DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

M1002N

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

**WARNING LETTER**

FLA-97-63

June 16, 1997

Nicholas G. Levandoski, Ph.D.
Acting President
Simplex Medical Systems, Inc.
430 Ansin Blvd., Suite G
Hallandale, Florida 33009

Dear Dr. Levandoski:

During an inspection of your firm located at 430 Ansin Blvd., Suite G, Hallandale, Florida, on March 19, 20, 25 & 31, 1997, FDA Investigator D. Janneth Caycedo determined that you manufacture/repack and distribute Saliva HIV Rapid Test Kits and Saliva HBsAg Rapid Test Kits which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act(the Act).

The Saliva HIV Rapid 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).

These devices have further been illegally exported in violation of section 802(f)(1) of the Act, since the FDA investigators documented serious violations that cause these devices to be adulterated within the meaning of section 501(h) of the Act.

Additionally, the HIV devices are misbranded within the meaning of section 502 of the Act in the following aspects:

502(b) in that the devices are in package form and fail to bear a label containing the place of business of the manufacturer, packer, or distributor; or an accurate statement of the quantity of contents;

502(f)(1) in that the labeling for both devices fail to bear adequate directions for use; and,

502(o) in that proper listing information has not been filed for either device.

The Simplex Saliva Hepatitis Rapid Test Kit device is adulterated under section 501(f)(1)(B) of the Act in that it is a class III device under section 513(f) and requires an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an approved application for investigational device exemption under section 520(g). The labeling for this device contains the following statement "02/27/97 For Research Use Only NOT FOR SALE IN THE UNITED STATES FOR EXPORT ONLY." However, performance characteristics and expected values for assay performance are provided, which are inappropriate or Research and Investigational Use labeling for in vitro diagnostic devices. FDA's Center for Devices and Radiological Health has determined that this is a class III, restricted device.

The Simplex Saliva Hepatitis Rapid Test Kit is misbranded under:

Section 502(b) in that the device is in package form and fails to bear a label containing the place of business oft he manufacturer, packer, or distributor; or an accurate statement of the quantity of contents;

Section 502(f)(1) of the Act in that the labeling fails to bear adequate directions for use in that it bears a claimed expiration date which in that such expiration date is not based on reliable, meaningful, and specific test methods as those described in 21 CFR 211.166, and required by 21 CFR 809.10;

Section 502(o) of the Act in that it is not included in a list as required by section 510(j); and,

Section 502(q) of the Act in that the labeling fails to provide prescription labeling for this restricted device.

Additionally, you are in violation of Section 802(g) of the Act since you have failed to comply with the requirements outlined in the statute, in that a 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)(I)(A)(i) or (ii) of the Act. For example, Simplex Saliva HIV Rapid Test Kits and Simplex HBsAg Rapid Test Kits were exported to Brazil on December 12, 1996, and February 25, 1997, respectively, without notification.

The inspection also disclosed that the devices have been exported in violation of Section 801(e)(2) of the Act since you did not receive permission from the FDA to export the devices or failed to comply with the export requirements of Section 802 of the Act. Specifically, you have not demonstrated that the export of the devices was in compliance with the requirements outlined in Section 802(b)(1)(A) of the Act.

Both devices are further adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage, or distribution of Saliva HIV Rapid Test Kits and HBsAg Rapid Test Kits are not in conformity with Current Medical Device Good Manufacturing Practices as specified in 21 CFR 820 and 809, as follows:

Saliva HIV Rapid Test and HBsAg Rapid Test:

1. Failure to test either finished devices or test kit components prior to inclusion in the finished kits or in lieu of testing receive a certificate of analysis from the manufacturer of the components (reagent test device and buffer solution).

2. Failure to establish or implement an adequate quality assurance program to provide adequate criteria for acceptance of components, assurance of proper approval/rejection of components manufactured under contract, or provide control over packaging and labeling operations.

3. Failure to establish adequate records (device master record, device history record) to document the repacking and labeling operations for each lot of test kits manufactured/repacked.

4. Failure to establish a stability program or to obtain data from the component manufacturer to support the expiration date listed on the test kits.

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 pending applications for premarket approval (PMA's) will be approved, no premarket notifications [510(k)'s]

will be found to be substantially equivalent, and no requests for Certificates for Exportability will be issued for products manufactured/repacked in the facility in which the above GMP violations were found 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 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 fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, 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; (3) the person responsible for effecting correction; and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your response should be sent to Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 262.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District