



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)279-1675 FAX: (781)279-1742

WARNING LETTER

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

NWE-22-98 W

September 21, 1998

Wayne T. Stone, President  
Subacute Medical Care, Inc.  
87 Brookhill Drive  
Seekonk, MA 02771

Dear Mr. Stone,

During an inspection of your manufacturing facility located at 87 Brookhill Drive, Seekonk, Massachusetts conducted on September 1-9, 1998, our investigator determined that your firm manufacturers liquid medical oxygen. The medical gas is a drug as defined by Section 201 (g) of the Federal Food Drug and Cosmetic Act (The Act).

The inspection revealed that this drug is adulterated under Section 501 (a)(2)(B) of the Act in that the methods used in, or the facilities and controls used for, its manufacturing, packing, holding, or shipping are not in conformance with Current Good Manufacturing Practice Regulations for Drugs, 21 CFR Parts 210 and 211, as follows:

1. Failure to test each incoming batch of liquid oxygen for identity.
2. Failure to use an appropriate standard gas to calibrate the Teledyne 60 T Oxygen Analyzer.
3. Failure to maintain a valid Certificate of Analysis on file for each LOX cylinder received from the supplier.

We received your response to the inspectional observations in which you state that Subacute Medical Care will witness each vessel prior to being loaded on the truck. You reference your procedure 8025.

No testing is required as long as the receiving firm witnesses the testing (identity and strength) of each large cryogenic vessel by the supplier, receives a valid COA for each vessel, documents that testing has been witnessed, and the witness is adequately trained in the analytical methodology being witnessed. The training should be documented.

The only change I can see in SOP 8025 is the elimination of your testing.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

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

Please 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 violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New England District Office, Attention: E. Frank Gesing, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts, 02180.

If you have any questions, contact Mr. Gesing at (781) 279-1675, EXT 127.

Sincerely,



John R. Marzilli  
District Director  
New England District Office