From: Pracht, Leigh
Sent: Tuesday, March 11, 2014 12:45 PM
To: Steve McGregor (smcgregor@Cangene.com)
Subject: Information request 125426/0

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

Our Reference: BL 125426/0

Cangene Corporation
Attention: Steve McGregor
March 11, 2014
Sent by email

Dear Mr. McGregor:

We are reviewing your January 27, 2014 resubmission to your biologics license application (BLA) for Coagulation Factor IX (Recombinant). We determined that the following information is necessary to continue our review:

1. Please submit the following samples and reagents:
   a. 10 vials of product from each of the lots (b)(4) (1000 Units) and (b)(4) (1500 Units).

      6 vials of product from each of the lots (b)(4) (500 Units) and (b)(4) (1000 Units).
   b. ~250 mL of your Formulation Buffer, containing histidine, mannitol, sodium chloride, trehalose, and polysorbate 80, (b)(4)
   c. 1 vial each of the FIX reference standards used in the (b)(4) assays, respectively.
   d. 1 box of (b)(4)
   e. 3 vials of Assay Control: Stock for factor IX potency assay
   f. 2 vials of Factor IX Reference Standard (FIX-RS) used in the (b)(4) assay.

      Please send samples and reagents to:

      Karen Campbell
      Regulatory Coordinator
      Division of Biological Standards and Quality Control (DBSQC)/OCBQ/CBER/FDA
      NLRC Bldg. B, Room 2410
      5516 Nicholson Lane

Kensington, MD 20895
office (301)594-6255

Submit responses to 2. and 3. as an amendment to the BLA

2. Please provide the following information for the (b)(4) assay.
   a. Please provide the SOP for the (b)(4) assay for the drug product (b)(4)

3. Please provide the SOP (WI-0437) for the (b)(4) assay for the drug product.

Please respond within 2 weeks with the materials and information or a date when we can expect the materials and/or information.

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

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh Pracht
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB