



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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February 28, 2003

WARNING LETTER NO. 2003-NOL-09

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Billy G. Dennis, President
Dennis Welding Supply, Inc.
619 North McDonough Street
Montgomery, Alabama 36104

Dear Mr. Dennis:

During the January 7-13, 2003, inspection of your facility, located at 619 North McDonough Street, Montgomery, Alabama, our investigators documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, Oxygen USP (*United States Pharmacopeia*), to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the controls used for the manufacturing, processing, packing or holding of this product are not in conformance with CGMP regulations, found in Title 21, *Code of Federal Regulations*, Part 211 (21 CFR 211). You may find guidance and more information regarding these regulations through links in FDA's Internet page at <http://www.fda.gov> and in the National Archives and Records Administration Internet page at <http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html>.

Specific observations made during the inspection include:

1. Your quality control unit failed to review and approve all the medical oxygen production and control records [21 CFR 211.192].
 - [REDACTED] lots of Oxygen USP, produced on 22 different dates in November/December 2002, were released for distribution without a quality assurance review of the daily pumper's log (production/control record).
 - [REDACTED] lots of liquid Oxygen USP, produced on nine different days in November/December 2002, were released without a quality assurance review of the daily pumper's log.
 - There was no date beside each signature of the quality assurance employee reviewing the daily pumper's logs for Oxygen USP and liquid Oxygen USP, from January 2002 through October 31, 2002.

- There were no initials in the “Released By” column on the daily pumper’s log for medical oxygen lots 031-01-072-1/3 on January 7, 2002; for lots 031-06-102-1/2 on June 10, 2002; and, lots 031-06-242-1/2 on June 24, 2002.
 - There was no documentation of review of your oxygen analyzer maintenance log by your quality assurance unit since December 2001.
 - There is no documentation to show the liquid Oxygen USP and the Oxygen USP labels were reviewed and accepted by the quality assurance unit prior to being placed in the master drug file and there was no documentation that new shipments of labels received by the firm were compared against the Oxygen USP label, for gas cylinders, in the label master file for accuracy and for acceptance/rejection testing of the incoming labels [21 CFR 211.125 and 211.186(b)(8)].
2. You failed to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)].
- There were no test results recorded for the post fill purity tests on the daily pumper’s log for medical oxygen for lot #031-01-072-3 filled on January 7, 2002, or for lot #031-01-292-1 filled on January 29, 2002.
 - A check off mark was placed on the daily pumper’s log for medical oxygen instead of the actual pressure and temperature readings taken during filling operations.
 - Your procedure for filling Oxygen USP cylinders did not include the USP monograph requirement of a final odor test after the filling operation.
 - Your procedure for filling liquid Oxygen USP did not require review of the daily pumper’s log for liquid Oxygen USP by the quality assurance unit prior to release of the product for distribution, the performance of a visual inspection of the liquid vessel prior to filling, or performing a final leak test after filling the liquid oxygen container.
 - Your “Calibration of Thermometers and Gauges” procedure does not state it is acceptable to use an outside contractor for the calibration of the vacuum and high-pressure gauges.
3. You failed to maintain complete records of the periodic calibration of the oxygen analyzer [21 CFR 211.194(d)].
- There was no documentation that the analyzer’s filter was being replaced every 24 weeks as required by your procedure.
 - There was no space to record the results on the nitrogen zero test on your oxygen analyzer log. Our investigators observed maintenance performed on your oxygen analyzer, during our inspection, which was not entered into the oxygen analyzer log within four hours of the maintenance being performed.

4. Your labeling procedure was not being followed and was inadequate, in that, label inventory records were incomplete or lacked required information [21 CFR 211.125].
 - You have no written procedures for inventory control, acceptance/rejection testing, etc. for liquid Oxygen USP labels.
 - Your Oxygen USP and liquid Oxygen USP monthly inventories have not been reconciled since October 2002.
 - Your procedure does not specify the frequency of label reconciliation.
 - There was no documentation that your “Medical Label Inventory Sheets” for Oxygen USP in cylinders, were reviewed by the quality assurance unit since August 31, 2000, or that the “Medical Label Inventory Sheet” for liquid Oxygen USP was reviewed by the quality assurance unit since March 3, 2001.
5. You failed to follow your written process control procedures in the execution of annual gas pumping operation audits [21 CFR 211.186(a)], in that, annual audits were not documented as per your “Audit of Gas Pumping Procedures.”
6. You have not documented routine calibration and equipment checks, at suitable intervals, according to a written program designed to assure proper performance [21 CFR 211.68(a)].
 - Your procedures for the testing of Oxygen USP do not require the documentation of the results of the calibration of the oxygen analyzer.
 - Your written procedure for “Calibration of Thermometers and Gauges, in the Medical Gas Pumping” was not being followed, in that, thermometers used during the filling operations were not being calibrated every 6 months and prior to initial use.
 - The calibration/recalibration dates for the vacuum gauge and high pressure gauge used in filling the oxygen into metal cylinders were not recorded on your “Gauge Calibration Log” as required by your procedures.

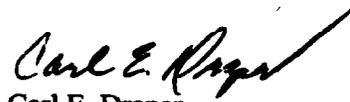
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the CGMP regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take 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. However, it is necessary that you notify this office in writing, within 15 working 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 Cynthia R. Crocker, Compliance Officer, U.S. Food and Drug Administration, at 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. Should you have any questions concerning the contents of this letter, please contact Ms. Crocker at telephone number (601) 965-4581.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483