

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

April 8, 2005

0321 5 APR -8 19:43

**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In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board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:

Hershey, PA

The Milton S. Hershey Medical Center
IRB: The Penn State Milton Hershey Medical Center
500 University Drive- PO Box 850
Hershey, PA 17033

Note: Oral presentations were given at community meetings that occurred on January 10, 2005 (Perry County), January 13, 2005 (Cumberland County), January 19, 2005

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(Dauphin County) and January 25, 2005 (Lancaster County) and January 27, 2005 (Lebanon County). The PolyHeme Backgrounder and Q&A were supplied at the meetings. The PowerPoint presentation was provided at information sessions given at the hospital.

Cincinnati, OH

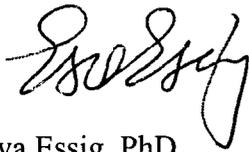
University of Cincinnati College of Medicine
IRB: University of Cincinnati Medical Center IRB
G08 Wherry Hall
Eden Avenue and Albert Sabin Way
Cincinnati, OH 45267-0567

Note: Please note that the PowerPoint presentation was identical across all meetings. Therefore, only the initial page with coverpage slide is provided for the January 15, 2004, January 20, 2004 (2 meetings), January 22, 2004, February 9, 2004 and February 10, 2004 meetings.

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,



Eva Essig, PhD
Vice President, Regulatory Affairs and Quality