



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

June 28, 2001

VIA FEDERAL EXPRESS

Merrill L. Ward
President
Ward Sales Company Inc.
115 19th Avenue East
Cordele, Georgia 31010

WARNING LETTER
(01-ATL-58)

Dear Mr. Ward:

Investigator B. Douglas Brogden conducted an inspection of your medical oxygen transfilling facility on June 1, 4, & 6, 2001. Our investigator documented several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code Of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen Compressed, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

You have failed to assure that all medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications prior to release. You have failed to appropriately calibrate and assure the accuracy of the [REDACTED] Analyzer currently in use. You were utilizing compressed air instead of high purity nitrogen to establish the instrument zero point. There was no documentation available of any calibration being performed on the analyzer prior to finished product assay since October 2000.

You have failed to maintain adequate batch production and control records for each batch of Oxygen USP produced, to include required information and documentation of each significant step in the production and testing of each batch. Documentation of the performance of all quality control checks and tests during prefill, filling, and postfill were not recorded for each manifold filling sequence. Your "Daily Pumper's Log Medical Oxygen Oxygen" form does not include the maximum cylinder pressure and temperature reached during the filling operation. This form also does not include a record of any postfill odor test.

Your quality control unit has failed to conduct an appropriate review of all production and control records, including labeling, prior to release of the lot for distribution. In actual practice, the individual performing the purity assay releases the oxygen lots. This release is prior to the final record review and approval by a second responsible individual. The final review that is performed does not include all pertinent records such as the analyzer calibration records and labeling inventory records. A comparison of the labeling issuance records on the Daily Pumper's Log Medical Oxygen Oxygen form and the Master Label Inventory revealed several discrepancies which should have been detected if an appropriate production record review was being conducted prior to lot release.

You have failed to establish formalized written procedures to cover all of the various aspects of the transfilling operations. You had attempted to adapt a generic set of procedures to your Cordele operation. These procedures did not always accurately reflect the actual operations at your location. The available procedures were deficient in a number of areas. Your procedure No. 110 for Accuracy of Oxygen Analyzers was outdated and contained conflicting instructions on how to calibrate the analyzer. There was no procedure that established specifications for the receipt, testing, and acceptance of liquid oxygen used in the production of transfilled cylinders of compressed oxygen. Procedure No. 112 for Calibration of Thermometers & Gauges required gauges to be calibrated utilizing the dead weight method. No one at your facility could explain what this method was. Your filling procedures did not require the performance of a daily calibration of the vacuum gauge or an odor test to be performed after filling.

You have failed to implement and follow an adequate calibration and maintenance procedures for your production equipment. The available documentation indicated that your vacuum and pressure gauges had last been calibrated in October 1998. Your procedures require an annual calibration of these gauges. Your procedures do not require, and you do not perform, a calibration of the vacuum gauge on each day of use.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. This training must be in the particular operation that the employee performs and include current good manufacturing practice as it relates to the employee's functions. There was no documentation that the individuals responsible for filling and testing of cylinders had been trained regarding the receipt, approval, and rejection of components and containers. No training records were available for one of your employees responsible for filling cylinders and also the individual responsible for reviewing records and releasing all finished product. No documentation was available of any annual refresher training being conducted for any of your employees although required by your training procedures.

At the conclusion of the inspection, our investigator issued his Inspectional Observations (FDA 483) to you and discussed his findings. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your facility. Of particular concern is the fact that several of these observations are repeat deviations from the previous inspection in March 1996. These include the lack of analyzer calibration records, concerns over the calibration procedure, and lack of calibration records for your gauges. It is your responsibility to ensure that all requirements of the Act are met at this and any other similar facility under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) working days of receipt of this letter of all additional steps you have taken, or intend to take, 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 the delay and the time within which corrections will be completed.

Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. You can also contact Compliance Officer Campbell at (404) 253-1280, if you have any questions about this letter.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director
Atlanta District