



Our STN: BL 125506/0

RESUBMISSION ACKNOWLEDGEMENT

Bio Products Laboratory

Attention: (b) (4)

Dear (b) (4)

We have received your April 23, 2015 resubmission to your biologics license application for Coagulation Factor X (Human) on April 27, 2015.

The resubmission contains additional CMC information that you submitted in response to our March 10, 2014 complete response letter.

We consider this a complete, class 2 response to our action letter. Therefore, the user fee goal date is October 27, 2015.

If you have any questions, please contact the Regulatory Project Manager, at pratibha.rana@fda.hhs.gov or (240) 402- 8433.

Sincerely yours,

Iliana Valencia, MS
Chief, Regulatory Project Management Staff
Office of Blood Research and Review
Center for Biologics
Evaluation and Research