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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202**

16 April 1997

WARNING LETTER BUF 97-15

Donald White, President
Associated Healthcare Systems, Inc.
85 Woodridge Drive
Amherst, NY 14228

Dear Mr. White:

An inspection of your liquid oxygen manufacturing facility at 22566 Fisher Road, Watertown, NY, was performed on 9, 10 and 11 April 1997 by Food and Drug Administration (FDA) Investigator William P. Chilton. The inspection revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. At the conclusion of the inspection, Steven C. Doe, Supervisor, was presented with a written list (FDA-483) of objectionable conditions and practices. A copy is enclosed for your reference.

Your product, liquid oxygen USP, is adulterated within the meaning of Section 501(a)(2)(B) of the Act, because the controls used for the manufacture, processing, packing or holding of this product are not in conformance with current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), parts 210 and 211) such as:

- Failure to include detailed written procedures in your Food and Drug Procedures Manual covering testing of incoming liquid oxygen; testing of cryogenic home vessels; personnel qualifications/training; and, equipment maintenance and calibration. The Manual fails to contain examples of batch production, product and equipment testing and distribution records [21 CFR 211.186].

-Failure to provide training to personnel responsible for witnessing the testing of incoming liquid oxygen, which is specific to the analytical methodology used by your supplier [21 CFR 211.25].



-Failure to follow your written procedures for the retention of liquid oxygen purity tags, and the analyses of new cryogenic vessels for identity and strength, when cryogenic vessels are not retained by customers, but switched due to malfunction and corresponding repair [21 CFR 211.100].

-Failure to document the testing of two [REDACTED] cryogenic vessels, serial #s [REDACTED] and [REDACTED], upon their return after being sent out for repair or maintenance [21 CFR 211.188].

-Failure to maintain a Certificate of Analysis for the certified oxygen standard used to calibrate [REDACTED] oxygen analyzers. The cylinder fails to bear a lot number and expiration date [21 CFR 211.160].

-Failure to document certified oxygen was used to calibrate hand held oxygen analyzers [21 CFR 211.188].

-Failure to review batch production and control records for accuracy and completeness [21 CFR 211.188].

It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure, and/or injunction, without further notice.

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) our inspection of your firm revealed deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

Associated Healthcare Systems, Inc.

Page 3

If, after reviewing this Warning Letter and the Compressed Medical Gases Guideline (copy enclosed), you still have questions regarding acceptable methods for complying with these requirements, you may contact Raymond D. Kent at our Buffalo office (716-551-4461, ext. 3126).

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations and to prevent recurrence of similar violations. Your response may be directed to Raymond D. Kent, Team Leader, at the above address.

Sincerely,



Edward W. Thomas
Acting District Director

Attachments:

FDA 483

Compressed Medical Gases Guideline

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