



August 31, 2004

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

**WARNING LETTER**  
**CHI-18-04**

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

Mr. Sam G. Tripas, President  
G.T. Laboratories  
2007 John's Drive  
Glenview, IL 60025-1616

Dear Mr. Tripas:

During inspection of your firm from July 12 to July 15, 2004, United States Food and Drug Administration (FDA) investigators determined that your firm manufactures gas permeable contact lens blanks. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed 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, storage, or installation are not in conformance with the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm failed to monitor a production process to ensure that a device conforms to specifications as required by 21 CFR 820.70(a). For example, the final processing step (curing the contact lens blanks), is conducted after the devices are tested for compliance with the finished device specifications. Your firm did not document that this processing step has no adverse effect on the characteristics of the finished device as related to the device specifications.
2. Your firm failed to document acceptance activities as required by 21 CFR 820.80(e). For example, the raw data for the two device specifications of oxygen permeability (DK value) and hardness are not maintained.
3. Your firm's Device Master Record fails to include or refer to the location of production and process specifications and device specifications as required by 21 CFR 820.181. For example, the [REDACTED] dated 4/1/87, as contained in the Device Master Record, does not refer to the location of the document that describes how to calculate oxygen permeability (DK value) and does not contain the measurement for the thickness of test lenses that is currently being followed. Also, your firm's specification for the amount of inhibitor that may be present in the raw material [REDACTED] is not listed in the Device Master Record.

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a).
5. Your firm failed to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. For example, although your firm's "Audit Procedures" require an annual audit of your quality system, since 2001 your firm did not conduct such an audit.
6. Your firm's procedures for receiving, reviewing, and evaluating complaints failed to ensure that Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under Part 803 or 804 of this chapter, Medical Device Reporting, as required by 21 CFR 820.198(a)(3)

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, Inspectional Observations, issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You should promptly initiate permanent corrective and preventive action on your Quality System.

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. No premarket submissions for Class III devices, to which the QSR deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge receipt of your responses to the Form FDA-483, dated July 20, 2004. Although it appears from your responses that you are working toward correcting the deviations noted at your firm, you must adequately implement and maintain each corrective action to ensure its effectiveness. We will verify the adequacy of your corrective actions during a subsequent inspection.

Page 3

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 (1) the time frames within which the corrections will be completed, (2) any documentation indicating that the corrections have been achieved, and (3) 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 be sent to Michael Lang, Compliance Officer, Food and Drug Administration. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott J. MacIntire", with a long horizontal flourish extending to the right.

Scott J. MacIntire  
District Director