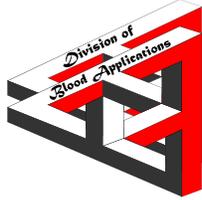


This Fax is regarding STN 125351\0



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

**FAX (301) 827-2857**

**TEL (301) 827-3898**

**March 4, 2010**

**FAX No. 610-878-4182**

To: Ms. Camilla Wamberg, Nycomed Denmark ApS

This Fax is regarding **STN 125351/0** that was submitted to the agency on **3-June-09**, designated as an **Original BLA Application** for Fibrin Sealant Patch

CBER has finished a preliminary review for the referenced submission and requests Nycomed to amend the submission by responding to the following request:

**Information Request:**

1. Please submit the narrative case reports and information on the pediatric patients in TC-019-IN and the narrative case reports on the deaths reported in TC-018-IN, specifically the 7 cases from thromboembolic events and the 8 cases from major bleeding events

Please submit the requested information to the Agency as soon as possible. If you have any questions, please contact me, at (301) 827-9167.

Jie He

Regulatory Project Manager  
HFM-380 FDA/CBER  
Office of Blood Research and Review  
Division of Blood Applications  
301-827-9167 fax 301-827-2857  
email: jie.he@fda.hhs.gov

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Information provided by: F. Barash Date: 04 March 2010

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Approved by F. Barash Date 05 March 2010 Transmitted by J. He Date 4-Mar-10

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Thank you.

Number of pages (including cover sheet) 2