

PURGED

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

February 21, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-35

Patrick Murphy
President
AGA Gas Co.
6225 Oak Tree Boulevard
Independence, Ohio 44131

Dear Mr. Murphy:

On January 27 and 28, 1997, the Food and Drug Administration conducted an inspection of your air liquefaction facility, AGA Gas, Inc. at 309 Sentry Drive, Waukesha, WI. The Investigator found your firm to be operating under significant deviations from Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)].

Oxygen USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

1. Failure to assure that the oxygen purity tests are being performed on all trailer loads filled. In several instances there were no purity test results recorded on either Tank Analyzer Calibration form or the Analyzer Calibration form.

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2. Failure to follow written procedures for performing and recording the purity and identity of the gas.
3. Failure to document maintenance of Servomex oxygen analyzer.
4. Failure to perform and document review of records by a responsible person.

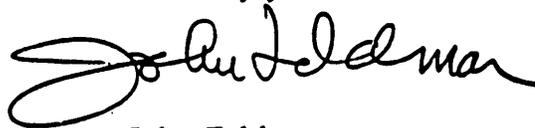
This letter is not meant to be all-inclusive. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Failure to do so may result in enforcement action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you advise us in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within the requested time-frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

Your reply should be addressed to Acting Compliance Officer Rodney L. Bong at the address indicated on the letterhead.

Sincerely yours,



John Feldman
Director
Minneapolis District

RLB/ccl