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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-02

October 24, 1997

Mark Hobbs, Owner
Hobbs Pharmacy
119 N. Banana River Drive
Merritt Island, Florida 32952

Dear Mr. Hobbs:

Inspection of your medical gas filling operation (dba Brevard Medical Equipment) located at 6300 N. Wickham Road, Suite #108, Melbourne, Florida, on October 9, 1997, by FDA investigator Jose R. Rodriguez, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not adequately tested for purity and identity prior to release for distribution. Testing is inadequate in that no documentation is available to show that the oxygen analyzer used by your firm for testing is calibrated properly as specified by the manufacturer.

Written procedures are not established for all production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for the receipt and acceptance of incoming bulk oxygen, calibration and maintenance of equipment, testing of filled cylinders for purity and identity, labeling, handling of complaints, recalls, and employee training. No documentation is available to show that personnel have been adequately trained.

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Batch production and control records fail to document that each significant step in the manufacturing operation was completed. A review of batch records from January to August 1997, reveals that all required pre and post fill cylinder inspections and tests were not performed and actual purity test results were not recorded. Ten batch records fail to document the serial number of the cylinder tested for purity, fourteen batch records identify the cylinder tested as serial number "M4141", and twenty-two batch records fail to document supervisory review and approval prior to release for distribution.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As owner, it is your responsibility to ensure that all medical gas products transfilled and distributed by your firm are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. Your response should include appropriate examples of documentation for review. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

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Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

A handwritten signature in black ink that reads "Michael A. Chappell". The signature is written in a cursive style with a large, sweeping initial "M".

Michael A. Chappell
Acting Director
Florida District