



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service *M 2073N*

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

September 10, 1998

WARNING LETTER
CIN-WL-98-379

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harold Beck, Owner
Benton Discount Pharmacy
2602 Main Street
Benton, KY 42025

Dear Mr. Beck:

The Food and Drug Administration conducted an inspection of your gas oxygen transfilling facility on June 25, 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 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 inspection included:

- There was no record of daily calibration for the [REDACTED] Oxygen Analyzer used to test the purity for Oxygen U.S.P.
- The transfilling record does not contain the results of the Oxygen U.S.P. tests but contains only a checkmark.
- The transfilling record does not indicate who performed the transfilling and purity tests and does not show that a member of management reviewed the record.
- There are no Certificates of Analysis or record of purity analysis for the incoming "H" cylinders that are used for transfilling.
- Signed, dated, written procedures for transfilling, quality control, distribution, recalls and complaints have not been established.

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.

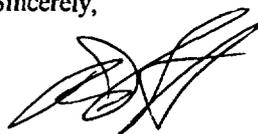
Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations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

You 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 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 within 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, 6751 Steger Road, Cincinnati, OH 45237-3097 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Duane Satzger', written in a cursive style.

R. Duane Satzger
Acting District Director
Cincinnati District

LEB/blc

Cc: Health Care Finance Administration
101 Marietta Tower, Suite 702
Atlanta, GA 30323
Attn: Mr. William R. Lyons

