



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

HFI-35  
Public Health Service

MJH5N  
Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

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

**WARNING LETTER**

FLA-99-36

February 19, 1999

Gerald H. Glickstein, President  
Supermed, Incorporated  
525 Shadow Lakes Boulevard  
Ormond Beach, Florida 32174

Dear Mr. Glickstein:

Inspection of your medical gas filling operation on February 9, 1999 by FDA Investigator Jose R. Rodriguez, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality and purity in that you have failed to test each component lot of bulk compressed medical oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not adequately tested for purity and identity prior to release for distribution. Testing is inadequate in that the [REDACTED] oxygen analyzer used by your firm is not being calibrated properly as specified by the manufacturer. For example, a nitrogen standard is not being used to "zero" the analyzer. In addition, records documenting calibration and maintenance of the analyzer are not maintained.

Written procedures are not established for all production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for receipt of components, calibration and maintenance

of equipment, analytical testing, labeling, complaints, recalls, record keeping, or training of personnel. Your established written procedures for oxygen transfilling are incomplete and inadequate. For example, according to the procedures, there is no need to monitor filling temperature, purity test must be performed on 4% of all cylinders filled, and after all procedures are complete the batch records are to be filled in completely in lieu of as performed. In addition, the calibration procedures specified for the oxygen analyzer are not in accordance with the manufacturer's instruction. These written procedures also fail to identify the person(s) who wrote, reviewed, and approved the procedures, or specify implementation dates.

Batch production records are incomplete and fail to document that each significant step in the manufacturing operation was performed, for example, all required pre and post fill cylinder inspections and tests. Batch records fail to document prefill vacuum, fill temperature and pressure, and post fill purity and identity testing. In addition, unique lot numbers are not assigned to filled cylinders of compressed medical Oxygen USP produced from each uninterrupted filling sequence and there is no documentation that batch records are reviewed by a supervisor prior to release for distribution.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

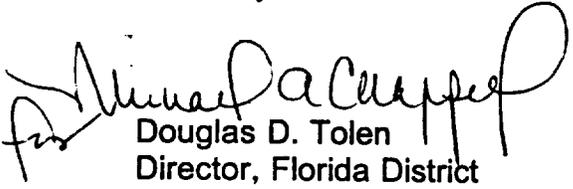
In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as president to ensure that all medical gas products you repack and distribute are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen  
Director, Florida District