

From: Ward-Peralta, Cherie
Sent: Monday, September 14, 2015 11:29 AM
To: Fernandez, Alexander Maximilian (max_fernandez@baxter.com)
Cc: Bjornson, Erik John (Erik.Bjornson@baxalta.com)
Subject: STN 125577 - Information Request - Please respond by September 28, 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:

Labeling

1. You provided a table with the NDC codes and Product information of the two carton packages of your product at the end of the section of the "Package/Label Principal Display Panel" in your SPL Label. The first package in this table is for the 450-850 IU VONVENDI carton package with the NDC code 0944-7551-02. Part 1 of the 2 sections is for the 450-850 IU VONVENDI vial, that appears with an incorrect NDC code of "0944-7552-01". Please correct the code to NDC code "0944-7550-01".
2. Please use the UNII code (b) (4) for your product.
3. Please revise your package insert according to the tracked changes and comments made within the attached document. Please note that the (b) (4) is under internal discussions in CBER. We will notify Baxter with a decision.



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 28, 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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