



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

April 10, 1997

WARNING LETTER
CIN-WL-97-320

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harold Miller, Owner
Reliance Bottle Gas Co., Inc.
6025 Secor Road
Toledo, Ohio 43613

Dear Mr. Miller:

The Food and Drug Administration conducted an inspection on March 24 & 25, 1997 of your gas-oxygen transfilling facility. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations For Finished Pharmaceuticals [Title 21 Code of Federal Regulations (CFR) Parts 210 & 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:

- Failure to receive a certificate of analysis from the gaseous oxygen supplier to document the strength and identity of the incoming oxygen.
- Failure to perform, required prefill checks such as the odor test, color coding inspection and the dead ring tests on transfilled metal D&E cylinders.
- Failure to properly operate the [REDACTED] oxygen analyzer used to assay the transfilled cylinders. Examples are the analyzer was not being calibrated on a daily basis, the unit was not zeroed before use and the calibration procedure was unknown to the transfilling employees as no operating manual was on hand.
- Failure to have written, approved, signed and dated procedures for acceptance criteria for incoming oxygen cylinders, review and control of oxygen labeling, complaints, distribution and recalls.
- Failure to provide adequate training for transfilling personnel such as operation of the oxygen analyzer.

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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. We are enclosing a speech entitled "Fresh Air 96 A Look at FDA's Medical Gas Requirements" by Duane Sylvia, Consumer Safety Officer, Center for Drug Evaluation and Research on December 4, 1996.

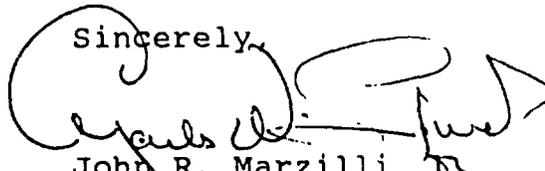
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant 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, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,



John R. Marzilli
District Director
Cincinnati District

LEB/clc

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

Enclosure