



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our STN: BL 125577/0

Baxter Healthcare Corporation  
Attention: Maximilian Fernandez, PhD  
One Baxter Way  
Westlake Village, CA 91362

Dear Dr. Fernandez:

Attached is a copy of the memorandum summarizing your September 3, 2015 Late-Cycle teleconference with CBER. This memorandum constitutes the official record of the teleconference. If your understanding of the teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to the appropriate Submission Tracking Number (STN) in your future submissions related to the subject product.

If you have any questions, please contact the Regulatory Project Manager, Cherie Ward-Peralta, MS, at (240) 402-8447.

Sincerely,

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

## **Late-Cycle Meeting Summary**

**Meeting Date and Time:** September 3, 2015; 9:30 to 11:30 am  
**Meeting Location:** WO71-1535/1540  
**Application Number:** STN 125577  
**Product Name:** von Willebrand Factor (Recombinant)  
**Proposed Indications:** The proposed indication for rVWF is prevention and treatment of bleeding episodes in adults (age 18 years and older) diagnosed with von Willebrand disease.  
**Applicant Name:** Baxter Healthcare Corporation  
**Meeting Chair:** Chava Kimchi-Sarfaty, PhD  
**Meeting Recorder:** Cherie Ward-Peralta, MS

### **FDA ATTENDEES**

Meghna Alimchandani, MD, Medical Officer, Division of Epidemiology (DE), OBE  
Marie Anderson, Consumer Safety Officer, Division of Manufacturing and Product Quality (DMPQ), OCBQ  
Victor Baum, MD, Medical Officer, Division of Hematology Clinical Review (DHCR), OBRR  
Karen Campbell, Biologist, Division of Biological Standards and Quality Control, OCBQ  
Howard Chazin, MD, MBA, Deputy Director, DHCR, OBRR  
John Eltermann, Director, DMPQ, OCBQ  
Mahmood Farshid, PhD, Deputy Director, Division of Hematology Research and Review (DHRR), OBRR  
Mitchell Frost, MD, Acting Branch Chief, DHCR, OBRR  
Basil Golding, MD, Director, DHRR, OBRR  
Jie He, MS, Consumer Safety Officer, DMPQ, OCBQ  
Patricia Holobaugh, Chief, Bioresearch Monitoring Branch, Division of Inspections and Surveillance, OCBQ  
Christopher Jankosky, MD, Supervisory Medical Officer, DE, OBE  
Chava Kimchi-Sarfaty, PhD, Research Chemist, DHRR, OBRR  
Colonious King, Consumer Safety Officer, DIS, OCBQ  
Nancy Kirschbaum, PhD, Chemist, DHRR, OBRR  
Hyesuk Kong, Consumer Safety Officer, DMPQ, OCBQ  
Shuya (Joshua) Lu, PhD, Mathematical Statistician, Division of Biostatistics (DB), OBE  
Marion Michaelis, Chief, Branch II, DMPQ, OCBQ  
Ginette Y. Michaud, MD, Deputy Director, OBRR  
Paul D. Mintz, MD, Director, DHCR, OBRR  
Loan Nguyen, PharmD, Consumer Safety Officer, Advertising and Promotional Labeling Branch (APLB), Division of Case Management (DCM), OCBQ  
Anne M. Pilaro, PhD, Supervisory Toxicologist, DHCR, OBRR  
Renee Rees, PhD, Lead Mathematical Statistician, DB, OBE  
Zuben Sauna, PhD, Senior Staff Scientist, DHRR, OBRR  
Lisa Stockbridge, PhD, Chief, APLB, DCM, OCBQ  
Cherie Ward-Peralta, MS, Regulatory Project Manager, RPMS, OBRR

## **EASTERN RESEARCH GROUP (ERG) ATTENDEES**

Christopher Sese, Contractor, Office of Strategic Programs, CDER  
Peggh Khorrami, Contractor, Office of Strategic Programs, CDER

## **APPLICANT ATTENDEES**

Mehrshid Alai, PhD, Senior Director, Global Regulatory Affairs  
Erik Bjornson, Director, Global Regulatory Affairs  
Maximilian Fernandez, PhD, Senior Manager, Global Regulatory Affairs  
Nikhil Mehta, PhD, Head of Global Regulatory Affairs  
Bruce Ewenstein, MD, PhD, Vice-President, Clinical Strategy, Hemophilia  
Anne Prener, MD, PhD, Global Head of Therapeutic Area Hematology  
Arthur Sytkowski, MD, Senior Medical Director, Hematology  
Yuli Wu, MD, Medical Director, Pharmacovigilance  
Sandor Fritsch, PhD, Senior Director, Global Biostatistics  
Werner Hoellriegl, Director, Nonclinical Development  
Ortrun Obermann-Slupetzky, PhD, Senior Manager, Clinical Research, Hemophilia  
Jennifer Anuran-Reyes, Senior Manager, Quality  
Natalia Seibel, Senior Quality Product Owner

## **BACKGROUND**

BLA 125577 was submitted on December 19, 2014, for von Willebrand factor (Recombinant).

Proposed indication: The proposed indication for rVWF is prevention and treatment of bleeding episodes in adults (age 18 years and older) diagnosed with von Willebrand disease.

PDUFA goal date: December 18, 2015

In preparation for this meeting, FDA issued the Late-cycle Meeting Materials on August 19, 2015.

## **DISCUSSION**

### **1. Information Requests**

- a. Responses to our information requests sent on August 19, and August 26, 2015, have been received. These amendments are currently under review.
- b. Response to our information requests on Polysorbate 80 by (b) (4) sent on August 17, 2015, is due by September 25, 2015.
- c. Response to our information requests sent on August 27, 2015, regarding cleaning validation for equipment and (b) (4) at the Thousand Oak facility is due on September 8, 2015.

Baxter agreed that these are the current outstanding information requests and there was no further discussion.

2. Postmarketing Requirements/Postmarketing Commitments

FDA informed Baxter that at this time there are no Postmarketing Requirements or Commitments.

3. Major Labeling Issues

FDA informed Baxter that the label is currently under review and an information request with revisions would be provided in the next few weeks.

Baxter asked if APLB's revisions or comments will be included in this information request.

FDA informed Baxter that APLB's review will be included.

4. Review Plans

FDA will continue to finalize their reviews and will be in communication, if needed.

5. Applicant Questions

Baxter requested a status update on the review of the preclinical section and if there were any questions from the Agency.

FDA informed Baxter that although the review for all sections of the BLA is still on-going, we do not have any major concerns or substantive review issues.

6. Wrap-up and Action Items

FDA will complete the review of the BLA and will communicate any information requests or concerns. The comments on the labeling will be provided to Baxter in the next few weeks.

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.

**END**