

From: Maruna, Thomas
Sent: Tuesday, May 05, 2015 10:28 AM
To: 'max_fernandez@baxter.com'
Cc: Ward-Peralta, Cherie; Alimchandani, Meghna
Subject: Information Requested: BLA 125577/0 - Please Respond by May 7, 2015

Importance: High

Sent on behalf of Ms. Cherie Ward-Peralta

Our Reference: BL 125577/0

Baxter Healthcare Corporation
Attention: Maximilian Fernandez, PhD
May 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:

1. Regarding Baxter's submission of the Pharmacovigilance Plan (dated November 19, 2014) to BLA 125577 (module 1.16); on page 61, under "ANNEX II Ongoing Study Protocols that are Part of the Pharmacovigilance Plan: Clinical Study Protocol for (b) (4) [REDACTED] and Clinical Study Protocol for (b) (4) [REDACTED]:"
 - We are unable to locate these study protocols. If they are submitted in the original BLA, please clarify where the protocols are located in your application. If the protocols have not been submitted, when can FDA expect to receive the protocols? Please submit study protocols (b) (4) [REDACTED] to BLA 125577.

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 May 7, 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,

Thomas J. Maruna, MSc, MLS(ASCP)^{CM}
Lieutenant, U.S. Public Health Service

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