



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

1141 Central Parkway
Cincinnati, OH 45202-1097

December 2, 1997

WARNING LETTER
CIN-WL-98-77

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roger B. Stackhouse, President
RDS Enterprises, Inc.
D.b.a. The Medical Connection, Inc.
104 W. Main Street
Van Wert, Ohio 45891

Dear Mr. Stackhouse:

During a Food and Drug Administration inspection of your medical oxygen transfilling facility located at the above address on November 3-4, 1997, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, 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).

Specific deviations are as follows:

Failure to assay the filled high pressure cylinders of medical oxygen for identity and strength, prior to release for distribution.

None of the lots of medical oxygen produced and distributed by your firm over the past five years have been tested for identity and strength (Approximately lots). The FDA inspection revealed that your firm does not have an oxygen analyzer for testing strength and/or identity of oxygen.

Failure to establish and maintain adequate batch production and control records for each batch of medical oxygen produced including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance.

No records are kept of any of the significant steps performed during the medical oxygen transfilling operation.

Failure to establish adequate written procedures for production and process controls covering all aspects of the medical oxygen transfilling procedure designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

For example, the procedure for filling medical oxygen does not reference or describe sampling and testing methods. Prefill and post fill procedures such as leak tests and evacuation via vacuum pump of each cylinder prior to filling are not addressed in the procedure. Also, the written procedure is not signed and dated as approved by a responsible individual. There are no written procedures for calibration of equipment used during the transfilling operation and there are no written complaint procedures.

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Failure to perform adequate prefill and post fill operations on each high pressure cylinders of medical oxygen.

For example, employees performing the transfilling operation fail to use a thermometer and to consult a temperature/pressure chart during the filling operation in order to prevent the dangerous overfilling of the high pressure cylinders. Cylinders are not evacuated by means of a vacuum pump capable of pulling a vacuum of up to 25 inches of mercury at sea level. Your firm does not even have a vacuum pump. No leak tests are performed on cylinders during filling and after filling.

Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used, and returned during the transfilling operation.

- Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

The FDA inspection also revealed that the medical oxygen you transfill is misbranded within the meaning of Section 502 of the Act as follows:

The article is misbranded in that its labeling fails to contain a statement of the quantity of the contents as required by Section 502(b)(2) of the Act and 21 CFR 201.51.

The article is misbranded in that its labeling fails to contain the established name of the drug product as required by Section 502(e) of the Act and 21 CFR 201.50.

The article is misbranded in that it is regarded as a prescription drug and its labeling fails to bear adequate directions for use in accordance with Section 502(f)(1) of the Act and 21 CFR 201.100(c).

The article is misbranded in that its labeling fails to indicate whether or not the oxygen has been produced by the air-liquefaction process as required by the United States Pharmacopeia (USP XXIII) and in accordance with Section 502(g) of the Act.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information 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 product in violation of state or federal law.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

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Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Evelyn D. Forney, Compliance Officer. Any questions regarding this letter may be directed to Mrs. Forney at telephone no. (513) 684-3501, extension 163.

Sincerely,

A handwritten signature in black ink, appearing to read "Diana Kolaitis". The signature is stylized and somewhat cursive, with a large initial "D" and "K".

Diana Kolaitis
Acting District Director
Cincinnati District