



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

51534a

60 8th Street, N.E.  
Atlanta, Georgia 30309

July 12, 2001

VIA FEDERAL EXPRESS

Norbert D. Thompson  
President  
Technical Products, Inc.  
2416 Park Central Boulevard  
Decatur, Georgia 30035

WARNING LETTER  
(01-ATL-60)

Dear Mr. Thompson:

An inspection of your facility was conducted on May 22-24, 2001, by Investigator Karen A. Coleman. Our investigator found that you continue to operate as a manufacturer, specification developer, and distributor of products such as silicone tubing, silicone rods, silicone sheeting, and foley catheters. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

You had failed to establish, implement, or maintain a quality system that was appropriate for the medical devices you manufacture. You had failed to even establish a basic quality system or address any of the current quality system requirements. Management with executive responsibility must establish its policy and objectives for, and commitment to, quality. You must also ensure that the quality policy is understood, implemented, and maintained at all levels of the organization. Management must appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over the quality system. Management must also review the suitability and effectiveness of the quality system at defined intervals to ensure that the quality system meets the Quality System Requirements and your established quality policy and objectives. You must establish quality system procedures and a quality plan that defines the quality practices, resources, and activities relevant to the devices that are manufactured and designed at your firm. You had a copy of the current Quality System Regulation but had failed to make a meaningful effort to apply these regulations to your current operations.

You failed to establish adequate procedures for conducting quality audits which would assure that your quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Although audits were conducted they failed to detect any of the significant deviations noted during the current inspection.

You failed to ensure that all personnel were adequately trained to perform their assigned responsibilities. You exhibited a complete lack of familiarity with the terminology associated with the Quality System Regulation. Key personnel at your firm exhibited a complete lack of understanding of some of the basic requirements of the QSR. You had made no attempt to keep your policies and employees current with the current requirements. This lack of understanding would directly impact upon your ability to create adequate new procedures, implement them appropriately, and adequately assess their suitability.

You failed to establish and maintain procedures to control the design of devices in order to ensure that specified design requirements are met. This is of particular concern as you are currently working on two new products. Without appropriate design control procedures and design change controls, it is virtually impossible to determine what changes have been made as the final design is completed. You had also failed to establish and maintain procedures for implementing corrective and preventive action.

Your complaint handling procedure failed to include directions on the handling or reporting of complaints under the Medical Device Reporting requirements. The complaint procedure also lacked any requirements for receiving, reviewing, evaluating and investigation of complaints. Several of your procedures were noted to have no documentation of the individual(s) reviewing and approving the procedures and when they became effective.

You could provide no documented evidence that the recommended cleaning and sterilization procedures for your Sil-Tec devices were effective or adequate. You had no data to support the claim that the product could be resterilized three times without any deleterious effect. These instructions are in your 2001 product brochure.

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. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge receipt of your June 7, 2001, response to the FDA 483. Our review of your response found it to be inadequate in a number of critical areas. The following comments are provided as a result of our review. Comments correlate to the specific item number on the FDA 483.

Item #1 – Your SOP #003 and Attachment A were not adequate to assure effectiveness of your firm's quality system and management review. The procedure concentrated solely on the review of procedures. The Quality System SOP's did not address review of their effectiveness. You should also review quality data information such as complaints, quality of incoming components, and finished product data. No procedures were available for conducting management reviews.

Item #2 – Your Quality Audit SOP #5 and attachments were completely inadequate. You must establish written audit procedures that provide enough detail to show specific questions and information needed to be covered for each section of your operation.

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 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.

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

Please notify this office in writing within fifteen (15) 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. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director  
Atlanta District