



DEPARTMENT OF HEALTH AND HUMAN SERVICES

D1306B
Food and Drug Administration
Atlanta District Office

HE-35

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

November 25, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Duane B. Hopper
President/CEO
Graphic Controls Corporation
189 Van Rensselaer Street
Buffalo, New York 14240

WARNING LETTER

Dear Mr. Hopper:

An inspection of your firm located in Rock Hill, South Carolina, was conducted on October 8-20, 1997. Our investigator found that you are manufacturing and distributing a variety of products for operating room use. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented several significant deviations from the Good Manufacturing Practice for Medical Devices (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These observations would also be violations of the Quality System Regulation, 21 CFR Part 820, which became effective June 1, 1997. These deviations cause the devices you manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to appropriately validate the packaging equipment and processes currently utilized to seal product prior to sterilization. You could not provide documented evidence which established a high degree of assurance that the current packaging processes were effective and the [REDACTED] Machine and [REDACTED] Sealers could consistently produce a product meeting its predetermined specifications and quality attributes. Your firm had failed to establish operating parameters for this packaging equipment. Our review of the qualification studies for all packaging equipment revealed serious deficiencies.

The qualification study performed on the [REDACTED] Machine was performed with no approved protocol prior to the initiation of the study. The study instructions and the summary of results were presented on a document signed on 11/4/96. There was no statistical rationale for the number of samples tested during the study or any indication that the sample size used was representative of a routine packaging run. The study lacked any defined acceptance criteria. No one at the firm was able to describe the difference between the functional peel and seal peel testing outlined in the study instructions. In addition, no one at the firm could define what the term average seal strength meant in the data. No formalized procedure was established on how the testing was to be performed. Documentation was not sufficient to determine when or how the samples had been sterilized prior to testing.

The [REDACTED] qualification studies included similar deficiencies such as no approved protocol prior to conducting testing, no statistical rationale for the sampling size used, and no defined acceptance criteria. Summaries of both studies indicated that the bags tore before the seals opened. The test method to be used stated that if the bags tore, the results would not be used to determine acceptance or rejection of the bags. Your management agreed that these packaging results should not have been used. Review of recent device history records indicates that the operating parameters assigned during the qualification study are not being used during routine production.

Similarly, no validation has been conducted of the process utilized for molded components and devices. No qualification has been performed on any of the [REDACTED] injection molding extruders at the firm to assess the adequacy of the operating parameters currently in use. No validation has been conducted of the manufacturing process for Magna Drapes which utilizes the [REDACTED] Machine. No studies have been conducted of the process to assure the adequacy of the temperature, dwell, and vacuum settings currently in use.

You failed to utilize the appropriate product as a dose setter in the quarterly gamma dose audits. The [REDACTED] were used as the dose setter in November 1996. The drapes were selected because of their density and they had been identified as the most difficult to sterilize product. If the same guidelines were followed, the quarterly dose audit in 1997 should have been performed with the same product as used in the original dose setting.

You failed to establish and maintain complaint procedures which would assure the processing of complaints in a uniform and timely manner. Complaint records were disorganized and failed to include all relevant information. The complaint handling procedure did not describe the manner in which complaints are received and routed to the appropriate manufacturing site. The complaint documentation and follow-up information was not clearly identified. No complaint records or complaint investigations were available for complaints received at the Rock Hill facility prior to January 1997. Trending information on complaints was only available for complaints received in the last four months. The failure to evaluate complaints in a timely manner was exemplified in Complaint #971534. This complaint was received on September 4 which involved an incident potentially reportable under the Medical Device Reporting Regulation. The complaint had not been evaluated when the inspection was concluded.

You failed to conduct an appropriate investigation into complaints involving failures of your device to meet its specifications. No investigation was conducted and no corrective action was documented for complaints of cracking Sharps containers. At least three cracking complaints had been received in the last three months (Complaints #971214, #971474, and #971573). No documentation was available to indicating that any follow-up or corrective action was taken after receipt of these complaints.

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 Inspectional Observations (FDA 483) was issued to and discussed with David Walker, Operations Manager. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could 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 submission of devices to which the GMP deficiencies are reasonably related will be cleared until these violations have been corrected. Also, no request 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 actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We are in receipt of the October 23, 1997 response from James M. Arganda, Regulatory Affairs Associate Manager, to the FDA 483. If the corrective actions discussed are implemented, they would appear to address the investigator's concerns. Please notify this office in writing within fifteen (15) days of receipt of this letter, of any additional 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. The above response stated that some of the commitments for validation would not be completed until January 1998. Please keep us updated to any changes in the proposed completion dates for the corrective actions promised. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

**cc: David Walker, Operations Manager
Graphic Controls Corporation
456 Lakeshore Parkway
Rock Hill, SC 29730**