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EB 8/2/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

July 22, 1999

Telephone: (913) 752-2100

WARNING LETTER

John D. Lawson, Owner
Home Care Equipment, Inc.
1135 Lester Street
Poplar Bluff, MO 63901

KAN #99-022

Dear Mr. Lawson:

Recently an inspection was made of your medical oxygen transfilling operation located at 7707 East Osie, Wichita, Kansas. This inspection was conducted on June 23 to 25, 1999, by a Food and Drug Administration Inspector from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the medical oxygen transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

- failure to routinely assay incoming liquid oxygen for identity prior to filling cryogenic home units, and failure to document the witnessing of liquid oxygen testing at your distributor [21 CFR 211.165(a)];
- failure to establish the reliability of the supplier's certificate of analysis through appropriate validation of the supplier's test results, by conducting a complete audit of the supplier at least annually [21 CFR 211.84(d)(3)];
- failure to calibrate the Servomex 570A Oxygen analyzer following manufacturer's instructions, and failure to maintain a record of calibration [21 CFR 211.160(b)(4) & 21 CFR 211.194(d)]
- failure to calibrate equipment such as thermometers and gauges which is used in the filling of Compressed Oxygen USP [21 CFR 211.68].

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Home Care Equipment, Inc.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each location manufacturing medical gases, which is owned by you. At the conclusion of the inspection a Form FDA 483, List of Observations, was issued to and discussed with, Ms. Paula S. Cooper, Branch Manager. A copy of this form is enclosed for your information.

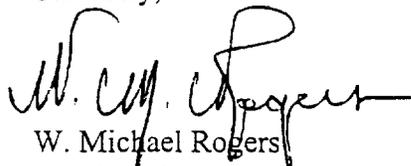
You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your liquid medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

By copy of this letter, we are advising the Health Care Finance 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 or federal law.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

Enclosure – Form FDA 483

cc: Paula S. Cooper, Branch Manager
Home Care Equipment, Inc.
7707 East Osie, Suite 404
Wichita, KS 67207