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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-97-69

June 27, 1997

Jimmy H. Halim, Owner
West Florida Home Health Care
205 Airport Road
Panama City, Florida 32405

Dear Mr. Halim:

Inspection of your medical gas filling operation on April 15, 1997, by FDA Investigator A. Blake Beville, revealed serious violations of the Federal Food, Drug, and Cosmetic Act. The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with your firm's 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 that there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you fail to test refilled cylinders of compressed medical Oxygen USP for identity and purity prior to release for distribution. The oxygen analyzer used by your firm is not being calibrated with gases of known purity each time prior to use. Batch history records are not completed for all refilled cylinders of compressed medical Oxygen USP. The lot numbering system used by your firm is not based upon an uninterrupted filling sequence which allows for several days production by different employees to have the same lot number.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm revealed the products to be misbranded within the meaning of Section 502(a) of the Act in that some cylinder labels bear the unqualified name and place of business of other firms, such as [redacted] and [redacted], in addition to your firm's name and place of business. Except as provided in 21 CFR 201.1(h)(1), no person other than the manufacturer, packer, or distributor may be identified on the label of a drug product. As the refiller, your firm is considered to be the manufacturer. Therefore, only your firm's name and place of business should appear on the label. The products are further misbranded within the meaning of Section 503(b)(4) of the Act in that labels fail to bear the statement "Caution: Federal law prohibits dispensing without prescription."

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 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.

You should 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, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,



Douglas D. Tolen
Director, Florida District