

Baxter

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April 18, 2000

Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. Rm 1-23
Rockville, MD 20857



RE: Investigational New Drug Application #6859

Dear Sir or Madam:

In accordance with 21 CFR §50.24, and §312.130 concerning Baxter Healthcare Corporation's Investigational New Drug Application #6859, we are enclosing copies of information concerning public disclosure following the completion of the clinical investigation of Diaspirin Crosslinked Hemoglobin (DCLHb) involving an exception to informed consent.

Each of the 18 clinical sites involved in the U.S. DCLHb trauma trial which completed pre-study community consultation/public disclosure activities and received investigational product (DCLHb) have completed their post-study disclosure activities.

This submission includes recently obtained post-study information from Parkland Health and Hospital System/University of Texas Medical Center (Dallas, TX). The post-study public disclosure information is a March, 2000 public notice that was printed in the *Dallas Morning News* and the *Dallas Weekly*, which focuses on the Afro-American community, and was translated into Spanish in *El Sol de Texas* (Attachments 1-3). This public notice summarizes the results of the DCLHb Trauma Study.

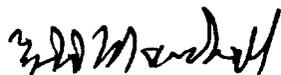
This submission also includes a copy of the November 1999 article in JAMA that presented the results of the DCLHb Trauma Study to the medical research community (Attachment 4).

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If there are any questions concerning this submission, please contact me at (303) 541-3320.

Sincerely,



Todd Marshall
Associate Director of Regulatory Affairs
BAXTER Hemoglobin Therapeutics

LIST OF ATTACHMENTS

Parkland Health and Hospital System/University of Texas Medical Center (Dallas, TX)

Attachments 1-3: Public notice printed in *Dallas Morning News*, *Dallas Weekly*, and in Spanish in *El Sol de Texas* (March, 2000)

Research Community

Attachment 4: *Diaspirin Cross-Linked Hemoglobin (DCLHb) in the Treatment of Severe Traumatic Hemorrhagic Shock*.
Original Contribution to JAMA, November 17, 1999 Vol. 282, No. 19,
Pages 1857-1864