W1330N.pdf #FI-35 10/15/97

Food and Drug Administration

19900 MacArthur Blvd Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 7, 1997 WL-4-8

Tuan Pham
President
Phamatech
9265 Activity Road
Suites 112-113
San Diego, CA 92126

Dear Mr. Pham:

During an inspection of your facility conducted between June 27 to July 3, 1997, our investigators determined that your firm manufactures and distributes HCG Pregnancy and HBsAg tests. These are in vitro diagnostic products. Our investigation also determined that your firm also distributes another in vitro diagnostic product, specifically an HIV test primarily for export. All of these in vitro diagnostic products are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Some of your in vitro diagnostic test kits, such as the One-Step Test for HBsAg (Dipstick and Cassette), HIV Test, Strep A, Chlamydia, and H. pylori; Microwell Enzyme Immuno Assay for Carcino Embryonic Antigen (CEA), Prostate Specific Antigen (PSA), Alpha Fetoprotein (AFP), Human Growth Hormone (hGH), Follicle Stimulating Hormone (FSH), T3, T4, and Thyroid Stimulating Hormone (TSH) are adulterated under section 501(f)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that they are class III devices under section 513(f) and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) or approved applications for investigational device exemptions under section 520(g).

The HBsAg One-Step Test and HIV Test is misbranded under section 502(b) of the Act in that the device is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents.

The HBsAg One-Step Test and HIV Test is misbranded under section 502(f)(1) of the Act in that the labeling for the device fails to bear adequate directions for use.

The inspection also revealed that the devices have been exported in violation of section 801(e)(2) of the Act since the firm has not received permission from FDA to export the device and has failed to comply with the export requirements of section 802 of the Act. Specifically, the firm

must demonstrate that the export of the device is in compliance with the requirements of sections 802(b)(1)(A), 802(f), and 802(g) of the Act.

Some of your devices, such as the HIV Test, Strep A, Chlamydia, and H. Pylori; and Microwell Enzyme Immuno Assays for Carcino Embryonic Antigen (CEA), Prostate Specific Antigen (PSA), Human Growth Hormone (hGH), and Alpha Fetoprotein (AFP) and HIV Test, are misbranded under section 502(o) of the Act in that listing information for these devices has not been filed with FDA in accordance with section 510(j) of the Act.

Some of your devices, such as the One-Step Test for HBsAg (Dipstick and Cassette), HIV Test, Strep A. Chlamydia, and H. Pylori; and Microwell Enzyme Immuno Assays for Human Growth Hormone (hGH), Follicle Stimulating Hormone (FSH), T3, T4, and Thyroid Stimulating Hormone (TSH), are misbranded under section 502(o) of the Act in that a notice or other information respecting the device was not provided to the FDA as required by section 510 (k).

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

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken taken to identify and make corrections. 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.

Requests for Export Permits should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance (HFZ-307)
Division of Program Operations
Information Processing and Office Automation Branch
2098 Gaither Road
Rockville, MD 20850

Requests for Export Permits related to the HIV test Kits should be sent to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance
Division of Case Management, HFM-610
1401 Rockville Pike, Suite 200N
Rockville, MD 20852

Your reply should addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320