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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

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

June 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary L. Manuel
President/Owner
Manuel Enterprises, Inc.
948 Shaw Drive
Key Largo, FL 33037

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Ref. # - DEN-97-21

Dear Mr. Manuel:

During an inspection of your firm, Manuel Enterprises, Inc., located at 1969 West Uintah Street, Colorado Springs, Colorado, on March 11, 1997, Investigator Lynnette I. Riggio, determined that your firm repacks liquid medical oxygen. Liquid 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 products are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, 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. Failure to assay incoming liquid oxygen for identity prior to filling home units, as required by 21 CFR 211.84(d)(2). Your firm is not documenting that testing of liquid oxygen performed by the bulk supplier is being witnessed by your employees in lieu of performing strength and identity testing.
2. Failure to appropriately train each person engaged in the manufacture, processing, packing, or holding of drug products to enable those persons to perform their assigned functions, as required by 21 CFR 211.25(a). For example, personnel assigned to witness the testing of liquid oxygen have received no training on the specific analytical methodology employed.

3. Failure to establish written procedures for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 CFR 211.100(a). For example, there are no written procedures for any of the firm's operations.
4. Failure to perform adequate prefill operations on each high pressure cylinder prior to filling, as required by 21 CFR 211.84(d)(3). For example, there is no documentation of prefill inspections being performed.
5. Failure to review and approve all drug product production records to determine compliance with all established, written procedures, as required by 21 CFR 211.192.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility.

As President and Owner, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Practice regulations.

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 for drug products so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations for the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

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;

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(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. David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,



Gary C. Dean
District Director

Enclosures:
As Stated

cc: Mr. Stephen F. Byford
Manuel Enterprises, Inc.
1969 West Uintah Street
Colorado Springs, CO 80904