



June 5, 2001

**VIA FEDERAL EXPRESS**

Mr. Rodney Logan, President  
L & M Medical, Inc.  
8791 Main Street  
Leighton, AL 35646

**Warning Letter No. 01-NSV-31**

Dear Mr. Logan:

During an inspection of your liquid oxygen transfilling facility on May 8-11, 2001, our investigator documented deviations from the current Good Manufacturing Practice Regulations (cGMPs), Title 21, Code of Federal Regulations, Part 211, which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed: failure to assay each filled cryogenic vessel for identity and purity prior to release; failure to perform identity analysis on incoming bulk liquid medical oxygen; inadequate Standard Operating Procedures; no documentation of supervisory review of batch records; no Quality Control Unit; and, inadequate employee training in cGMPs.

The inspection also revealed that your cryogenic vessels failed to bear the required labeling. We are enclosing a copy of a proposed label for your use.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the current Good Manufacturing Practice Regulations. Until the violations are corrected, federal agencies will be informed that the Food and Drug Administration (FDA) recommends against the award of contracts for the affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (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 corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper  
Director, New Orleans District

Enclosures:

21 CFR 211  
Compressed Medical Gases Guidelines  
Proposed Oxygen Label

cc: Marvin H. Lowery  
Treasurer/Owner  
L & M Medical Inc.  
PO Box 458  
Leighton, AL 35646