

## RECORD OF TELEPHONE CONVERSATION

**Submission ID:** BL 125566/0  
**Review Office:** OBRR  
**Product:** Antihemophilic Factor (Recombinant), PEGylated  
**Indication:** On-demand treatment and control of bleeding episodes; routine prophylaxis to reduce the frequency of bleeding episodes in adolescent (12 to <18 years) and adult (≥18 years) patients with hemophilia A  
**Sponsor:** Baxter Healthcare Corporation

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**Date/Time:** August 27, 2015, 2:00 PM to 2:30 PM  
**Initiated by FDA?** No.  
**Telephone Number:** (b) (4)  
**Author:** Yu Do  
**Purpose:** To provide Baxter with clarification on next steps for finalization of the proposal on Postmarketing Commitment (PMC)/Postmarketing Requirement (PMR) studies and revised Package Insert (PI).

### ***FDA Participants:***

Stephanie Omokaro, MD, CRB/DHCR/OBRR  
Leland Ross Pierce, MD, CRB/DHCR/OBRR  
Ze Peng, PhD, LH/DHRR/OBRR  
Yu Do, MS, RPMS/IO/OBRR

### ***Baxter Participants:***

Erik Bjornson, Director, Regulatory Affairs  
Nikhil Mehta, Vice President, Regulatory Affairs

***Amendments:*** None.

### **Summary of Discussion**

FDA stated that Study #261203, “Multi-center, open label study to investigate safety and immunogenicity of ADYNOVATE in previously untreated patients (PUPs), would be considered a PMC study.

For Study #261204 [“Prospective, open label multi-center study of efficacy and safety of ADYNOVATE in the perioperative management of bleeding in previously treated patients (PTPs)”] and Study #261303 [“Prospective, randomized, open-label multi-center clinical study to compare the safety and efficacy of PK guided ADYNOVATE treatment regimen targeting 2 different FVIII trough levels of 1-3% or approximately 10% (8 – 12%) in PTPs”], FDA suggested that adult and pediatric components be parsed and treated as an independent study under the same designation number, but distinctly labeled for each respective age group. The study labeled for pediatric patients would then be considered as PREA PMR study, while the study labeled for adults patients would be listed under PMC.

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Baxter agreed with the proposal on designation of PMR and PMC studies and shared a plan to submit their response capturing FDA's suggestions.

FDA stated that further revision on the annotated PI will be issued during the week of August 31, 2015, meriting an appropriate response from Baxter.

FDA informed Baxter that no CMC-related PMCs would be expected at this time.

Baxter asked for an update on FDA's timing of the approval and to elaborate on the possibility of reaching a regulatory decision before the action due date.

FDA declined to comment in response regarding such time frame and communicated that the review is still ongoing and that issues may be added, expanded upon, or modified as review of this application continues.

*Signature:* \_\_\_\_\_

Drafted: Yu Do/August 31, 2015  
Revised: Stephanie Omokaro/September 1, 2015  
Revised: L. Ross Pierce/September 2, 2015  
Reviewed: Ze Peng/September 1, 2015