



DEPARTMENT OF HEALTH & HUMAN SERVICES

M2175N

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232**WARNING LETTER**

November 4, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-1999-7

Mr. Myles Dempsey, Sr.
Chairman of the Board
Tech Air
A Division of Dempsey Enterprises, Inc.
465 Knollwood Road
White Plains, New York 10603

Dear Mr. Dempsey:

During an inspection of your medical gas repacking facility located in White Plains, New York on September 28 & 29 and October 6 & 8, 1998, our investigators documented deviations from Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211] concerning the repacking of medical gases. These deviations cause these drug products to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to, the following:

- (1) Failure to adequately test each batch of drug product for conformance with final specifications as required by 21 CFR 211.165 (a) in that your firm does not always test at least one finished compressed cylinder of medical grade oxygen per manifold filling sequence for identity and strength.
- (2) Failure to demonstrate that the test procedures used for testing Nitrogen N.F. is capable of producing equivalent or greater than N.F. test results as required by 21 CFR 211.165 (a) and 165 (e) in that the [REDACTED] Oxygen Analyzer was not validated for this purpose.

(3) Failure to assure that drug product containers are clean in accordance with 21 CFR 211.94 (c) by assuring evacuation of cylinders prior to filling. In the filling area, your firm has three stationary manifolds that share one common vacuum gauge. On occasion, portable oxygen racks may be connected to rack #3 (a stationary manifold) to fill additional high pressure cylinders that vary in size. Your firm has not demonstrated that this setup is capable of pulling a vacuum of at least 25 inches of mercury at sea level.

(4) Failure to establish adequate written procedures for all aspects of the filling operation to ensure that the drug product has the identity, strength, quality and purity it purports or is represented to possess in accordance with 21 CFR 211.100 (a). For example, the filling procedure fails to specify the number of cylinders that could be evacuated and filled per lot.

(5) Failure to establish adequate batch production and control records of each batch of drug product produced. These records should document that each significant step in the manufacture, processing, packing, and holding of the batch was accomplished as required by 21 CFR 211.188 (b). For example:

(A) there were no production records to show that U.S.P. grade oxygen, lot #8202, was transfilled into high pressure E size cylinders on or about 7/21/98 and that the oxygen was tested for purity and strength; and

(B) filling pressure and temperature readings of high pressure cylinders are not recorded on the pumper's log.

(C) Failure to maintain complete records of periodic calibration of laboratory instruments, apparatus, and gauges in accordance with 21 CFR 211.194 (d). For example:

(A) there were no calibration records maintained from January to August 1998 to demonstrate that the oxygen span gas was used to calibrate the [REDACTED] oxygen analyzer;

(B) there were no calibration records for the [REDACTED] Analyzer;

(C) there were no calibration records maintained for pressure gauges, such as fill check and manifold gauges; and

(D) there was no way to distinguish one pressure gauge from another since pressure gauges bear no form of identification, i.e., serial numbers.

(7) Failure to adequately implement procedures for the reconciliation, issuance, return and security of labels as required by 21 CFR 211.122. For example, on 9/29/98, there was a discrepancy noted in record keeping practices for the accountability of oxygen labels. According to the Labeling Control Record, a total of 189 high pressure oxygen labels were in stock, however, on 9/21/98, a total of 31 high pressure labels were actually in stock.

(8) Failure to follow your own firm's written procedures to inspect the bulk oxygen tank in 4/98 [21 CFR 211.100 (b)].

Neither the above identification of CGMP violations nor the inspectional observations (Form FDA 483)(copy enclosed) presented to Mr. Stanley Craig Dahlman, Vice President, at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drug products 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 without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which the corrections will be completed; (3) any reason why the corrective action has not been completed within the response time; and (4) any documentation necessary to show the corrections have been achieved.

Page 4 - Tech Air - Warning Letter NYK-1999-7

Your reply should be sent to the attention of Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn NY 11232, Tel. (718) 340-7000, ext. 5142.

Sincerely,


Brenda J. Holman
District Director

Attachment: Form FDA 483 dated 9/28,29 & 10/6,8/98