



4298 Elysian Fields Avenue  
New Orleans, LA 70122

November 19, 1996

WARNING LETTER NO. 97-NOL-17

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. O. Lee Dempsey  
President  
National Welding Supply, Inc.  
P O Box 9786  
New Iberia, Louisiana 70562

Dear Mr. Dempsey:

During an inspection of your facility, Welder's Equipment Center of New Iberia, Inc., located at 202 Deare Street, New Iberia, Louisiana, on October 7-11, 1996, our investigator documented deviations from Current Good Manufacturing Practice Regulations (CGMP), Title 21, Code of Federal Regulations, Parts 210 and 211. These deviations cause your product, medical oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our inspection revealed the following CGMP deviations:

1. Failure to properly calibrate the [REDACTED] Oxygen Analyzer used for the assay of Oxygen, USP, in that your firm (a) did not use Reference Standard Oxygen for the calibration, (b) did not zero the Servomex every time it was calibrated, (c) has no calibration documentation, and (d) has no SOP for calibration documentation;
2. Failure to assure that appropriate test procedures are used for the assay of Oxygen, USP, in that the Certificate of Analysis for incoming liquid oxygen does not state the Test Method used to determine the purity of this oxygen;

- 3. Failure to provide CGMP training for medical oxygen fill employees;**
- 4. Failure to calibrate thermometers and pressure and vacuum fill gauges;**
- 5. Failure to have SOP for filling medical oxygen reviewed and approved by management;**
- 6. Failure to establish adequate batch production records for each batch of medical oxygen produced, in that the Daily Pumper's Log/Medical Oxygen does not include pressure and temperature readings of the compressed oxygen cylinders being filled or the pounds per square inch of vacuum drawn;**

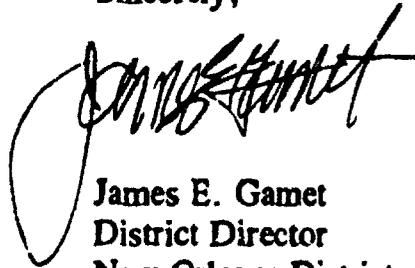
**The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.**

**You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction. This warning letter will serve as official notice that FDA expects all locations to be in compliance with the Federal Food, Drug and Cosmetic Act.**

**You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.**

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA-483

cc: Mr. Mike J. Dempsey  
Vice President  
National Welding Supply, Inc.  
P.O. Box 9786  
New Iberia, LA 70562

Mr. D. Keith McMullan  
Manager  
Welder's Equipment Center of New Iberia, Inc.  
202 Deare Street  
New Iberia, LA 70560

/tjt