



June 5, 1997

**WARNING LETTER**  
**CHI-30-97**Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**Thomas J. Fitzsimmons  
President  
Fitzsimmons Surgical Supply, Inc.  
2747 W. 95th Street  
Evergreen Park, Illinois 60642

Dear Mr. Fitzsimmons:

An inspection of your firm located at 1170 N. Farnsworth Avenue, Aurora, Illinois, 60505, conducted April 2, 1997, by our investigator, Lisa A. Hornback, determined that your firm fills Oxygen, U.S.P., in liquid form, into home oxygen units. This medical gas is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). This inspection revealed that your liquid oxygen is adulterated under the Act.

Your liquid oxygen filled into home oxygen units is adulterated under Section 501(a)(2)(B) of the Act in that the methods used in, or facilities or controls used for, its manufacturing, processing, packing, holding do not conform to or are not operated or administered in conformity with the current Good Manufacturing Practice Regulations (CGMPs) for drugs as specified in Title 21, Code of Federal Regulations, Parts 210 & 211, as follows:

1. You failed to maintain all copies of Certificates of Analysis for [redacted] oxygen filled into the firm's vehicle mounted Dewar tank.
2. You failed to document the witnessing of identity testing of liquid oxygen filled into tanks.
3. You failed to ensure that all personnel who witness identity testing of Oxygen, U.S.P., are fully trained to do so.
4. You failed to document that all personnel involved in the filling of home cryogenic vessels were fully trained.
5. You failed to ensure that all cryogenic home vessels were inspected prior to filling.

These findings were discussed with Victoria L. Lofton, Operations Manager, at the conclusion of the inspection. A copy of the FDA-483, List of Observations, given to Ms. Lofton originally on April 2, 1997, is enclosed.

The above identification of violations is not intended to be an all-inclusive listing of deficiencies at your firm. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These may include seizure and/or injunction. **This is your official notification that we expect all of your facilities to be in compliance.**

We have enclosed the latest copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '96' - A Look at FDA's Medical Gas Requirements." This speech will assist you in understanding your responsibilities as a medical gas manufacturer. Pages 4-6 specifically cover testing of incoming liquid oxygen and cryogenic home vessels.

If you wish to obtain a copy of the Act [DHHS Publication No. (FDA) 93-1051] or 21 CFR Parts 200 to 299 (SN 869-026-00071-9), you should contact the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders may be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00am to 4:00pm Eastern time, Monday through Friday, or FAX'd to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The Act is approximately \$20 and the CFR is approximately \$7.

You should notify this office in writing within 15 days of receipt of this letter regarding the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your written response should be directed to the attention of Richard Harrison, Acting Director of Compliance Branch, Food & Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

*RSI*

Raymond V. Mlecko  
District Director

Enclosures:

Copy of "Fresh Air"  
FDA-483

- cc: Ms. Victoria L. Lofton  
Operations Manager  
Fitzsimmons Surgical Supply, Inc.  
1170 N. Farnsworth Street  
Aurora, IL 60505
- cc: Mr. Mark Crowhurst  
Operations Manager  
Fitzsimmons Home Medical Equipment  
6442 W. Cermak  
Berwyn, IL 60402