



May 25, 2004

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-11-04**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Timothy J. Homola, President  
Color Change Corporation  
1545 Burgandy Parkway  
Streamwood, IL 60107

Dear Mr. Homola:

During an inspection of your establishment located at the above-referenced address on January 6 & 7, 2004, our investigator determined that your firm manufactures Liquid Crystal Temperature Strips. This product is a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

The above-stated inspection revealed that this device is adulterated under section 501(h) of the Act [21 U.S.C 351(h)], in that the methods used in, or the facilities or controls used for its manufacturing, packing, storage, or installation is not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820.

The inspection also revealed that your firm failed to document its complaint handling procedures for receiving, reviewing and evaluating complaints as required in 21 CFR 820.198. You also failed to develop, maintain, and implement written Medical Device Reporting (MDR) procedures as required in 21 CFR 803 and have management with executive responsibility appoint and document the appointment of a management representative over the quality system as required in 21 CFR 820.20(b)(3).

At the close of the inspection, you were issued a Form FDA 483, which lists a number of GMP inspectional observations which include, but are not limited to, the following:

- Failure to establish its policy and objectives for commitment to quality and to ensure that the quality policy is understood, implemented and maintained, as required by 21 CFR 820.20(a). Specifically, the firm does not have an established quality policy.

- Failure to establish procedures to review the suitability and effectiveness of the quality system at defined intervals, as required by 21 CFR 820.20(c). Specifically, the firm does not have any documented management review procedures.
- Failure to establish procedures for conducting quality audits to ensure your quality system is in compliance. Quality audit and quality re-audits results are to be reviewed, documented, and dated by management having the responsibility for the matters audited as required in CFR 820.22. The firm does not have any documented quality audit procedures, and as such has not performed any documented quality audits.
- Failure to establish and maintain procedures to control the design of the manufactured devices in order to ensure that specified design requirements are met, as required in 21 CFR 820.30(a). The firm does not have any documented design control procedures for their Class II Liquid Crystal Forehead Temperature Strips.
- Failure to establish and maintain procedures for implementing corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a). The firm does not have any documented CAPA procedures in place for the manufacture of their Class II Liquid Crystal Forehead Temperature Forehead Strips.

We have received your letters dated December 22, 2003 and December 31, 2003. The letters addressed your response to the inspectional observations listed on the Form FDA-483, issued to you at the close of FDA's inspection conducted on December 5, 2003. In the letters, you promised to implement by February 2004, document change order procedures; a corrective action plan; and a new Quality System Manual covering design control for new products under development and design changes to current distributed devices. We cannot consider these changes as satisfactory until FDA verifies these changes have been implemented by re-inspection of your firm.

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 FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. In addition, 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.

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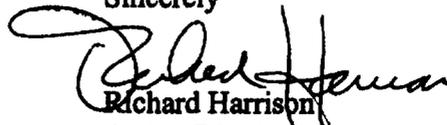
You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions may 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 prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Include all documentation of the corrective action you have taken.

Please send your reply to the attention of Matthew J. Sienko, Compliance officer, at the above address. If you have any questions regarding this letter, please contact Mr. Sienko at 312-596-4213.

Sincerely



Richard Harrison  
Acting District Director