



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAJ 029N HF 1-35
Public Health Service *Singed 5/17/99*
ryh

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
Fax: 504-589-6360

May 17, 1999

WARNING LETTER NO. 99-NOL-27

**OVERNIGHT DELIVERY
FEDERAL EXPRESS**

Mr. James A. Dunaway, Owner
Capweld, Inc.
d.b.a. Capital Welding Supply
Post Office Box 22562
Jackson, Mississippi 39205-2562

Dear Mr. Dunaway:

During an inspection of your manufacturing facility, located at 233 East Rankin Street, Jackson, Mississippi, conducted on March 22-26, 1999, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug products, oxygen, nitrogen, nitrous oxide, carbon dioxide and medical air, to be adulterated within the meaning of 502(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The controls used for manufacture, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (Title 21 *Code of Federal Regulations*, Parts 210 and 211).

Our inspection revealed the following CGMP deficiencies:

1. Failure to assay incoming bulk or filled high pressure cylinders of Nitrous Oxide, USP, or of Nitrogen, USP, for identity and strength, prior to release;
2. Failure to establish appropriate, written procedures for the filling and testing of cylinders of Nitrous Oxide, USP, or of Nitrogen, USP;
3. Failure to establish written procedures which accurately reconcile the use of Oxygen labels;
4. Failure to establish quarantine areas for the holding of cylinders of Carbon Dioxide, USP, separate from cylinders of industrial carbon dioxide;
5. Failure to establish quarantine areas for the separate holding of various empty and filled cylinders of Oxygen, USP and Carbon Dioxide, USP;

6. Failure to document periodic calibration of thermometers, pressure gauges or vacuum gauges used in the transfilling of medical gases;
7. Failure to follow your firm's established, written procedures in that the names of the Quality Control Unit have not been established in writing, batch production records for Oxygen, USP, and Medical Air, USP, do not indicate who performed identity tests, gas filling operation audits have not been performed and written procedures are not approved and dated; and
8. Failure to establish and qualify adequate cleaning and testing procedures for the conversion of industrial nitrogen cylinders to medical oxygen use.

The above identification of violations is not intended to be an all inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of 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 properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA-483. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that 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, 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, please contact Ms. Hardin.

Sincerely,


for James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483