



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
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November 24, 1999

VIA FEDERAL EXPRESS

Phil Stone, President
Option Care
4190 Pleasantdale Road
Doraville, Georgia 30340

WARNING LETTER

Dear Mr. Stone:

Investigator Robert L. Lewis conducted an inspection of your medical oxygen transfilling facility on October 27-29, 1999. Investigator Lewis documented several very serious 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).

Your firm admitted fabricating analytical test results for transfill records for numerous cylinders filled between (approximately) 5/10/99 and 8/17/99. Oxygen purity test results of "100.0%" were written onto transfill records. For that same period of time, the Servomex oxygen analyzer was out of service and no testing could be performed. Calibration records for the Servomex showed no calibration was done during this period. Shipping records and invoices indicated the Servomex was sent out for service between 12/07/98 and 12/14/98; yet filling records completed during this time frame also indicated that purity testing was performed. A "checkmark" was entered in the "PURITY TEST" column even though the Servomex was not in the plant.

Based on the transfilling records, ● lots of compressed medical oxygen were produced between 5/10/99 and 8/17/99, and based on distribution records, approximately ● cylinders were distributed during that time frame. Transfill records covering 8/7/98 through 3/18/99 record only a "checkmark" in the purity analysis column rather than numerical results. This time frame covers more than ● lots of medical oxygen (@ approximately ● cylinders/month distribution).

This recurring practice of forging the analytical purity results make all the purity results in all the batch records questionable. Such misrepresentation of oxygen purity test results appears to be an attempt to cover up your firm's lack of testing.

In addition, your firm has no written specification for the transfilled oxygen purity. Transfill records show no evidence of a secondary review and approval by management, no label attached to transfill records, and no program for calibrating the thermometer.

Mr. Phil Stone

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At the conclusion of the inspection, Investigator Lewis issued an Inspectional Observations (FDA 483) to you and discussed his findings with you. He explained the seriousness of his observations. 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 and regulations promulgated thereunder are being met.

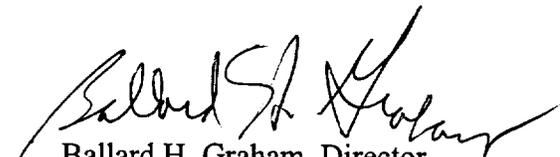
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts

We are in receipt of your Corrective Action Plan and Recall dated November 4, 1999.

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, injunction, and/or prosecution without further notice to you.

You are requested to call this office for a meeting, and to notify this office in writing within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your call and response should be addressed to Barbara A. Wood, Director of Compliance, at the address noted in the letterhead. Ms. Wood's telephone number is 404/253-1274.

Sincerely,



Ballard H. Graham, Director
Atlanta District