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

PURGED RAK

October 29, 1998

cc: (HFI-35/FOI Staff)
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99- 02

Stephen R. Statz
President
Statz Company, Inc.
2812 W. 41st Street
Sioux Falls, South Dakota 57105

Dear Mr. Statz:

During our inspection of your Statz Drug and Home Health medical oxygen transfiller operation located in Mitchell, SD, 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 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)] in that

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- a) You are calibrating your  oxygen analyzer using ambient air as a zeroing gas instead of high purity nitrogen.
 - b) You are not adjusting the span control of the  oxygen analyzer correctly. You are adjusting the span control to the percent oxygen value of your incoming oxygen (K cylinders) and not the percent oxygen value of the certified oxygen.
 - c) You are not calibrating your  oxygen analyzer as per your SOPs. You have no accurate record when the analyzer is calibrated.
 - d) There is no evidence that you are performing a periodic calibration of laboratory equipment, including the vacuum gauge, pressure gauge and thermometer.
2. 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)] in that there is no evidence that the employees performing the manufacturing and testing procedures are trained or have the knowledge to fill Oxygen U.S.P. They do not know how to calibrate the , record information accurately on the pumper's log, and they continue to use faulty equipment.
 3. Failure to ensure each person responsible for supervising 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 assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess [21 CFR 211.25(b)] in that each person responsible for supervision is not aware of the need to periodically calibrate the pressure gauge, temperature gauge, and thermometer. There is no evidence of any record review and there were no records available for review prior to May 1998.

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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)] in that you are recording on the pumper's log a calibration of the  oxygen analyzer with each manifold fill when this is not performed. Also, the hammer test is not performed on all steel cylinders.

Review of the Establishment Inspection Report for your firm revealed your transfilled oxygen is misbranded within the meaning of:

5. 502(b)(1) of the Act in that the label fails to bear your name and place of business;
6. 502(b)(2) of the Act in that the label fails to bear an adequate statement of the contents in terms of weight, measure, or numerical count;
7. 502(f)(1) of the Act in that its label fails to bear adequate directions for use; and
8. 503(b)(4)(A) of the Act in that its label fails to bear, at a minimum, "Rx only."

Also, cursory review of your Standard Operating Procedures (SOPs) revealed the following deficiencies (these are in addition to the problems cited on the form FDA-483 issued to your firm on October 14, 1998):

9. Your SOP for "Calibrating Analyzer" is incorrect. There is no mention of the calibration standards (nitrogen, with a minimum purity of 99.9%, and oxygen, with a minimum purity of 99.2%) required to calibrate your  oxygen analyzer. Also, your calibration standards are to have valid Certificates of Analysis (COA). I recommend contacting the MADA or  to obtain an updated instruction manual.
10. Your SOP for the COA received with your oxygen used for transfilling lacks the following requirements: (a) date of the analysis; (b) name of product;

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and (c) established reliability of your supplier's analyses through appropriate validation of your supplier's test results at appropriate intervals.

11. Your SOP for "Transfilling Checks for Documentation" doesn't indicate how to fill out the form. For example, employees have been documented filling the boxes with "-". What does this mean? Was the test performed or not? You may want to use "X", a "√," or employee's initials. Also, your Pumper's Log states "State Snyder Drug, 102 W. Main, Parkston, SD." Your records should be updated to accurately reflect the name of your business location.

I have included copies of *Gas What?* and *Fresh Air '98* to give you some guidance.

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 to 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 FDA expects all your locations to be in compliance.

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.

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Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Rahto". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James A. Rahto
Director
Minneapolis District

CAH/ccl
Enclosures (2)

xc: Richard C. Swank
Vice President of Operations
Statz Drug and Home Health
1307 North Main
Mitchell, SD 57301