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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service *m234Dr*

Food and Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237

February 5, 1999

**WARNING LETTER**  
**CIN-WL-99-117**

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

Allen Lipsyc, Executive Director  
Medic Home Health Care  
701 Beta Drive  
Mayfield Village, Ohio 44143

Dear Mr. Lipsyc:

During an FDA inspection on January 11, 1999 of your oxygen transfilling facility located at the above address our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21 Code of Federal Regulations, Parts 210 and 211). These deviations cause your medical gas, liquid oxygen, USP to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the ACT).

Our investigations revealed the following:

Failure to establish batch production and control records for each batch of liquid Oxygen, USP produced including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.

Failure to establish and follow written procedures for production and process controls covering all aspects of the transfilling operation designed to assure that liquid Oxygen, USP has the identity, strength, quality, and purity that it purports or is represented to possess. For example, there are no written procedures for calibration of the gauges used in the transfilling operation and calibration of the gauges is not documented. In addition, the written procedure for calibration of the scales is not followed.

Failure to assure that each person engaged in the transfilling of liquid Oxygen, USP has the education, training or experience to enable that person to perform assigned functions. For example, there are no written procedures describing how or when employees are trained in performing transfilling operations.

Page 2

Failure to assay each filled cryogenic home vessel (that is either new or has been out of service for repair/maintenance) for identity prior to release for distribution.

Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used, and returned during the transfilling operation.

Additionally, the FDA inspection revealed that your drug product, liquid Oxygen, USP in cryogenic home vessels is misbranded within the meaning of section 502(f)(1) of the Act in that the labeling fails to bear the prescription legend as required in 21 CFR 201.100(b)(1) and fails to bear adequate directions for use in accordance 21 CFR 201.100(c). It is also misbranded within the meaning of section 502(b)(1) of the Act in that its labeling fails to contain the place of business of the manufacturer or distributor.

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. 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 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.

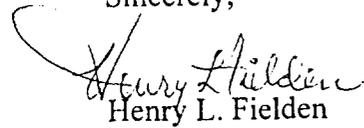
You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

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.

Page 3

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

A handwritten signature in cursive script that reads "Henry L. Fielden". The signature is written in dark ink and is positioned to the left of the printed name.

Henry L. Fielden  
Acting District Director  
Cincinnati District