



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1291B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

March 26, 1997

WL-18-7

Robert Chen
President
Cal-Test Diagnostics, Inc.
13781 Roswell Avenue, Suite C&D
Chino, CA 91710

Dear Mr. Chen:

During an inspection of your manufacturing facility conducted between February 11 to 12, 1997, our investigators determined that your firm manufactures and commercially distributes in-vitro diagnostic kits, including the "Red Dot HIV 1&2" human immunodeficiency virus (HIV 1&2) antibody test kits. The "Red Dot HIV 1&2" test kit is intended for use as a rapid membrane-based immunodiagnostic assay for detection of HIV 1&2 antibodies that may be performed outside a laboratory by any individual. Therefore, your "Red Dot HIV 1&2" test kit is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your "Red Dot HIV 1&2" test kit 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 you do not 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, the device is misbranded within the meaning of Section 502(o) in that the device was manufactured, prepared, or propagated, compounded, or processed in an establishment not duly registered under Section 510, was not included in a list required by Section 510(j), and a notice or other information respecting these devices were not provided to the FDA as required by Section 510(k).

In addition, all your 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, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to review, evaluate, and maintain written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device by a formally designated unit: and to investigate any complaint involving the possible failure of a device to meet any of its performance specifications [21 CFR 820.198]. For example, there is no established complaint handling system to ensure complaints are reviewed, evaluated and investigated. Our investigation disclosed there was no determination made by your firm to ascertain if an investigation was warranted concerning reported malfunctioning of your devices. Some complaints included written reports of "false positives" from users of the "Red Dot HIV 1&2" test kit and these complaints were not investigated.

2. Failure to prepare and maintain device history records including, or referring to the location of the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used, to demonstrate that the device was manufactured in accordance with the device master record [21 CAR 820.184]. For example, there are no device history records maintained for any of your in-vitro diagnostic products including your human immunodeficiency virus (HIV 1&2) antibody test kits.

3. Failure to maintain a device master record prepared, dated, and signed by a designated individuals for each type of device including, or referring to the location of device specifications including appropriate drawings, composition, formulation, and component specifications; and production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications; and quality assurance procedures and specifications including quality assurance checks used and the quality assurance apparatus used [21 CFR 820.181]. For example, there are no device master records for any in-vitro diagnostic products manufactured by your company including your human immunodeficiency virus (HIV 1&2) antibody test kits.

4. Failure to establish and control written manufacturing procedures and processing procedures to assure devices conform to their original design or any approved changes in the design [21 CFR 820.100]. For example, there are no written manufacturing specifications which assure that the design basis for your devices, components, and packaging are correctly translated into approved specifications. Additionally, there are no written procedures describing any processing procedures necessary to assure conformance to specifications for your devices.

5. Failure to establish and implement quality assurance procedures adequate to assure that a formally established and documented quality assurance program is performed [21 CFR

820.20]. For example, there are no written procedures to assure the review of production records; approval or rejection of all components, manufacturing materials, in-process materials, packaging materials, labeling, and finished devices, assuring that all quality assurance checks are appropriate and adequate for their purpose and are performed correctly. Additionally, there are no written audit procedures nor have any periodic audits ever been performed to verify compliance with the quality assurance program.

6. Failure to maintain any written documentation necessary to assure that employees have a thorough understanding of their jobs and responsibility [21 CFR 820.25]. For example, there is no documented evidence that any employees have received any training pertaining to their assigned duties.

Additionally, based on the deficiencies noted during our inspection, we have determined that export of your product at this time may be in violation of Section 802(f)(1) of the Act as the products have not been manufactured, processed, packaged or held in substantial conformity with the Good Manufacturing Practice (GMP) for Medical Device Regulation. In addition, if export of your product is desired in the future, you must comply with the requirements set forth in Section 802(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. 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 firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

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. Such actions includes, but is not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of the 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 actions cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. All corrective actions will be verified during reinspection of your facility.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
1990 MacArthur Boulevard
Irvine, California 92612-2445

Sincerely,

Elaine C. Messa

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814