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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-40

April 7, 1997

Mr. Steven Swank, President
MD-HLP, Inc.
2113 Gulf Blvd.
Indian Rocks Beach, FL 33785

Dear Mr. Swank:

During an inspection of your facility at the above address on January 8 and 10, 1997, FDA Investigators Joan Norton and Ernest Clausnitzer determined that you distribute the Red Dot HIV 1+2 Diagnostic Test Kit for home use which is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This device is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) and neither you nor the device manufacturer have an approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g).

Additionally, this device is misbranded within the meaning of section 502 of the Act in the following aspects:

502(b) in that the device is in packaged form and it fails to bear a label containing the name and place of business of the manufacturer, packer or distributor; or an accurate statement of the quantity of contents;

502(f)(1) in that its labeling fails to bear adequate directions for use; and,

502(o) in that the device was manufactured, prepared, propagated, or processed in an establishment not duly registered under section 510, was not included in listing information required by section 510(j), and a notice or other information regarding this device was not provided to the FDA as required by section 510(k).

For your information, the only HIV test kits that have been approved for use in this country are those where the actual testing procedure is performed in a laboratory or a doctor's office.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to requirements of the Act and applicable regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please direct your reply to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, Ext. #262.

Sincerely,

Douglas D. Tolen/ekt

Douglas D. Tolen
Director, Florida District

cc: [redacted]