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9/9/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

August 29, 1997

WL-32-7

Wanjun Li
President
Biokwitech, Inc.
4204-L Sorrento Valley Blvd.
San Diego, CA 92121

Dear Dr. Li:

During an inspection of your manufacturing facility conducted between July 3 to July 9, 1997, our investigators determined that your firm manufactures and distributes a wide variety of in vitro diagnostic products. These in vitro diagnostic products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your in vitro diagnostic products, such as, HAV IgM Antibody EIA, HBeAB Antibody EIA, HBsAg Antigen EIA, HBsAb Antibody EIA, Quantitative HBsAb, HBcAb Antibody, HCV Antibody, HBs Antigen Strip Test, HBs Antigen Card Test, HIV 1/2 Antibody, Immunogold HIV 1/2, AFP, CEA, PSA, PSA Strip, PSA Card, Ferritin, IgE, Strep A Strip Rapid Test, Strep A Card Rapid Test, Cholerae Strip Rapid Test, and Cholerae Card Rapid Test, TSH EIA, T3 EIA, T4 EIA, hCG EIA, hCG, hCG Strip Rapid Test, hCG Card Rapid Test, LH Strip Rapid Test, LH Card Rapid Test, LH EIA, FSH EIA, Prolactin EIA devices are adulterated under section 501(f)(1)(B) of 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 exemption under section 520(g).

Your in vitro diagnostic products, such as, TSH EIA, T3 EIA, T4 EIA, hCG EIA, hCG, LH EIA, hCG Strip Rapid Test, hCG Card Rapid Test, Ferritin Test, IgE, Strep A Strip Rapid Test, Strep A Card Rapid Test, Cholerae Strip Rapid Test, and Cholerae Card Rapid Test, LH EIA, FSH EIA, Prolactin EIA, LH Strip Rapid Test, LH Card Rapid Test devices are misbranded under section 502(o) of the Act in that the devices were manufactured, prepared, and processed in an establishment not duly registered under section 510, were not included in a list required by section 510(j), and notices or other information respecting the devices were not provided to the FDA as required by section 510(k).

The inspection also disclosed that the devices may have been exported in violation of section 801(e)(2) of the Act since you have not received permission from the FDA to export the devices or failed to comply with the export requirements of section 802 of the Act. Specifically, you must

demonstrate that the export of the devices are in compliance with the requirements of sections 802(b)(1)(A), 802(f), and 802(g) of the Act. We have enclosed a packet of information on basic regulatory requirements.

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.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that 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 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.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to assure that each of the noted violations has been corrected. Your response should also include an explanation of the specific steps taken to prevent the recurrence of similar violations. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

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,

Robert W. Nicol

for 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

Enclosure