



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

June 12, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven L. Love
Owner
Love Homecare
1958 Parkway Blvd.
Salt Lake City, Utah 84119

PURGED

Ref. # - DEN-98-13

Dear Mr. Love:

During an inspection of your Salt Lake City, Utah, facility on April 21 through 22, 1998, Investigator James E. Moore determined that your firm transfills compressed medical oxygen. Medical oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to maintain complete records of any testing and standardization of laboratory reference standards [21 CFR 211.194(c)]. For example, the [X X X X X] Oxygen Analyzer, is calibrated using nitrogen from a cylinder which is not tested to the same precision and accuracy as a reference or calibration nitrogen gas from a speciality gas manufacturer or a supplier of standards, which gas is accompanied by a valid certificate of analysis.

For your information, the "ADDENDUM TO [X X X X X] INSTRUCTION MANUAL" has been discontinued effective October 9, 1997, Rev. 5. Therefore, the zero calibration step using ambient air is no longer acceptable. The revised verification procedure calls for the use of high purity nitrogen with a minimum potency of [X] % for the "zero" step, and oxygen with a minimum potency of [X] % for the "span" step.

2. Failure to calibrate laboratory instruments at suitable intervals in accordance with the manufacturer's instructions [21 CFR 211.160(b)(4)]. For example, the operation manual for the Oxygen Analyzer requires the filter to be checked once a week. These checks are not performed or documented.
3. Failure to test each shipment of incoming oxygen for conformity with all appropriate written specifications for purity, strength, and quality; or receive a Certificate of Analysis (COA) from the supplier and perform at least one specific identity test [21 CFR 211.84(d)(2)]. For example, the delivery ticket for shipments of oxygen from your supplier does not include all information required for a COA.

For your information, a COA should contain the following information at a minimum:

- 1) Supplier's name and address
- 2) Name of the product
- 3) An Air Liquefaction Statement for Oxygen U.S.P.
- 4) A Lot Number or other unique identification number
- 5) The Actual Analytical results obtained for identity and strength
- 6) The Test Method used to perform the analysis
- 7) Supplier's signature and the date
- 8) If applicable, the signature of the employee witnessing the testing at the supplier

4. Failure to have a master production and control record containing all written procedures, an actual specimen of the label applied to the oxygen, the date and signature of the individual responsible for the preparation of all required records, and the signature of a second person who independently checked and dated these records [21 CFR 211.186]. For example, several different manuals of procedures were observed rather than a single manual of all procedures used by the facility. Procedures for some operations were not found, such as procedures for filling operations; calibration standards; testing and release; equipment calibration, cleaning, and maintenance; employee training, and copies of forms and labels.
5. Failure to routinely calibrate equipment used during its operations [21 CFR 211.68]. For example, calibration records were not observed for vacuum gauges, pressure gauges, and thermometers.
6. Failure to train personnel engaged in the manufacture of medicinal gas in current good manufacturing practice regulations and written procedures [21 CFR 211.25(a)]. For example, in-house training of the employee responsible for oxygen filling operations was not recorded on the Technician Certification Training form.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As the Owner, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Regulations.

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At the conclusion of the inspection, Investigator Moore issued a written report of observations (FDA 483) to you. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,



Gary C. Dean
District Director

Enclosure:
As stated

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cc: Ms. Mary Kay Smith
Regional Administrator
Health Care Finance Administration, DHHS Region VIII
Byron G. Rogers Federal Building
1961 Stout Street, Fifth Floor
Denver, Colorado 80294-3538