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

April 23, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 30

James Scott, Director
Carmell Scott, Director
Christopher Koenigs, Director
Kevin Koenigs, Director
Susan Johnson, Director
Jeffrey Johnson, Director
R.W.K., Inc.
620 East Main
Albert Lea, Minnesota 56007

Dear Mr. & Mrs. Scott, Messrs. Koenigs, and Mr. & Mrs. Johnson:

During our inspection of your Family Medical Services medical oxygen transfilling operation, on February 26-28, 2002, located in Mankato, Minnesota, our investigator found serious violations of the Current Good Manufacturing Practices (cGMP) 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 adequately calibrate your wavy oxygen analyzer used to test the purity and identity of Oxygen USP [21 CFR 211.160(b)(4)] in that room air was used as the span gas rather than high purity nitrogen.
2. Failure to ensure that each person engaged in the manufacture, processing, or holding of a drug product shall have the education, training, and experience to enable that person to perform the assigned functions. Training shall be in the particular operations the employee performs and in

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- cGMP regulations as they relate to the employee's functions [21 CFR 211.25(a)].
- a. There is lack of cGMP training for personnel responsible for filling medical grade gases; and
 - b. There is no documentation of training for personnel who perform transfilling/testing of Oxygen USP.
3. Failure to calibrate gauges 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 your pressure gauges and vacuum gauges used in the transfilling of medical oxygen USP were not calibrated.
4. Failure to establish written operating procedures, to include:
- a. Procedures and responsibilities of Quality Control Unit [21 CFR 211.22(d)];
 - b. Maintenance of equipment used for transfilling/testing [21 CFR 211.67(b)];
 - c. Sampling and testing of finished product [21 CFR 211.165(c)];
 - d. Receipt, identification, storage, and handling of drug components [21 CFR 211.80(a)];
 - e. Receipt, identification, storage, and handling of labeling (21 CFR 211.130);
 - f. Warehousing of drug products (21 CFR 211.142); and
 - g. Distribution of drug products (21 CFR 211.150).

In addition, an initial review of your firm's labeling reveals a lack of compliance with current labeling regulations for drug products. Labeling for medical gas USP is required to conspicuously bear the name and place of business of the manufacturer, packer, and distributor. This shall include the street address, city, state, and ZIP code. The street address may be omitted if it is shown in a current city directory or telephone directory. Please be aware that medical gas labeling is defined as ONE label on a container, not a combination of labels to meet this requirement. This does not include the device label that is required to be on the cryogenic vessel or high pressure cylinder. Small possession/ownership labels are permitted on a vessel as long as the sticker does not obstruct required labeling. In addition, the sticker must not be misleading. For example, it should be qualified by a statement such as, "This empty vessel or this vessel when empty is the property of, or belongs to, 'Firm X, address, and telephone number.'"

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The label of a prescription drug in package form shall bear a declaration of the net contents. This shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.

In addition, as of February 19, 2003, the new "Rx Only" statement must be used on all medical gas labels.

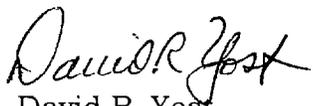
The above indication of violations, as well as the form FDA-483 issued to you and discussed with you, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal 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, and 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. 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 Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,


David R. Yost
Acting Director
Minneapolis District

CAH/rfk