



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

May 27, 1999

WARNING LETTER NO. 99-NOL-33

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Michael J. Dempsey, President
National Welding Supply Company, Inc.
3114 Highway 90 East
New Iberia, Louisiana 70560-9789

Dear Mr. Dempsey:

During an inspection of your manufacturing facility, located at 7480 East Industrial Avenue, Baton Rouge, Louisiana, conducted on March 24, 26 and April 5, 1999, our investigators documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, oxygen, to be adulterated within the meaning of 501(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 properly calibrate the [REDACTED] used for the assay of Oxygen, U.S.P.;
2. Failure to assay at least one cylinder per uninterrupted filling sequence for identity and strength;
3. Failure to adequately train the pumper/tester employee in your firm's written procedures and CGMP's;
4. Failure to properly perform pre-fill operations in that industrial grade Nitrogen was used to odor test cylinders received empty and the hammer test was performed on aluminum cylinders;
5. Failure to establish adequate written filling procedures for the manufacture of Oxygen, U.S.P.; and,

6. Failure to maintain documentation for the periodic calibration of the thermometer.

Additionally, your filled cylinder labels do not declare the net contents and some cylinder labels were torn, mutilated or illegible.

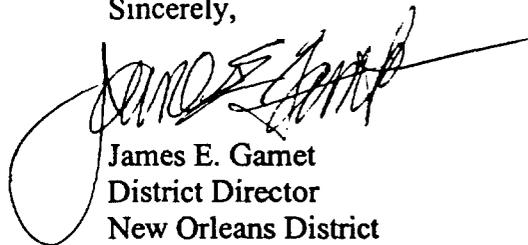
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and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



James E. Garnet
District Director
New Orleans District

Enclosure: FDA 483