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Food and Drug Administration
Atlanta District Office

purged Row 7/18/97

HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 8th Street, N.E.
Atlanta, Georgia 30309

April 14, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven P. Griggs, President
Rotech, Incorporated
4506 L.R. McLeod Road
Suite F
Orlando, Fl 32811

WARNING LETTER

Dear Mr. Griggs:

An inspection of your medical oxygen transfilling facility, located on 631 North Cobb Street, Milledgeville, Georgia, was conducted February 28 through March 5, 1997. Our investigator documented several significant deviations from the Current Good Manufacturing Practice Regulations (CGMPs) as set forth in Title 21 of the Code of Federal Regulations (CFR), Part 211. These deviations cause your transfilled Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include identity and strength. Also, you have failed to maintain any records for the transfilling of compressed medical oxygen. There was no indication that any of the regulations (CGMP) for drug products (21 CFR Parts 210 and 211) are being adhered to.

Our investigator did observe that your firm does have a [REDACTED] oxygen analyzer. However, no records are maintained on the calibration of the [REDACTED] analyzer.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. This training must be in the particular operations that the employee performs and include current good manufacturing practice as it relates to the employee's functions.

The article, Oxygen USP, is misbranded in that it was manufactured in an establishment not duly registered under Section 510 of the Act and the article has not been listed as required by Section 510(j).

During the inspection, management stated that the firm was only a distributor of compressed medical oxygen. However, by the conclusion of this inspection it was determined that this firm was transfilling medical oxygen for distribution, and your firm admitted to this in an affidavit.

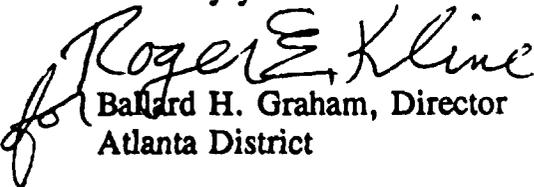
Please be aware that you are subject to provisions of Title 18, Section 1001 of the United States Code (U.S.C.). This statutory provision makes it a criminal offense to knowingly and willfully make a false or fraudulent statement in any matter within the jurisdiction of a department or agency of the U.S.

At the conclusion the inspection, Investigator Neligan issued his Inspectional Observations (FDA 483) to and discussed his findings with Mr. Richard C. Whirley, Area Manager. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility and any other similar operation under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should be addressed to Barbara A. Wood, Compliance Officer, at the address noted in the letterhead.

Sincerely yours


Ballard H. Graham, Director
Atlanta District

cc: Mr. Richard C. Whirley
Area Manager
Respiratory HomeCare, Inc.
631 North Cobb Street
Milledgeville, Georgia 31061

HFI-35 REK
BAW TURNER
HFA-224 MID,GA - RP
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