

From: Valencia, Iliana  
Sent: Wednesday, August 05, 2015 8:44 AM  
To: max.fernandez@baxalta.com  
Cc: Ward-Peralta, Cherie  
Subject: 125577 von Willebrand Factor (Recombinant): Information Request (IR)

Baxter Healthcare Corporation  
Attention: Maximilian Fernandez, PhD  
August 5, 2015  
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:

In both the Full Clinical Study Report of Study 071001 and the draft label, the number of bleeding episodes is numbered at both 192 and 193. Please explain the difference. Is it due to the one subject who received an incorrect medication?

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 August 19, 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.

Thank you.

On behalf of Cherie-Ward Peralta.

Iliana Valencia, MS  
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