



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
DETROIT DISTRICT

Purged by S. Davis 12/2/16

D1054B

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Detroit, MI 48207-3179
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-01

DEC 18 1997

Michael Robbins
Chief Marketing Officer
Convacare Services Inc.
1201 5th St. P.O. Box 549
Bedford, Indiana 47421

Dear Mr. Robbins:

During an inspection of your Home Respiratory Care Company located in South Bend, Indiana conducted on November 4-18, 1997 Investigator Myra Casey documented significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211].

Oxygen USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (The Act).

Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

Failure to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units. [21 CFR 211.165(a)].

For example, the revised guideline for Compressed Medical Gases February 1989 includes guidance for Home Respiratory Care Companies (HRC). If the HRC obtains bulk liquid oxygen from a bulk supplier who supplies a certificate of analysis but the test is not witnessed by the HRC, the HRC must perform an identity test on each lot received and establish the reliability of the supplier's analyses at appropriate intervals. An alternative is no testing is required if the receiving firm witnesses the testing,

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receives a valid certificate of analysis and documents that the testing has been witnessed. The person witnessing the testing is required to receive training specific to the analytical methodology being witnessed and this training should be documented.

Failure to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)].

For example the firm did not have written procedures available for the filling of liquid oxygen.

Failure to assure that each person engaged in the transferring of Oxygen, U.S.P. has the education, training or experience to enable that person to perform the assigned function. [21 CFR 211.25(a)]

For example the driver technician was not familiar with the analytical methodology used by the supplier nor Current Good Manufacturing Practices.

The medical oxygen is misbranded.

The label for the product fails to bear an adequate statement of the quantity of contents.(21CFR 201.51)

The article, Oxygen, U.S.P. is a prescription drug. Its labeling fails to bear the statement "Caution: Federal law prohibits dispensing without prescription. [21U.S.C. 353(b)(4)].

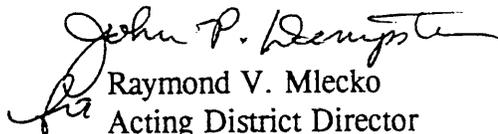
The above violations are not meant to be an all-inclusive list of deficiencies in your operation. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. We acknowledge receipt of Jacalyn A. Goodman's response to the to the inspectional observations on the FDA 483 issued at the close of the inspection. It is important that you assess your compliance with the Federal Food Drug and Cosmetic Act and regulations for not only this recently inspected location but all of your drug establishments. This letter will serve as an official notification that FDA expects all of your locations to be in compliance. 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. A copy of "Compressed Medical Gases Guideline" is enclosed for your reference.

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Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct these violations and prevent their recurrence. Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Avenue, Detroit, Michigan 48207 (Telephone: 313-226-6260 ext 137).

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District

2 Enclosures:

Fresh Air '97 - A look at FDA's Medical Gas Requirements
Compressed Medical Gases Guideline (Revised) February 1989

cc: Ms. Tammy Bowerman
ConvaCare Service Inc.
919 East Jefferson Ave.
South Bend, IN 46617

Patrick Robbins
ConvaCare Services Inc.
1201 5th Street
Bedford, IN 47421