



11/22/98

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *EFK*

November 30, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 05

Larry W. Lindberg
Chief Executive Officer
Midwest Medical, Inc.
8400 Coral Sea Street N.E., Suite 200
Blaine, Minnesota 55449

Dear Mr. Lindberg:

During our recent inspection of your Midwest Medical, Inc. medical oxygen transfilling operation located in Blaine, MN, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to ensure each person engaged in the manufacture, processing, packaging, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions [21 CFR 211.25(a)]. For example, there is no evidence that the employees performing the manufacturing and testing

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procedures are trained or have the knowledge to fill Oxygen USP. They do not know how to calibrate the  record information accurately on the pumper's log, and continue to use faulty equipment.

2. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met [21 CFR 211.160(b)(4)]. For example, you are not calibrating your thermometers traceable to an NIST thermometer.
3. Failure to have master production and control records for each drug product prepared, dated and signed (full signature, hand written) by one person and independently checked, dated and signed by a second person [21 CFR 211.186]. For example, there is no approved master batch record or procedure regarding the manufacture/transfilling of medical oxygen in high pressure cylinders or cryogenic vessels.
4. Failure to have documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)]. For example, the medical oxygen gas cylinder batch record does not include documentation of the post fill oxygen strength, filling temperature and pressure. Also, no post fill odor test is conducted on cylinders and at least one cylinder is not checked for settling pressure and temperature.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction. This is official notification that the Food and Drug Administration expects all your locations to be in compliance.

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You should notify this office in writing within 15 working days of receipt of this letter of 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 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 Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edwin S. Dee".

Edwin S. Dee
Acting Director
Minneapolis District

CAH/ccl