



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
New Orleans District Compliance

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4298 Elysian Fields Avenue  
New Orleans, LA 70122

December 30, 1996

**WARNING LETTER NO. 97-NOL-23**

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

Mr. James A. Walker  
President  
Walker Welders Supply Co., Inc.  
1341 Desoto Avenue  
Clarksdale, MS 38614

Dear Mr. Walker:

During an inspection of your facility, Walker Welders Supply Co., Inc., 1341 Desoto Street, Clarksdale, Mississippi, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, *Code of Federal Regulations (CFR)*, Part 211), regarding the repacking/manufacturing of medical oxygen. These deviations cause your product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (Act). Your product is also misbranded in that it was manufactured in an establishment not duly registered under Section 510 of the Act.

Our inspection conducted November 21-22, 1996, revealed the following objectionable conditions: (1) failure to maintain batch production records for any batches produced from 2/96-11/96; (2) failure to document the testing of each batch of oxygen prior to release for conformance to final specifications; (3) failure to document the calibration of the [REDACTED] 570A Analyzer prior to use; (4) failure to have batch production records checked by a second person prior to release and sale; (5) failure to assure that each person engaged in the manufacture of USP oxygen has the training, education, and experience to enable them to perform the assigned functions; and, (6) failure to establish a written procedure for the receiving and handling of complaints.

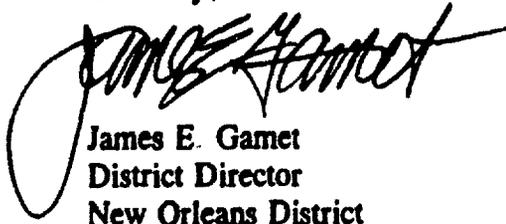
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters 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.

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 Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122, 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. Olsen.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA-483  
21 CFR, Part 211