



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

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4298 Elysian Fields Avenue
New Orleans, LA 70122

November 7, 1996

WARNING LETTER NO. 97-NOL-16

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Kennedy
President
Rotech Medical Corp.
4506 L.B. McLeod Rd Suite F
Orlando, Florida 32811

Dear Mr. Kennedy:

During an inspection of one of your facilities, Taylor Home Health Supply, Inc, 401 West 2nd Street, Broussard, Louisiana, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211), regarding the repacking/manufacturing of medical oxygen. These deviations cause your product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our inspection, conducted on October 9-11, 1996, revealed the following objectionable conditions: (1) failure to receive a Certificate of Analysis from the filler of the cryogenic vessels denoting the identity and strength of the oxygen; (2) failure to establish a written procedure to assure the oxygen has the identity and strength it purports; (3) failure to label product showing the name and address of the filler/supplier and the lot number on each filled tank.

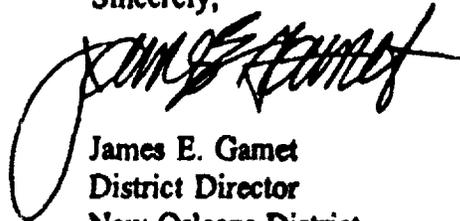
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters 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 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 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 Carolyn S. Olsen, 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. Olsen.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483
21 CFR, Part 211

cc: Mr. Ray Lemoine
Taylor Home Health Supply, Inc.
401 West 2nd Street
Broussard, LA 70518