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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M 1996 W

Refer to: CFN 1125463

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

August 17, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph F. Wilson, President
Lifeguard, Inc.
401 Riverview Drive
Belmont, West Virginia 26134

Dear Mr. Wilson:

The Food and Drug Administration (FDA) conducted an inspection of your Belmont, West Virginia facility on July 27, 1998. We determined that your facility manufactures Oxygen, USP. Oxygen, USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Our records indicate that your facility is not registered with the FDA and your drug product is not listed with the agency. Therefore, the article, Oxygen, USP, is misbranded, as it was manufactured in an establishment not duly registered under Section 510 of the Act and the articles have not been listed as required by Section 510(j).

In addition, the following deviations from Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed during the inspection, which cause your compressed Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Act:

1. Failure to assay the filled high-pressure cylinders of Oxygen, USP for identity, strength, quality, and purity they purport or are represented to possess prior to release.
2. Failure to properly calibrate the oxygen analyzer used for the assay of Oxygen, USP, in that your firm did not have the high purity nitrogen standard required to calibrate the "zero" on the meter in accordance with the manufacturer's instruction manual.

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3. Failure to assure that each person engaged in the transfilling of compressed Oxygen, USP has the education, training, or experience to enable that person to perform their assigned function.
4. Failure to assure that incoming Oxygen, USP has the identity, strength, quality, and purity it purports or is represented to possess, prior to filling.
5. Failure to perform and/or adequately document the pre-fill, fill, and post-fill operations on each high-pressure cylinder filled.
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 and verified for accuracy and completeness by a second individual.
7. Failure to establish the following written procedures designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess:
 - a. employee training;
 - b. production and process controls;
 - c. control of components and drug product containers and closures, including the testing of incoming Oxygen, USP;
 - d. laboratory controls, including the testing of Oxygen, USP and calibration and maintenance of laboratory equipment;
 - e. holding and distribution; and
 - f. complaint files.
8. Failure to establish a quality control unit or person that has the authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

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 concerning drugs and devices so that they may take this information into account when considering the award of contracts.

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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.

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.

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. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,


ELAINE KNOWLES COLE
Director, Baltimore District

cc: West Virginia Board of Pharmacy
236 Capitol Street
Charleston, West Virginia 25301