

From: Do, Yu
To: Erik.Bjornson@baxalta.com
Cc: [Thompson, Edward](#)
Subject: Mid-Cycle Communication Summary for BL 125566/0 (ADYNOVATE): Teleconference, May 19, 2015, 10:00 a.m. to 11:00 a.m., EDT
Date: Wednesday, June 10, 2015 5:02:00 PM
Attachments: [BL125566_May 19 2015_Mid Cycle Communication Teleconference CERT3.pdf](#)

Dear Mr. Bjornson:

Attached is the Mid-Cycle Communication summary for BL 125566/0.

Please acknowledge receipt of this document and let me know if you have any questions.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
FDA/OMPT/CBER/OBRR/IOD/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

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Mid-Cycle Communication Teleconference

Application: Biologics License Application (BLA)

Tracking Number: STN 125566/0

Product name: Antihemophilic Factor (Recombinant), PEGylated [BAX 855]

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 and time: May 19, 2015, 10:00 a.m. to 11:00 a.m., EDT

Committee Chair: Ze Peng

RPM: Edward Thompson and Yu Do

Attendees:

CBER

Ze Peng, OBRR/DHRR/LH
Edward Thompson, OBRR/IO/RPMS
Yu Do, OBRR/IO/RPMS

Baxter Healthcare Corporation

Erik Bjornson, Director, Global Regulatory Affairs
Iraj Daizadeh, Associate Director, Global Regulatory Affairs
Nikhil Mehta, Vice President, Global Regulatory Affairs
Brigitt Abbuehl, Medical Director, Hematology
Werner Engl, Senior Manager, Biostatistics
Anne Prener, Vice President, Clinical Research, Hematology
Graeme Lowe, Senior Manager, Laboratories
Florence Maniere, Quality Manager
Klara Palfrader, Quality Product Owner
Werner Hoellriegl, Director, R&D (non-clinical)

Other

Christopher Sese, Eastern Research Group (ERG)

Discussion Summary:

- 1.&FDA stated that no significant issues or major deficiencies have been identified by the Review Committee to date.

No further discussion.

- 2.&FDA stated that 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.

No further discussion.

- 3.&FDA stated that the current thinking of the review committee is that this BLA will not be presented at the *Blood Products Advisory Committee* meeting

No further discussion.

- 4.&FDA stated that the current thinking of the review committee is that inspection of the manufacturing facilities is not required for this BLA.

No further discussion.

- 5.&FDA stated that the following information requests (IRs) were sent to Baxter but responses from Baxter have not been received:

- a. FDA sent an IR on 1 May 2015 and is expecting Baxter's response by 2 June 2015.
- b. 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.

No further discussion.

- 6.&FDA stated that the Agency will send Baxter another IR on stability studies and impurities in May 2015, and that the review is ongoing and additional information may be requested as the need arises.

Additional discussion:

Baxter asked about the details on this new IR. FDA explained that Baxter had not included the test results for *Free PEG*, *Total PEG*, and *Degree of PEGylation* on the conformance lots of BAX 855 final drug product (FDP). FDA asked Baxter to take these parameters into account in the ongoing stability studies and to include the test results of these parameters when Baxter submits updated stability data for these conformance lots of BAX 855 FDP.

7.&Baxter and FDA agreed to hold the Late-Cycle Meeting on Thursday, 6 August 2015 from 1:30 p.m. to 3:30 p.m. via teleconference.

No further discussion.

8.&FDA stated that the action due date for this BLA is Wednesday, 25 November 2015.

No further discussion.

Additional Discussion

9.&Baxter asked for an update on the status of the review on the clinical and non-clinical sections of the BLA. FDA responded that the reviews of the clinical and non-clinical data are still ongoing.

10. Baxter asked for the schedule of the labeling review. FDA stated that the labeling review meeting is scheduled in late August, and revisions of the label are expected to be conducted by mid-September.

11. Baxter asked for an update on the status of the review of the proprietary name and the issuance of the proprietary name acceptance (PNA) letter. FDA stated that the PNA letter is being drafted and is expected to be sent to Baxter in early June. Additionally, Baxter confirmed that the request of the proprietary name review for this product was not submitted to IND 12599.

End
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