



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

d1824b

**Food and Drug Administration**  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-98-49

May 12, 1998

Nourdine Bouhamid, President  
Premier Home Medical Inc.  
406 N. Indiana Avenue, #5  
Englewood, Florida 34223

Dear Mr. Bouhamid:

Inspection of your medical gas filling operation at Premier's Englewood location on April 6-9, 1998, by FDA Investigator Shari J. Hromyak, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, 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 test at least one cylinder of Oxygen USP from each uninterrupted filling sequence for purity and identity prior to release for distribution. The oxygen analyzer used by your firm is not being calibrated properly as specified by the manufacturer. No certified oxygen standard of known purity is available to verify the accuracy of the analyzer, and calibration records are not maintained.

Established written procedures 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 are not being followed. For example, written procedures in your respiratory service manual for transfilling oxygen, training or personnel, label control, and assignment of lot numbers are not being followed.

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Batch production and control records are not maintained documenting that each significant step in the manufacturing operation was accomplished. For example, pre and post fill cylinder inspections and testing records are not maintained. The investigator also documented batch production records with recorded test results for prefill, fill and post fill tests of cylinders that were not performed by your transfilling employee. No documentation is available to show that personnel have received adequate CGMP training, and no documentation is available to show that batch production and control records are reviewed and approved by a supervisor prior to release for distribution.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm reveals the products to be misbranded within the meaning of Sections 502(a), 502(b)(1) and (2), 502(e)(1)(A)(i), 502(f)(1) and (2), and 503(b)(4) of the Act. Some labels bear the unqualified names and places of business of other firm's, such as Northern AirGas, John Nageldinger & Son, and B&F Medical Products, in addition to the name of your firm, and some labels fail to bear the 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. Other labels fail to bear an accurate statement of the quantity of contents, the established name of the product as it appears in the official compendium (Oxygen USP produced by the air liquefaction process), adequate directions for use, adequate warnings against use, and the statement "Caution: Federal law prohibits dispensing without prescription".

With respect to the above referenced 502(b)(2) violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen U.S.P. in liters at 70° F (21.1° C) and one (1) 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 GMP 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. 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, 555 Winderley Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen  
Director, Florida District