

PDUFA V The Program Filing Meeting
STN 125566/0
Factor VIII (Recombinant), PEGylated Lyophilized Powder for Solution For
Intravenous Injection
Baxter Healthcare Corporation

January 8, 2015
11:30 a.m. to 12 p.m.
White Oak Building 71
Room 4244

Filing Meeting Agenda:

1. Review Team Introductions

Chair Person: Dr. Ze Peng

Clinical Reviewer: Dr. Stephanie Omokaro

CMC Product Reviewer: Dr. Alexey Khrenov

Clinical Pharmacology: Dr. Carl-Michael Staschen

Toxicology Reviewer: Dr. La’Nissa Brown

Chief Toxicology Reviewer: Dr. Anne Pilaro

Postmarketing Safety Epidemiological Reviewer: Dr. Jane Baumblatt

Statistical Reviewer: Dr. Judy Li

DMPQ Reviewer: Cmdr Jeremy Wally

DMPQ Reviewer: Anthony Lorenzo

OCBQ/DBSQC Representative: Karen Campbell

OCBQ/BIMO Reviewer: Dennis Cato

OCBQ/DBSQC Reviewer: Dr. Lokesh Bhattacharyya

OCBQ/DBSQC Reviewer: Hyesuk Kong

Regulatory Project Manager: Edward Thompson

Dr. Loan Nguyen was not present at this meeting. She presented the filing status of this application in an email message prior to the meeting.

Non-Review Team members

OBRR/DHCR Division Director: Dr. Paul Mintz

OBRR/DHCR Deputy Division Director: Dr. Howard Chazin

OBRR/DHRR, Laboratory of Hemostasis Acting Chief: Dr. Timothy Lee

Chief Regulatory Project Manager: Iliana Valencia

2. Introduction of application, including important dates

Summary Description of Product: Factor VIII (Recombinant), PEGylated Lyophilized Powder for Solution For Intravenous Injection used to to treat adolescent (12 to less than 18

years) and adult (greater than or equal to 18 years) patients with hemophilia A (congenital factor VIII deficiency) for:

1. Control and prevention of bleeding episodes
2. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Receipt Date: 11/25/14

Filing Date: 1/23/15

Day 74 Letter Date: 2/6/15

Review Completion Goal Date according to GRMP: 11/11/15

PDUFA Goal Date: 11/25/15

For all applications that are being reviewed under the PDUFA V Program, the following questions need to be addressed at the filing meeting:

- Were there agreements made at the application's pre-submission meeting (and documented in the minutes) regarding certain late submission components that could be submitted 30 days after receipt of the original application? **NO**
 - If so, were the late submission components all submitted within 30 days? **NA**
 - What late submission components, if any, arrived after 30 days? **NONE**
 - Was the application otherwise complete upon submission, including those applications where there were no agreements regarding late submission components?
All reviewers considered the application to be complete for their respective discipline
3. Filing Review by Discipline: potential RTF Issues; studies/info submitted; identification of info requests; day 74 letter items
- a. CMC – Dr. Peng and Dr. Khrenov stated this application is complete at this time.
 - b. P/T – Dr. Brown and Dr. Pilaro stated this application is complete at this time.
 - c. Clin Pharm/Biopharm – Dr. Staschen stated this application is complete at this time.
 - d. Clinical – Dr. Omokaro stated this application is complete at this time.
 - e. Epidemiologist – Dr. Baumblatt stated this application may be filed and the PVP plan is included in the application.
 - f. Stats – Dr. Li stated this application is complete at this time.
 - g. Labeling – Dr. Loan Nguyen stated that this application is complete at this time.
 - h. Other disciplines: Cmdr Wally, Mr. Lorenzo, Ms. Campbell, Ms. Kong, Dr. Bhattacharyya and Mr. Cato stated this application is complete at this time.
4. Reach agreement on filing decision
- a. CMC – Dr. Peng and Dr. Khrenov stated this application can be filed.
 - b. P/T – Dr. Brown and Dr. Pilaro stated this application can be filed.
 - c. Clin Pharm/Biopharm – Dr. Staschen stated this application can be filed.

- d. Clinical – Dr. Omokaro stated this application can be filed.
- e. Epidemiologist – Dr. Baumblatt stated this application may be filed and the PVP plan is included in the application.
- f. Stats –Dr. Li stated this application may be filed.
- g. Labeling – Dr. Loan Nguyen stated that this application may be filed.
- h. Other disciplines: Cmdr Wally, Mr. Lorenzo, Ms. Campbell, Dr.. Kong, Dr. Bhattacharyya and Mr. Cato stated this application may be filed.

Drafted: Edward Thompson

Revised: Ze Peng