

LETTER

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VIA FEDERAL EXPRESS

Docket Number 95S-0158 (BB IND # 10719)
Dockets Management Branch
Food and Drug Administration
Room 1061, Mail Stop HFA-305
5630 Fisher's Lane
Rockville, MD 20852

July 14, 2005

**RE: BB IND 10719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®]
Protocol RTBSE-11-(N): Publicly Disclosed Information**

Dear Sir:

Reference is made to our Investigational New Drug Application (IND) for Poly-SFH-P Injection for acute trauma, BB IND # 10719.

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the following sites:

Durham, North Carolina

Duke University Medical Center
IRB: Institutional Review Board for Clinical Investigations
2400 Pratt Street, Suite 9000
Box 2991 Medical Center
Durham, NC 27710

95S-0158

SUP 42

Docket Number 95S-0158

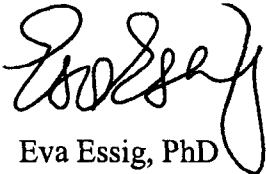
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A copy of this submission is being submitted to BB IND #10719.

If you have any comments or questions, please contact the undersigned at 847-864-3500.

Sincerely,

A handwritten signature in black ink, appearing to read "Eva Essig". The signature is fluid and cursive, with a large initial "E" and a long, sweeping tail.

Eva Essig, PhD

Vice President, Regulatory Affairs and Quality