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February 7, 1997

WARNING LETTER
CIN-WL-97-211

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas L. Seiber, President
Bethesda Hospital
2951 N. Maple Avenue
Zanesville, OH 43701

Dear Mr. Seiber:

During a January 13-17, 1997 inspection of your medical oxygen transfilling facility, Carelife Home Medical Services, located at 1014 Bellefontaine Ave., Lima, OH 45804, 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, 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 assure that each lot of incoming liquid oxygen (LOX) conforms to the specifications for identity and strength prior to use.
- (2) Failure to assure that the oxygen analyzer used for conducting identity testing is calibrated prior to use.
- (3) Failure to maintain adequate written procedures in that procedures do not specify acceptance criteria (specifications) for incoming LOX nor do they include requirements for periodic audit of supplier's certificates of analyses.

It is our understanding that you have two additional Carelife Home Medical Services, Inc. medical oxygen transfilling facilities, located at 132 Graceland Blvd., Columbus, OH and 945 Bethesda Drive, Zanesville, OH. On 4/29/92, a previous Warning Letter was issue to you for similar deficiencies at your Zanesville, Ohio facility. This letter will also serve as warning to you to correct any similar deficiencies at all of your medical oxygen facilities.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facilities. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. 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. By copy of this letter, we are advising Health Care Finance 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.

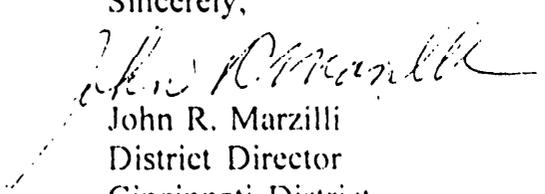
You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

For your information, I have enclosed a copy of the FDA speech "FRESH AIR '96" - A LOOK AT FDA'S MEDICAL GAS REQUIREMENTS", which describes current FDA requirements and policy on medical gases.

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.

Sincerely,


John R. Marzilli
District Director
Cincinnati District

Enclosure: Fresh Air

copies to:

George J. Gans, Director
Carelife Home Medical Services
132 Graceland Blvd.
Columbus, OH 43214

David Wood, Branch Manager
Carelife Home Medical Services
1014 Bellefontaine Ave.
Lima, OH 45804