



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
M3445n

February 28, 2000

VIA FEDERAL EXPRESS

Roger K. Alligood
General Manager/Owner
Allied Industrial Gases, LLC
331 South Houston Lake Road
Warner Robins, GA 31088

WARNING LETTER
(00-ATL-29)

Dear Mr. Alligood:

An inspection of your medical oxygen transfilling facility was conducted on 1/25-26/00 by FDA Investigator Robert P. Neligan. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a) (2) (B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications prior to release. You have failed to document the calibration of the [REDACTED] Oxygen Analyzer currently in use. Between the time period of 9/23/99 and 1/25/00, there were no records indicating that the oxygen analyzer was calibrated. During this time period, your facility transfilled and distributed approximately [REDACTED] medical oxygen cylinders. In addition, a review of your batch records revealed that 107 oxygen cylinders were transfilled on 6/4/99 with no assay results.

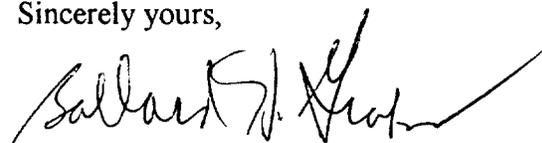
At the conclusion of the inspection, our investigator issued the inspectional Observations (FDA 483), and discussed the findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your facility. It is your responsibility to ensure that all requirements of the Act are met at your facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving drugs so that they may take this information into account when considering the awards of contracts.

You are requested to notify this office within fifteen (15) working days of receipt of **this** letter of all steps you have taken, or intend to take, 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 corrections will be completed.

Your response should also address any proposed actions regarding any oxygen lots **currently** in distribution, which were not properly documented. Your response should be addressed to Serene A. Kimel, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham", with a long, sweeping horizontal stroke extending to the right.

Ballard H. Graham, Director
Atlanta District