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Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000

March 3, 1997

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Scott Parker  
President  
Intermountain Health Care (IHC), Inc.  
36 South State Street  
Salt Lake City, Utah 84111

PURGED

Ref. # - DEN-97-12

Dear Mr. Parker:

During an inspection of your firm, IHC Home Care Services, 2250 South 1300 West, Suite A, Salt Lake City, Utah, on January 17 through 23, 1997, Investigator James E. Moore determined that your firm transfills liquid and compressed medical oxygen. Medical oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. A failure to perform the additional USP tests for carbon dioxide and carbon monoxide when bulk medical grade Oxygen was delivered by a supplier in cylinder banks of "T" sized cylinders and the method of manufacture of Oxygen by the supplier, i.e., was not listed on the supplier's certificate of analysis (COA) or was not maintained in-house by IHC Home Care Services. [21 CFR 211.84(d)(2)]
2. A failure to always include the following information on the COA for medical grade liquid Oxygen filled by the supplier into the firm's transfilling vehicles:

- (a) the specific test method used by the supplier to determine identity and purity,
  - (b) the supplier's signature and date, and
  - (c) that the firm witnessed the supplier's analysis. [21 CFR 211.84]
3. A failure to periodically verify through full USP testing the reliability of the supplier's analysis of medical grade Oxygen when the firm relied on the supplier's COA to reduce the amount of testing it needed to perform. [21 CFR 211.84(d)(2)]
4. A failure to always include one or more of the following items in batch production records for the manufacture of high pressure cylinders of Oxygen:
  - (a) signature and date of review by a second official,
  - (b) temperature during the transfilling operation,
  - (c) valve or snoop test during the transfilling operation,
  - (d) pre-fill inspections,
  - (e) lot numbers,
  - (f) the filler's name,
  - (g) results of the oxygen purity analysis,
  - (h) serial numbers of cylinders analyzed, or
  - (i) cylinder pressure. [21 CFR 211.188(b)]
5. A failure to always include one or more of the following items in batch production records for the manufacture of Liquid Oxygen:
  - (a) signature and date of review by a second official, and
  - (b) pre-fill inspections. [21 CFR 211.188(b)]
6. A failure to perform an identity retest on cryogenic (reservoir) home units after repair or maintenance and before redistribution. [21 CFR 211.87]
7. A failure to have the following written procedures for production and process control to assure the drug products had the identity, strength, quality, and purity they purported or were represented to possess:
  - (a) analysis of incoming medical grade liquid Oxygen, and
  - (b) the delivery and transfilling of medical grade liquid Oxygen into the patients' home units. [21 CFR 211.100]
8. A failure to have a written procedure describing in sufficient detail the approval or rejection of compressed gas cylinders which were past their expiration date. [21 CFR 211.80(a)]

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As President of this company, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Regulations.

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At the conclusion of the inspection, Investigator Moore issued a written report of observations (FDA 483) to Mr. J. Mark Huggins, Respiratory Manager. A copy of this report is enclosed for your reference.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,

  
Gary C. Dean  
District Director

Enclosure

cc: Mr. Ken Trowbridge  
Director, IHC Medical Equipment  
2250 South 1300 West  
Salt Lake City, Utah 84119

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