

# **FACSIMILE TRANSMISSION RECORD, September 9, 2010 - Corifact**

**FACSIMILE TRANSMISSION RECORD  
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**To: David Desris, PharmD, CSL Behring, LLC**

**From: Nannette Cagungun, OBRR/CBER/FDA**

**Date: September 9, 2010**

**Re: STN 125385/0**

In order to facilitate the review of your submission, we have the following request for information regarding your Factor XIII BLA:

## **Study # BI 71023/0-1003 (Healthy subjects' PK)**

1. Please provide FXIII concentration-time data plot on a semi-log scale for each subject separately (only baseline corrected FXIII activity (U/mL). In other words, 20 plots for 20 subjects. Please also provide a mean plot.

Please ensure that in future submissions you do not use non-standardized PK terms. For example, area under the curve from time zero to t (AUC(0-t)) or area under the curve from time zero to infinity (AUC(0-∞)) are standardized PK terms whereas AUC or AUD are not.

Mean residence time (MRT) is standardized PK term whereas MRT<sub>vss</sub> is not.

**Study # BI 71023\_2002 (Patients' PK)**

2. Please provide the following information in a single table: age, weight, gender, and dose given to individual subjects.
3. Please provide individual subject's FXIII concentration-time data (activity and antigen) along with individual subject's PK parameters. If you have already submitted these data then please point out the location of these data.

We request that you submit the information as an amendment to the BLA as soon as possible.

Sincerely yours,

**Nannette Cagungun**  
**Regulatory Project Manager**  
**DBA/OBRR/CBER/FDA**  
**Tel: (301) 827-6174**