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Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

June 11, 2001

WARNING LETTER  
CHI-34-01

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Dr. Marius C. Teodorescu  
President and Chief Executive Officer  
TheraTest Laboratories, Inc.  
2201 W. Campbell Park Drive  
Chicago, IL 60612

Dear Dr. Teodorescu:

During an inspection of your firm, from February 12 to February 14, 2001, Investigator Tamara Brey determined that your establishment manufactures in vitro diagnostic kits. In vitro diagnostic kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.
2. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. For example, according to the Device Master Record for your EL-ANA Profile Jo-1 kits, the use of sterile water USP is required in the formulation of the kits. Investigator Brey observed that your firm uses "in-house" deionized water, filtered with a       $\mu\text{m}$  filter. Your firm does not test this "in-house" filtered water to assure it meets the requirements of sterile water USP.
3. Failure to establish and maintain procedures for implementing corrective and preventive action.

4. Failure to ensure that your Device Master Record is prepared and approved in accordance with 21 CFR 820.40, Document Controls. For example, the EL-ANA Jo-1 Antigen Kit Device Master Record has the following deficiencies:
  - 4.1 The approval of written procedures, including the date and signature of the individual(s) approving the documents, is not documented.
  - 4.2 The Device Master Record contains obsolete documents such as labeling revision, component list, and manufacturing forms.
5. Failure to establish and maintain procedures to control the design of devices in order to ensure that specified design requirements are met.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to establish medical device reporting procedures as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR Part 803.

We acknowledge receipt of your response, dated March 7, 2001, to our FDA-483, dated February 14, 2001. We have reviewed your response and find that it does not address the following concerns:

1. You have not shown that the use of "in-house" deionized water is equivalent to using sterile water, USP, which is required by the Device Master Record for the formulation of your products.
2. You have not explained how your firm intends to prevent similar violations from recurring.

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. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action with respect to your Quality System.

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. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

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We request that you 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, injunction, and/or civil penalties.

Please notify this office in writing within 30 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 to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer, at the above address.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director