



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Detroit District Office  
Central Region  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: (313) 226-6260  
FAX: (313) 226-3076

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

July 20, 2000

WARNING LETTER  
2000-DT-29

Mr. Roy Speck  
Authorized Official  
Universal Reagents, Inc.  
2858 N. Pennsylvania Street  
Indianapolis, Indiana 46205

Dear Mr. Speck:

An inspection of your plasmapheresis facility was conducted on June 12 – 16, 2000 by the Food and Drug Administration. The inspection revealed significant deviations from the Current Good Manufacturing Practice Regulations for Blood and Blood Products, Title 21, Code of Federal Regulations, Part 606, 610, and 640 (21 CFR 606, 610, and 640). These deviations cause your product, Source Plasma, to be in violation of the Food, Drug, and Cosmetic Act (FD&C Act), Section 501(a)(2)(B), as follows:

1. Failure to maintain/follow standard operating procedures (SOPs) [21 CFR 606.100] in that:
  - a. In-process immunizing Red Blood Cells from donors are not always immediately transferred into sterile pyrogen free glass vials for overnight storage [21 CFR 606.100(b)(10)];
  - b. There is no written procedure for the performance of the daily weight checks required by the manufacturer of the autopheresis machines [21 CFR 606.100(b)(14)];
  - c. The SOP for the nomogram used to determine the maximum volume of product yield for Source Plasma shows the value as [REDACTED] as opposed to the true value of 690ml [21 CFR 606.100(b)];
  - d. The record for microhematocrit timer checks shows the time period to be checked as [REDACTED] minutes, while routine testing occurs at [REDACTED] minutes [21 CFR 606.100(b)(14)];

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- e. During the blood collection procedure, in-process precautions are not always taken to ensure that an accurate quantity of blood is removed from the donor in that the investigator observed [REDACTED] overbleeds (quantities greater than the maximum allowed) in six donor charts reviewed [21 CFR 100(b)(5)].
2. Failure to adequately document donor suitability in that a disease state donor was allowed to donate [REDACTED] times within a [REDACTED] month period with an expired physician approval on file [21 CFR 640.63(c)].
3. Failure to assure that equipment performs in the manner in which it was intended [21 CFR 606.60(a)] in that:
  - a. Daily weight calibration tests for the autopheresis machines continuously failed to meet the [REDACTED] limit over a [REDACTED] year period. There was no documentation that management was aware of the problem and/or made appropriate corrections;
  - b. Daily refractometer calibration tests continuously failed to meet the [REDACTED] specification over a [REDACTED] year period. There was no documentation that management was aware of the problem and/or made appropriate corrections;
  - c. [REDACTED] of [REDACTED] quarterly timer checks for the microhematocrit centrifuges failed to meet the [REDACTED] minute [REDACTED] second limit. There was no documentation that management was aware of the problem and/or made appropriate corrections.
4. Failure to maintain appropriate quality control records for calibration/standardization of equipment [21 CFR 606.160(b)(5)(i)] in that:
  - a. There is no record to show that the one kilogram weight used to calibrate the autopheresis machines and manual collection scales is traceable to a known standard;
  - b. There is no documentation to show that donor thermometers are calibrated against a standard traceable thermometer;
  - c. There is no documentation to show that donor thermometers were calibrated monthly after December 1999.

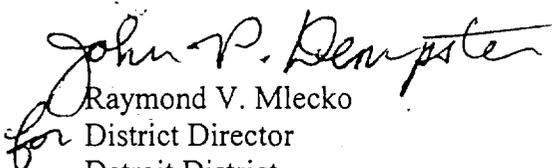
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your plasmapheresis facility is in full compliance with the Act and regulations promulgated thereunder. You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action against your firm without further notice. Such actions may include but are not limited to seizure, injunction, license suspension and/or revocation.

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

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

Sincerely yours,

  
for Raymond V. Mlecko  
District Director  
Detroit District