



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

MISSN

CFN: 1123055

HFI-35

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

August 17, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James T. Kelly, Chairman and CEO
Lincare, Inc.
19337 U. S. 19 North
Clearwater, Florida 34624

Dear Mr. Kelly

A Food and Drug Administration (FDA) inspection was conducted July 31 to August 6, 1998 at your Medic-Aire facility in Millersville, Maryland. The inspection determined that you manufacture Liquid Oxygen, USP, at that facility. Liquid Oxygen, USP, is a drug product as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) regulations (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be 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, manufacturing, processing, packing, storage, or holding, are not in conformance with the GMP regulations.

The deviations included the following:

1. Failure to receive a valid report of analysis from your supplier and to establish the reliability of your supplier's analysis at appropriate intervals, in lieu of testing incoming Liquid Oxygen, USP, for conformity with all appropriate written specifications for purity, strength, and quality.
2. Failure to properly calibrate and document the calibration of equipment used in the testing, manufacture, processing, packing, and holding of Liquid Oxygen, USP.
3. Failure to follow written production and process control procedures.
4. Failure to inspect cryogenic home vessels for conformance with all appropriate specifications before filling them with Liquid Oxygen, USP.

5. Failure of the quality control unit to review records adequately and to investigate when errors occur.
6. Failure to assure that each person engaged in the manufacture, processing, packing, or holding of Liquid Oxygen, USP, has the education, training, or experience to enable them to perform their assigned functions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your Millersville, Maryland facility and at all facilities operated by your firm. It is also your responsibility to assure that newly acquired subsidiaries are audited and their employees trained promptly after becoming a part of your organization.

The specific violations noted in this letter and on the FDA-483 issued to and discussed with Ms. Nancy J. Kitchen at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

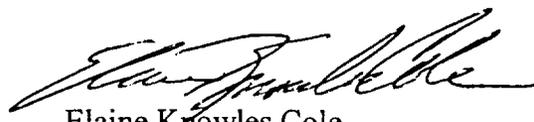
Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have 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 the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Mr. James T. Kelly
August 17, 1998
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cc: Nancy J. Kitchen, Center Manager
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Millersville, Maryland 21108

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