



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

D1258 B

297 Plus Park Boulevard
Nashville, TN 37217

*Guarjed 3/12/97
JEH*

March 12, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. James Edward Johnston
President
Ed Medical, Inc.
106A Freehill Road
Hendersonville, TN 37077

WARNING LETTER - 97-NSV-02

Dear Mr. Johnston:

During an inspection of your oxygen gas repacking facility on February 20-21, 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 the release of at least 24 lots of medical oxygen with no documentation of purity and identity testing being performed, no supervisory review of records, inadequate GMP training of firm's personnel, no documentation of the calibration of the [REDACTED], and the pumper employee did not zero the analyzer as required by the manufacturers operating instructions.

The inspection further revealed the equipment used in the repacking operation had not been calibrated, you had failed to perform purity and identity assays on each individual cryogenic home unit filled at your firm, your batch production records and written standard operating procedures were inadequate and incomplete, and there was no label accountability.

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.

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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 corrective action 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,



Raymond K. Hedblad, Director
Nashville District

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Enclosure: Compressed Medical Gas Guidelines