



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

CPSC  
1/20 D1098B  
Food and Drug Administration  
Atlanta District Office  
HFI-35

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

January 15, 1997

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

William H. Wall, III  
President  
Wall Medical Inc.  
5139 Jimmy Carter Blvd., Suite 103  
Norcross, Georgia 30093

**WARNING LETTER**

Dear Mr. Wall:

An inspection of your medical device facility was conducted between November 22 and December 17, 1996. Our investigators 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, Part 820. These deviations cause your anesthesia extension tube products to be adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

You have failed to establish appropriate written procedures for finished device inspection to assure that all device specifications and requirements are met prior to release for distribution. Your anesthesia tubes are routinely released without pyrogen testing being performed. No written procedures had been established and no requirement had been implemented, that would assure that each lot of these products was tested for pyrogens prior to release. Each of these products includes the statement "Non-pyrogenic fluid path" on the package labeling. No pyrogen test records were available for any lot of any of the four products.

You have failed to establish if the written manufacturing specifications and processing procedures currently in place will consistently produce a product which meets its predetermined specifications and quality attributes. No validation data was available pertaining to the cap closure system which is utilized to maintain a sterile fluid pathway on your products. No studies were available to indicate if this closure system could provide an effective microbial barrier and maintain sterility in the fluid pathway.

You also had failed to assess the effect of subjecting your product to dual sterilization cycles. Four lots of extension tubes, lot numbers 60402A, 60504A, 60404A, and 60505A, were subjected to a double dose of irradiation exposure. No studies had been conducted to determine the potential effect of this level of exposure on the devices.

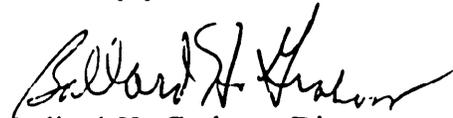
This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality 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 system 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 submissions of the 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 Exports 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. We are in receipt of your response dated January 9 to the FDA 483. That response is currently under review. 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 should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director  
Atlanta District