



Food & Drug Administration  
Olympic Towers, Suite 100  
300 Pearl Street  
Buffalo, NY 14202

June 3, 1998

**WARNING LETTER BUF 98-8**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Jyoti S. Mehta, President  
Shiv Respiratory Equipment, Inc.  
d/b/a American Respiratory Equipment, Inc.  
515 Troy Schenectady Road  
Latham, New York 12110

Dear Mrs. Mehta:

Inspection of your oxygen manufacturing facility at 515 Troy-Schenectady Road facility was performed May 12, 14 and 18, 1998, by Food and Drug Administration (FDA) Investigator Michael G. Sinkevich. The inspection revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and regulations promulgated thereunder. At the conclusion of the inspection, you were presented with a written list of objectionable conditions and practices (FDA-483).

Medical oxygen processed and distributed by your firm is considered a drug within the meaning of Section 201(g) of the Act. Your product, Compressed Oxygen U.S.P., is considered adulterated within the meaning of Section 501(a)(2)(B) of the Act, since controls used for the manufacture, processing, packing or holding of this product are not in conformance with current Good Manufacturing Practice regulations for Drugs (Title 21, CODE OF FEDERAL REGULATIONS (CFR), Parts 210 and 211 as follows:

- Failure of your technicians performing the assay on the transfilled oxygen to follow written specifications and test procedures [21 CFR 211.160(b)].

The U.S. Pharmacopeia defines oxygen U.S.P. as oxygen containing not less than 99.0 percent, by volume, of oxygen, as does your own written procedures. Your assay of the first filled cylinder of each manifold of oxygen manufactured between August 5, 1997 and March 11, 1998 identified 117 of 696 batches which fell below this release specification.

- Failure to adequately calibrate the [REDACTED] Oxygen Analyzer according to the current manufacturer's directions, using specific gases for the zero calibration step [21 CFR 211.160 (b)(4)].

Your written procedures contain the calibration addendum "U.S. Instruction Manual for [REDACTED] Oxygen Analyzer (Addendum)," which was discontinued by [REDACTED] October 9, 1997. Your technicians have continued to calibrate the [REDACTED] using ambient air rather than high purity nitrogen as required by the [REDACTED] Operations Manual.

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- Failure to maintain written records of the calibration of the [REDACTED] oxygen analyzer [21 CFR 211.194(d)].

- Failure to review and approve all drug production and control records prior to batch release [21 CFR 211.192].

It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure and/or injunction, **without further notice.**

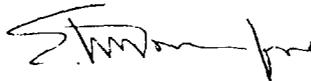
Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

If, after reviewing this Warning Letter, you still have questions regarding acceptable methods for complying with these requirements, please contact Joseph H. Erdmann, Supervisory Investigator, at our Syracuse Office (315/448-7601).

**Please notify this office, in writing, within fifteen (15) days of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations.** Your response should be directed to:

Joseph H. Erdmann, Supervisory Investigator  
U.S. Food and Drug Administration  
P.O. Box 7197  
Syracuse, New York 13261-7197.

Sincerely,



Brenda J. Holman  
District Director

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