

HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d18106

Refer to: CFN 1121475

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

May 13, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John H. Gaffney, President
Eastern Oxygen & Medical Equipment, Inc.
818 Professional Place
Chesapeake, Virginia 23320

Dear Mr. Gaffney:

The Food and Drug Administration (FDA) conducted an inspection of your Chesapeake, Virginia facility on April 8 - 10, 16 and 22, 1998. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Liquid and Compressed Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to have the appropriate documentation to demonstrate that each batch of Liquid Oxygen USP is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess upon receipt and prior to release.
2. Failure to perform or have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder and home cryogenic unit filled.
3. Failure to hold Liquid Oxygen USP in quarantine until the batch had been released by the Quality Control person or unit.
4. Failure to establish batch production records for each batch of Liquid Oxygen USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance.

Mr. John H. Gaffney
Page 2
May 13, 1998

5. Failure to have appropriate documentation to assure that each person engaged in the transfilling of Liquid Oxygen has the education, training, or experience to enable that person to perform their assigned functions.
6. Failure to establish adequate written procedures for the production and process controls designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.
7. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.
8. Failure to establish written procedures describing the handling of all written and oral complaints and to maintain a file designated for drug product complaints.

At the conclusion of the inspection, a written list of inspectional observations (FDA-483, enclosed) was issued to Mr. Lance A. Oglesby, Senior Driver.

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 concerning 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 document provided by FDA National Expert, Mr. Duane Sylvia, titled, "FRESH AIR '98" which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please 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.

Mr. John H. Gaffney
Page 3
May 13, 1998

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, extension 14.

Sincerely,



William M. Ment
Acting Director, Baltimore District

Enclosures

cc: Virginia Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717