

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
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IOD
240-402-8444
202-591-6054
iliana.valencia@fda.hhs.gov

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action

based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."