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Food & Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, NY 14202

December 15, 1997

WARNING LETTER BUF #98-3

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Donald B. White, President
Associated Healthcare Systems, Inc.
85 Woodridge Drive
Amherst, New York 14228

Dear Mr. White:

A Food and Drug Administration (FDA) inspection of your Associated Healthcare Systems, Inc. Facility at 418 Spring Street in Jamestown, New York 14701, was performed on November 21 and 25, 1997, by Investigator Joseph A. Famiglietti.

The inspection revealed violations of the Federal Food, Drug and Cosmetic Act (the Act) which cause Oxygen, USP, repacked at this facility to be adulterated and misbranded as follows:

•501(a)(2)(B): The product is adulterated because the controls used for its manufacture, processing, packing or holding are not in conformance with current good manufacturing practice regulations (Title 21, *Code of Federal Regulations*, Parts 210 and 211), such as:

- failure to document identity and strength testing on all lots of bulk liquid oxygen used to fill home cryogenic vessels [211.165(a)];

-failure to document all visual inspections of home cryogenic vessels prior to filling [211.80(a)];

-the quality assurance unit does not always perform an adequate review of liquid oxygen receiving and Batch Production Records to assure completeness and accuracy [211.22(a)].

•502(g): The product is misbranded because the labeling of the vehicle-mounted vessel which holds bulk liquid oxygen does not identify the oxygen as being produced by the air liquefaction process, as required by the U.S. Pharmacopeia.

These deviations were included on an FDA-483, Inspectional Observations, form issued to David R. West, General Manager, at the conclusion of the inspection. A copy is enclosed for your reference.

Donald B. White, President
December 15, 1997
Page 2

You should take prompt action to correct these deviations and to assure they do not recur at this or other Oxygen USP repacking sites under your control. Failure to achieve prompt correction may result in regulatory action - without further notice. This may include seizure or injunction.

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

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Team Leader, at the above address.

Sincerely,



Brenda J. Holman
District Director

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Enclosures: FDA 483
Compressed Medical Gases Guideline

cc: David R. Wesp, General Manager
Associated Healthcare Systems, Inc.
418 Spring Street
Jamestown, New York 14701