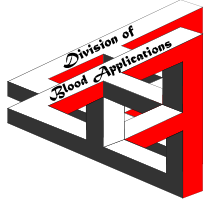


This fax is regarding STN 125317/0



FACSIMILE TRANSMISSION RECORD
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15 October 2008

FAX No.: 610-878-4182

To: David Desris, Regulatory Affairs

This Fax is regarding STN **125317/0** that was submitted to the agency on **18 July 2008**, designated as an **original BLA** for the treatment of congenital fibrinogen deficiency. CBER has finished a preliminary review for the reference submissions and requests CSLB to provide responses to the following information request.

- With reference to page 4 of section 3.2.R.3-4, please provide the validation data for the ----
----- (b)(4) ----- technique (---- (b)(4) ---- test) used to verify the existence of
----- (b)(4) ----- protein and the absence of ---- (b)(4) ---- protein in the samples.

Please submit a response to this information request as an amendment to the file by October 29, 2008.

Vasanth Kumar
Regulatory Project Manager
FDA/CBER/DBA/OBRR/RPMB

This fax is regarding STN 125317/0

Information provided by: JZe Peng Date: 15 October 2008

Approved by Ze Peng Date 15 October 2008 Transmitted by V.Kumar Date 15 October 2008

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