



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

PURGED AH

January 6, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 -11

Lawrence Orick
President
Northwest Home Care, Inc.
6585 Edendale Boulevard, Suite 130
Eden Prairie, Minnesota 55346

Dear Mr. Orick:

During our recent inspection of your Northwest Home Care, Inc. medical oxygen transfilling operation, located at 809 West Tenth Street, Sioux Falls, 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 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 witnessing the filling of your truck-mounted

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vessel have received training specific to the analytical methodology being witnessed. This training should be documented and maintained on file.

2. Failure to test each component for conformity with all appropriate written specifications for purity, strength, and quality [21 CFR 211.84(d)(2)]. For example, the Certificate of Analysis (COA) you receive from   does not contain the following information: (1) the name of the product, Oxygen U.S.P.; and (2) the specific model number of the oxygen analyzer used to analyze the product. Also, your COA does not state that the oxygen was produced by the air-liquefaction process. You are therefore required to test for Carbon Dioxide and Carbon Monoxide. Oxygen produced by the air-liquefaction process is exempt from the requirements of the tests for Carbon Dioxide and Carbon Monoxide.
3. Failure to have written procedures describing in sufficient detail the testing and approval or rejection of drug product containers [21 CFR 211.80(a)]. For example, written procedures do not include an external vessel inspection or a label inspection.
4. Failure to have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, and examination of labeling materials (21 CFR 211.122). For example, you have no written procedures for label inventory control.

These violations are 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.

In addition, you are required to apply a drug label to all medical oxygen vessels your firm fills. Failure to do so misbrands your product. Medical gas labels should bear, at the very least, the following information: (1) the name of the medical gas in the container; (2) an air liquefaction statement, if appropriate; (3) the name and place of business; (4) quantity of contents, and (5) at a minimum, "Rx only." Cryogenic vessels come from the manufacturer with a

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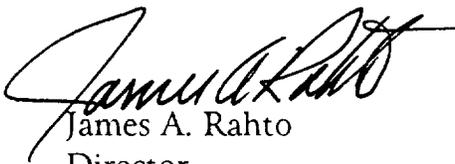
device label; this is not to be confused with the drug label and must not be removed.

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 with all of the requirements of the Federal Food, Drug and Cosmetic Act.

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 indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: David Kvien
Branch Manager
Northwest Home Care, Inc.
809 West Tenth Street
Sioux Falls, SD 57104