

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

January 8, 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In conformance with 21 CFR 312.54 (a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board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:

**95S-0158**

**RPT 13**

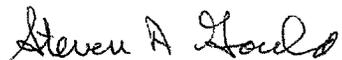
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**Denver Health Medical Center**  
777 Bannock St.  
Denver, CO 80204  
**IRB: Colorado Multiple Institutional Review Board**  
**(COMIRB)**

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,



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