

From: Thompson, Edward
Sent: Friday, May 15, 2015 9:54 AM
To: 'Erik Bjornson (Erik_Bjornson@baxter.com)'
Cc: Do, Yu (Yu.Do@fda.hhs.gov)
Subject: Mid-Cycle Communication Document for BL 125566/0

Contacts: Erik Bjornson - Baxter Healthcare Corporation

Dear Erik,

Please find attached the Mid-Cycle Communication memo for our conference scheduled for May 19, 2015 at 10 a.m.



[125566.MC.C...](#)

The list of participants is found in the memo.

Sincerely,
Ed

Edward Thompson
Regulatory Project Manager
FDA/CBER
Office of Blood Research and Review
(240) 402-8443
email: edward.thompson@fda.hhs.gov
10903 New Hampshire Avenue
WO71-4212
Silver Spring, MD 20993-0002

Mid-Cycle Communication

Application type: Original BLA

Tracking number: STN 125566/0

Product name: Antihemophilic Factor (Recombinant), PEGylated

Proposed Indications: For the treatment of adolescent (12 to < 18 years old) and adult (\geq 18 years old) patients with hemophilia A for (1) control and prevention of bleeding episodes; and (2) routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Applicant: Baxter Healthcare Corporation

Meeting date & time: 19 May 2015, Tuesday at 10:00 AM

Committee Chair: Ze Peng, PhD

RPM: Edward Thompson and Yu Do

FDA Attendees:

Ze Peng, PhD, Biologist, Division of Hematology Research and Review/OBRR/CBER Yu Do, MS, RPM, OBRR/CBER
Edward Thompson, RPM, OBRR/CBER

Other Attendee:

Christopher Sese, Independent Assessor, Eastern Research Group
Azada Hafiz, Operations Research Analyst, PEIS/OPSA/OSP/CDER

Discussion Summary:

1. No significant issues or major deficiencies have been identified by the review committee to date.
2. The review of the clinical data to date did not raise major safety concerns. The current thinking of the review committee is that a *Risk Evaluation and Mitigation Strategy* (REMS) is not required. However, routine pharmacovigilance is recommended.
3. The current thinking of the review committee is that this BLA will not be presented at the *Blood Products Advisory Committee* meeting.
4. The current thinking of the review committee is that inspection of the manufacturing facilities is not required for this BLA.

5. Information requests (IRs) sent but responses from Baxter have not been received:
 - FDA sent an IR on 1 May 2015, and is expecting Baxter's response by 2 June 2015.
 - FDA sent two additional IRs on 12 May 2015 and 13 May 2015, and is expecting Baxter's responses to these two IRs by 27 May 2015.
6. FDA will send Baxter another IR on stability studies and impurities in May 2015. Please note that the review is ongoing and additional information may be requested as the need arises.
7. Baxter and FDA have agreed to hold the *Late-Cycle Meeting* on Thursday, 6 August 2015 from 1:30 PM to 3:30 PM via a teleconference.
8. The action due date for this BLA is Wednesday, 25 November 2015.

END