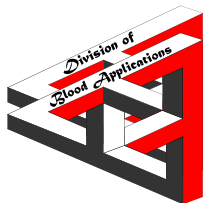


This Fax is regarding STN 125351\0



FACSIMILE TRANSMISSION RECORD
Division of Blood Applications
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Rockville, Maryland 20852-1448

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October 22, 2009

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 requests Nycomed to amend the submission by responding to the following request:

Information Request:

1. Please submit updated stability data for three TachoSil Conformance Lot samples that have been stored up to 9 months under the $5^{\circ} \pm 3^{\circ} \text{ C}$, 25° C /-----(b)(4)----- storage conditions, and up to 6 months at -----(b)(4)----- . Also, please provide updated stability data for the three Validation Lots.
2. Please submit a summary of post-marketing clinical experience for TachoSil in the European Union (reflecting efficacy, safety, adverse events and complaints) in the past 3 years.

Please submit the requested information to the Agency as soon as the stability data for the 9-month time-point are collected.

END

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.Ananyeva Date: 05 October 2009

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Approved by N.Anayeva Date 09 October 2009 Transmitted by J. He Date 22-Oct-09

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