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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

98-PHI-14

February 25, 1998

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Jordan Sitnick, President  
Jordan-Reses Home Healthcare  
701 Chester Pike  
Sharon Hill, PA 19079

GEN.	SPEC.
RELEASE	
F# _____	DATE 2/28/98
Reviewed by: <i>Lynn S. Bane</i>	

Dear Mr. Saposnick:

On February 3, 4 1998, Philadelphia District Investigator Valerie H. Wright conducted an inspection of your medical oxygen facility located at 701 Chester Pike, Sharon Hill, PA. The medical oxygen filled by this facility is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

At the conclusion of the inspection, Investigator Wright issued form FDA-483, Inspectional Observations, to Allan B. Saposnick, Director of Clinical Services, and discussed the observations with him. A copy of the FDA-483 is enclosed for your information. This inspection revealed that medical oxygen manufactured by the Sharon Hill, PA facility is adulterated under Section 501(a)(2)(B) of the FD&C Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Parts 210 and 211 as indicated below:

1. Failure to calibrate the Servomex Oxygen Analyzer in accordance with the manufacturer's recommendations and instructions [21 CFR 211.160(b)(4)].

The inspection revealed that during Investigator Wright's visit on February 3, 1998, the Sharon Hill, PA facility was calibrating their analyzer with room air using the span control on the front panel of the analyzer. The employee's calibrating the analyzer were also unaware that the "zero" calibration step, that uses room air, has been discontinued.

Please be advised that the procedure known as the "U.S. Instruction Manual for Servomex Model 570A Oxygen Analyzer"

(Addendum) has been discontinued, effective October 9, 1997, Rev.5. Therefore, any firm using a Servomex Model 570A and calibrating the analyzer via the Addendum needs to stop using this method immediately and begin calibrating the analyzer according to the original or new manual. The calibration procedure calls for the use of high purity nitrogen with a minimum potency of 99.9% for the "zero" step, and oxygen with a minimum potency of 99.2% for the "span" step.

2. Failure to test one cylinder from each manifold filling sequence for identity and strength [21 CFR 211.165(a)].

Investigator Wright observed that, between January 20, 1998 and the time of the inspection, your firm conducted testing for both identity and strength only when one or more of the "H" cylinders on the manifold was changed. Your firm should test one cylinder from each twelve cylinder batch of transfilled oxygen gas prior to release for distribution.

3. Failure to test the cryogenic home vessels for identification after the vessel was sent out for maintenance or repairs [21 CFR 211.87].

If a cryogenic home vessel is sent out for repair or maintenance, then upon return, the vessel should be retested for identification at the least prior to redistribution.

4. Failure to establish written procedures for the training of individuals involved in the gaseous and liquid medical oxygen operations [21 CFR 211.25(a)].

Investigator Wright observed that your firm has no written procedure for training. Your firm is expected to establish detailed written procedures (training program) outlining the specific areas of the firm's operation to be covered. On-the-job training is acceptable, as long as the training is conducted by a qualified individual.

5. Failure to establish written procedures addressing a calibration schedule for all equipment, especially the Servomex Oxygen Analyzer and the [REDACTED] digital thermometer [21 CFR 211.68].

Investigator Wright observed that your firm has no written procedures addressing a calibration schedule for the equipment used in the gaseous and liquid oxygen operations. It was noted that the calibration of the analyzer varied from everyday to as long as ten (10) days. Your firm should establish written procedures addressing a calibration

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schedule for all equipment used during its operations. You may reference the manufacturer's instruction manual for the recommended calibration schedule, however, the manual should be made available and should be followed to assure proper functioning of all equipment.

6. Failure to follow SOP (Number CL 100.0 - Transfilling Manifold Inspection) in that the transfilling manifold is not inspected twice monthly [21 CFR 211.100(b)].

Investigator Wright observed that your firm has not inspected the transfilling manifold since 2/18/94 in accordance with your own SOP. Medical gas manufacturers are expected to establish and follow detailed written procedures covering all aspects of their operation. These procedures must be read, understood, and followed by all employees.

7. Failure to establish written procedures covering the receipt, identification, storage, handling and examination of all labeling [21 CFR 211.122].

Investigator Wright observed that your firm has no written procedures addressing label control. Labels for compressed oxygen cylinders were stored in a box in an office file drawer and in a desk in the transfilling area. Your firm should establish written procedures addressing label control which includes receipt, identification, storage, handling, and examination of all labeling.

In addition, Investigator Wright reviewed approximately seventy (70) oxygen purity analysis forms from [REDACTED] for dates 9/8/97 to 12/26/97. Seven (7) of the forms were not signed by the witness to the testing. Please note that individuals involved in the witnessing of the oxygen purity testing at their supplier of liquid oxygen are required to receive training specific to the analytical methodology being witnessed, and this training should be documented. If you cannot assure that these individuals are properly trained for this purpose, your firm is required to establish the reliability of your supplier's analyses through appropriate validation of the supplier's assay results at appropriate intervals. Additionally, you would be required to perform an identity test for each shipment of bulk liquid oxygen received.

We acknowledge the fact that Mr. Saposnick instituted steps to correct some of the observations before the inspection was concluded and that, during the discussion of the FDA-483 observations, Mr. Saposnick told Investigator Wright that all of the deficiencies will be corrected. To assist your company in

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this endeavor, we are enclosing a copy of "Fresh Air '97: A Look at FDA's Medical Gas Requirements", a copy of the Compressed Medical Gases Guideline, revised February 1989 and a copy of 21 CFR 210 and 211 is also provided for your information and review. We recommend you take into consideration the deficiencies listed in this Warning Letter and proactively evaluate the compliance status of all Valley National Gases sites engaged in the manufacture and distribution of medical gases.

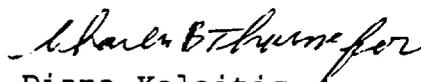
The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all of your company's operations are in compliance with the Act and its associated regulations.

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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be directed to the attention of Lynn S. Bonner, Compliance Officer, at the address noted on the letterhead.

Sincerely,



Diana Kolaitis  
District Director

Enclosures

cc: Mr. Alan B. Saposnick, Director of Clinical Services  
Jordan-Reses Home Healthcare  
701 Chester Pike  
Sharon Hill, PA 19079

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