



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
Peggha 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