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 11, 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:

1. Your response to Item 1b in amendment Sequence 44 is acceptable. Please include Tables 2-5 of this supplement in the CTD component of the application.

2. You have provided a general description of the lab scale (b) (4) used for testing the new (b) (4) lot. Please provide a complete SOP for the Agency's review with your exact plan for testing a new (b) (4) lot, which should include (b) (4) testing and other parameters related to rFIX testing.

3. Your response to Item 2a in amendment Sequence 44 is acceptable. Please include Tables 2-5 of this supplement in the CTD component of the application.

4. You have confirmed that the validation study regarding CHOP contamination did not examine (b) (4) and was not a representation of the worst case condition. Please submit the results for the studies examining (b) (4) and also include those data in the CTD component of the application.

5. Your response to Item 2d in amendment Sequence 44 is acceptable. Please include Table 20 of this supplement in the CTD component of the application.

6. 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 February 26, 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