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Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-97-70

June 27, 1997

Paul Frank, President
Frank's Pharmacy and Home Care
202 Southwest 17th Street
Ocala, Florida 34474

Dear Mr. Frank:

Inspection of your medical gas filling operation on May 15, 1997, by FDA Investigator José R. Rodríguez, 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 causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed that 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 adequately tested for purity and identity prior to release for distribution. Testing is inadequate in that there is no documentation to show that the [REDACTED] Oxygen Analyzer used by your firm for testing is calibrated properly as specified by the manufacturer, and there is no documentation of the testing performed.

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, written procedures are not established for calibration and maintenance of equipment, filling and testing of cylinders, issuance of lot numbers, labeling, handling complaints, training of personnel, or supervisory review. Batch production records are incomplete and fail to document that filled cylinders were properly tested prior to release. There is no documentation that batch records are reviewed and approved by a supervisor prior to release.

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 GMP 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.

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.

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,



Douglas D. Tolen
Director, Florida District