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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-97-74

July 29, 1997

Donald J. Messemer, President
Palm Beach Respiratory Service, Inc.
d/b/a National Home Respiratory Service
1723 Costa Del Sol
Boca Raton, Florida 33432

Dear Mr. Messemer:

Inspection of your medical gas filling operation on July 1, 1997, by FDA investigator Philippe L. Noisin, 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 [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 each component lot of bulk compressed oxygen 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 of compressed medical Oxygen USP are not adequately tested for purity prior to release for distribution. The [REDACTED] Oxygen Analyzer used by your firm is not an acceptable test device for oxygen purity in that the accuracy of the device is $\pm 2\%$ which is not equivalent to the USP test accuracy of $\pm 0.1\%$.

During the filling of cylinders (serial numbers BC7643, BC0651, BC4631, BC12825, and BC7983) with medical oxygen, the investigator observed that you failed to perform significant steps such as performing an odor test, a leak test, pressure test and temperature reading of the cylinders. The investigator also observed a test procedure performed using the [REDACTED] Oxygen Analyzer where you subsequently obtained three different purity results; 100.3%, 100.0%, and 99.8% on a filled cylinder tested. The 99.8% result was recorded on your transfill log as the official test result without any documentation or justification for rejecting the first two results.

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 calibration and maintenance of equipment, labeling, handling of complaints, and training. Your established written procedure for cylinder filling and testing is inadequate in that it fails to provide instructions for completion of all required manufacturing steps in the transfilling operation, and there is no assurance that you have received adequate CGMP training.

Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. Results of oxygen purity tests documented in your batch production records are unreliable as reflected by the use of an unacceptable test device and our investigator's observations. No batch production records, dating prior to May 1997, were available for review by the investigator during the inspection.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm also 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. Four cylinders (serial numbers BC7643, BC0651, BC4631, and BC12825) filled with medical oxygen failed to bear any labels specifying the name of the product, adequate direction for use, and adequate warnings against use. One cylinder label bears the unqualified name of Mada Medical Equipment, in addition to the name of your firm, and fails to bear the place of business of your firm. Except as provided in 21 CFR 201.1(h), 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. Some cylinder labels also fail to bear the established name of the product as it appears in the official compendium (Oxygen USP produced by the air liquefaction process), an accurate statement of the quantity of contents, and if not distributed for emergency use, 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 USP 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 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. As president and owner, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of 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 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