



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

g1530d
Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-67

July 9, 2001

Ken M. Peters, President
World Diagnostics, Inc.
16250 N.W. 59th Avenue, Bldg.
Miami Lakes, Florida 33014

Dear Mr. Peters:

During an inspection of your firm located at 15271 N.W. 60th Avenue, Suites 107 and 201, on January 29 through February 1 and 5, 2001, FDA Investigator Bill Tackett, Jr. determined that you purchase and distribute the Smart Check TB, Smart Check Strep A, Smart Check Cotinine, Smart Check/Strip Opiates, Dengue IgM and IgG Double Spot, Anti-HAV IgM EIA, HIV Serum Plasma Double Spot, Fecal Occult Blood Slide Test, HIV 1 & 2 ELISA and other invitro diagnostic test kits, which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection determined that the IVDs referenced above are in domestic commerce because the IVDs are sold by your firm to distributors in the United States. Therefore, the IVDs are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f) of the Act, and there are no approved applications for premarket approval in effect pursuant to section 515(a), or approved applications for investigational device exemptions under section 520(g).

The exportation of Dengue IgM Double Spot, Anti-HAV IgM EIA to [REDACTED] and HIV 1 & 2 Antibody Elisa and HIV Serum Plasma Double Spot to [REDACTED] is also in violation of the FD&C Act. The requirements of section 801(e)(2)(C) are not met since you did not receive permission from the Food and Drug Administration to export the devices. In addition, the requirements of section 802(b)(1)(A) are not met since you did not obtain valid marketing authorizations in these countries or any listed country.

You are in violation of section 802(g) of the Act since you failed to comply with the requirements outlined in the Act, in that simple notification was not provided to the Secretary identifying the devices and the country to which such devices were being exported when the exporter first began to export the devices to a country not listed in Section 802(b)(1)(A)(i) or (ii) of the Act. For example, you ship to several unlisted countries such as [REDACTED] and [REDACTED]

Additionally, the in-vitro diagnostic test kits 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, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2) as follows:

1. Your firm failed to conduct internal quality audits as required by 21 CFR 820.22 (FDA 483, Item #1).
2. Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198 and no written MDR procedures have been established and maintained as required by 21 CFR 803.17. For example, missing inserts or reagents/components were not considered to be complaints, complaints are not received, reviewed, and evaluated by a formally designated unit, no evaluation was made of complaints related to repackaging and relabeling (FDA 483, Item #s 2, 15, 16, & 18).
3. Your firm failed to establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the quality system requirements as required by 21 CFR 820.20. Two members of your firm's quality management staff held the same responsibilities concurrently (FDA 483, Item #6).
4. Your firm failed to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. For example, only seven suppliers of [REDACTED] have been audited (FDA 483, Item #7).
5. Your firm failed to establish and maintain procedures to ensure that specified requirements for in-process or finished product are met and controlled until released as required by 21 CFR 820.80(c) and (d). For example, in-process and finished IVDs are not adequately segregated to ensure released product is separated from non-released product (FDA 483, Item #9).
6. Your firm failed to establish and maintain procedures for the control of storage and stock rotation to prevent mixups, damage, deterioration, and to ensure that no obsolete or rejected product is used or distributed as required by 21 CFR 820.150. For example, there was no procedure to assure that received product is rotated based on expiration date rather than date received (FDA 483, Item #10).
7. Your firm failed to establish and maintain procedures to control labeling activities as required by 21 CFR 820.120. For example, there was no review or verification that proper label procedures were followed and documented (FDA 483, Item #s 11 & 14).

8. Your firm failed to identify by suitable acceptance procedures that all products received conform to acceptance criteria as required by 21 CFR 820. 86. For example, no Certificate of Analysis is obtained for product dropped shipped to other distributors or customers (FDA 483, Item #s 3 &12).
9. Your firm failed to ensure that all inspection, measuring and test equipment is suitable for its intended use and capable of producing valid results as required by 21 CFR 820. 72. For example, there were no records documenting calibration and maintenance of monitoring and storage equipment (FDA 483, Item #19).
10. Your firm failed to establish and maintain procedures for control and distribution of finished devices to ensure that devices whose fitness for use or quality deteriorates over time, during shipping, or because of shipping conditions are not distributed as required by 21 CFR 820.160. For example, there are no procedures or controls in place to assure that temperature sensitive devices are not compromised during shipping and handling (FDA 483, Item #21).
11. Your firm failed to adequately train all personnel and keep training records current as required by 21 CFR 820.25(b). For example, personnel assigned to quality control, production, receiving and shipping were not aware of recent packaging changes (FDA 483, Item #13).
12. Your firm failed to establish and maintain adequate Device History Records (DHRs) as required by 21 CFR 820.184. For example, there were no DHRs generated from 1997 to August 2000 (FDA 483, Item #5).

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

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. The actions include, but are not limited to, seizure, injunction, and/or civil penalties. We are in receipt of your written response dated February 16, 2001 addressing the Inspectional Observations (FDA 483) issued to you during the inspection. We have reviewed your response and found it to be inadequate because it fails to provide specific corrective and preventive action and there is no documentation provided showing the specific corrections that have been established and are currently in use.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, 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; and (3) any corrections that cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please respond to Timothy J. Couzins, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,



Emma R. Singleton
Director, Florida District

cc: DRP Laboratories, Inc.
68 Hooper Hill Rd.
New Boston, NH 03070

AmeriTek, Inc.
7030 35th Avenue, N.E.
Seattle, WA 98115

Applied Biotech, Inc.
10237 Flanders Ct.
San Diego, CA 92121

Rapid Diagnostics, Inc.
1429 Rollins Rd.
Burlingame, CA 94010

Caldon Biotech, Inc.
2270 Camino Vida Roble #K
Carlsbad, CA 92009