



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M3550n
Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

March 9, 2000

*Purged
JEH*

CERTIFIED MAIL—RETURN RECEIPT REQUESTED

Mr. Jerome H. Dodds, Owner
Home Care Medical Equipment, Inc.
614 Alcorn Drive
Corinth, MS 38834

Warning Letter No. 00-NSV-11

Dear Mr. Dodds:

During an inspection of your oxygen gas repacking facility on February 10-11, 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 that standard oxygen and nitrogen gases were not used to calibrate your ~~_____~~ resulting in oxygen cylinders being released since 1996 with improper assays, no batch production records for 27 released oxygen cylinders and incomplete batch production records for other released cylinders, no calibration of equipment used in your repacking operation, no Quality Control Unit, no employee training in GMPs, no label controls 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.

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, TN 37217.

Sincerely,



Lawrence A. D'Hoostelaere, Ph.D.
Acting Director, New Orleans District

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Enclosures:

21 CFR Part 211
Fresh Air "99"