



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

ACI-35

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

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March 22, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

D. S. Carter
President
Action Welding Supply, Inc.
6683 Stuart Avenue
Jacksonville, Florida 32205

WARNING LETTER
(99-ATL-14)

Dear Mr. Carter:

An inspection of your medical oxygen transfilling facility located in Waycross, Georgia, was conducted on February 9 & 10, 1999, by Investigators B. Douglas Brogden and Jackie M. Douglas. Our investigators 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 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 establish formalized written procedures to cover the various aspects of the transfilling operations at the Waycross location. In fact, prior to February 10, 1999, there were no written procedures available at this location that addressed any aspect of the transfilling operations. The procedure manual forwarded to the firm during the inspection had been adapted from another location and was not applicable to several of the operations currently in place at your Waycross facility. The procedures included a manual for an oxygen analyzer that is not used at this location.

These procedures included references to another firm's personnel and record keeping practices. The procedures did not discuss any of the Waycross quality assurance personnel and their responsibilities. The procedures contained instructions for the maintenance of a "Quality Assurance Log" for daily testing that is not maintained in Waycross. Other deficiencies noted in the procedures include a lack of any reference to calibration procedures or schedule for the filling equipment (thermometers and gauges), no example of the master labeling to be used on cylinders, and no recall procedure. The current procedure for conducting leak testing includes only an audible check with no leak testing solution being utilized.

You have failed to maintain appropriate batch production and control records to document each significant step in the transfilling of your drug product. Individual prefill checks performed on cylinders prior to filling are not recorded. The current procedure requires only a single check mark to document all prefill tests performed on cylinders. This batch record revision was made in December 1998. A review of the bulk oxygen testing records revealed that there were no purity testing results available for 3 of the bulk deliveries received since transfilling operations started in Waycross.

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 analyzer currently in use. The calibration standards in use are of an unknown purity. No certificates of analysis were available for the oxygen or nitrogen standards. The oxygen standard was a cylinder that had been filled and tested at the Waycross location. In addition, a review of your batch records revealed seven production dates (since 11/6/98) with no record available of a calibration of the analyzer being performed.

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. Production records have been routinely reviewed and approved by personnel with no training in, or knowledge of, the applicable requirements. There was only one individual at the firm that had received any GMP training.

At the conclusion of the inspection, our investigators issued their Inspectional Observations (FDA 483) to, and discussed the findings with, Ms. Margaret W. Leggett, Office Manager. A copy of the FDA 483 is enclosed for your review. Additional reference materials were provided to assist your firm 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 facility. It is your responsibility to ensure that all requirements of the Act are met at this and any other similar facility under your authority.

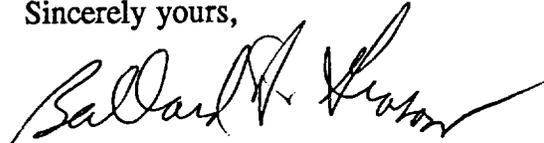
You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving 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 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. We acknowledge that some corrections were initiated during the course of the inspection, to include obtaining a procedure manual and a training record for your transfiller. Additional corrections were promised such as new calibration gases, additional training, and a new batch

record. If corrective action cannot be completed with 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,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ballard H. Graham, Director
Atlanta District

Enclosure