



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

608

8/27
B

PHILADELPHIA DISTRICT

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

97-PHI-35

July 15, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen P. Griggs
President and Chief Operating Officer
RoTech Medical Corporation
4506 L.B. McLeod Road, Suite F
Orlando, FL 32811

(GEN)	SPEC.
RELEASE	
F# _____	DATE <u>8-19-97</u>
Reviewed by: <u>Ross J. de Marco, Sr.</u>	

Dear Mr. Griggs:

On June 10-13, 1997 FDA Investigator Cynthia L. Rakestraw conducted an inspection of a RoTech subsidiary firm, Respiratory Home Care Consultants located at 3739 New Castle Road West Middlesex, PA. During this inspection, the Investigator observed deviations from current good manufacturing practices for pharmaceuticals (CGMP's) with regards to controls for manufacturing medical oxygen U.S.P. These observations were summarized on a FDA 483 List of Observations form that was issued to Michael D. Stubbs, Supervisor, on 6/13/97.

These deficiencies render your medical oxygen U.S.P. in home cryogenic vessels adulterated within the meaning of Section 501 (a)(2)(B) of the Food Drug & Cosmetic Act (FD&C) 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) as follows:

1. Failure to assay the incoming liquid oxygen for identity and strength prior to filling liquid home units [211.165(a)].
2. Failure to establish a system of documentation to reliably correlate supplier lot numbers with filling and receiving records [211.184(c)].
3. Failure to establish procedures for quality control, including provision for timely review of production records to assure they are complete and that no errors have occurred, including transcription errors [211.22(a)].

The June '97 inspection was conducted as a follow-up to two prior inspections conducted 9/5-10/96 and 11/26- 27/96 during which significant CGMP deficiencies were also

bcc: HFA-224/HFC-210(2530236)/HFC-240/HFI-35(purged)/HFC-200
(Schweichert)/HFD-320/HFR-SE240/HFR-MA100/HFR-MA150/HFR-MA1515
(Rakestraw)/EF/Legal File/ALD/ WIL BOOK (MAZ)

Page 2
July 15, 1997
Stephen P. Griggs

observed. Copies of the FDA 483 List of Observations issued at the close of each of these inspections are enclosed for your information. After each inspection, corporate management has proposed corrective actions to the specific items identified by the FDA Investigator. This non-systemic approach to quality management, however, falls far short of FDA expectations for CGMP compliance. The lack of adequate controls in processing of medical gases for respiratory care has the potential to cause serious injury to patients, including death. It is your responsibility to preclude such a hazard by implementing proactive quality controls which assure that each of your subsidiary firms meets all regulatory and quality requirements. It is not the responsibility or the role of the FDA to serve as your surrogate quality control unit.

Concerning our review of your company's June 16, '97 response to the FDA 483, we have serious concerns about the adequacy of your corporate program to oversee your medical gas facilities. The following is a representative example which particularly highlights what we believe are systemic, corporate-wide deficiencies. You will note that the FDA 483 issued 6/13/97 cited Respiratory Home Care for failing to review records for accuracy and completeness. The June 16 response to this FDA 483 included updates to several RoTech corporate-wide procedures, including one entitled "QUALITY CONTROL FOR OXYGEN USP" . (A copy is attached for reference.) Within this document, slightly over one-half page in length, we have identified at least 18 typographical errors. We cannot conclude, therefore, that Respiratory Home Care personnel will understand the significance of reviewing records to assure accuracy when they are subject to corporate procedures that are so ill prepared and inadequately reviewed.

The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Food, Drug & Cosmetic (FD&C) Act and its associated regulations are met in all of your facilities subject to FDA regulations. Failure to promptly take corrective action may result in regulatory action without further notice. Possible actions include seizure and/or injunction. 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.

Please advise this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the cited violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections may be completed.

Page 3
July 15, 1997
Stephen P. Griggs

Your reply should be directed to the attention of Ann deMarco, Compliance Officer, at the address noted on the letterhead.

Sincerely yours,



Diana J. Kolaitis
District Director
Philadelphia District

Enclosure: Forms FDA 483 dated 9/10/96, 11/27/96 and 6/13/97
RoTech procedure for Quality Control of Oxygen USP

cc: Robert E. Bastian, Director
Division of Primary Care and Home Health Services
Pennsylvania Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104

David W. Graves, FDA Coordinator
RoTech Medical Corporation
4506 L.B. McLeod Road, Suite F
Orlando, FL 32811

Michael D. Stubbs, Supervisor
Respiratory Home Care Consultants
3739 New Castle Road
West Middlesex, PA 16159