

**From:** [He, Jie](#)  
**To:** [Fernandez, Alexander Maximilian](#)  
**Cc:** [Badiei, Bitia](#); [Silvey, William Bryan \(Bryan.Silvey@baxalta.com\)](#); [Ward-Peralta, Cherie \(Cherie.Ward-Peralta@fda.hhs.gov\)](#)  
**Subject:** Information request Baxter rVWF BLA STN125577/0  
**Date:** Tuesday, June 02, 2015 10:14:00 AM  
**Importance:** High

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Our Reference: BL 125577/0  
Baxter Healthcare Corporation  
Attention: Fernandez, Alexander Maximilian, PhD

June 2, 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. Please provide a list of FDA licensed products that use the same diluent (Sterile Water for Injection) as the one used for VONVENDI from the same manufacturer ((b) (4) ) and same manufacturing location. Please provide a tabular comparison of the following: vials used, fill volumes, fill equipment, manufacturing process, container closure system used, sterilization process and testing performed. Please also provide the relevant STN numbers and DMF numbers.**

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 June 22, 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.

Kind regards,

*Jie He*  
Consumer Safety Officer  
DHHS/FDA/CBER/OCBQ/DMPQ  
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Silver Spring, MD 20993-0002  
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