



DEPARTMENT OF HEALTH AND HUMAN SERVICES

RB 12/5/00 mH986n

Food and Drug Administration  
Kansas City District  
Southwest Region  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

December 4, 2000

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

KAN #2001-008

James Martin, President  
Health-n-Home, Inc.  
15100 North 90<sup>th</sup> Street  
Scottsdale, AZ 85260

Dear Mr. Martin:

Recently an inspection was made of your medical gas transfilling operation known as Health-n-Home, Inc., 14719 West 112<sup>th</sup> Street, Lenexa, Kansas. This inspection was conducted on November 2 & 3, 2000, by a Food and Drug Administration Investigator 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 Liquid Oxygen USP (LOX) 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 establish adequate batch production and control records for each batch of your LOX produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, and failure to adequately review those records [21 CFR 211.188(b) and 211.192].

Failure to establish and follow written procedures designed to assure that LOX has the identity and strength it purports or is represented to possess [21 CFR 211.100(a)].

Failure to have an established quality control unit with documented procedures describing the responsibilities of the unit and its personnel [21 CFR 211.22].

Failure to fully document the training of your employees in current good manufacturing practices (CGMPs) in the filling of LOX [21 CFR 211.25(a)].

- James Martin, President  
Health-n-Home, Inc.  
December 4, 2000  
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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 facility within your corporation which transfills or manufactures medical gas. We are enclosing a copy of the Form FDA 483 that was issued to John W. Kovelan, Area Manager of Operations, at the conclusion of the inspection.

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.

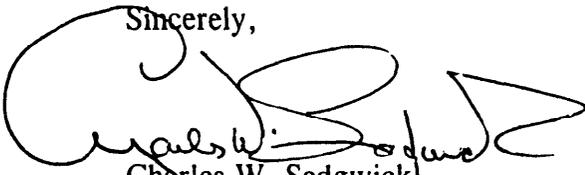
The FDA has received a response from Mr. Kovelan dated November 5, 2000, which is a response to the observations listed on the Form FDA 483 issued at the close of the inspection. We will review Mr. Kovelan's letter and respond to him by separate letter.

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 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.

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 problems. 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,



Charles W. Sedgwick  
District Director  
Kansas City District

Enclosure - Form FDA 483

cc: John W. Kovelan  
Area Manager of Operations  
Health-n-Home, Inc.  
14719 West 112<sup>th</sup> Street  
Lenexa, KS 66210