



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2341n

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 2, 1998

WL-14-9

Mr. Guy R. Hall, President
AZ-TX Medical Services, Inc.
294 S. Arizona Boulevard
Coolidge, Arizona 85228

Dear Mr. Hall:

An inspection of your medical equipment distribution and medical oxygen transfilling firm located at 294 S. Arizona Blvd., Coolidge, Arizona, was conducted by an investigator of the Food and Drug Administration (FDA) on November 4, 1998. During that inspection, our investigator observed deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211). These deviations cause your compressed medical oxygen products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Deviations noted during the inspection included, but were not limited to the following:

- (1) Failure to adequately calibrate and/or document the routine maintenance and calibration of the [REDACTED] oxygen analyzer used to test Oxygen USP. Specifically, your firm receives medical oxygen without an accompanying Certificate of Analysis and uses uncertified gases to calibrate the [REDACTED] oxygen analyzer used to test this incoming drug product [21 CFR 211.160(b)(4)].
- (2) Failure to establish complete written procedures for production and process controls covering all aspects of your firm's operations. Specifically, your firm does not have any written procedures governing the maintenance and calibration of the [REDACTED] analyzer used to analyze medical oxygen for strength and identity [21 CFR 211.100(a)].

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- (3) Failure to maintain complete records of the periodic calibration of the [REDACTED] oxygen analyzer in that your firm does not maintain a log for recording the calibration data of this analyzer [21 CFR 194(d)].
- (4) Failure to assay refilled cylinders of compressed medical oxygen USP for identity and strength prior to release for distribution [21 CFR 211.165(a)].
- (5) Failure to establish that the test procedure used to determine the strength and identity of Oxygen USP will provide test results that are equivalent or superior to the official test procedure. For example, the use of [REDACTED] and/or [REDACTED] analyzers at the customer's residence is not an acceptable test for oxygen purity in that the accuracy of these devices is not equivalent to the USP test accuracy of plus or minus 0.1% [21 CFR 211.165(e)].

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. At the end of the inspection, you were given a written list of inspectional observations (FDA-483, copy enclosed) which was discussed with you. As President and Owner, it is your responsibility to assure that your establishment is in compliance with Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

In addition to the above citations we wish to inform you that the use of [REDACTED] and/or [REDACTED] analyzers at the customer's residence does not serve as a substitute for the requirements of final product testing, as cited in item 4 above. Additionally, the findings of our investigator indicate that your firm is not providing employees with adequate training to assure that they can perform their assigned functions in such a manner that the drug product you manufacture has the safety, identity, strength, quality, and purity, that it purports or is represented to possess.

Enclosed is a copy of the Food and Drug Administration's booklet entitled "Compressed Medical Gases Guideline." This publication and the copy of Mr. Duane Sylvia's speech entitled "Fresh Air" given to you at the close of the inspection, will assist you in complying with the requirements of 21 CFR 211.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to:

Thomas L. Sawyer
Compliance Director
Food and Drug Administration
Los Angeles District Office
19900 MacArthur Blvd., Suite 300
Irvine, California 92612-2445

Sincerely,



Elaine C. Messa
Director, Los Angeles District

cc: California DHS/Food and Drug Branch
Attn: Stuart E. Richardson, Jr.
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320

Enclosures:
Form FDA 483
Compressed Medical Gases Guideline