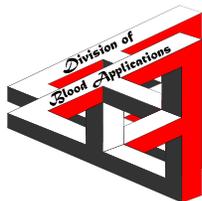


This Fax is regarding STN 125351\0



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

February 25, 2010

FAX No. 610-878-4182

To: Ms. Camilla Wamberg, Nycomed Danmark 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 the review committee requests responses to the following question in the form of an amendment to the file by COB March 10th, 2010 in order to continue their review.

Information Request:

1. Please submit Qualification Reports for the Immunogenicity Assays (to be used in planned clinical studies).
2. Please submit final Validation Reports for the Immunogenicity Assays, when available, as Amendment to existing IND-(b)(4)-.

If you need clarification please call me at 301-827-9167.

Thanks,

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: N.Anayeva Date: 25-Feb-10

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Approved by N.Anayeva Date 25-Feb-10 Transmitted by J. He Date 25-Feb-10

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