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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

April 8, 1997

97-PHI-22

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lawrence G. Bowman, President
Lanco Med Homecare, Inc.
320 East Liberty Street
Lancaster, PA 17602-1965

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>4/10/97</u>
Reviewed by: <u>[Signature]</u>	

Dear Mr. Bowman:

From January 30 through February 7, 1997, Food and Drug Administration (FDA) investigators Edward D. McDonald, Colleen M. Damon, and Calvin W. Edwards conducted an inspection of your facility located at 320 East Liberty Street, Lancaster, Pennsylvania, regarding the manufacture and distribution of liquid and gaseous oxygen, USP, for medical use. At the conclusion of the inspection, a Form FDA 483, List of Inspectional Observations (copy attached) was issued to and discussed with you and Ernest McCraven, Director of Patient Services. The FDA-483 dated February 7, 1997 lists serious deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations Part 211. Consequently, your product, compressed medical Oxygen USP, is adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with CGMP regulations as follows:

1. Failure to perform identity and purity tests on each batch of transfilled gaseous medical oxygen USP prior to release [21 CFR 211.165(a)].
2. Medical oxygen USP which failed to meet the USP specification of not less than 99.0% was released for medical use on 12/1/95, 12/20/95, 12/21/95, 2/14/96, 4/1/96, and 5/9/96 [21 CFR 211.165].

3. Failure to obtain a valid Certificate of Analysis (COA) for bulk liquid oxygen [21 CFR 211.84(d)(2)].

According to records reviewed at your firm, analytical testing was not witnessed on 8/12/96, 8/16/96, 8/27/96, 8/30/96, and 9/5/96 and oxygen potency was not recorded on the COAs received for 4/24/96 and 8/19/96.

Individuals who witness the analytical testing (purity) of liquid oxygen must be trained and possess the knowledge to determine that the analytical testing is conducted in accordance with the USP monograph for Oxygen USP or its equivalent.

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

5. Failure to calibrate the transfilling manifold pressure and vacuum gauges used during the transfilling of medical oxygen USP [21 CFR 211.160(b)(4)].

6. Failure to identify each cylinder filled with medical oxygen with a lot number [21 CFR 211.150(b)].

7. Failure to adequately train employees engaged in transfilling of gaseous and liquid medical oxygen USP [21 CFR 211.25(a)(b)]. For example:

(a) the [REDACTED] Oxygen Analyzer was incorrectly calibrated and improperly maintained;

(b) gas cylinders were filled even though the hydrostatic test date had expired;

(c) the transfill operator does not pull a vacuum of [REDACTED] of Hg during the transfill process as required by written procedures;

(d) medical oxygen is released for distribution when analytical testing determines that the medical oxygen purity fails the firm's specification [REDACTED] or the USP specification [REDACTED] and

(e) truck drivers are not trained adequately to witness analytical testing for bulk liquid oxygen.

Warning Letter: Lanco Med Homecare, Inc.

Our inspection revealed that individuals (truck drivers) who receive bulk liquid oxygen from your supplier are not adequately trained to witness the analytical testing for oxygen purity conducted by your supplier. 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

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 requirements of the CGMP regulations are being met as well as all other requirements of the Act.

No quality assurance evaluation requests for procurement by government agencies will be approved for drug products affected by the alleged violations until adequate corrective action has been taken with respect to the violations noted above.

We have enclosed a copy of the Compressed Medical Gases Guideline, revised February 1989, to assist you in understanding the CGMP regulations as they apply to your oxygen transfilling operation. A copy of 21 CFR 211 is also provided for you information and review.

Please advise this office in writing with 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 sent to the attention of the Compliance Officer noted above.

Sincerely,



Diana J. Kolaitis
District Director
Philadelphia District

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Warning Letter: Lanco Med Homecare, Inc.

Enclosures: As Stated

cc: PA Department of Health
Health and Welfare Building
7th and Forster Streets
P.O. Box 90
Harrisburg, PA 17120
Attn: Division of Primary Care and Home Health Services
Robert E. Bastian, Director