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Food and Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202

December 19, 1997

**WARNING LETTER  
CIN-WL-98-91**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Carl C. Barker, President  
Carl's Medical Home Care, Inc.  
4011 Outer Loop Road  
Louisville, KY 40219

Dear Mr. Barker:

During a November 17-18, 1997 inspection of your medical oxygen home respiratory care service, located at the above address, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211). These deviations cause your drug product, liquid Oxygen USP, to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Specific observations made during the Inspection include:

- (1) Failure to test incoming liquid oxygen for both identity and strength according to one of the methods outlined in the February 1989, Compressed Medical Gases Guideline, in that your service representatives have not been trained in the analytical method used by your supplier in performing the assays witnessed by your employees.
- (2) Failure to conduct or document finished product testing on one cryogenic home vessels which was sent out for service, prior to redistribution. Each cryogenic home vessel must be assayed if it has been outside your firm's customer distribution controls.
- (3) Failure to establish and maintain appropriate batch production records (delivery records), which include documentation of each appropriate control check as defined by your cryogenic home vessels service manual.
- (4) Failure to establish and follow appropriate written operating procedures covering distribution records, recalls, complaints, training, relabeling,

testing and acceptance of incoming liquid oxygen, testing of units sent out for service, and procedures for transfilling of home respiratory care units.

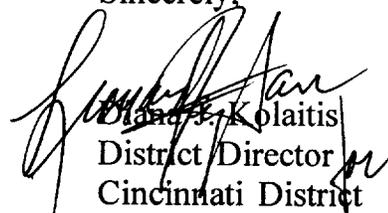
The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products. You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. 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.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 684-3501 extension 165.

We understand that you may begin transfilling compressed medical Oxygen USP in high pressure cylinders in the near future. For your information and to assist you in compliance with FDA regulations, I have enclosed copies of the FDA documents "Compressed Medical Gases Guideline" and the FDA speech, FRESH AIR "97" - A LOOK AT FDA'S MEDICAL GAS REQUIREMENTS. These documents describes current FDA requirements and policy on medical gases.

Sincerely,

  
Donald S. Kolaitis  
District Director  
Cincinnati District