



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

NE-35 1223301

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

January 13, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward Hammond
President
Convacare Inc.
247 Columbia Street
Chester, South Carolina 29706

WARNING LETTER

Dear Mr. Hammond:

An inspection of your medical oxygen transfilling facility was conducted on December 22, 1998, by Investigator Jerry H. Bridgers. Our investigator documented numerous 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 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 maintain records of analytical testing of any of your transfilled cylinders. You have failed to establish if the [REDACTED] analyzer has the sensitivity and accuracy required for release testing of transfilled units. You could provide no documentation associated with this analyzer as to how it was to be calibrated, maintained, or operated to determine the purity of medical gases. We question the appropriateness of this analyzer to release your transfilled units.

The required calibration steps are not performed on your [REDACTED] Analyzer in accordance with the manufacturer's instructions. The calibration steps, described by the [REDACTED] manual on file, require the use of ambient air to zero the analyzer and certified oxygen for the span gas. Your firm's current calibration procedure consists of a single reading from the certified oxygen. No zero or span readings are taken.

Our investigator was told that you test 25% of each batch of finished cylinders. There was no way to determine the accuracy of this statement. In addition to having no test records for filled cylinders, no record is maintained of the number of cylinders making up a batch. The determination of a batch of cylinders could not be related to a manifold filling sequence or

changes in the H cylinders. There were no records available to indicate what H cylinder lot numbers were used in the transfilling of each batch of oxygen.

You have failed to maintain appropriate batch production and control records to document each significant step in the transfilling of your product. You could provide none of the required production records to our investigator to indicate the various steps taken in the filling process and in the analysis of transfilled cylinders. No records were available to indicate that any prefill inspections are conducted on the cylinders such as a visual examination, venting, evacuation, odor testing, and hammer testing. Reportedly no odor testing is conducted on these cylinders.

You have failed to establish formalized written procedures to cover the various aspects of your transfilling operation. The only procedures available were seriously deficient and were not indicative of the operations currently conducted at your firm. The only filling procedures which could be located consisted of a wall poster provided by the filling equipment manufacturer and an operators manual for the [REDACTED] which you do not follow. No formalized written procedures could be provided for the sampling and analysis of incoming H cylinders or transfilled oxygen cylinders prior to release.

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 operations that the employee performs and include current good manufacturing practice as it relates to the employee's functions. In fact there was no documentation available to indicate that anyone at the firm had received training commensurate with their responsibilities.

This lack of training was exemplified by the total absence of meaningful procedures, the failure to maintain appropriate testing records, the deficiencies noted in the production records maintained, and the lack of familiarity with GMP requirements exhibited by you and your employees. Our investigator was informed that Victor Medical provided some training to your firm. There was no documentation available as to who was trained, when the training occurred, or what activities were covered during the training.

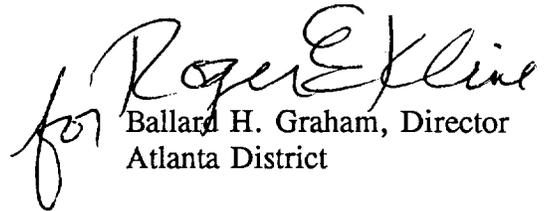
At the conclusion of the inspection, Investigator Bridgers issued his Inspectional Observations (FDA 483) to and discussed the findings with you. Mr. Bridgers also provided additional reference materials to assist you in complying with the law. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

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 all 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) days of receipt of this letter of all 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 also address any proposed actions regarding any oxygen lots currently in distribution which have not been properly tested. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

for Roger E. Kline
Ballard H. Graham, Director
Atlanta District