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SB
E-117

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

RB 7/31/97

Certified/Return Receipt Requested

July 30, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

Stephen P. Griggs, President
Rotech Medical Corp.
4506 L.B. McLeod Road
Orlando, FL 32811

Ref. # - KAN-97-023

Dear Mr. Griggs:

During an inspection of your compressed medical oxygen transfilling operation known as Hamilton Medical Equipment d/b/a Homecare Helping Hands, Inc., 123 North Vine Street, West Union, Iowa, conducted on July 8 through 14, 1997, an Investigator with the Iowa Board of Pharmacy documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

Failure to perform assays of the contents of one filled cylinder for identity and strength, per manifold filling sequence [21 CFR 211.165(a)]. For example:

Your manifold fills a maximum of three cylinders at one time, yet you are filling nine cylinders prior to conducting the assay of contents.

Failure to establish complete written procedures for labeling, equipment calibration, training, recalls and complaints, assigning lot numbers, and quality assurance [21 CFR 211.100].

Failure to assign specific lot numbers to each fill of three cylinders on the manifold [21 CFR 211.130(b)].

Failure to maintain calibration records for gauges and the ~~oxygen~~ oxygen analyzer [21 CFR 211.68(a)].

DISTRIBUTION:

Orig. & enclosure: Addressee
bcc: LF; FF(1937681); HFA-224; HFD-325(Sylvia); HFI-35/DIB(via FOI); HFC-210; Drug Team; WMR; SW-400 (Breen); FLA-DO(HFR-SE250); IBRF

CRP:ak

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Rotech Medical Corp.

At the conclusion of the inspection Form FDA 483, List of Inspectional Observations, was prepared, issued to and discussed with Ms. Nancy J. Hanson, Business Manager. This is a comprehensive list of deviations observed by the investigator during the inspection. We have enclosed a copy for your information.

We have received and reviewed a letter from Ms. Nancy J. Hanson dated July 22, which is a response to the Form FDA 483 observations. The letter was reviewed prior to the issuance of this letter. It appears from the letter that proper steps are being taken to correct the noted deviations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and 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. Such actions may include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, to inform us if the July 22 letter will suffice as your response to this letter, or you may expand on that letter with additional information concerning corrections being made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Brad L. Johnson, Manager

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Rotech Medical Corp.

Homecare Helping Hand, Inc.
123 North Vine
Box 474
West Union, Iowa 52175

Daniel Bunting, Regional Manager
Hamilton Medical Equipment
2740 1st Avenue NE
Cedar Rapids, IA 52402