



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

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60 8th Street, N.E.  
Atlanta, Georgia 30309

December 2, 1996

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Roger L. Folsom, President  
Chancey-Folsom Inc.  
(dba) Med 1st  
1016 Claxton Dairy Road  
Suite 2C  
Dublin, Georgia 31021

**WARNING LETTER**

Dear Mr. Folsom:

An inspection of your medical oxygen transfilling facility was conducted on November 15, 1996, by Investigators B. Douglas Brogden and Jackie M. Douglas. Our investigators documented numerous significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal, Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include identity and purity, prior to release. Although the H cylinders used for transfilling are labeled as Oxygen USP, you could provide no other assurance as to the purity or suitability of these drug products. You could provide no analytical test results for any of the H cylinders utilized for transfilling. No Certificate of Analysis had been received for any incoming H cylinder. In addition, you could provide no documentation that any cylinder transfilled over the last year had been tested for purity or identity.

The required calibration steps were not performed on your ~~Analyzer~~ Analyzer each day of use. No calibration records for the analyzer were available and the required calibration standard had never been purchased.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that

it purports or is represented to possess. This training must be in the particular operations that the employee performs and include current good manufacturing practice as it relates to the employee's functions. In fact no one at the firm had received training commensurate with their responsibilities.

This lack of training was exemplified by your firm's total lack of compliance with the applicable regulations for the transfilling of Oxygen USP. You were not familiar with the appropriate quality control steps required for transfilling. Prefill and filling tests such as odor testing, leak testing, and checking of hydrostatic test dates were not being performed. You expressed a complete lack of understanding of any of the GMP or registration requirements for drug manufacturers.

You have failed to establish formalized written procedures to cover any of the various aspects of the transfilling operation. None of the required production records were maintained to document each significant step in the transfilling of this drug product. No records were available of the number of cylinders filled, the parent lot of oxygen used, the dates cylinders were transfilled, or any lot numbers utilized by your firm.

In addition, the label placed on the drug product transfilled to your cylinders is woefully inadequate. Your medical gas product is misbranded within the meaning of Section 502(f)(1) of the Act. Oxygen USP is a prescription drug and your label fails to bear adequate directions for use in accordance with 21 CFR 201.100(c). The requirement of 201.100 would be satisfied if your labeling met the requirements described in the Federal Register of March 16, 1972, (37 FR 5504) entitled "Oxygen and Its Delivery Systems, Proposed Statement of Policy". A copy of this policy is enclosed.

In addition, your product is misbranded in accordance with Section 502(b)(2) of the Act, in that its labeling fails to contain a statement of the quantity of the contents. Your product is also misbranded in accordance with Section 502(g) of the Act, in that its labeling fails to indicate if the oxygen has been produced by the air-liquefaction process.

In addition, your product is misbranded in accordance with Section 502(o) of the Act, in that the drug was transfilled in an establishment not duly registered under Section 510 and the drug has not been listed as required by Section 510(j). You were provided registration and listing forms by the investigators.

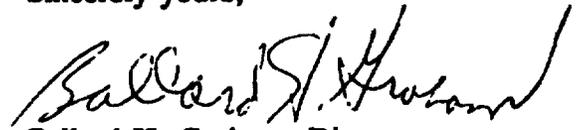
At the conclusion of the inspection, Investigators' Douglas and Brogden issued their Inspectional Observations (FDA 483) to and discussed their findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all

warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should address any proposed actions regarding any oxygen cylinders currently in distribution which have not been properly tested and any determination on whether you plan to continue transfilling. We acknowledge your decision to voluntarily cease transfilling operations until you can bring your firm into compliance. We are also requesting that you notify this office prior to resuming distribution of transfilled oxygen. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director  
Atlanta District

Enclosure

cc: Hubert Chancy, Vice President  
Chancy Health Care Services  
205 E. Main Street  
Hahira, Georgia 31632