



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Mid-Atlantic Region

D1047B

1/20/98

Telephone (201) 331-2901

January 7, 1998

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

WARNING LETTER

CERTIFIED MAIL -  
RETURN RECEIPT REQUESTED  
Mr. Charles K. Schwartz  
Vice-President, Operations  
Allied Health Care Services, Inc.  
89 Main Street  
Orange, NJ 07050

RELEASE

REVIEWED BY JPK 1/8/97  
C.O. DATE

FILE: 98-NWJ-14

Dear Mr. Schwartz:

During an inspection of your firm between December 3 and December 9, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's manufacturing/transfilling of compressed and liquid oxygen, USP. These deviations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act as follows:

1. Your firm cannot assure the identity and strength of [redacted] lots of compressed oxygen, USP, nor the identity of [redacted] lots of liquid oxygen, USP, (LOX), transfilled and distributed by your firm. For example:
  - A. Liquid oxygen, USP, which was transfilled into cryogenic home vessels and distributed between July 19, 1995 and Dec. 4, 1997, was not assayed for identity nor did Allied Health Care personnel witness the testing, i.e. identity and strength, performed by your supplier.
  - B. Your firm failed to conduct identity and strength testing on [redacted] lots of compressed oxygen, USP, transfilled into size D, E, and M6 cylinders which were distributed between August 22, 1997 and December 4, 1997.
2. Your firm cannot assure that the Oxygen Analyzer used, [redacted], is properly calibrated according to the manufacturer's instructions. For example:
  - A. It was noted that your firm lacks the high purity nitrogen standard required to calibrate the analyzer to "zero."

- B. It was observed, on Dec. 3, 1997, that the [REDACTED] Oxygen Analyzer could not be calibrated in order to check the purity of 8 "D" size cylinders and 22 "E" size cylinders of compressed oxygen, USP, supplier's lot #IC19K82.
3. Your firm lacks documentation to demonstrate that pre-fill inspections of liquid oxygen (LOX) cryogenic home vessels are being conducted, prior to filling.
  4. Your firm lacks written procedures regarding the receipt, manufacturing/transfilling, analytical testing, labeling, and distribution of compressed oxygen, USP. Furthermore, it was noted that your firm does not have written procedures for training of employees, equipment calibration and maintenance, nor for complaint handling.

It was also noted that your firm used a [REDACTED] Oxygen Analyzer to conduct purity testing on compressed oxygen cylinders filled on December 4, 1997. According to the manufacturer's operating/instruction manual, collected during the inspection, the accuracy of this analyzer is +/- 2%. Any oxygen analyzer used for strength testing must have an accuracy of +/-0.1%.

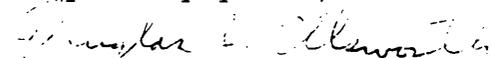
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken 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 reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,



DOUGLAS I. ELLSWORTH  
District Director