



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35  
Public Health Service  
1586b

Food & Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202

December 3, 1996

**WARNING LETTER**  
**CIN-WL-97-118**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Rick L. Doans, President  
Doansco Welding Supplies, Inc.  
2801 Tylersville Road  
Hamilton, Ohio 45015

Dear Mr. Doans:

The Food and Drug Administration conducted an inspection on November 6 & 7, 1996 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 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 involved the following:

- Failure to maintain complete batch product records (Daily Record Of Medical Oxygen Filling) such as;

Records dated 11/16/95, 1/15/96, 4/1/96, 8/13/96, 8/16/96 and 10/16/96 do not contain the analysis result of the cylinder analyzed.

Records dated 11/14/95, 1/15/96 & 4/1/96 do not contain the lot number of the cylinder analyzed.

Records dated November 1995 to November 1996 are not signed off by a reviewer or management to assure accuracy and completeness.

Records do not document the examination of each cylinder prior to transfilling which assures the cylinder is within its hydrostatic testing date; the cylinder has been examined for dents, arc burns or other signs of damage; the valve assembly is examined for damage and for the presence as debris; the cylinder is the correct color (green) and the cylinders labeling is examined to remove old lot numbers and that it is readable.

- Failure to properly calibrate the [REDACTED] Oxygen Analyzer used for the assay of the transfilled Oxygen U.S.P. in that certified high purity oxygen and nitrogen standards are not used.
- Failure to establish and maintain written approved signed and dated procedures for each step in the transfilling operation such as calibration and maintenance of the oxygen analyzer and control of the labels used on the cylinders.

The above identification of deviations 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 copy of a speech entitled "Fresh Air, A Look at FDA's Medical Gas Requirements for Liquid To Liquid Filling" by Duane Sylvia of the Center For Drug Evaluation and Research at a Medical Gases GMP workshop in July 1995. It contains a paragraph on Prefill Inspections; Filling Operations - High Pressure Cylinders; Gas To Gas Filling; Packaging & Labeling Control; Test Procedures and Testing; Oxygen Analyzers; and Equipment Calibration which apply to your firm.

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.

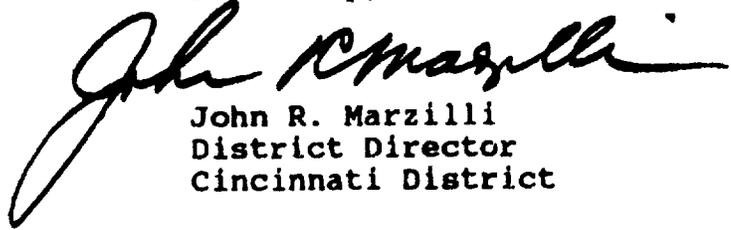
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

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.

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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,

A handwritten signature in black ink, appearing to read "John R. Marzilli". The signature is fluid and cursive, with a large loop at the end of the last name.

John R. Marzilli  
District Director  
Cincinnati District

LEB/clc

Enclosure

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