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VIA FEDERAL EXPRESSFood and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, Fl 32751WARNING LETTER

FLA-99-91

September 22, 1999

Michael I. Pass, Owner  
Family Healthcare Supply, Inc.  
3672 Webber Street  
Sarasota, Florida 34232

Dear Mr. Pass:

- Inspection of your medical gas filling operation on August 31, 1999, by FDA Investigator Karen G. Hirshfield, 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 and 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 you have failed to test each component lot of bulk compressed and liquid oxygen received to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders and cryogenic vessels of compressed and liquid medical Oxygen USP are not being tested for purity and identity before release for distribution.

You have failed to establish written procedures for all 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 the receipt and acceptance of incoming bulk oxygen, completion of batch production records, maintenance of equipment, labeling, handling of complaints, recalls, employee training, or supervision. Your established written procedures are inadequate and/or incomplete and fail to specify who wrote the procedures, approved the procedures, and implementation dates.

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Batch production and control records are not maintained documenting that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. In addition, batch records fail to identify the individual who performed the filling operation and no documentation is available to show that batch records are reviewed and approved by a supervisor prior to release for distribution. Records documenting calibration and maintenance of your oxygen analyzer are not maintained, required battery and filter checks are not being performed, and no certificate of analysis is available for the Nitrogen reference standard used to calibrate the device.

Review of labeling used on cryogenic vessels of liquid medical Oxygen USP filled by your firm reveals the products to be misbranded within the meaning of Sections 502(b)(1), 502(b)(2), and 503(b)(4)(A) of the Act. Labels bear the unqualified name and place of business of another firm (██████████) in addition to the name and place of business of your firm. 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. Labels also fail to bear an accurate statement of the quantity of contents and a statement "Caution: Federal law prohibits dispensing without prescription" or at a minimum "Rx Only". With respect to the 502(b)(2) and 503(b)(4)(A) violations, the contents of cryogenic vessels may be expressed in pounds or liters, and only medical oxygen used for emergency resuscitation is allowed to be dispensed without a 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.

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The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As owner, 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 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.

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,



Douglas D. Tolen  
Director, Florida District