



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTRAL REGION

*Revised by J. Drees
3/21/98
d18206
6/17/98*

Detroit District Office
1560 East Jefferson Avenue
Detroit, MI 48207-3179
TELEPHONE: 313-226-6260 ext. 178
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CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER

98-DT-08

April 14, 1998

Lee Ann Weitekamp, M.D.
Responsible Head
Michigan Community Blood Centers
1036 Fuller Avenue
Grand Rapids, Michigan 49503

Dear Dr. Weitekamp:

An inspection of your facility was conducted on March 25 - April 3, 1998 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 606 and 640 (21 CFR 606 and 640), and Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR Part 211). 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 provide written Standard Operating Procedures (SOPs)[21 CFR 606.100(b) (1) relative to donor deferral when information is discovered during the medical history review and/or subsequent to the donation that would require the deferral of a donor.:
2. Failure to adequately defer donors [21 CFR 640.3(b) and (c)] when information provided during the medical history review and/or subsequent to the donation indicates that a donor should be deferred.

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 center is in full compliance with the Act and regulations promulgated thereunder.

Warning Letter 98-DT-08
Michigan Community Blood Centers
Grand Rapids, MI 49501

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: Mr. James K. Haveman, Director
Michigan State Department of Community Health
Lewis Cass Building
320 S. Walnut Street
Lansing, Michigan 48913

Mr. Bob Ulieru, Director
Board of Pharmacy
Michigan State Department of Consumer & Industry Services
611 West Ottawa Street
P.O. Box 30670
Lansing, Michigan 48909