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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-90

August 29, 2000

Julie Campbell, Director of Durable Medical Equipment
Medical Center Home Health Care Services, Inc.
1660-12 North Monroe Street
Tallahassee, Florida 32303

Dear Ms. Campbell:

Inspection of your medical gas filling operation located at 1408-D Capital Circle NE, Tallahassee, Florida on August 9, 2000, by FDA investigator Paul L. Figarole, 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 liquid medical Oxygen USP 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 incoming bulk liquid Oxygen USP vessels are not certified to meet the USP testing requirements for purity and identity. No documentation is available to show that purity and identity testing of bulk liquid oxygen performed by your supplier is witnessed and no identity testing is conducted. Transfilled cryogenic vessels of liquid medical oxygen are not being adequately tested for purity and identity before release for distribution. No testing equipment is available at your facility to perform purity and/or identity testing of your medical oxygen products.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality and purity they are represented to possess. For example, no written procedures are established for receipt and acceptance of incoming bulk liquid oxygen, purity and identity testing, prefill inspections, completion of batch records, review of production records, labeling, quarantine procedures, training of personnel and quality control.

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Batch production and control records for cryogenic vessels filled by your firm are not maintained documenting that each significant step in the manufacturing operation was accomplished, for example, pre and post fill cryogenic vessel inspections and tests.

Review of labeling used on cryogenic vessels of liquid medical Oxygen USP filled by your firm reveals the products to be misbranded within the meanings of Sections 502(a), 502(b)(1) and 502(b)(2) of the Act. Labels bear the unqualified name and place of business of other firms, such as Sunrise Medical, Caire, Inc., and Medical Product Services, in addition to the name of your firm, which fails to include your place of business. In addition, the labels also fail to bear an accurate statement of the quantity of contents. The contents of cryogenic vessels should be expressed in pounds or liters.

Other Federal agencies are routinely advised of Warning Letters issued and they may take this information into account when considering the award of government 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 to ensure that all medical gas products you repack and distribute comply 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 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including any documentation showing that corrections have been achieved. 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.

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

Sincerely,

Edward R. Atkins for

Emma R. Singleton
Director, Florida District