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U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

M845N

Telephone: [718] 340-7000 [Ext 5053]

WARNING LETTER

April 21, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Virginia Lewin, President
Lewin Agency, Inc.
d.b.a./Lewin Medical Supply
165 Oliver Street
Riverhead, New York 11901

Ref: 47-NYK-97

Dear Ms. Lewin:

An inspection of your medical gas transfilling facility was conducted by our investigator between March 12 and 20, 1997. This inspection documented deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (CGMP), Title 21, Code of Federal Regulations (CFR), Part 211 in conjunction with your firm's transfilling of liquid and compressed medical oxygen which cause these drugs to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the inspection, our investigator presented and discussed the attached list of inspectional observations (Form FDA 483) with you and your management staff. The following deviations were found:

- 1) Failure to test each component for conformity with all appropriate written specification for purity, strength and quality. Specifically:
 - There was no Certificate of Analysis (C. O. A.) for every lot of liquid medical oxygen nor was there documentation that a test for strength was performed on the bulk liquid oxygen used in patient cryogenic vessels.
 - There was no C. O. A. for the calibration gas.

- For those C. O. A.'s received from the supplier, there was no documentation of the reliability of their analysis.
- There neither was a C. O. A. for the bulk compressed oxygen nor did you conduct a test on the bulk oxygen for strength.
- There was no lot number affixed to the calibration gas cylinder.

2) **Failure to perform for each batch of a drug product an appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Specifically:**

- Automatic, mechanical, or electronic equipment used in the manufacture, processing, packing and holding of a drug product is to be routinely calibrated, inspected or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections will be maintained. There are no calibration records maintained for the [REDACTED] Oxygen Analyzer, the [REDACTED] Oxygen Analyzer or for any of the pressure gauges.
- The transfilled D, E, J, MP's and K sized cylinders of compressed medical oxygen were not tested for strength. The method that you employed to test the percent purity was not in conformity to the U.S.P. method in that the [REDACTED] oxygen analyzer is neither equal to nor superior to the U.S.P. method.

3) **Failure to maintain a batch production and control record which includes complete information relating to the production and control of the batch. These records will include documentation that each significant step in the repacking was accomplished. The batch production and control records for compressed medical oxygen represented by your firm's filling and testing records lacked the following, in addition to numerous omissions of the identity test dates on bulk oxygen, lot numbers on the bulk oxygen cylinders and calibrated gas, the percent and strength of calibrated gas, the reviewer's signature and date, percent of purity for a tested compressed cylinder:**

- The firm began transfilling liquid medical oxygen in August of 1995. However, filling and testing records were not implemented until October 2, 1996. There were no filling and testing records for 11/21/96, 1/17/97 and 2/18/97.
- The liquid oxygen transfilling records dated 10/2 and 22/96 were not reviewed and dated. The 11/8, 12, 13 and 12/26/96 filling and testing records do not indicate that a bulk identity test was performed and these records were not reviewed and dated.
- The filling and testing records for compressed medical oxygen do not indicate at what pressure various size cylinders are filled and these records do not record the external temperature of these cylinders.
- There are no filling and testing records to indicate that a dead ring test on compressed medical oxygen steel cylinders was performed.

- 4) Failure to document the reconciliation of quantities of labels issued, used, and returned, such that evaluation of discrepancies found between the quantity of drug products finished and the quantity of labeling issued can be determined. Specifically:
 - The filling and testing records for compressed medical oxygen do not indicate that cylinder labels are checked.
 - Your facility failed to follow its own Standard Operating Procedures regarding the inspection and replacement of labels to be recorded in that the label log with the date of inspection/replacement, serial number of tank and date of hydrostatic tests were not recorded.
 - Your facility failed to maintain a labeling record to show the amount of the labels issued, returned, destroyed and the amount of labels in the inventory.

- 5) Failure to have established written procedures for the calibration procedures of instruments, apparatus, gauges and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications will not be used. Specifically:
 - There is no written procedure specifying at what time intervals the [REDACTED] Oxygen analyzer should be calibrated. In addition, there is no documentation to show that the [REDACTED] was calibrated within the past five years.
 - Failure to follow the manufacturer's instructions regarding filter change for the [REDACTED] Oxygen analyzer.
 - There are no written sampling procedures describing the number of filled compressed medical oxygen cylinders or bulk liquid/patient cryogenic vessels to be tested.
 - The pressure gauge of the compressed medical oxygen filling gauge failed to move when the valve was initially opened.

- 6) Failure to provide documentation that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Specifically, there is no documentation that the employees who are involved in the transfilling and testing of both liquid and compressed medical oxygen has received formal training regarding drug GMP's.

- 7) Failure to have written procedures describing the handling of all written and oral complaints regarding a drug product.

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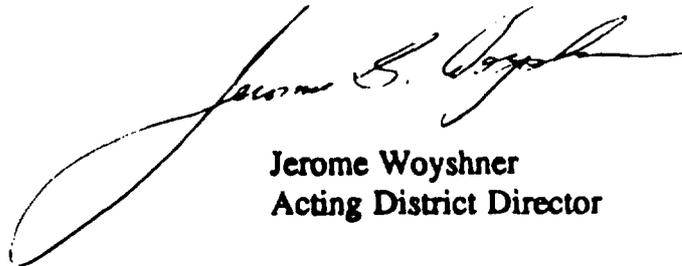
The above identifications of violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with requirements of the Good Manufacturing Practice Regulations. This letter serves as official notification that the Food and Drug Administration expects your transfilling facility to be in compliance. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by this Agency without further notice. These include seizure and/or injunctions.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken 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 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U. S. Food and Drug Administration, New York District Office, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer.

Sincerely,



Jerome Woyshner
Acting District Director

Attachment
Form FDA 483