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6/9/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

Refer to: CFN 1113321

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

April 28, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Santo M. Bramande, President
Wilson Supply Company, Inc.
15401 McMullen Highway
P. O. Box 870
Cumberland, Maryland 21502

Dear Mr. Bramande:

The Food and Drug Administration (FDA) conducted an inspection of your Cumberland, Maryland facility on April 2, 3 and 9, 1998. During the inspection, the following deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Liquid and Compressed Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to test and have the appropriate documentation to demonstrate that each batch of Liquid Oxygen is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess upon receipt and prior to release.
2. Failure to calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual. Your firm fails to document the calibration of the oxygen analyzer and to maintain a certificate documenting the purity of the standard oxygen used to calibrate the analyzer.
3. Failure to perform or have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder and home cryogenic unit filled.
4. Failure to hold Oxygen USP in quarantine until the batch has been released by the Quality Control person or unit.

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5. Failure to maintain the Certificate of Analysis for each batch of Liquid Oxygen that includes the complete test data and all other necessary information for product contained in the vehicle mounted vessels filled by your facility.
6. Failure to establish batch production records for each batch of Oxygen USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance.
7. Failure to establish written procedures and provide documentation to assure that each person engaged in the transfilling of Liquid Oxygen has the education, training, or experience to enable that person to perform the assigned functions.
8. Failure to store Oxygen USP labels in a secure location and to document that labels received match the quantities ordered, and are compared against the master label to assure correctness.
9. Failure to establish adequate written procedures for the production and process controls designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.
10. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of manufacture and control of the batch. Your Liquid Oxygen and Compressed Oxygen USP vessels and cylinders were not assigned a new lot number for each manifold filling sequence, each uninterrupted filling sequence, each cryogenic vessel filled, or for each storage tank following a delivery of oxygen.
11. Failure to establish adequate written recall procedures and to validate the computer software programs designed to facilitate recall of distributed drug products.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. 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.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection 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.

Mr. Santo M. Bramande

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You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence.

If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



ELAINE KNOWLES COLE
Director, Baltimore District

Enclosure

cc: Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215-2299