



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

6/14/98
d18046

4298 Elysian Fields Avenue
New Orleans, LA 70122

June 1, 1998

WARNING LETTER NO. 98-NOL-22

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert N. Elkins, CEO
Integrated Health Services
10065 Red Run Boulevard
Owings Mills, MD 21117

Dear Dr. Elkins:

During the April 29-30, May 4,6,1998 inspection of your manufacturing facility, Distinct Home Healthcare, Inc. dba Samaritan Home Medical, located at 9162 Mansfield Road, Shreveport, Louisiana, our investigator documented deviations from the Current Good Manufacturing Practices regulations. These deviations cause your drug product, USP Oxygen, to be adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing or holding of this product are not in conformance with current good manufacturing practice regulations (Title 21 Code of Federal Regulations, Parts 210 and 211).

Our inspection revealed the following deviations:

1. Failure to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units. Your firm does not witness the Certificate of Analysis, does not perform identity testing on the bulk supply of USP liquid Oxygen, and does not perform full USP testing on the bulk supply or on the individual cryogenic home vessels transfilled from the bulk supply.
2. Failure to properly calibrate hand-held Oxygen analyzers used to perform identity testing on the USP liquid Oxygen, in that Standard Calibration Oxygen is not used for the calibration process.
3. Failure to periodically verify the reliability of the supplier's analysis of the bulk USP liquid Oxygen.

4. Failure to properly document that each significant step of the manufacture, processing, packing, or holding of USP Oxygen was accomplished. For example, there is no documentation on March 6, 13, April 14 & 20, 1998, of the person(s) who performed the calibrations of the oxygen analyzers; Liquid Oxygen Transfill Log batch production records between April 13 and April 20, 1998, do not contain a signature or date to indicate that they have been reviewed for accuracy and completeness.
5. Failure to maintain a master labeling file.

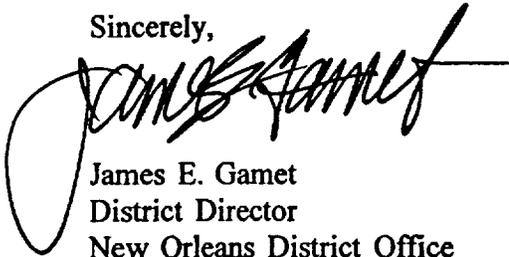
The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters 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 promptly correct them may result in regulatory action without further notice. This may include seizure and/or injunction. This letter serves as official notice that FDA expects all your firm locations to be in compliance.

You should notify this office in writing, within 15 working days of the 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 within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, 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 Mrs. Hardin.

Sincerely,



James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

cc: **Mr. Darwin M. Thornhill**
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