



Food & Drug Administration  
Olympic Towers, Suite 100  
300 Pearl Street  
Buffalo, NY 14202

December 18, 1997

**WARNING LETTER BUF 98-4**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

David M. Verity, President  
First Community Care, Inc.  
210 John Glenn Drive - Suite 12  
Amherst, New York 14228

Dear Mr. Verity:

Inspection of your liquid oxygen manufacturing facility at 22 Ossian Street, Dansville, New York 14437, was performed from December 10-12, 1997, by Food and Drug Administration (FDA) Investigators Russ E. Davis and Gifford Whitehurst, Jr. The inspection revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. At the conclusion of the inspection, Bernie E. Barnett, Branch Manager, was presented with a written list of objectionable conditions and practices (FDA-483). A copy is enclosed for your reference.

Medical oxygen processed and distributed by your firm is considered a drug within the meaning of Section 201(g) of the Act. Your product, Liquid Oxygen USP, is considered adulterated within the meaning of Section 501(a)(2)(B) of the Act, since the controls used for the manufacture, processing, packing or holding of this product are not in conformance with current Good Manufacturing Practice regulations for Drugs (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211) as follows:

*- Failure to perform an identity test on incoming liquid oxygen (LOX) received under a supplier's Certificate of Analysis (COA). Failure to periodically verify the reliability of the supplier's analysis of LOX when relying on a supplier's COA. Failure to assay LOX home cryogenic vessels for identity and strength when an identity test is not performed on incoming LOX and the reliability of the supplier's analysis established [21 CFR 211.165 (a)]. LOX in large cryogenic vessels (VGLs) are delivered to your firm with accompanying COAs. Your firm is unable to witness the supplier's testing of LOX and therefore relies on the supplier's COA for purity results. Your firm has not established the reliability of the supplier's analysis and does not perform an identity test on the contents of the VGLs prior to transfilling into home cryogenic units. Further, your firm does not assay each home cryogenic vessel filled, as required, when incoming LOX is not adequately tested.*

*- Failure to have adequate written procedures describing: the receipt and testing requirements for incoming LOX when your firm is unable to witness the supplier's assay;*

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*the periodic verification of the reliability of the supplier's assay; the prefill checks of home cryogenic vessels; a program for providing specific training to personnel responsible for performing and supervising LOX operations; and the correct labels and labeling used for liquid Oxygen USP home cryogenic vessels [21 CFR 211.100 (a), 211.160 (b), 211.25, 211.130].* The current written procedures for Liquid Oxygen USP operations are incomplete and do not accurately describe the operations of the Dansville, New York, Branch.

*-Failure to perform adequate prefill operations on each LOX home cryogenic vessel, prior to filling [21 CFR 211.84 (d) (3)].*

*-Failure to establish adequate batch production and control records for each batch (lot) of LOX transfilled, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188 (b)].* Daily Oxygen Logs prepared by your firm lack documentation identifying the individual performing transfilling operations and record review, as well as a place to document the performance of each prefill check of the home cryogenic vessel. Additionally, your Service Technician does not always complete the Daily Oxygen Log at the time the operations are performed.

*-Failure to follow written procedures for maintaining a Liquid Oxygen Log for VGL's and the performance of an identity test on a sample from the first LOX home cryogenic vessel filled with a new lot of LOX from the supplier [21 CFR 211.100 (b)].* Your written procedures entitled, "IDENTIFICATION AND ASSAY OF LIQUID OXYGEN USP," require the completion of a Liquid Oxygen Log for VGL's and the performance/documentation of an identity test on the contents of the first home cryogenic vessel filled from a new supply lot. Your firm does not maintain the Liquid Oxygen Log for VGL's and does not document performance of the aforementioned identity test.

*-Inadequate training of personnel engaged in the performance and supervision of liquid oxygen transfilling operations with respect to written procedures and current good manufacturing practices for drugs as evidenced by testing and record keeping deficiencies, as well as the failure to follow written procedures [21 CFR 211.25 (a) and (b)].* Your Service Technician and Branch Manager are not familiar with the requirements of your written procedures manual and have never received training specific to the current good manufacturing practice regulations.

*-Failure to maintain distribution records covering LOX distributions between October 1 and December 8, 1997 [21 CFR 211.180 (a), 211.196].* Delivery Tickets (Order Forms) completed by your firm are not retained as required by regulations.

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In addition, your product, Liquid Oxygen USP, is misbranded within the meaning of Section 502 of the Act, because the labeling of the home cryogenic vessels does not bear the name and place of business of the manufacturer [Section 502 (a) and 502 (b) (1); 21 CFR 201.1]; does not bear an accurate statement of the quantity of contents [Section 502 (b) (2); 21 CFR 201.51]; and does not bear a lot or batch number [Section 502 (c); 21 CFR 201.18].

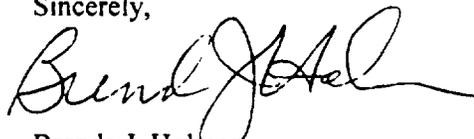
It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. This Warning Letter serves as official notification the FDA expects all branch locations under your control to be in compliance. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure and/or injunction, without further notice.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy attached) you still have questions regarding acceptable methods for complying with these requirements, you may contact Joseph H. Erdmann at our Syracuse office (315-448-7601).

Please notify this office, in writing, within 15 days of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Joseph H. Erdmann, Team Leader, U.S. Food and Drug Administration, P.O. Box 7197, Syracuse, New York 13261-7197.

Sincerely,



Brenda J. Holman  
District Director

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Enclosures: -Compressed Medical Gases Guideline  
-Fresh Air '97 - A Look at FDA's Medical Gas Requirements

cc: Bernie Barnett, Branch Manager  
First Community Care, Inc.  
22 Ossian Street  
Dansville, New York 14437