



San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

May 19, 2000

Our Reference No. 2951098

Mr. Edward Lang, President
Americair East Bay
875 Cotting Lane, Suite # G
Vacaville, CA 95688

WARNING LETTER

Dear Mr. Lang:

On April 4 - 17, 2000, FDA Investigators Rochelle B. Young and Steven R. Gillenwater conducted an inspection at your medical oxygen transfilling and distribution facility located at 875 Cotting Lane, Suite # G, Vacaville, CA 95688. The medical oxygen filled by your facility is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act) and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

This inspection revealed that medical oxygen transfilled and distributed by your facility is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Parts 210 and 211, as indicated below:

1. Your quality control unit failed to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and you did not review production records to assure that no errors had occurred or, if errors had occurred, that they had been fully investigated [21 CFR 211.22(a)]. At least 27 batch records examined were not signed as approved by a quality control person. In addition, at least three of the batch records had no record of any testing or process controls being performed and no investigation was conducted.
2. You failed to document the responsibilities and procedures applicable to the quality control unit [21 CFR 211.22(d)].

3. You failed to train personnel performing the transfilling, holding, and other operations related to Oxygen, USP in current good manufacturing as they relate to the employee's functions. Training in current good manufacturing practice was not conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them. [21 CFR 211.25(a)]. There is no documentation that the employee who performs the transfilling has ever received CGMP training.
4. You failed to maintain records of the qualifications for consultants advising on the manufacture, processing, packing, or holding of drug products [21 CFR 211.34]. [REDACTED] provided training and the *Transfilling Policy and Procedure Manual*; however, there are no records to indicate the consultant is qualified to provide these services.
5. You failed to adequately test post-fill Oxygen, USP for odor prior to release for distribution [21 CFR 211.165(a)].
6. You failed to use an official test procedure for the assay of Oxygen, USP. There is no documentation that the sensitivity and accuracy of the test procedure will produce identity and strength results equivalent or superior to those obtained using the official test procedure [21 CFR 211.165(e)].
7. You failed to routinely calibrate, inspect, or check equipment used in the manufacture, processing, packing, and holding of a drug product according to a written program designed to assure proper performance. You did not maintain written records of calibration checks and inspections [21 CFR 211.68(a)]. Your calibration of the [REDACTED] Oxygen analyzer is performed weekly, not daily as required by your *Oxygen Transfilling Policy and Procedure Manual*. In addition, there are no calibration or inspection records for the thermometer, vacuum and pressure gauges used in the transfilling process.
8. You failed to reconcile the quantities of labeling issued, used, and returned, and evaluate discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. You did not investigate these discrepancies [21 CFR 211.125(c)]. From 1/3/2000 to 4/6/2000 only one out of 68 batch records had been completed for label reconciliation.
9. You failed to retain production, control, or distribution records associated with Oxygen, USP for at least 1 year after the expiration date of the batch or, for products lacking expiration dating, a minimum of three years after distribution of the batch [21 CFR 211.180(a)]. There were no batch records for 4/1997 through 12/1998.

At the conclusion of the inspection the investigators issued Form FDA 483, Inspectional Observations, to Angelo H. Oliva, Operating Officer. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may exist at your facility. It is your responsibility to ensure that all requirements of the Act are met.

We acknowledge your initiation of a voluntary product recall of the Oxygen cylinders manufactured by your firm. In addition, we also acknowledge your verbal commitment to the investigators that you have ceased the oxygen transfilling operations and have no immediate plans to resume those operations.

Our review of your drug registration history found that you have failed to file your annual drug registration since 1997. If you resume your transfilling operation you will be required to file a new registration with FDA as a human drug establishment. In addition you will be required to correct the above identified deficiencies and ensure that your operations are meeting all the requirements of the Act.

If you resume your transfilling operations without promptly correcting these deviations, the Food and Drug Administration may initiate enforcement action without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please 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 taken to ensure that similar violations will not recur. If corrective action cannot be completed within this time limit, state the reason for the delay and the time needed to complete the corrections. If your plans are to permanently cease the transfilling operations, please notify this office in writing of your decision.

Send your reply to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070, Attention: Russell A. Campbell, Compliance Officer.

Sincerely,



Charles D. Moss
Acting Director
San Francisco District

Enclosures:

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