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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

March 24, 1999

WARNING LETTER
CHI-14-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John J. Halpin, President
Vandenberg Med-Tech Equipment, Inc.
6813 W. 167th Street
Tinley Park, Illinois 60477

Dear Mr. Halpin:

During an inspection of your facility on January 28, 1999, our investigator, Lisa Hornback, determined that your firm manufactures Oxygen, U.S.P., in a compressed gas form. This medical gas product is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that your high-pressure compressed oxygen is adulterated under the Act.

Your Oxygen, U.S.P., is adulterated under Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the Current Good Manufacturing Practice regulations (CGMPs) for drugs specified in Title 21, Code of Federal Regulations, Parts 210 & 211, as follows:

1. Failure to document calibration of the [REDACTED] instrument.
2. Failure to review all filling records prior to product release.
3. Failure to document that incoming H size tanks are tested or that the method of testing for oxygen purity is appropriate.
4. Failure to assign unique lot numbers to each manifold load or filling sequence.
5. Failure to document training for employees who conduct filling and testing of Oxygen, USP.
6. Failure to have written procedures indicating the responsibilities of the Quality Control unit.

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These findings were discussed with you at the conclusion of the inspection when the FDA-483, List of Observations, was given to you by Ms. Hornback.

The above does not represent an all-inclusive listing of the violations noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the CGMPs. Federal agencies are advised of the issuance of all warning letters concerning 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 without further notice. These include seizure and/or injunction.

We have enclosed the latest copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '97 - A look at FDA's Medical Gas Requirements." This speech will assist you in understanding your responsibilities as a medical gas manufacturer.

If you wish to obtain a copy of the Act [DHHS PUBLICATION No. (FDA) 93-1051] or 21 CFR Parts 200 to 299 (SN 869-026-00071-9), you should contact the Superintendent of Documents, Attention: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders may be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00 a.m. to 4:00 p.m. Eastern Time, Monday through Friday, or faxed to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The Act is approximately \$20 and the CFR is approximately \$9.

You should notify this office in writing within 15 working days of receipt of this letter regarding 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 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written response should be directed to the attention of Richard Harrison, Acting Director, Compliance Branch, Food & Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/

Raymond V. Mlecko
District Director