

NORTHFIELD
LABORATORIES INC

1560 SHERMAN AVENUE

SUITE 1000

EVANSTON, IL 60201-1800

(817) 864-3500

FAX (817) 864-0353

www.northfieldlabs.com

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

September 14, 2004

**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, which was originally submitted to the Office of Blood Products on October 8, 2002 (Serial No. 000). Please also refer to Protocol RTBSE-R1-11-(N) entitled "A Phase III Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries".

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board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

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Virginia Commonwealth University Medical Center
401 North 12th Street
Richmond, VA 23219
IRB: Western IRB (WIRB)

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 cursive script that reads "Steven A. Gould".

Steven A. Gould, M.D.
Chairman and Chief Executive Officer