



**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-99-35

February 18, 1999

Don R. Millward, Administrator
Flagship Durable Medical Equipment
4200 Northwest 16th Street, #100
Lauderhill, Florida 33313

Dear Mr. Millward:

Inspection of your medical gas filling operation on January 25, 1999 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 causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The 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 adequately test refilled cylinders of compressed medical Oxygen USP for purity and identity prior to release for distribution. Testing is inadequate in that 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 not equivalent to the USP test accuracy requirement of $\pm 0.1\%$ and no documentation of testing is maintained.

Written procedures are not established 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 a quality control unit, calibration and maintenance of equipment, training of personnel, labeling, or recalls. No documentation is available to show that vacuum gauges and thermometers have been calibrated or that personnel have received training, including CGMP training, in the duties they perform. Your established written procedures for cylinder filling and testing are incomplete and are not being followed. These written procedures fail to identify the person(s) who wrote, reviewed, and approved the procedures, or specify implementation dates.

Batch production records are incomplete and fail to document that each significant **step** in the manufacturing operation was completed, for example, all required pre and post fill cylinder inspections and tests. Batch records fail to identify your firm, the **person** who filled the cylinders, or fill dates. In addition, unique lot numbers are not **assigned** to filled cylinders of compressed medical Oxygen USP produced from each **uninterrupted** filling sequence and there is no documentation that batch records are **reviewed** by a supervisor prior to release for distribution.

Review of labeling used on some cylinders of compressed medical Oxygen USP filled by your firm reveals the products are misbranded within the meaning of **Sections** 502(a), 502(b)(1) and (2), 502(e)(1)(A)(i), and 502(f)(1) and (2) of the Act. **Some** labels bear the unqualified name and place of business of another firm, such as **Nellcor Puritan Bennett**, 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. Some labels also 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 air liquefaction), adequate directions for **use**, and adequate warnings against use. Some cylinders are further misbranded **within** the meaning of Section 503(b)(4) of the Act in that labels fail to bear 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.

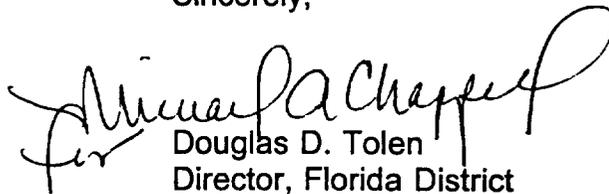
In order to facilitate the Food and Drug Administration (FDA) in making the **determination** that such corrections have been made and thereby enabling FDA to **withdraw** its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, 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 as president 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.

We request that you 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