



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m4159n
Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

August 30, 2000

Quap
9/7/00
JBR

CERTIFIED – RETURN RECEIPT REQUESTED

Mr. Gordon M. Woodard, President
Appalachian Medical Equipment Co. Inc.
4050 Highway 67 West
Mountain City, TN 37683

Warning Letter No. 00-NSV-22

Dear Mr. Woodard:

During an inspection of your oxygen gas repacking facility on June 13-14, 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 the failure to perform all of the required fill and post-fill tests on high pressure cylinders, inadequate Standard Operating Procedures, incomplete batch records, and inadequate compressed gas label reconciliation.

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 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 the corrections will be completed.

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

Sincerely,



Howard E. Lewis
Acting Director, New Orleans District

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Enclosures

21 CFR Part 211
Compressed Medical Gases Guidelines
Proposed Liquid Oxygen label