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11/14/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1122436

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

November 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Zorayda Lee-Llacer, President
L & L Oxygen and Medical Equipment
8909 Old Branch Avenue
Clinton, Maryland 20735

Dear Mrs. Lee-Llacer:

The Food and Drug Administration (FDA) conducted an inspection of your Clinton, Maryland facility on October 22 through October 24, 1997. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP) (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Liquid Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to test each batch of Liquid Oxygen to demonstrate conformance with appropriate specifications for identity, strength, and purity prior to release.
2. Failure to maintain batch production and control records.
3. Failure to perform or document pre-fill operations on each cryogenic home vessel.
4. Failure to establish written procedures for filling of liquid oxygen, pre-fill inspections of cryogenic home vessels, cleaning and maintenance of cryogenic home vessels, complaint handling, recalls, distribution, and quarantining finished drug product prior to distribution.
5. Failure to re-test cryogenic home vessels for identity and suitability after repair or maintenance prior to distribution.

6. Failure to follow written production procedures, in that all lot and batch numbers for distributed liquid oxygen were not recorded.
7. Failure to document that employees involved in filling liquid oxygen have been trained in all aspects of that operation and in CGMPs.

The above listed violations 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. 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.

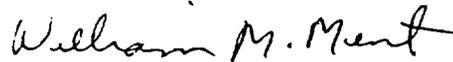
By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the CGMPs to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 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, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



William M. Ment
Acting Director, Baltimore District

Enclosure