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

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675 Fax 781.279.1742

WARNING LETTER
NWE-01-99W

October 7, 1998

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John P. Byrnes
President and CEO
Lincare, Inc.
19337 U.S. 19 North
Suite 500
Clearwater, FL 33764

Dear Mr. Byrnes:

During an inspection of Lincare, Inc., 8 Filko Avenue, Swansea, MA on September 21, 23, and 28, 1998, our investigator determined that this firm transfills liquid oxygen from vehicle mounted vessels to customers' home reservoirs. This medical gas is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection at your firm in Swansea, MA 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 (GMP) for drugs specified in Title 21 Code of Federal Regulations, Parts 210 and 211. Our investigator presented her observations regarding your firm's deviations from the GMP regulations to Mr. Steven N. Poletta, Area Manager (see enclosed copy of *Form FDA-483*). The areas of concern to us are as follows:

1. Failure to assure the liquid oxygen transfilled from your vehicle mounted vessels to patients' reservoirs has been properly tested for identity and purity. Your standard operating procedure, #04-03-02, "Testing Procedures," offers three acceptable methods: witnessing of the testing at your supplier, obtaining a certificate of analysis along with conducting identity testing, or conducting full USP testing. According to

local management, your firm has selected the first option, witnessing the testing at your supplier. However:

- a. There is no documentation indicating that your personnel have been properly trained in the analytical methods used by your supplier. Without proper training, witnessing of the testing would not be meaningful.
 - b. Review of your records demonstrates the witnessing of the testing is not documented consistently. For example, both the certificate of analysis and shipping ticket for lot #862-082698-2, transfilled to your vehicle mounted vessel on August 28, 1998, fail to indicate that the testing was witnessed by the vehicle driver, a Lincare, Inc. employee.
2. Failure to review and approve batch fill records, as required by your standard operating procedure, #04-06-01, "Quality Control Unit," to assure completeness and accuracy.
 3. Failure to account for labeling on your inventory log for oxygen labels, as required by your standard operating procedure, #04-12-01, "Labeling and Marking."

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.

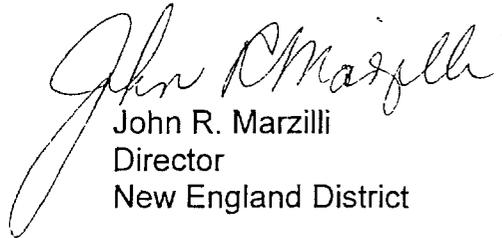
You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations and any documentation necessary to show that the correction has been achieved. 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 David K. Elder, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Elder at 781.279.1675 ext. 125.

Sincerely,



John R. Marzilli
Director
New England District

Enclosure: FDA-483, dated 9/28/98

cc (w/out enclosure):

Scott M. Crowley
Center Manager
Lincare, Inc.
8 Filko Ave.
Suite 5
Swansea, MA 02777

Steven N. Poletta
Area Manager
Lincare, Inc.
61 Commerce Dr.
Brookfield, CT 06804