



March 14, 2001

**WARNING LETTER NO. 2001-NOL-15**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. Gene Crisman, President and CEO  
Home Care Supply, LLC  
2155 I-H 10 East  
Beaumont, Texas 77701

Dear Mr. Crisman:

During an inspection of your manufacturing facility, d.b.a. Medi-Rents and Sales, located at 3025 Edenborn Avenue, Metairie, Louisiana, conducted January 11 through February 1, 2001, a U.S. Food and Drug Administration (FDA) investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, oxygen, to be adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The controls used for manufacture, processing, packing or holding of this product are not in conformance with CGMP regulations (Title 21, *Code of Federal Regulations*, Parts 210 and 211), such as:

- Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacturing, processing, or holding of the batch was accomplished;
- Failure to document the initials or signature of the person who performed final product testing on 10 cryogenic vessels of oxygen and to document the date of all final product testing of liquid Oxygen U.S.P.;
- Failure to follow established written procedures for assigning a lot number to each cryogenic vessel of liquid Oxygen U.S.P. filled at your facility;
- Failure to follow established written procedures by preventing the use of labels that do not meet written specifications; and,
- Failure to document employee training in CGMP requirements in the production of oxygen.

The above identification of violations is not intended to be an inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the CGMP regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices 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 properly correct these violations may result in regulatory action, such as seizure and/or injunction, and/or administrative sanctions without further notice. We are aware that at the close of the inspection Mr. Marcel J. Farnet, III, Branch Manager, made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA-483. However, it is necessary that you notify this office in writing, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time in which the corrections will be completed.

Your response should be directed to Mr. Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,



Richard D. Debo  
Acting District Director  
New Orleans District

Enclosure: FDA-483

cc: Mr. Marcel J. Farnet, III, Branch Manger  
Home Care Supply, LLC  
3025 Edenborn Avenue  
Metairie, Louisiana 70002