



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

D1297B

297 Plus Park Boulevard
Nashville, TN 37217

March 28, 1997

Carroll
3/28/97
JLH

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. J. Trent Messick
Division President
Housecall Medical Resource, Inc.,
dba/Messick Homecare, Inc.
307 Hickerson Drive
Murfreesboro, TN 37129

WARNING LETTER 97-NSV-04

Dear Mr. Messick:

During an inspection of your oxygen gas transfilling facility located at 1350 Cedar Lane, Tullahoma, TN, on March 18 and 20, 1997, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211), which cause your liquid medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The inspection revealed your firm to utilize an oxygen analyzer, ~~model~~, to perform purity and identity testing which is not equal to or better than the USP Method and your firm failed to properly collect the test samples. There are no batch records, documentation of purity/identity assay, labeling and lot numbers assigned for individual home cryogenic units filled at your firm. There is inadequate supervision of the oxygen transfilling operation and employees are not adequately trained in Good Manufacturing Practice Regulations. In addition, your Standard Operating Procedures were inadequate, lot numbers were not traceable to fill records and scales used in your oxygen transfilling operations were not calibrated.

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.

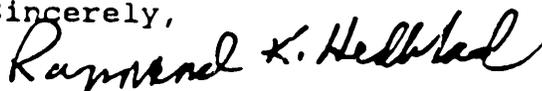
Mr. J. Trent Messick - Page 2

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:

FDA-483
21 CFR Part 210 and 211
Compressed Medical Gas Guidelines

cc: Daniel J. Kohl
President and Chief Executive Officer
Housecall Medical Resources, Inc.
1000 Abernathy Road
Building 400, Suite 1825
Atlanta, GA 30328

cc: Sherri L. Morton
Branch Manager
Housecall Medical Resources, Inc.
dba/Messick Homecare, Inc.
1350 Cedar Lane
Tullahoma, TN 37388