DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

# WARNING LETTER

**Via FEDEX**

Our Ref: 2954465

October 1, 1999

Farid Shirzadi, President
Sovo Tec Diagnostics, Inc.
526 Professional Center Drive
Novato, CA 94947

Dear Mr. Shirzadi:

During an inspection of your firm located in Novato, CA, conducted June 28 through June 30, 1999, our investigator determined that your firm repackages, labels, and distributes HIV 1/2 STAT-PAK ULTRA FAST and HIV 1/2 Whole Blood test kits for the detection of HIV antibodies. These test kits are devices within the meaning of 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The inspection determined that the HIV 1/2 STAT-PAK ULTRA FAST and the HIV 1/2 Whole Blood test kits are in domestic commerce because the test kits are sold by your firm to distributors in the United States. Therefore, HIV 1/2 STAT-PAK ULTRA FAST and HIV 1/2 Whole Blood test kits are adulterated within the meaning of 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 pre-market approval in effect pursuant to section 515(a), or approved applications for investigational device exemption under section 520(g). The inspection further showed that the HIV 1/2 STAT-PAK ULTRA FAST and the HIV 1/2 Whole Blood 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, these products may not be legally exported, and are fully subject to the Act and other requirements.

The HIV 1/2 STAT-PAK ULTRA FAST and HIV 1/2 Whole Blood test kits are also 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 current good manufacturing practice, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, Quality System Regulation for Medical Devices, as follows:

1. A Quality System is not established as required. Our investigator noted on the FD-483 that quality system requirements, including a quality policy, management responsibility and authority, quality audit reviews and documented procedures, have not been established. [21 CFR 820.20]

2. Procedures for identification of the product during all stages of receipt, production, and distribution are not established. During the inspection, the investigator noted that a bag of unlabeled recalled HIV diluent was placed beside a bag of unlabeled replacement diluent, creating the possibility of a product mix-up. [21 CFR 820.60]

3. Procedures to ensure that all received products conform to specified requirements are not established. You have not established a way of ascertaining that the products you receive meet your requirements or specifications. [21 CFR 820.80]

4. Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been established. There is no procedure that describes how to repackage your products and how to ascertain that the proper controls are carried out. [21 CFR 820.70]

5. Procedures are not established for the control of products that do not conform to specifications. In the event that product does not meet your specifications, you have no instructions for review and disposition of nonconforming product. [21 CFR 820.90]

6. Acceptance procedures for inspections, tests, or other verification activities are not established. [21 CFR 820.80]. You have no criteria established to identify the acceptance status of your products. [21CFR 820.86]

7. Quality systems records such as Device Master Records have not been established. You have no records establishing criteria for each product that you are repackaging including specifications, production methods, quality assurance procedures, and packaging and labeling methods. [21 CFR 820.181]

8. Quality systems records such as Device History Records containing dates of manufacture/repackaging, quantity released, acceptance records, primary identification label and labeling used and any control numbers used are not established. [21 CFR 820.184]

9. Complaint handling procedures are not established to ensure that all complaints are processed in a uniform and timely manner. [21 CFR 820.198]

In addition, repackaged HIV 1/2 STAT-PAK ULTRA FAST and HIV 1/2 Whole Blood test kits are misbranded under section 502 (o) of the Act in that they were repacked in an establishment not duly registered under section 510, and were not included in a list required by section 510(j).

Please note that the exportation of the HIV 1/2 STAT-PAK ULTRA FAST and HIV 1/2 Whole Blood test kits must comply with the export requirements in sections 801(e) and 802 of the Act. Specifically, an exporter must receive permission from the FDA to export the devices pursuant to section 801(e)(2) of the Act or demonstrate that the export of the devices is in compliance with the requirements of sections 802(b)(1)(A), 802(f), and 802(g) of the Act. You discussed some of these issues over the telephone with James Wyman and Andrea Scott of my office and you have indicated that you have obtained the information from the FDA Website (http://www.fda.gov/cdrh/devadvice/39.html) outlining the requirements.

We acknowledge receipt of the letter dated July 14, 1999 from Deborah Colby, Regulatory Affairs Manager, responding to the inspectional observations (Form FD 483) issued at the end of the inspection. We are unable, on the basis of that letter, to fully assess your firm's corrective measures. A follow-up

inspection will be required to assure that corrections are adequate. Additionally, we acknowledge receipt of your letter dated August 5, 1999, concerning your voluntary destruction of the remaining inventory of unapproved HIV test products. We would advise you that no product should be repacked at your facility until such time that all corrections have been made. The manual you requested, entitled Exporting Medical Devices, A Workshop Manual, is currently being revised and is not yet in print. Please refer to the above website for the most current information on exporting a medical device.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. You should examine your firm's operations and determine if such conditions apply to other products repacked and distributed by your firm. 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 FD-483 issued at the close out of the inspection may be symptomatic of serious underlying problems in your firm's 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.

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 devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Export Certificates 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 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 15 working days of receipt of this letter, of the specific steps you have taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should include your intentions with regard to the test kits that have been shipped in domestic commerce. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Andrea P. Scott, Acting Director, Compliance, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions, Ms. Scott's telephone number is (510) 337-6840.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro,
Director
San Francisco District