



March 23, 1999

WARNING LETTER NO. 99-NOL-15

FEDERAL EXPRESS

Mr. Stewart Pace, Executive Vice President  
Med-South, Inc.  
406 Medical Center Drive  
Jasper, Alabama 35501

Dear Mr. Pace:

During the February 24 - March 8, 1999, inspection of Baptist Home Medical Services, LLC, located at 822 Foley Street, Jackson, Mississippi 39202, our investigator documented deviations from the Current Good Manufacturing Practice regulations. These deviations cause your drug product, USP Oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the controls used for the manufacturing, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice Regulations (Title 21, *Code of Federal Regulations*, Part 211).

Our inspection revealed the following objectionable conditions:

- Failure to have Certificates of Analysis (COA's) for 12 lots of Liquid Oxygen, USP, which were received from suppliers;
- Failure to verify the reliability of supplier's analyses for Liquid Oxygen, USP;
- Failure to document that an identity test had been performed on 3 lots of Liquid Oxygen, USP, prior to transfilling;
- Failure to list the actual date the oxygen identification test is performed on all receipt entries in the Liquid Oxygen Receipt Log;
- Failure to provide accurate and complete records regarding the receiving, identity testing, and transfilling of Liquid Oxygen, USP;
- Failure to provide accurate and complete records regarding calibration of the test instrument used for the identification test, and failure to use certified oxygen for calibration of the identification test instrument;

- Failure to have an operator's manual, preventive maintenance schedule, or any documentation of the last maintenance performed on 51 of approximately 250 oxygen concentrators in service at the firm; and,
- Failure to provide accurate CGMP training records for employees responsible for transfilling and testing of Liquid Oxygen, USP.

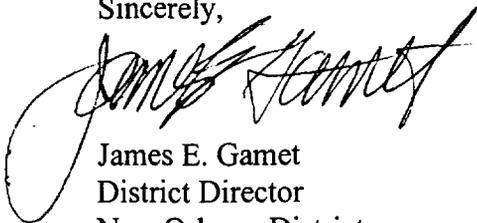
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and 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 them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that 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 within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number 504-589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA 483

cc: Mr. Michael C. Simmons, Director  
Baptist Home Medical Services, LLC  
822 Foley Street  
Jackson, MS 39202

bcc: HFA-224 (Records Section)  
HFC-210 (CFN 2320588) DCMO, OE  
HFI-35 FOI Staff (PKLN Bldg.)  
HFC-240 GWQAP, Div. of Medical Products Quality Assurance  
HFD-320, CDER  
HFR-SE1 ATL-RO, RFDD  
NOL-DO Drug Specialist  
Legal file (W.L.)  
DFOB/PKS/EJR  
Jackson RP  
EI File (CFN 2320588)  
NOL-DO R/F  
CB R/F

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