

HF1-35

Reviewed 1/3/97
N.L. Rose

1/6/97
NLR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
A1067B

Refer to: CFN 1117647

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

January 3, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronald F. Brower, President
Wayne Oxygen & Supply Co., Inc.
11100 East Market Street
Charlottesville, Virginia 22901

Dear Mr. Brower:

The Food and Drug Administration (FDA) conducted an inspection of your Charlottesville, Virginia facility on December 17, 1996. Deviations from the current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which 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 cryogenic vessel filled with Liquid Oxygen, U.S.P. for conformance to final specifications for the drug product prior to release. [21 CFR 211.165(a)]
2. Failure to establish adequate batch production and control records for each batch of Liquid Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. Your firm's batch production records for the filling of cryogenic vessels lacked the required purity of each vessel filled. [21 CFR 211.188(b)]

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.

Mr. Ronald F. Brower

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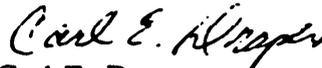
By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

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 current Good Manufacturing Practice Regulations 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, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



Carl E. Draper
Acting District Director

Enclosure

bcc: EI file, Legal file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFA-224, HFC-210, HFI-35 (purged), HFC-240, HFD-300, HFR-MA2545, HFR-MA295, SJM

Mr. Dennis Carroll
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

Tracking #: 97-BLT-15