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Food and Drug Administration
New Orleans District Compliance



DEPARTMENT OF HEALTH AND HUMAN SERVICES

4298 Elysian Fields Avenue
New Orleans, Louisiana 70122
(504) 589-7166 Fax (504) 589-4657

December 23, 1996

WARNING LETTER 97-NOL-22

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Harvey E. Mitchell
Director
Regional Medical Rental & Sales
5519 Coliseum Blvd.
Alexandria, LA 71303

Dear Mr. Mitchell:

During an inspection of your facility conducted on November 25-27, 1996, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, *Code of Federal Regulations (CFR)*, Parts 210 & 211). These deviations cause your product, medical oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The medical oxygen GMP deviations include:

1. Failure to assay incoming oxygen for identity and strength prior to filling home units;
2. Failure to perform adequate prefill checks on cryogenic home units prior to filling;
3. Failure to have an adequate Certificate of Analysis (COA) from the supplier;
4. Failure to properly train employees who witness the supplier's oxygen testing.

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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 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 these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not 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, 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 Ms. Hardin.

Sincerely,


James E. Gamet
District Director
New Orleans District Office

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Enclosure: 21 CFR, Part 210 & 211