



mSDR

January 12, 2001

VIA FEDERAL EXPRESS

Mr. Andrew P. Simmons, Sr.
President/CEO
Cornerstone Medical Inc.
7878 Roswell Road, Suite 100
Atlanta, GA 30350

*Quoted 1/12/01
JSA*

Warning Letter No. 01-NSV-10

Dear Mr. Simmons:

During an inspection of your medical oxygen transfilling facility located at 9694 Madison Boulevard, Madison, Alabama, on December 8 and 11, 2000, our investigator documented deviations from the Good Manufacturing Practice Regulations (GMPs), 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 a failure to verify certificates of analysis received from your supplier, no Quality Control Unit, no supervisory review of production records, no employee training in GMPs, incomplete Standard Operating Procedures and no master label in your master production and record file.

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 Good Manufacturing Practice regulations. Until the violations are corrected, federal agencies will be informed that 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 corrections will be completed.

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

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:JEH:man

Enclosures:

FDA 483
21 CFR Part 211
Compressed Medical Gases Guidelines

Cc: Larry S. Snyder
Branch Manager
Cornerstone Medical, Inc.
9694 Madison Blvd., Suite A-8
Madison, AL 35758