



Our STN: BL 125574/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

Bayer HealthCare LLC
Attention: Ms. Vicki Chen
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-09115

Dear Ms. Chen:

We received your September 25, 2015 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Antihemophilic Factor (Recombinant) on September 25, 2015.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is March 16, 2016.

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

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research