



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service JEH

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Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

March 23, 2001

Mrs. Alicia Moore, President  
Pioneer Express Respiratory  
Care Incorporated  
1300 Greenleaf Road  
Coldwater, MS 38618

Warning Letter No. 01-NSV-19

Dear Mrs. Moore:

During an inspection of your oxygen gas repacking facility on February 28 and March 1, 2001 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 that standard oxygen and nitrogen gases were not used to calibrate your ~~oxygen gas repacking facility~~ resulting in oxygen cylinders being released since 1994 with improper assays, no Quality Control Unit, incomplete batch production records, no label controls, no calibration of equipment used in your repacking operation, and no written Standard Operating Procedures.

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.

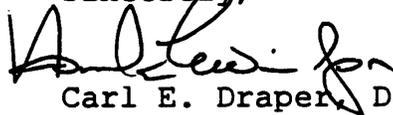
Please notify this office in writing, within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

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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 addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper, Director  
New Orleans District

CED/k1

Enclosures:

21 CFR Part 211  
Compressed Medical Gases Guidelines