

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125577/0.0
<b>Review Office</b>	OBRR
<b>Applicant</b>	Baxter Healthcare Corporation / Lic. # 0140
<b>Product</b>	von Willebrand Factor (Recombinant)
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	18-SEP-2015 09:00 AM
<b>Author</b>	WARD-PERALTA, CHERIE
<b>EDR</b>	Yes
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	(b) (4)
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	To request for a new analysis on the clinical data provided in Amendment 20 received on Sept 16, 2015.
<b>FDA Participants</b>	Mitch Frost, MD; Acting Chief, OBRR/DHCR  Cherie Ward-Peralta, Regulatory Project Manager, OBRR

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<b>Applicant Participants</b>	Arthur Sytkowski, MD, Sr Medical Director Bruce Ewenstein, MD, PhD, VP Clinical Strategy, Hemophilia Erik Bjornson, Director, Global Regulatory Affairs Max Fernandez, Sr Manager, Global Regulatory Affairs Ortrun Obermann-Slupetzky, Manager, Clinical Affairs Sandor Fritsch, Sr Director, Global Biostatistics
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### Telecon Body:

FDA reviewed Table 39 from the final study report for clinical trial 071001 and Table 1 in the attached document within the September 16, 2015 amendment and would like the following analysis performed on the date provided to get a better understanding of the actual doses used per infusion for bleeding episodes.

FDA would like a table with descriptive statistics for the first infusion with both VONVENDI and ADVATE for the 164 bleeding episodes. Then, FDA requested a similar analysis for the 30 bleeding episodes that were treated with VONVENDI alone for the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> infusions. FDA also requested a similar analysis for the 46 bleeding episodes that were treated with either VONVENDI and ADVATE or VONVENDI alone for the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> infusions.

Baxter agreed to provide these analyses by September 25, 2015.

FDA also asked Baxter the reason for not being able to determine the dose of VONVENDI for 18 bleeding episodes due to not documenting the lot number of product.

Baxter stated that exact dose cannot be calculated without the lot number.

Action Items for Baxter:

To provide the following statistical analysis by September 25, 2015:

1. Dose for Vonvendi, dose for Advate in the first infusion (in addition to descriptive statistics) for 164 bleeding episodes.
2. Dose for Vonvendi only for 30 infusions for BEs treated with Vonvendi alone in the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> infusion.
3. Dose for Vonvendi only for 46 infusions for BEs treated with Vonvendi/ADVATE or Vonvendi alone in the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> infusion.

End of Meeting