



DEPARTMENT OF HEALTH & HUMAN SERVICES

d11016 HFI-35

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

1141 Central Parkway
Cincinnati, OH 45202-1097

June 11, 1998

WARNING LETTER
CIN-WL-98-300

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. Michael Frantz
President
Medi-Care Orthopedic & Hospital Equipment
402 Tiffin Avenue
Findlay, OH 45840

Dear Mr. Frantz::

The Food and Drug Administration conducted an inspection of your liquid and gas Oxygen U.S.P. transfilling facility at 1900 West State Street, Fremont, Ohio 43420 on May 11 to 13, 1998. Our investigator documented significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product 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 documented during the inspections included:

- ▶ No result of finished product testing was entered on 38 of the approximately 200 Oxygen Transfill Records for the time period of January 1997 to May 1998.
- ▶ No test for purity and identity was performed on the Liquid Oxygen U.S.P. received even though there was no documented witnessing of the testing performance by the supplier and no periodic third party challenge to the Certificate of Analysis had been made.
- ▶ The [redacted] Oxygen Analysis Model [redacted] was being calibrated with ambient air as the lower limit calibration which is not the correct calibration method since October 1997.
- ▶ The vacuum pump used for evacuation of the high pressure cylinders on lots transfilled on 5/11&12/98 (minimum of 3 lots) was unable to pull the required vacuum of 25 p.s.i.
- ▶ Documentation of significant steps in the transfill of high pressure cylinders does not include the targeted pressure of 2015 p.s.i. According to the noted temperature on any batch production and control records reviewed since January 1997.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

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

Page 2

June 11, 1998

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed with fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

Charles W. Sedgwick
Acting District Director
Cincinnati District

cc: Ms. Carol A. Smith, Manager
Medi-Care Orthopedic and Hospital Equipment
1900 W. State Street
Fremont, OH 43420

Health Care Finance Administration
Chief Carrier Operations Branch
Division of Medicine
105 West Adams St., 15th Floor
Chicago, IL 60603-6201