



DEPARTMENT OF HEALTH & HUMAN SERVICES

John E. Klemmer, C.O. 9-29-97
Public Health Service

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

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
97-DT-19

September 24, 1997

Luis N. Galup, M.D.
President and Responsible Head
South Bend Medical Foundation, Inc.
530 N. Lafayette Boulevard
South Bend, Indiana 46601

Dear Dr. Galup:

An inspection of your blood bank and testing facility was conducted on July 28 - August 11, 1997 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 Part 600 - 680). These deviations cause your licensed product, Whole Blood, to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), Section 501(a)(2)(B), as follows:

1. Failure to follow/maintain Standard Operating Procedures (SOPs) [21 CFR 606.100(b)] in that there are no written procedures for the reentry of Hepatitis B Surface Antigen (HBsAg) donors whose first donation is repeatably reactive, but negative for the confirmatory test and Hepatitis B Core, while the second donation is negative for Surface antigen, but repeatably reactive Hepatitis B Core (HBc).

2. Failure to promptly report errors and accidents that may affect the safety, purity, or potency of biologic products as required [21 CFR 600.14(a)] in that several incidents were not reported and/or were not promptly reported.

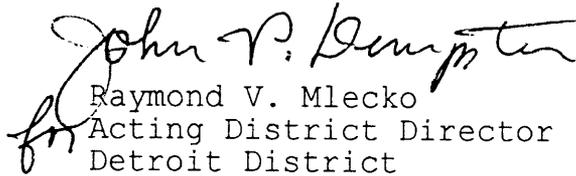
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your plasmapheresis center is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your 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, please state the reason for the delay, and the time in which the corrections will be completed.

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

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District

cc: Mrs. Mary Azvill, Director
Indiana State Department of Health
Acute Care Service Division
1330 West Michigan Street
P.O. Box 1964
Indianapolis, Indiana 46206-1964