



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
781.279.1875 FAX: 781.279.1742

WARNING LETTER

NWE-14-98W

June 22, 1998

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Kreykes
President and CEO
Lifespan, Inc.
167 Point Street
Providence, RI 02903

Dear Mr. Kreykes:

During an inspection of VNA Technicare, 67 Cedar Street, Providence, RI 02903, on May 27, and June 1, 1998, our investigator determined that liquid medical oxygen is being transfilled into cryogenic home units and distributed. This medical gas is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that this drug is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to Current Good Manufacturing Practice Regulations for drugs specified in Title 21 Code of Federal Regulations, Parts 210 and 211. Deviations documented by our investigator (see enclosed copy of Form FDA 483) and presented to Mr. Gary Thurber, Respiratory Program Manager include:

- Failure to properly assay the incoming liquid oxygen for identity and strength prior to filling the cryogenic home units. During the inspection it was noted that your firm has not witnessed/verified the analytical testing by the supplier since September 1995. Note that this should be witnessed/verified on an annual basis.

Please note that the need for testing cryogenic home units is obviated **only under certain conditions**—liquid oxygen must be the only liquefied gas being filled on site; the incoming liquid oxygen must have been **adequately** tested for identity and strength; and the home units must be filled and retained by your firm.

Adequate testing of the large cryogenic vessels of incoming liquid oxygen can be demonstrated in one of the following ways:

- if a **trained** representative of your firm **witnesses** your supplier's testing (for identity and strength), receives a **valid** certificate of analysis (COA), and **documents** that the testing has been witnessed. The minimum information that should be provided in a valid COA is as follows:

- supplier's name
- name of product
- air-liquefaction statement
- lot number or other unique identification number
- actual analytical results for identity and strength
- test method used (letter on file from supplier is acceptable)
- supplier's signature and date

The training received by your firm's representative must be documented.

- if, for those instances when the testing is **not witnessed**, a valid COA is obtained and an identity test is performed on each large cryogenic vessel received or filled. The reliability of the supplier's analysis must be verified periodically—preferably annually—by:

- full USP testing of a recently delivered vessel by a third party, or verifying the supplier's analysis by:
 - confirming that the supplier is registered with FDA
 - confirming that the supplier is following appropriate written procedures
 - witnessing the testing, including any calibration, and
 - documenting these steps

- If your firm neither witnesses the testing nor obtains a valid COA, full USP testing is required for each cryogenic vessel delivered by your supplier.

- Failure to establish adequate batch production and control records for each batch of drug produced, including documentation that each significant step in the manufacture, processing,

packing, or holding of the batch was accomplished. For example, your batch records do not contain documentation that each cryogenic home unit has undergone a prefill inspection, prior to filling.

- Failure to establish written procedures for the receiving of any complaints.
- Failure to establish written procedures designed to assure that correct labels and labeling are used. For example, your cryogenic home units do not bear appropriate medical gas drug labels that include the following information:
 - name and address of the manufacturer or distributor,
 - official product name,
 - contents, in units of measure commonly used, eg., liters,
 - lot number

In addition, the transfilled liquid oxygen manufactured by your firm is misbranded in that it is regarded as a prescription drug and its labeling fails to bear adequate directions for use in accordance with 21 CFR 201.100(c). The article, Oxygen USP, is also misbranded in that its labeling fails to indicate whether or not the oxygen has been produced by the air-liquefaction process as required by the United States Pharmacopeia (USP XXII).

We note that these above labeling deficiencies apply to both the [REDACTED] cryogenic units that you transfill. As a medical gas repacker, you must place your own drug label on these units which include all the information noted above. We look forward to reviewing your proposed labeling.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning 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 do so may result in regulatory action by FDA without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

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You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at 781-279-1675 ext. 113.

Sincerely,

/s/

John Marzilli
Director
New England District

Enclosure

cc: Gary Thurber, RPT
Respiratory Program Manager
VNA Technicare
67 Cedar Street
Providence, RI 02903