



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 2, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-71

Leo Ehrlich, President and Chief Executive Officer
Saliva Diagnostic Systems, Inc.
419 Park Avenue South, Fourth Floor
New York, New York 10016-8410

WARNING LETTER

Dear Mr. Ehrlich:

We inspected your firm located at 11710 NE 95th Street, Suite G, Vancouver, Washington, on January 10-12, 2000. An investigator from the Food and Drug Administration (FDA) determined that your firm manufactures and distributes the Sero Strip[®] HIV-1/2, the Hema Strip[®] HIV-1/2, and the Saliva Strip[™] HIV-1/2 test kits. These test kits are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Inspection determined that the Sero Strip[®] HIV-1/2, the Hema Strip[®] HIV-1/2, and the Saliva Strip[™] HIV-1/2 test kits are in domestic commerce because the test kits are sold by your firm to distributors in the United States. Therefore, the Sero Strip[®] HIV-1/2, the Hema Strip[®] HIV-1/2, and the Saliva Strip[™] HIV-1/2 test kits 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 is no approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g). The inspection showed that the Sero Strip[®] HIV-1/2, the Hema Strip[®] HIV-1/2, and the Saliva Strip[™] HIV-1/2 test kits do not meet the requirements for either of the applicable export exemptions of the Act, sections 801(e)(2) and 802. As a result, the products may not be legally exported, and are fully subject to the Act and other requirements.

With respect to exportation of the devices, your firm is in violation of the Act as follows:

1. The exportation of Sero Strip[®] HIV-1/2 test kit, the Hema Strip[®] HIV 1/2 test kit and the Saliva Strip[™] HIV-1/2 test kit does not meet the requirements of the Act. These products are in domestic commerce, because your firm sells the test kits to distributors in the United States. Under section 801(e)(1)(D) of the Act, unapproved devices intended for export cannot be sold or offered for sale in domestic commerce.

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2. You have failed to comply with the requirements of Section 802(g) of the Act in that you did not submit a simple notification to the Agency prior to exporting the Sero Strip® HIV-1/2 test kit, the Hema Strip® HIV-1/2 test kit and the Saliva Strip™ HIV-1/2 test kit to several foreign countries including Lebanon, Equator, India, Romania and others.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your facility is in compliance with the provisions of the Act and all applicable regulations.

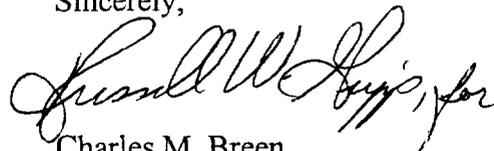
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Other Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may consider this information when awarding government contracts. Please be advised that requests for Export Certificates will not be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken or will take to correct or prevent these deviations. Your response should include your intentions with respect to the test kits that have been shipped in domestic commerce. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Additionally, please advise us of any action you have taken or plan to take to address the previously distributed products.

Your reply should be sent to Bruce W. Williamson, Compliance Officer at U. S. Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

FDA has many regulatory requirements pertaining to the manufacturing and marketing of medical devices. This letter addresses issues of premarket approval and export and does not necessarily address other requirements under the Act. Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of reporting corrections and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 800-638-2041 or through the Internet at www.fda.gov.

Sincerely,



Charles M. Breen
District Director

Enclosures:
Form FDA 483