



DEPARTMENT OF HEALTH AND HUMAN SERVICES

418
Food and Drug Administration
Atlanta District Office

HEI-35 (B)

60 8th Street, N.E.
Atlanta, Georgia 30309

July 10, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James L. Moore
Owner/President
Moore Oxygen Supply, Inc.
266 New Airport Road
LaGrange, Georgia 30240

WARNING LETTER

Dear Mr. Moore:

An inspection of your medical oxygen transfilling facility was conducted on June 20, 1997, by Investigator Robert L. Lewis. Investigator Lewis 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 compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include purity, prior to release. A review of the Oxygen Filling Reports revealed your continued failure to maintain documentation of the calibration of the [REDACTED] Oxygen Analyzer. No record of calibration was available since December 14, 1995. Approximately [REDACTED] lots of Oxygen USP have been filled and distributed in that period of time. In fact, after January 11, 1996, the Oxygen Filling Reports did not even include a designated area on the reports to record calibration results.

You have also failed to document that each lot of transfilled cylinders is tested for purity prior to release. No analytical records were available for product transfilled on March 20, 1997 and April 2, 1996. The Filling Reports indicated that 107 cylinders and 39 cylinders of Oxygen USP, respectively, were filled on those dates.

These deviations have been brought to your attention during previous FDA inspections. The importance of properly calibrating your analytical equipment was first brought to your attention during the July 1983 inspection. The failure to maintain calibration records and test each lot of product was noted in the Warning Letter issued to you on August 2, 1994. Although corrections

were noted in the March 1995 inspection, the calibration records were still noted to be deficient. We would question your firm's commitment to compliance with the applicable regulations due to the above mentioned eighteen month lapse in maintenance of any semblance of the required calibration records.

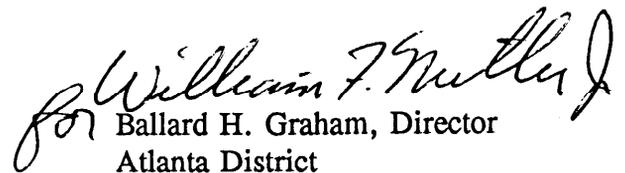
At the conclusion of the inspection, Investigator Lewis issued his Inspectional Observations (FDA 483) to and discussed his findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being 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 all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

We are particularly concerned about the apathetic attitude exhibited in regards to these chronic violations. You attempted to justify these persistent deviations as an expected consequence of the routine nature of the records. You have failed to exhibit the appropriate level of diligence and supervision to assure that these records are appropriately filled out and reviewed by a responsible individual. It is your ongoing responsibility to ensure that the individuals responsible for the transfilling of this drug product understand the importance of the GMPs, are properly trained, and maintain an appropriate level of dedication to their assigned duties. You should also carefully review the procedures for, and importance of, proper testing and maintenance of records with your employees. The additional concerns discussed with you by Investigator Lewis, about the identical purity results for twenty eight consecutive lots, should also be discussed with your employees.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. We strongly urge you to prepare a written response. We have no record of a written response to your previous Warning Letter. Your response should address any proposed actions regarding the oxygen cylinders currently in distribution which have not been properly tested. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,


for William F. Nutley
Ballard H. Graham, Director
Atlanta District