

August 20, 1997

WARNING LETTER
CHI-42-97Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863CERTIFIED MAIL
RETURN RECEIPT REQUESTEDMr. Patrick Murphy, President
AGA Gas, Inc.
6225 Oaktree Blvd.
Cleveland, OH 44131

Dear Mr. Murphy:

During an inspection of your AGA Gas Central, Inc. facility located at 3150 Woodford, Decatur, Illinois, conducted January 2, 1997, our investigator determined that your firm manufactures Oxygen, U.S.P., in liquid, gaseous, and compressed form. This medical gas is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). The inspection revealed that your Liquid Oxygen, U.S.P., and Liquid Nitrogen, NF are misbranded and adulterated under the Act.

Your Oxygen, U.S.P. and Nitrogen, NF are adulterated under Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, their manufacturing, packing, holding, or shipping are not in conformance within the Current Good Manufacturing Practice Regulations (CGMPs) for drugs specified in Title 21, Code of Federal Regulations, Parts 210 & 211, as follows:

1. Your Decatur facility failed to assay the incoming liquid nitrogen for identity and strength prior to filling the dewars. You do not receive a valid Certificate of Analysis (COA) from your supplier and perform no testing of the incoming liquid nitrogen at your firm. Your Decatur facility uses the supplier invoice as the COA. The COA is not complete. The COA did not list the analytical method used by the supplier and the test results in three instances.
2. Your Decatur facility failed to test the Liquid Nitrogen, N.F. prior to release for distribution. Because you failed to test the incoming Liquid Nitrogen, N.F. for identity and strength you are required to perform full testing of each vessel.

Mr. Bernie Lozar of your corporate headquarters provided a letter dated July 26, 1995, to our investigator (copy enclosed). The letter, signed by Mr. Duane S. Sylvia, Consumer Safety Officer, Center for Drug Evaluation and Research (CDER), concerns the testing requirements for liquid nitrogen filled into large mouth, non-pressurized dewars which in turn are supplied to doctors for

use in cryosurgery. This letter states that as long as your incoming drug product meets all established specifications and complies with the four specific GMPs requirements listed on the letter, finished product testing is not required.

Your Decatur facility failed to meet the criteria listed in the 1995 letter. The letter stated a test for oxygen should be taken directly from the storage tank immediately after each delivery. You are not testing for oxygen. The letter stated a valid certificate of analysis should be received with each delivery. As noted in Item 1 of this warning letter, your Decatur facility is not receiving valid COAs.

3. Your Decatur facility failed to establish complete written procedures and to follow the procedures you do have.

a. Your procedure number F-70, "Receipt of Liquid Nitrogen" dated August 1, 1984, was provided to our investigator as part of her review of your procedures. This procedure states your firm is to conduct an assay and identity test on new commingled lots of bulk Nitrogen, N.F. Your Decatur facility does not conduct an assay or identity test.

b. Your procedure number F-90, "Filling of NF liquid Nitrogen Cylinders" dated August 1, 1989 directs the Decatur facility to conduct an assay and odor test of units prior to release for distribution. Your Decatur facility does not conduct assay and odor tests of units prior to release for distribution.

c. Your Decatur facility based its November 19, 21, and 22, 1996 releases of Liquid Nitrogen, N.F. on invoice number 004577 dated November 19, 1996. Invoice number 004577 concerns a delivery of bulk liquid oxygen.

It appears the procedures for the Decatur facility have not been updated to reflect the information on Mr. Sylvia's July 26, 1995 letter.

4. Your Decatur facility failed to establish complete written procedures assuring that the correct labels and labeling are used on your Oxygen, U.S.P. and Liquid Nitrogen, N.F. Your labels identified your corporate office as a distributor, when it should be identified as the manufacturer. This violation was not listed on your FDA-483; it was observed during a review of your labeling.

In addition, your Oxygen, U.S.P and Liquid Nitrogen, N.F. are misbranded under Section 502(a) of the Act in that the labeling identifies your drugs as being "Marketed By". The phrase "Marketed By" is used only when the distributor is named on the label. Your firm manufactures as well as distributes these drugs. Your label is not clear regarding the fact you manufacture the Oxygen, U.S.P. and Liquid Nitrogen, N.F. Your Oxygen Compressed, U.S.P. label contains the following obsolete statement which should be deleted:

"Warning! For Oxygen deficiency or emergency resuscitation when used by personnel properly instructed in oxygen administration. For other medical application only as directed by a licensed practitioner."

However, if you sell Oxygen Compressed, U.S.P. to emergency medical services for resuscitation, then the following statement would be appropriate and may be used in place of the federal caution statement:

"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, **Caution: Federal law prohibits dispensing without prescription.**"

It is our understanding from a previous inspection at another AGA facility that your firm had previous communications with FDA concerning the "Marketed By" issue. Our headquarters unit is unaware of these communications or that your "Marketed By" issue was deemed acceptable. If you have documentation concerning the acceptability of the "marketed by" issue, please provide the documentation in your response to this warning letter.

The filling of home liberator units, cryogenic home vessels, etc., for any home care company, consignee, or [REDACTED] requires your firm to comply with all of the applicable GMPs. This would include establishing and following written procedures, documentation, all of the required prefill inspections, **the testing of each and every home liberator unit filled**, and applying an AGA label, if appropriate, etc.

This letter as well as the Inspectional Observations, Form FDA 483 (enclosed), which was presented to and discussed with Ms. Beverly Copass, Branch Manager, at the close of the current inspection, is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to insure that all requirements of the Act, and regulations promulgated thereunder, are being met.

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You should notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to prevent a recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be implemented.

Your written response to the warning letter should be directed to Richard E. Harrison, Acting Director, Compliance Branch.

Sincerely,

RSI

Raymond V. Mlecko
District Director