

FACSIMILE TRANSMISSION RECORD, December 2, 2010 - Corifact

FACSIMILE TRANSMISSION RECORD
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FAX No. 610-878-4182
To: David Desris, PharmD, CSL Behring, LLC
Date: December 2, 2010

Re: STN 125385/0

We are reviewing you August 18, 2010 biologics license application for Factor XIII Concentrate (Human) for the routine prophylaxis treatment of congenital Factor XIII deficiency. We determined that the following information is necessary to continue our review:

CMC:

1. Please include data on ---(b)(4)--- in microbiological testing of -----(b)(4)-----, which we had requested during the review of the IND.
2. Regarding the specification for residual moisture, please provide the results to one decimal place (e.g., (b)(4)), or the validated limit of quantitation of the analytical method (e.g., ≤ 0.1 %).
3. Please provide the report for the validation of the -----(b)(4)-----.
4. Please provide the reports for the validation of methods to assess container closure integrity -----(b)(4)-----.
5. In the Container Closure System section, you stated that the vials used for FXIII Concentrate (Human) are 30-mL injection vials, glass -(b)(4)-. However, the vials described in the stability report STR-642-013-02-US are 30-mL injection vial, glass -(b)(4)-.
 - A. Please clarify the type of glass vials used for FXIII Concentrate (Human) in the US market.

- B. If different types of glass vials are used, please describe the differences between the ----(b)(4)---- injection vials, and demonstrate their compatibility with the product.

Clinical Pharmacology:

6. In study entitled: "A 12-week, multicenter, pharmacokinetic and safety study of human plasma-derived factor XIII concentrate in subjects with congenital factor XIII deficiency", you report an MRT value of 236 ± 13 (baseline non-adjusted, standard) which is shorter than the reported half-life (310 hours). Generally, MRT is longer than half-life but in this case the MRT is shorter than half-life. Please re-calculate the MRT to ensure that your MRT calculation is correct. Please check your calculations also for amended and antigen methods.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission. If we determine that your response to this information request constitutes a major amendment, we will notify you in writing. Please submit your response to this information request as an amendment to this file by December 13, 2010. 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 February 17, 2011.

If you have any questions, please contact me at (301) 827-6174.

Sincerely yours,

Nannette Cagungun, MS, PD, RAC
Regulatory Project Manager