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

April 28, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 29

Mrs. Peggy L. Coyne
President
Presidents Specialty Health Care
Baken Park Shopping Center
715 Mountain View
Rapid City, South Dakota 57702

Dear Mrs. Coyne:

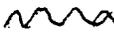
During our inspection of your Presidents Specialty Health Care medical oxygen transfilling operation on January 28, 1999, located in Rapid City, SD, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). A two-item form FDA-483 was issued. These two items are repeat violations from our October 28 and 29, 1997, inspection. You were informed of those violations by a letter dated December 31, 1997. 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.

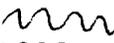
The violations observed during our inspection include but are not limited to the following:

Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written procedures containing

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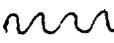
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specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met [21 CFR 211.160(b)(4)]. For example, (a) you are not periodically calibrating your vacuum gauge and the thermometer that is used in the transfilling of oxygen USP; (b) you are not calibrating your  each day of production. This is in direct conflict with your written standard operating procedures (SOPs) and in violation of the current Good Manufacturing Practice regulations.

Also, upon review of your records I discovered your " Calibration Log" records are not always reviewed by a responsible person. This repeat violation was also listed on the previous form FDA-483 and included in our letter dated December 31, 1997. Our investigator documented evidence that your " Calibration Log" records had not been reviewed between December 14, 1998, and January 18, 1999. These records are to be reviewed, initialed and dated in a timely manner. 21 CFR 211.194 states:

Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards and assays, as follows: The initials or signature of the person who performs each test and the date(s) the tests were performed. The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Furthermore, one person (MM) approving the batch production records appears to have different handwriting styles. You may want to verify that the person reviewing and approving the batch production records is the person initialing (or signing) and dating the batch production record review.

Also, you may wish to revisit the training for the individuals responsible for reviewing the  Calibration Log. Your nitrogen cylinder numbers and lot numbers are not being recorded accurately. I identified at least seven different combinations of numbers. Why does your firm have two  Calibration Logs for the same week? You have a daily calibration log for the week of "4-3 - 4-10" and "4-6-98."

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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 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.

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

Sincerely,



James A. Rahto
District Director
Minneapolis District

CAH/ccl