

From: Ward-Peralta, Cherie
Sent: Wednesday, November 25, 2015 4:25 PM
To: 'Fernandez, Alexander Maximilian'
Subject: STN 125577 - Information Request - Please respond by December 2, 2015

Follow Up Flag: Follow up
Due By: Wednesday, December 02, 2015 8:00 AM
Flag Status: Flagged

Our Reference: BL 125577/0

Baxalta US Inc.
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:

VIAL AND CARTON LABELS

Vial Label



1. Delete the vial size (i.e., 10 mL) from the description of the vial. Simply use the term “Single-use Vial” instead. There has been a report of medication error due to mistaken of this vial size with the final solution volume.
2. Use consistent terminology for the route of administration if space permits. The carton has “For intravenous administration after reconstitution only.”

Carton Label



3. Delete the vial size (i.e., 10 mL for 650 IU and 30 mL for 1300 IU size) from the description of the vial.
4. Ensure that the storage information is consistent with the information presented in the PI. As currently presented, the carton has 6 months room temperature storage while the PI has up to 12 month room temperature storage.

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 December 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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