



Our Reference: BL 125426/0

Cangene Corporation
Attention: Steve McGregor
July 9, 2013
Sent by email

Dear Mr. McGregor:

We are reviewing your April 5, 2012 biologics license application (BLA) for Coagulation Factor IX (Recombinant). We are providing the following comments to your June 13, 2013 inquiry:

1. Your proposal to have (b)(4) performed the (b)(4) final drug product release testing appears feasible since (b)(4) originally developed/validated the procedures and are currently responsible for the release and stability testing of all clinical drug products, (b)(4). However, a formal technology transfer exercise still needs to be performed, which should include, but not be limited to, demonstration of (b)(4) capability to perform the intended tests and comparability of test results generated by (b)(4). This information can be provided as part of your complete response to the CR letter, which should be indicated in the cover letter of the resubmission. Please note that discrepancies in test results due to changes in laboratory facilities could complicate the interpretation of data to establish comparability, and the review of your responses to the CR letter. So, it would be more preferable to request the change in testing facilities post-licensure.

Since Cangene/Cangene Biopharma has not been involved in the development and performance of release and stability assays for IB1001, we strongly recommend that the request for Cangene/Cangene Biopharma to assume responsibility as test facilities be submitted after the licensure of the product in a post-approval supplement. In this case, we expect that the transfer of technology, validation of assays and demonstration of comparability would be more complicated than those of (b)(4), which has prior experience in the testing of IB1001.

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