

From: Ward-Peralta, Cherie
Sent: Wednesday, August 26, 2015 3:24 PM
To: Fernandez, Alexander Maximilian (max_fernandez@baxter.com)
Subject: STN 125577 - Information Request - Please respond by September 2, 2015

Our Reference: BL 125577/0

Baxter Healthcare Corporation
Attention: Maximilian Fernandez, PhD
Sent by email

Dear Dr. Fernandez:

We are reviewing your December 19, 2014, biologics license application (BLA) for von Willebrand Factor (Recombinant). We determined that the following information is necessary to continue our review:

Clinical

1. This BLA refers to 66 unique subjects with von Willebrand disease who received Vonvendi. 32 subjects were treated in trial 070701 and 37 subjects in trial (b) (4). Given that a single subject was enrolled in both trials, how was the number of 66 derived?

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by September 2, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is December 19, 2015.

Very Respectfully,

Cherie Ward-Peralta, M.S.

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