



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 0 2000

Public Health Service  
Food and Drug Administration

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

July 6, 2000

Mr. Doug Weeks, Vice President  
Baptist Health Medical Center Blood Bank  
9601 Interstate 630, Exit 7  
Little Rock, AR 72205

Dear Mr. Weeks:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises, 9601 Interstate 630, Exit 7, Little Rock, Arkansas on May 9, 2000, by a representative of the U.S. Food and Drug Administration (FDA). We are providing this report as part of an effort to improve communication and to make FDA's regulatory process and inspection activities more understandable to the regulated industry.

FDA has concluded this inspection report is disclosable under 21 CFR 20.64(d). Your copy of the narrative report may contain business or personal information, which is disclosable only to you or your firm.

Inspection and enforcement documents are available through the Freedom of Information Act (FOIA) only after thorough review by FDA and deletion of those portions of the document FDA deems not disclosable. You may obtain earlier inspection reports, as well as additional releasable documents, through the Freedom of Information by sending a written request to the following address:

Freedom of Information Staff (HF1-35)  
Food and Drug Administration  
5600 Fishers Lane, Room 12A-16  
Rockville, MD 20857

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Mr. Doug Weeks, Baptist Health Medical Center Blood Bank

If there is any question about the released information, please feel free to contact William D. Aken at (214) 655-5310 x 549, or write him at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell".

Michael A. Chappell  
District Director

MAC:WDA:SMM

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 6, 2000

Mr. Doug Weeks, Vice President  
Baptist Health Medical Center Blood Bank  
9601 Interstate 630, Exit 7  
Little Rock, AR 72205

Dear Mr. Weeks:

A representative of the Food and Drug Administration (FDA) conducted an inspection of your firm's blood bank/transfusion service facility at 9601 Interstate 630, Exit 7, Little Rock, AR on May 9, 2000. The inspection covered the products described below.

**Product covered: Human Blood**

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and implementing regulations.

Based on these findings, the agency is prepared to endorse applicable pending export certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address quality system/good manufacturing practices (QS/GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to ensure you are continuing to maintain conformance with QS/GMP's.

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Mr. Doug Weeks, Baptist Health Medical Center Blood Bank

For further information, please contact William D. Aken at (214) 655-5310  
x 549, or write to him at the above referenced address.

Sincerely,

  
Michael A. Chappell  
District Director

MAC:WDA:SMM

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