



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service

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JEW

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

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-97-41

April 8, 1997

Steven R. Muzzillo, President  
Redi Oxygen and Medical Supplies  
9937 Pines Boulevard  
Pembroke Pines, Florida 33024

Dear Mr. Muzzillo:

Inspection of your medical gas filling operation on March 14 and 21, 1997, by FDA investigator Clara E. Santiago, 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 Regulations, 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 refilled cylinders of compressed medical Oxygen USP are not being tested for purity and identity prior to release for distribution. During the inspection, the investigator observed your [REDACTED] Oxygen Analyzer to be unplugged and stored on a shelf during a filling operation. There is no documentation available to show that the analyzer is being calibrated properly as specified by the manufacturer, and the calibration gases required to perform calibration of the analyzer are not available. Failure to properly calibrate your oxygen analyzer makes any determination of purity unreliable.

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 cylinder filling and testing, calibration and maintenance of equipment, labeling, handling of complaints, employee training, or supervision. 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. No documentation is available to show that batch records are reviewed and approved by a supervisor prior to release, and there is no assurance that personnel have been adequately trained.

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), 502(b)(1) and (2), 502(g), and 503(b)(4) of the Act. Some labels bear the unqualified name and place of business of other firms, such as Mada Medical Products and Veriflo Corporation, in addition to the name and place of business of your firm. Some labels fail to bear 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. If a distributor is named on the label, the name must be qualified in accordance with 21 CFR 201.1(h)(5). Other labels fail to bear an accurate statement of the quantity of contents, a statement that the Oxygen USP is produced by the air liquefaction process, 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 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. 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.

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,

  
for Douglas D. Tolen  
Director, Florida District