



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
287 Plus Park Blvd.
Nashville, TN 37217

August 5, 1999

August 8/6/99
JEM

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. Ronald C. England, President
RCS Home Medical Equipment, Inc.
739 Cosby Highway
Newport, Tennessee 37821

WARNING LETTER - 99-NSV-20

Dear Mr. England:

During an inspection of your medical oxygen transfilling facility located at 739 Cosby Highway, Newport, TN, on July 13-14, 1999, our investigators 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 record the readings from the calibration of your ~~calibration records~~, inadequate Standard Operating Procedures, incomplete batch production records, no label accountability, failure to calibrate thermometers and pressure gauges, and a failure to conduct a post fill odor test.

Your medical oxygen units should also meet all of the labeling requirements described in the enclosed Fresh Air "98" document including a "Rx Only" statement and an emergency use statement "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only". The label should also bear the statement "Produced by Air Liquefaction" as required by the United States Pharmacopoeia.

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.

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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

RKH/k1

Enclosures:

21 CFR Parts 210 and 211
Fresh Air "98"
Oxygen - USP 23 page 1135