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

October 5, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 05

John Morrison
Chairman of the Board
Allina Corporation
5640 Smetana Drive
Minnetonka, Minnesota 55343

Dear Mr. Morrison:

During our inspection of your Twin City Oxygen medical oxygen transfilling operation, on September 6 and 10, 2001, located in New Brighton, 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 have written procedures for production and process controls designed to assure that the drug product has the identity, strength, quality and purity it purports to possess or is represented to possess [21 CFR 211.100(a)], in that Nitrous Oxide USP cylinders are connected to the argon gas filling manifold and vacuumed to $-26''$ of Hg and there is no back flow prevention valve on the manifold to prevent argon from inadvertently entering these cylinders.
2. Failure to test each component for conformity with appropriate written specifications for purity, strength and quality [21 CFR 211.84(b)(2)], in that the bulk stand tanks are not tested prior to the filling of liquid or high pressure cylinders to assure the identity and purity of the gas, nor are the vehicle-mounted vessels tested for identity and purity after filling.

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3. Failure to adequately calibrate your . oxygen analyzer used to test the purity and identity of Oxygen USP [21 CFR 211.160(b)(4)], in that Nitrogen NF filled on-site is used as the span gas rather than high purity nitrogen.
4. 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 current good manufacturing practice (cGMP) regulations as they relate to the employee's functions [21 CFR 211.25(a)], in that there is lack of cGMP training for personnel responsible for filling medical grade gases and personnel responsible for Quality Control.

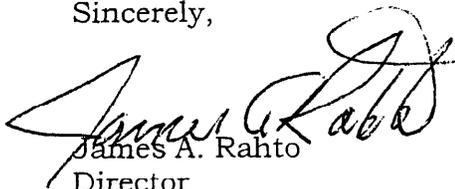
The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about 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.

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

Sincerely,


James A. Rahto
Director
Minneapolis District

CAH/ccl

