



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

91690d
Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

August 27, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2001-030

Mr. Robert E. Scott, Owner
American Home Health Care Company
916 Grandview Boulevard
Sioux City, IA 51101

Dear Mr. Scott:

On August 9-10, 2001 an Investigator representing the Federal Food and Drug Administration (FDA) conducted an inspection at your medical gas transfilling operation located at 501 Pearl Street, Sioux City, Iowa. During this inspection serious deviations from the Current Good Manufacturing Practice (CGMP) Regulations, Title 21 Code of Federal Regulations, Part 211 (21 CFR 211) were documented. These findings cause the medical gas transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Significant deviations include but are not limited to the following:

- There is no documentation of the Batch Production Records being reviewed and approved by the Quality Control Unit since January 1, 2001 [21 CFR 211.192].
- There is no documentation that members of the Quality Control Unit possess the education, training and/or experience to perform this function [21 CFR 211.25(b)].
- The calibration procedures and documentation for the Servomex Oxygen Analyzer are inadequate in that the frequency for calibration to be performed is not specified and the standards used for calibration are not certified cylinders of nitrogen and oxygen as specified in your procedures [21 CFR 211.68(a)].
- There is no documentation that you receive a Certificate of Analysis, as your procedures indicate, upon receipt of each cylinder of incoming source oxygen [21 CFR 211.84(d)(2)].
- There is no documentation of a complaint received regarding released product [21 CFR 211.198(b)].

Although not discussed during the inspection the following significant deviation is also noted:

- The procedures used for your transfilling operation do not adequately identify the originators or the Quality Control Unit members who reviewed and accepted the procedures. In addition there is no signature of the responsible individuals on the described procedures as accepting the procedures [21 CFR 211.100].

In addition it was observed during the inspection that your firm has not registered or drug listed as required by 21 CFR 207.20(a). Failure to register and drug list your products cause medical gases processed at your facility to be misbranded within the meaning of Section 502(o) of the Act.

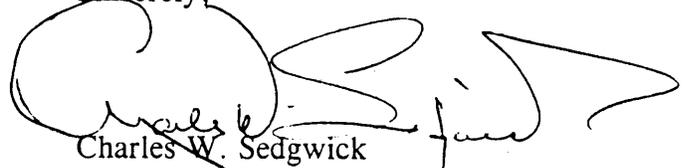
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the implementing regulations. At the close of the inspection Form FDA483 was issued to Peggy R. Hughes, Manager. A copy of that form is enclosed.

Please be advised that 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 Federal Court injunction against further marketing of adulterated or misbranded medical gases. In addition other Federal agencies are informed about Warning Letters that are issued so that they may consider this information when awarding government contracts.

It is necessary for you to correct these deviations immediately. Please inform this office, in writing, within fifteen (15) working days from the receipt of this letter on the specific steps you are taking to correct the violations. In your response you should identify how your corrective actions will prevent future deviations from occurring. Within your response you should identify when each of the corrections will be corrected.

We acknowledge the verbal response your firm's Manager Ms. Peggy R. Hughes provided to our staff. It is necessary to document your commitment to the corrective actions in writing, in the manner described above, when you respond to this letter. Please direct your response to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles W. Sedgwick', is written over a circular stamp. The signature is fluid and cursive.

Charles W. Sedgwick
District Director
Kansas City District