



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

John E. Klammes, C.O.
11-2-98
M21617

Detroit District Office
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October 30, 1998

WARNING LETTER
99-DT-01

David F. Keren, M.D.
Medical Director
Warde Medical Laboratory
5025 Venture
Ann Arbor, Michigan 48108

Dear Dr. Keren:

An inspection of your facility was conducted on September 10 – 15, 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). These deviations cause the products in which you assist in the manufacture 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 manufacturer's package insert in the performance of HbsAg, and HCV assays [21 CFR 606.65(e)];
2. Failure to follow standard operating procedures requiring documentation of incubation/read times and temperatures for anti-HCV, HbsAg, and anti-HIV-1/2 assays [21 CFR 606.100(b)(7); 606.160(a)(1)];
3. Failure to review records used to document kit lots, incubation times, and read times [21 CFR 606.100(c)];

4. Failure to maintain written procedures for receipt of incoming assay kits to include the review of the package insert, quality control of the incoming reagents, and the procedure for release of a new master lot for use [21 CFR 606.100(b)(14), and 21 CFR 606.100(c)];
5. Failure to document corrective action for out of range temperatures recorded for refrigerators and freezers [21 CFR 606.100(c)];
6. Failure to maintain raw data tapes for verification of linearity and drift tests for the [REDACTED] for a three month period [21 CFR 606.160(b)(5)(i); 21 CFR 606.160(c)].

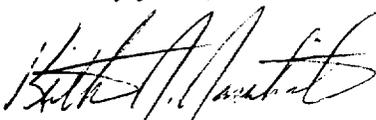
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your center is in full compliance with the Act and regulations promulgated thereunder.

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 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,


for Raymond V. Mlecko
Acting District Director
Detroit District