CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NOTICE OF ADVERSE FINDINGS

September 26, 1989

William M. Dugan, M.D.
Responsible Head
Universal Reagents, Inc.
1935 North Capitol
Indianapolis, IN 46202

Dear Dr. Dugan:

During an inspection of Universal Reagents, Inc., 1935 North Capitol, Indianapolis, Indiana, on May 8 through 12, 1989, Food and Drug Administration (FDA) Investigator Lawrence Boyd documented the following deviations from Title 21, Code of Federal Regulations (21 CFR), Parts 600-680:

Standard Operating Procedures (SOPs)

Written standard operating procedures are not properly maintained as required to include all steps to be followed in the processing, storage and distribution of Source Plasma. [21 CFR 606.100(b)] in that:

a) the SOPs for collection and processing of units positive for the Hepatitis B Surface Antigen (HBsAg) and/or antibodies to the Human Immunodeficiency Virus (Anti-HIV-1) does not include instructions for the proper handling and shipment of potentially hazardous material.

b) there is no SOP covering the thawing, pooling, refreezing, and relabeling of [redacted] received in broken bags from another licensed facility.

Failure to Report Changes

Failure to notify the Center for Biologics Evaluation and Research prior to a July 18, 1988 shipment of [redacted] known to be positive for anti-HIV-1 to an unapproved consignee ([redacted]). [21 CFR 610.45(c)]

Labeling

Factor [redacted] Lots 4632 and 4633, that were relabeled and transshipped failed to include the name and address of the collection facility. In accordance with 21 CFR 610.63 and 21 CFR 606.121(b) the label must include the name, address and license number of all establishments participating in the manufacturing process.

We are aware that your firm received an October 26, 1988 letter from the Center for Biologics Evaluation and Research granting approval to ship anti-HIV-1 positive units to George King Biomedical Inc. Please be advised that you must receive approval from the Center for Biologics prior to shipment of anti-HIV-1 positive units to any consignee not included in your license amendment.

The above listed violations are not intended to be all-inclusive. It is your responsibility as Responsible Head, as defined in 21 CFR 600.10(a), to assure adherence to each requirement of the federal regulations. We request that you take prompt action to correct these deviations.

Please respond within thirty (30) days of receipt of this letter with a summary of the corrective measures you have taken to address the noted deviations. Please direct your written response to Ms. Sandra Williams, Compliance Officer, Food and Drug Administration, Detroit District, 1560 East Jefferson Avenue, Detroit, MI 48207.

Sincerely yours,

John P. Dempster
Director Compliance Branch
Detroit District

[redacted]

SW/jc