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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NOTICE OF ADVERSE FINDINGS

October 20, 1988

William Dugan, M.D.
Responsible Head
Universal Reagents, Inc.
1828 North Illinois
Indianapolis, Indiana 46202

Dear Dr. Dugan:

An inspection of your plasmapheresis center was conducted on August 30, 1988 by Investigator Charles M. Spyr. During this inspection, Investigator Spyr observed significant deviations from the Current Good Manufacturing Practice for Blood and Blood Components (21 CFR 606), Additional Standards for Human Blood and Blood Products (21 CFR 640), and your Standard Operating Procedures; as follows:

1. Donor samples are not always tested for HIV as directed in the test kit instructions or as specified in your Standard Operating Procedures Manual.
2. Six lots of initially HBsAg reactive plasma were shipped without adequate retesting. In addition, your SOP does not adequately describe the HBsAg testing which should be performed on initially reactive units.
3. Your actual procedures are not always performed in accordance with your Standard Operating Procedures manual.
4. Written Standard Operating Procedures are not maintained in a manner which will insure that they are complete, and accurate.

An investigator's list of Inspectional Observations (copy enclosed) was presented to and discussed with Mr. Donald W. Barnhart, Director of Operations, at the conclusion of the inspection.

We recommend that you take immediate action to assure that your Standard Operating Procedures are current and appropriate, and that they will be followed.

Please notify us in writing, within thirty (30) days of your receipt of this letter, of the specific steps you have taken or intend to take to bring your firm into compliance.

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Universal Reagents, Inc.

Your response should be directed to this office to the attention
of Ms. Sandra Williams, Compliance Officer.

Sincerely yours,



John P. Dempster
Director, Compliance Branch
Detroit District

Enclosures: A/s

cc: Mr. Donald W. Barnhart
Director of Operations
Universal Reagents, Inc.
1935 North Capitol Ave.
Indianapolis, Indiana 46202



SW/saj
10/19/88