



**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-29

January 28, 1999

Harry Levey, President  
All Medicare Home Aids, Inc.  
3400 S.W. 26th Terrace  
Fort Lauderdale, Florida 33312

Dear Mr. Levey:

Inspection of your medical gas filling operation on January 11-12, 1999 by FDA Investigator Jennifer M. Donzanti, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality and purity in that you have failed to adequately test each lot of bulk oxygen received to determine conformance with appropriate specifications prior to use, and you have failed to adequately test refilled cylinders of compressed medical Oxygen USP for purity and identity prior to release for distribution. Testing is inadequate in that certificates of analysis are unavailable for the oxygen and nitrogen calibration standards being used to calibrate your oxygen analyzer. Therefore, proper calibration of the analyzer prior to testing is not possible causing your test results to be invalid.

You have failed to establish written procedures for calibration of vacuum gauges and thermometers, training of personnel, and for the responsibilities and procedures applicable to your quality control unit. No documentation is available to show that vacuum gauges and thermometers have ever been calibrated or that personnel have been trained in the duties they perform. Your written procedure for label reconciliation is not being followed. We note that your established written procedures fail to specify implementation dates and do not identify the person(s) who wrote, reviewed, and approved the procedures.

Batch production records are incomplete and fail to document that each significant step in the manufacturing operation was completed. For example, unique lot numbers are not assigned to filled cylinders of compressed medical Oxygen USP produced from each uninterrupted filling sequence, ditto marks are used to record information in lieu of actual data for pressure, temperature and purity, test results for purity are repeatedly recorded as 100%, and there is no documentation the batch records are reviewed by a supervisor prior to release for distribution.

Review of labeling used on cylinders of compressed medical Oxygen USP filled by your firm reveals the products to be misbranded within the meaning of Sections 502(b)(2) of the Act in that labels fail to bear an accurate statement of the quantity of contents. With respect to this violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen USP in liters at 70° F (21.1° C) and one atmosphere.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as president to ensure that all medical gas products you repack and distribute are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,

  
Douglas D. Tolen  
Director, Florida District