



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

97-PHI-38

August 6, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Peter Schwarz, CEO/President
Redeemer Nazareth Medical Supply Company
12265 Townsend Road, Suite 600
Philadelphia, PA 19154

8/11/97
512

GEN.	SPEC.
RELEASE	
F# _____	DATE 8/8/97
Reviewed by <i>Jay M. Campbell</i>	

Dear Mr. Schwarz:

From July 7-10, 1997, Philadelphia District Investigators Edward D. McDonald and Viada Matusovsky conducted an inspection of your medical oxygen manufacturing facility. 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, Investigators McDonald and Matusovsky issued you form FDA 483, Inspectional Observations, and discussed the observations with you. This inspection revealed that medical oxygen manufactured by your facility is adulterated within the meaning of 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. Your firm has failed to assay incoming liquid oxygen for identity and strength prior to filling liquid home units [21 CFR 211.165(a)]. In addition, laboratory records do not contain an accurate statement of the results of analytical testing performed on incoming liquid oxygen [21 CFR 211.194(a)(6)].

Part of every inspection conducted by the Food and Drug Administration involves observation of a firm's overall operations and interviews and discussions with employees involved in those operations. Investigator McDonald interviewed several employees as part of his evaluation of the adequacy of your medical oxygen manufacturing operations. As a result, Investigator McDonald received information during the course of the inspection that was contradictory to your firm's stated practices. For example, he was told that vertical gas liquid (VGL) units are tested after filling and that the ~~oxygen analyzer~~ oxygen analyzer had been working properly the week before the inspection. He was also told that the drivers did not test oxygen filled into VGL's but transferred the supplier's oxygen results to your

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firm's Cryogenic Vessel Analysis tags. Investigator McDonald subsequently learned that the [REDACTED] unit was last functioning properly approximately one and one-half years ago, and personnel responsible for testing of incoming liquid oxygen admitted to Investigator McDonald that they do not test incoming oxygen and have arbitrarily assigned a result of [REDACTED] to the Cryogenic Vessel Analysis tags since 1993.

Failure to assay incoming liquid oxygen is a serious violation; however, we regard the falsification of records required by CGMP's as a very grave matter. Furthermore, making false, fictitious, or fraudulent statements or representations to a United States government agency representative during a matter that falls within the jurisdiction of that agency is a criminal offense under Title 18 United States Code § 1001. The fact that both employees and management are implicated in the above-referenced statements causes us great concern in that it leads us to believe that this type of activity may be regarded as acceptable at your firm or that the appropriate level of quality control is lacking at this facility.

We acknowledge your efforts to voluntarily recall available lots of the affected drug product. We have also reviewed your letter of July 18, 1997, which we received on July 28, 1997. The corrective actions you describe for this item do not include steps you have taken to assure that future records will not be falsified and that employees and managers alike fully understand their responsibilities and duties with respect to oxygen manufacturing operations and CGMP's.

We also note that your written procedure for [REDACTED] Calibration and Maintenance, dated July 21, 1997, is not adequate in that it directs employees to use room air (21% oxygen) as a span gas. Since your firm manufactures medical oxygen which must meet a minimum USP purity specification of 99.0%, you must select a span gas that extends to the upper range of the scale. [REDACTED] recommends that manufacturers of high purity oxygen, like Oxygen USP, use ambient air as the zero and high purity oxygen as the span gas. We advise you to contact [REDACTED] and obtain the addenda regarding calibration that [REDACTED] has made available to manufacturers of high purity oxygen. In addition, your written procedure fails to identify how often the [REDACTED] is to be calibrated.

Lastly, we note that the copies of the in-service records you have included in your response as Attachment B show that Ron Bachich, Warehouse Supervisor, provided training on calibration and maintenance of the [REDACTED] analyzer on July 21, 1997; however, the record documenting Mr. Bachich's receipt of this same training from a [REDACTED] representative is dated July 22, 1997, one day later. Please provide an explanation for this discrepancy.

2. Cryogenic home units that have been sent out for repairs are not retested prior to being placed back into service [21 CFR 211.87].

We note that your July 18th response includes a copy of a written procedure instituted to correct this observation. The procedure appears satisfactory; however, please be advised that the same requirements apply to VGL's that are taken out of service for repair and/or are emptied. We suggest that you amend this procedure to include VGL's and any other type of medical gas container used in your manufacturing operation that falls into this category.

3. The [REDACTED] oxygen analyzer is not calibrated and maintained in accordance with the manufacturer's instructions [21 CFR 211.160(b)(4)], and calibration of the [REDACTED] is not documented [21 CFR 211.194(d)].

During the inspection, Investigator McDonald observed two employees attempt to calibrate the [REDACTED] unit. The first employee could not get the unit to function properly, and the second used the incorrect control knob to set the zero for the analyzer. In addition, Mr. Bachich told Investigator McDonald that your firm does not keep calibration records for the analyzer. We note that your July 18th response includes a copy of a calibration and maintenance log implemented for the [REDACTED] however, your calibration procedure is deficient as described in the narrative following item 1 above.

4. Employees are not adequately trained in all aspects of medical oxygen manufacturing, including requirements of the current good manufacturing practice regulations [21 CFR 211.25(a)].

Investigators McDonald and Matusovsky observed several instances of inadequate employee training during this inspection; examples include those scenarios described in the narratives following items 1 and 3 above. We note that your July 18th response specifically pertains to training regarding medical gas manufacturing and testing; you need to ensure that all of your employees have a firm grasp of CGMP requirements as they pertain to medical gas manufacturing, particularly with respect to recordkeeping and following established procedures. We will evaluate the adequacy of this corrective action during the next inspection at your facility.

5. Drug product containers are not tested to ensure that they are suitable for use [21 CFR 211.84(d)(3)].

We note that your July 18th response includes a copy of the revised procedure for transfilling liquid oxygen to home cryogenic units. Item one of this procedure directs the employee to "... fill out all information and complete stationary unit check list," which is the stamp on the delivery ticket. The copy of the stamp that you have also provided with your response shows, among other items, these three prefill checks -- "External Vessel," "Cryo Connection," and "Label." Your procedure fails to provide any further explanation

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as to how these prefill checks are to be performed, nor does it reference where this information may be obtained. In addition, this procedure applies solely to home cryogenic units; please be advised that prefill checks also apply to VGL's. You should amend your procedure to include VGL's and to either provide more information regarding how the prefill checks are to be conducted or reference where such information is documented.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to assure 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 Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,


Diana J. Kolaitis
District Director

cc: Michael Laign, President
Redeemer Nazareth Health System
727 Welsh Road
Huntingdon Valley, PA 19006

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