



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-23

January 4, 1999

Mark J. Fiorenza, Owner
Sunshine Home Care Services, Inc.
101 State Road 7, #109
Margate, Florida 33063

Dear Mr. Fiorenza:

Inspection of your medical gas filling operation on November 24, 1998, by FDA Investigator Jennifer M. Donzanti, 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 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 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 of compressed medical Oxygen USP are not being tested for purity and identity 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 device is not equivalent to the USP test accuracy of $\pm 0.1\%$.

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, filling and testing of compressed oxygen, completion of batch production records, calibration and maintenance of equipment, labeling, quarantine procedures, handling of complaints, employee training, or supervision.

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. Unique lot numbers are not assigned to filled cylinders of compressed medical Oxygen USP produced from each uninterrupted filling sequence, and records documenting calibration and maintenance of equipment are not maintained.

Review of labeling used on cylinders of compressed medical Oxygen USP filled by your firm reveals the products to be misbranded within the meaning of Sections 502(a) of the Act in that labels bear the unqualified name and place of business of another firm (MADA INC.) 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.

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, 555 Winderly Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen
Director, Florida District