



520 8/20/97  
Food and Drug Administration  
Nashville District Office

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

297 Plus Park Boulevard  
Nashville, TN 37217

August 12, 1997

**CERTIFIED-RETURN RECEIPT REQUESTED**

Mr. Stewart Pace  
Executive Vice President  
Med-South, Inc.  
406 Medical Center Drive  
Jasper, AL 35501

**WARNING LETTER - 97-NSV-07**

Dear Mr. Pace:

During an inspection of your medical oxygen transfilling facility located at 1416 South Beltline Highway, Mobile, AL on July 11, 14 and 22, 1997, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 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.

Our inspection revealed a failure to verify certificates of analysis received from your supplier, failure to calibrate your ~~Analyzer~~ Analyzer with a certified oxygen gas, incomplete production records and inadequate standard operating procedures.

The inspection also revealed that your facility at 1416 South Beltline Highway, Mobile, AL was not currently registered with the Food and Drug Administration. We are enclosing registration forms 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 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.

**Mr. Stewart Pace - Page 2**

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

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

Sincerely,

Raymond K. Hédblád  
Director, Nashville District

RKH/kl

**Enclosures:**

FDA 483  
21 CFR Parts 210 and 211  
Compressed Medical Gas Guidelines  
Form FDA 2656 - Registration of Drug Establishment  
Instruction Booklet

cc: Kendall W. Miller  
District Sales Manager  
Med-South, Inc.  
1416 South Beltline Highway  
Mobile, AL 36693

bcc: HFA-224                    HFD-300                    HFR-SE1(J.Turner)  
BDS/DIB(Tracking)            W/L File(CB)                MBL-RP  
HFC-210(CFN 1062550)        HFI-35(Purged)              WL/CB(Purged)  
EI File                                    JEH                                    RF(2)