Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
93-DT-3

October 19, 1992

Donald W. Barnhart
Universal Reagents, Inc.
2858 North Pennsylvania Street
Indianapolis, Indiana 46205

Dear Mr. Barnhart:

An inspection of your plasma collection facility was conducted on June 29 - July 2, 1992 by the Food and Drug Administration. The inspection revealed significant deviations from current good manufacturing practice regulations for Blood and Blood Products, Title 21, Code of Federal Regulations, Part 600-680 (21 CFR 600-680). These deviations cause your products to be in violation of the Federal Food, Drug, and Cosmetic Act, Section 501(a)(2)(B), as follows:

1. Failure to adequately identify and handle all test samples so that they are accurately related to the specific unit of product being tested and to its donor [21 CFR 606.140(c)] in that:

   a. Discrepancies exist between viral marker test result printouts and the corresponding data sheets. Units 10354 and 9933, which tested initially reactive for hepatitis B surface antigen, and unit 10111, which tested initially reactive to the antibody to hepatitis C virus encoded antigen, were not correctly identified on the data sheet. Consequently, the units were not retested in duplicate.

b. Printouts of test results for the antibody to the human immunodeficiency virus type-1 (anti-HIV-1) on September 20, 1991, March 4, 1992, and June 12, 1992, and the corresponding data sheets do not show the same number of samples tested, thus providing no assurance that all samples were tested.

2. Failure to follow manufacturer's instructions for anti-HIV-1 testing [21 CFR 606.65(e)] in that unit 8979, which tested initially reactive for anti-HIV-1, was not retested in duplicate.

3. Failure to follow written SOPs that include all steps to be followed in the collection, processing, storage, and distribution of blood and blood components [21 CFR 606.100(b)]. Contrary to your SOP 30.20, units 9969 and 10030, which tested repeatedly reactive for anti-HCV, were shipped for further manufacture without approval from the Director, Center for Biologics Evaluation and Research (CBER).

We note that SOP 30.20 is not consistent with CBER's April 23, 1992, Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded (Anti-HCV) (copy enclosed). We recommend that your SOP be revised to be consistent with current recommendations regarding Plasma and Red Blood Cells [redacted] April 23, 1992 memorandum.

The above is not intended to be an all-inclusive list of deviations that may exist at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to this office to the attention of Mrs. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,

Carl C. Reynolds
District Director
Detroit District

enclosures: a/s