.3. You may include additional information as needed.

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 3, 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.

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

Sincerely,

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