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Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

~~CERTIFIED~~ RETURN RECEIPT REQUESTED

January 28, 1998

WARNING LETTER

John Byrnes, Chief Executive Officer
Lincare, Inc.
19337 U.S. 19 North, Suite 500
Clearwater, FL 34624

Ref.# - KAN-98-007

Dear Mr. Byrnes:

During an inspection of your medical liquid oxygen transfilling operation known as Universal HomeCare, 4225 N.E. Port Drive, Lee's Summit, Missouri, conducted on January 5 to 7, 1998, Food and Drug Administration Investigators from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's liquid medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

failure to routinely assay incoming liquid oxygen for identity prior to filling liquid home units; document the witnessing of liquid oxygen testing when picked up by truck; and failure to conduct a USP test (at least once a year) for identity and strength to verify the reliability of your supplier's certificate of analysis [21 CFR 211.165(a)];

failure to maintain complete and accurate batch production records in that "Oxygen Home Unit Logs" are lacking required information [21 CFR 211.188];

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failure of the quality control unit to perform in accordance with the SOP in that record review is incomplete and inadequate [21 CFR 211.22(a)].

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Mr. Arnold H. McMann, Center Manager. A copy of this form is included for your information.

This letter is not intended to be an all-inclusive list of deficiencies at the stated facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

We received and reviewed a letter dated January 8, 1998, from Mr. John E. Drewett, HCRM, concerning the Form FDA 483 observations, prior to the issuance of this letter. Item number seven concerning an audit of Puritan Bennet is unclear as to what was trying to be conveyed.

Federal agencies are advised of the issuance of all Warning Letters about drugs 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 promptly correct these deviations may result in regulatory action without further notice. Such actions may 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, in addition to those covered in the letter, that are being taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 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 Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

/s/

W. Michael Rogers
District Director
Kansas City District

cc: Arnold H. McMann, Center Manager
Lincare, Inc. d/b/a Universal HomeCare
4225 N.E. Port Drive
Lee's Summit, MO 64064