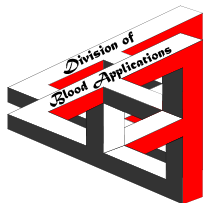


This fax is regarding STN 125039/335



FACSIMILE TRANSMISSION RECORD

**Division of Blood Applications
1401 Rockville Pike, Suite 400N, HFM-380
Rockville, Maryland 20852-1448**

FAX (301) 827-2857

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5 September 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.

1. Please provide -----(b)(4)----- evaluation of stability data for the tests for clottable fibrinogen and ----(b)(4)---- tests on stability samples stored at 25°C/-(b)(4)- RH. Refer to *ICH Guidance for Industry, Q1E Evaluation of Stability Data*.
2. Please provide any data available on the stability of the excipients in the lyophilized HFCP product.
3. Please provide SOP NTE-37, or if it was included in the original submission, please point out its location.

Please submit a response to this information request as an amendment to the file by September 24, 2008.

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

This fax is regarding STN 125039/335

Information provided by: James Crim Date: 27-Aug-07

Approved by Ewa Marszal Date 30-Aug-07 Transmitted by M. Shields Date 30-Aug-07

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Thank you.

Number of pages (including cover sheet) 2