

HFI-35

M978 N

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

Refer to: CFN 1123919

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4012

June 6, 1997

**WARNING LETTER**

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

Mr. Kenneth R. Suter, President  
Family Respiratory and Medical Supply Corp.  
5522 Harford Road  
Baltimore, Maryland 21214

Dear Mr. Suter:

During an inspection of your facility, conducted by the Food and Drug Administration (FDA) from May 14 to May 20, 1997, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) were observed in your firm's operation. These deviations cause your compressed medical gas and liquid oxygen products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The deviations are as follows:

1. Failure to assure that liquid oxygen conforms to the requirements for identity and strength, in that employees are not trained to witness testing done by the supplier, the supplier's analysis is not periodically verified, and the firm's oxygen analyzer is not calibrated in accordance with manufacturer's instructions.
2. Failure to properly calibrate the oxygen analyzer used for the assay of Oxygen, USP, in that the oxygen analyzer is not calibrated in accordance with the manufacturer's instructions and calibration records are not maintained.
3. Failure to assure that personnel have education and training to perform their assigned functions, in that there are no records to indicate that personnel are trained to witness testing of the Oxygen, USP at the supplier and no written procedures for training employees in the use of the oxygen analyzer.

**Mr. Kenneth R. Suter**

**June 6, 1997**

**Page 2**

4. Failure to have batch production records reviewed and approved by a quality control unit prior to release of the batch for distribution.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the 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.

By copy of this letter, we are advising the Health Care Financing Administration that our inspection revealed significant deviations from the FD&C Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

FDA acknowledges receipt of your response to the FDA-483 issued at the conclusion of the above referenced inspection. FDA has the following comments on the documentation submitted:

1. The calibration log is not complete, in that it does not identify the results reported, the material used for the calibration, or the machine being calibrated.
2. The documentation regarding the quality assurance team reviewing the batch records does not include information about how the review will be documented.
3. The training information provided does not indicate that employees will be trained periodically in Good Manufacturing Practices.
4. The procedure for calibration of the oxygen analyzer is not complete, in that it does not indicate that it was approved by the quality control unit and that the results of the calibration must be documented. In addition, the procedure itself should not be used to document that personnel have been trained on the procedure.

You should notify this office in writing, within 15 working days of receipt of this letter, of additional steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Mr. Kenneth R. Suter  
June 6, 1997  
Page 3

Your reply should be directed to the Food and Drug Administration, Baltimore District Office,  
900 Madison Avenue, Baltimore, Maryland 21201, Attention: Jennifer A. Thomas, Compliance  
Officer.

Sincerely,



Elaine Knowles Cole  
District Director