



DEPARTMENT OF HEALTH AND HUMAN SERVICES,

d1814b HFI-35 4/1/98
FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
Fax (504) 589-4657

May 21, 1998

WARNING LETTER NO. 98-NOL-21

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William P. Kennedy, CEO
Rotech Medical Corporation
4506 L. B. McLeod Road
Orlando, FL 32811

Dear Mr. Kennedy:

During the March 30, 1998 inspection of your manufacturing facility, Samaritan Medical Equipment Company, located at 112 South Trenton Street, Ruston, 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 502(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). 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 failure to perform full USP testing on each cryogenic home unit of oxygen filled on premises where other gases are present and transfilled; failure to witness liquid oxygen testing performed by supplier; and, failure to document prefill inspections and identity tests of six cryogenic home vessels.

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.

Your 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.

We received your written response to the deficiencies listed on the Inspectional Observations, Form FDA 483, presented to firm management at the conclusion of the inspection. The corrections described will be reviewed and documented at our next inspection.

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 Ms. Hardin.

Sincerely,



James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

cc: Mr. Steven R. Davis
Branch Manager
Samaritan Medical Equipment, Co.
112 South Trenton Street
Ruston, LA 71270

/tjt