



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

December 7, 1998

WARNING LETTER
CIN-WL-99-56

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Raymond Brunner, President
Brunner Healthcare Inc.
8460 Mentor Avenue
Mentor, OH 44060

Dear Mr. Brunner:

The Food and Drug Administration conducted an inspection of your liquid Oxygen USP transfilling facility on November 16, 1998. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product, Oxygen USP, 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 inspection included:

- A. Failure to maintain satisfactory and complete liquid oxygen transfilling records of the cryogenic home vessels (CHV) as follows:
 1. There are no correspondence/traceability of liquid oxygen lot numbers between the [REDACTED] Certificates of Analysis to those noted on the Liquid Oxygen Fill Log.
 2. No documentation of prefill inspections such as an external vessel inspection, all inlet and outlet connection examination, a volume or contents gauge inspection or a label inspection., prior to filling the CHV's
- B. Failure to establish detailed written procedures for employee training program.
- C. The person responsible for picking up the liquid oxygen and witnessing the testing (Orsat USP Analysis) has not received training specific to the analytical method being witnessed. All training should be documented.
- D. Failure to establish and maintain signed and dated standard operating procedures for the following:
 1. Recall procedures
 2. Complaint procedures for Medical Oxygen
 3. Labeling Procedures
 4. Written procedures/documentation for scale calibration used during transfilling
 5. Maintenance and repairs of Cryogenic Home Vessels and placing them back into service
- E. The Master Production & Control Records are incomplete in that none of the procedures used for transfilling and distribution of medical gases are signed and approved

In addition the liquid drug, Oxygen U.S.P. in cryogenic home vessels is misbranded under the Act, Section 502(b)(2) in that it's label fails to bear an accurate statement of the quantity of the contents; under Section 502(f)(1) in that it's label fails to bear adequate directions for use and under Section 503(b)(4) in that it's label fails to bear the statement "RX ONLY".

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 product in violation of state or federal law.

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

Please notify this office 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 within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

We are enclosing a copy of "FRESH AIR '98 " by Duane Sylvia, Consumer Safety Officer, Center for Drug Evaluation, which covers FDA's Medical Gas Requirements.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45239, to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with a large initial "C" and a long horizontal stroke.

Charles W. Sedgwick
Acting District Director
Cincinnati District

cc: Health Care Finance Administration
Chief Carrier Operations Branch
105 West Adams, 15th Floor
Chicago, Illinois 60603-6201