



DEPARTMENT OF HEALTH & HUMAN SERVICES

m276/n
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas Haendler
President
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763

July 6, 1999

Ref.: NYK-1999-51

Dear Mr. Haendler:

During an inspection of your firm located in Medford, NY, conducted between the dates of March 23 and April 16, 1999, our investigator determined that your firm manufactures and distributes HIV 1/2 STAT-PAK ULTRA FAST, a test kit for the detection of HIV antibodies. The test kit is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection determined that the HIV 1/2 STAT-PAK ULTRA FAST test kit is 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 test kits are 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) 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 further showed that the HIV 1/2 STAT-PAK ULTRA FAST test kit does 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's adulteration and other requirements.

The HIV 1/2 STAT-PAK ULTRA FAST 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. Failure to validate processes as required by 21 CFR 820.75. During the inspection our investigator observed that for processes, such as, the preparation of solutions, lamination of cassettes, printing of tests and control lines, cutting and filling of diluent and extraction bottles and assembly of cassettes, there was no established validation protocol nor complete validation data.
2. Failure to establish and maintain adequate procedures for changes to a specification, method, process, or procedure as required by 21 CFR 820.70(b). For example, there was no change order for the process change involving preparation of CGC impregnated HIV conjugate strips from immersion method to pipetting method. The device master record was not updated to reflect the change and consequently device history records, such as for lot HIV021098/2 do not record the actual process used.
3. Failure of the device master record (DMR) to contain, or refer to the location of, the production process specifications including appropriate equipment specification, production methods, production procedures, and production environment specifications as required by 21 CFR 820.181(b). For example, the device master record's list of revisions (pages to the DMR) fails to include the revision for the addition of the [REDACTED] printer.
4. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation as required by 21 CFR 820.30(i). For example, the Design Changes procedure, sec. 4.9, Section QSM-04 dated June 1998 does not adequately address how all design control requirements will be satisfied, including review, verification, validation, and approval of design changes before implementation, to ensure that the changes are appropriate for the design.

Additionally, relating to the exportation of the device, your firm is in violation of the Act as follows:

1. The HIV 1/2 STAT-PAK ULTRA FAST test kits which are exported are in violation of section 802(f)(1) of the Act, because they are adulterated within the meaning of section 501(h) of the Act as described above.
2. During the inspection, you provided the investigator with copies of what you claimed to be marketing authorizations for countries of [REDACTED] and [REDACTED]. Review of the documentation you provided demonstrates that they are actually import permits and not valid marketing authorizations. Based on your failure to establish either affirmative marketing authorization or that the HIV 1/2 STAT-PAK ULTRA FAST test can be legally sold in [REDACTED] or another listed country, the devices do not comply with the requirements for export in section 802 of the Act. Specifically, you have not demonstrated that export of the devices was in compliance with the requirements outlined in section 802(b)(1)(A) of the Act. In addition, the devices do not comply with section 801(e)(2) of the Act since you did not receive

permission from the Food and Drug Administration (FDA) to export the devices.

3. The HIV 1/2 STAT-PAK ULTRA FAST test kit is in domestic commerce contrary to section 801(e)(1)(D) of the Act, which sets forth one of the requirements for export under both section 802 and section 801(e)(2) of the Act, because the test kits are sold by your firm to distributors in the United States. During the inspection, documentation was collected of your draft EXPORT GUIDELINES AND PROCEDURES. CBER has reviewed this draft procedure and finds that it is in direct conflict with the FD&C Act section 801(e)(1)(D). Section 5.1, bullet 4 of Chembio's procedure, specifies that Chembio may offer (sell) the unapproved product to companies in the United States that are serving as exporters. Unapproved products for export cannot be sold or offered for sale in domestic commerce.

4. You are in violation of section 802(g) of the Act since you have failed to comply with the requirements for simple notification.

a) During the inspection you provided our investigator with a copy of your firm's letter dated January 21, 1998 addressed to FDA's Center for Devices and Radiological Health (CDRH). The letter identifies several foreign countries. The inspection determined that this notification did not include a listing of all countries to which your firm has exported the HIV 1/2 STAT-PAK ULTRA FAST test kits. In addition, since this product is a biological device, simple notification should be sent to FDA's Center for Biologics Evaluation and Research, rather than CDRH.

b) A simple notification was not provided to the Secretary identifying the device when the exporter began to export the device to any country listed in section 802(b)(1)(A)(i) or (ii). For example, no notification has been made for shipments of HIV 1/2 STAT-PAK ULTRA FAST to [REDACTED] on or about March 3, 1998, and to [REDACTED] on or about April 3, 1998.

c) A simple notification was not provided to the Secretary identifying the device and the country to which such device was being exported when the exporter first began to export a device to a country not listed in section 802(b)(1)(A)(i) or (ii). For example, no simple notification has been made for shipments of HIV 1/2 STAT-PAK ULTRA FAST to [REDACTED] on or about February 23, 1998, and to [REDACTED] on or about June 9, 1998.

We acknowledge receipt of the letter dated May 6, 1999 from Karen Keskinen, Quality Manager, responding to the Inspectional Observations (Form FDA 483) issued at the end of the inspection. A follow-up inspection will be required, however, to assure that corrections are adequate. We have the following comment with regard to process validation. The protocol submitted specifies that processes will be validated by studies involving one product as representative of others because processes are similar amongst the various devices manufactured. Since different products may have different performance specifications, your validation data must substantiate that a process can consistently produce a product meeting its specific performance specifications. The protocol also specifies that historical data will be used, but does not specify a

Chembio Diagnostic Systems, Inc.
page 4

procedure for such a retrospective review. Also, while your response indicates that all devices have been listed with FDA, CBER has informed us that the HIV 1/2 STAT-PAK ULTRA FAST test kit has not been listed. Please be advised that ALL devices must be listed with FDA.

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 relate to other products manufactured 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 FDA 483 issued at the close out 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.

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 Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

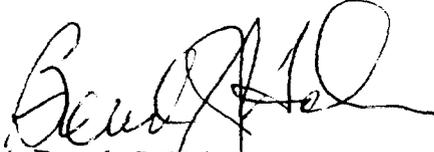
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to 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. Your response should include your intentions with regard to the test kits which 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 corrections will be completed.

Chembio Diagnostic Systems, Inc.
page 5

Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232. If you have any questions, Mr. Daurio's telephone number is 718-340-7000 x 5708.

Sincerely,



Brenda J. Holman
District Director