



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1508d

CERTIFIED MAIL
RETURN RECEIPT REQUEST

1990 MacArthur Blvd., Ste
Irvine, California 92612-24
Telephone (949) 798-7600

WARNING LETTER

July 12, 2001

Raymond L. Hsaio, M.D.
President
Panatrex, Inc.
1648 Sierra Madre Circle
Placentia, CA 92870

WL-63-01

Dear Dr. Hsaio:

During an inspection of your firm located in Placentia, California, on June 12 to 14, 2001, our investigator determined that your firm manufactures single and multiple use skin test applicators. Skin test applicators are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that these devices 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 manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, and control procedures to ensure that Device History Records for each production lot are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record and the Quality Systems regulation [21 CFR 820.184]. Specifically, your Device History Record(s) do not include the sterilization activities conducted on the devices, the quantity of devices manufactured, the quantity of devices released for distribution or the primary identification label and labeling for each device. These deficiencies were not isolated instances; our investigation determined that 11 out of 13 records examined by our investigator failed to disclose this relevant information and was not made part of the Device History Records nor was any reference made to the location where this documentation of the quality system activities could be located.
2. Failure to ensure that complete complaint files are maintained [21 CFR 820.198(a)]. Specifically, our investigation disclosed that your complaint handling procedures were not followed to ensure that all complaints are processed in a uniform and timely manner or that all complaints are reviewed and evaluated to determine whether an investigation is necessary. It was described to our investigator that all your internal complaint forms for the past twelve months had been destroyed.

3. Maintenance activities for production equipment, including the date and individual(s) performing the maintenance activities have not been documented [21 CFR 820.70(g)(1)]. Specifically, no documentation was maintained describing any maintenance activities conducted on your injection molding machines used in the production of your devices.
4. Failure to control procedures for identifying training needs to ensure that employees have been adequately trained to perform their assigned responsibilities [21 CFR 820.25(b)(1)]. Specifically, training activities are not documented.
5. Failure to designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of the Quality System Regulation [21 CFR 820.40(a)]. Specifically, your established quality system procedures and records are not dated nor signed by any authorizing official(s).

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. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. 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 pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability 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.

Additionally, our investigation disclosed the following conditions which are requirements of the Quality System Regulation:

- your firm has no documented evidence which provides a high degree of assurance that the manufacturing specifications and processing controls used in the injection molding manufacturing process for your devices will consistently produce a product meeting its pre-determined specifications and quality attributes, (traditionally termed validation);

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- acceptance procedures for the acceptance or rejection of finished device production runs have not been documented describing the number of devices rejected or the reason for rejection of any devices;
- devices that do not conform to specifications are not adequately controlled, Specifically, no evaluations of nonconforming products are conducted or documented.

While these above three cited activities were not delineated to your firm on the form FDA-483 issued or discussed with your firm's representatives at the exit interview, the events were described in the investigator's written narrative report and were discussed with your firm's representatives during the course of the inspection. These activities may present problems to your company and your devices.

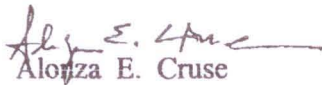
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,


Alorza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320