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February 9, 1998

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

Telephone: (913) 752-2100

WARNING LETTER

James L. Higgins, Owner
Home Health Care Plus
316 Neosho Street
Burlington, KS 66839

Ref.# - KAN-98-010

Dear Mr. Higgins:

During an inspection of your compressed medical oxygen transfilling operation located at the above address, conducted on January 23, 1998, Food and Drug Administration Investigators from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's medical oxygen 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 establish and document a Quality Control Unit [21 CFR 211.22(a)];
- failure to document the training of employees in CGMP's and the transfilling of compressed medical oxygen [21 CFR 211.25(a)];
- failure to establish the reliability of the supplier's certificate of analysis through appropriate validation of the supplier's test results, by conducting an audit of the supplier at least annually [21 CFR 211.84(d)(3)];
- failure to establish written procedures designed to assure that the compressed medical gas has the identity and strength it purports or is represented to possess [21 CFR 211.100]; examples include 1) complaints; 2) calibration; 3) acceptance/rejection of filled cylinders; 4) labeling; 5) warehousing/quarantine; 6) training;

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failure to calibrate the Servomex 570A oxygen analyzer per the operator's manual, and the gauges used in the transfilling process [21 CFR 211.160(b)(4) and 21 CFR 211.194(d)];

failure to conduct release testing, i.e., identity and potency, on filled cylinders [21 CFR 211.165(a)];

failure to establish adequate batch production and control records of each batch of compressed medical oxygen produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)].

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. We received and reviewed your letter dated January 23, 1998, concerning the Form FDA 483 observations, prior to the issuance of this letter. We will provide our response by separate letter.

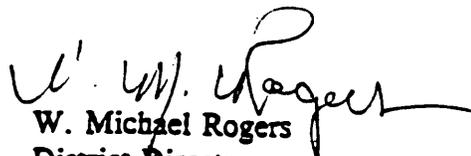
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

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.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, in addition to those covered in the letter, that are being taken to correct the noted violations and to prevent their recurrence. If you feel the December 18 letter adequately addresses your corrections we will accept it as your response to this letter.

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

Sincerely,


W. Michael Rogers
District Director
Kansas City District