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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone. 303-236-3000
FAX: 303-236-3100

December 12, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bruce L. Ballard, President
Scholzen Products Company, Inc.
548 West 100 North
Hurricane, Utah 84737

Ref. # DEN- 01-8

Dear Mr. Ballard:

During an inspection of your firm, Scholzen Products Company, Inc., 1313 East 700 North , St. George, Utah 84770, on August 28 – 30, 2000 Consumer Safety Officer Shelly H. Roberts determined that your firm distributes gas and liquid Medical Oxygen U.S.P. to patient home cryogenic units, hospitals, dental offices, medical offices and emergency medical use. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your gas and liquid Oxygen, U.S.P., is adulterated under section 502(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations, parts 210 and 211 (21 CFR 210 and 211). Deviations noted during the inspection include, but are not limited to the following:

1. Failure to properly calibrate instruments, as required by 21 CFR 211.160 (b)(4). For example, your firm does not have the high purity nitrogen standard required to calibrate the "zero" on your Servomex Oxygen Analyzer used for the assay of Oxygen U.S.P.
2. Failure to determine satisfactory conformance to final specifications, including identity and strength, as required by 21 CFR 211.165(a). For example, your firm does not test a filled cylinder from each manifold filling sequence for identity and purity.
3. Failure to test each lot of incoming liquid oxygen for identity and strength prior to filling large cryogenic units, or in lieu of such testing, failure to maintain a report or certificate of analysis from the supplier of the incoming liquid oxygen, to assure that the component

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conforms with written specifications, as required by 21 CFR 211.84(d)(2). For example, your firm does not witness the testing of your liquid oxygen upon arrival from the supplier, nor maintain Certificates of Analysis to assure that the oxygen conforms to specifications.

4. Failure to test containers for conformance with all appropriate written procedures, as required by 21 CFR 211.84(d) (3). For example, your firm does not perform a pre-fill inspection of large cryogenic units (VGLs) prior to filling with liquid oxygen U.S.P.
5. Failure to establish written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they are represented to possess, as required by 21 CFR 211.100(a). Your firm has not written manufacturing instructions nor standard operating procedures for the repacking of Oxygen U.S.P.
6. Failure to establish a quality control function with the responsibility to approve or reject all components, drug product containers, labeling, and drug products, and the authority to review all records to assure that no errors have occurred, as required by 21 CFR 211.22(a). We recognize that your firm is a small operation, however, there must be some type of quality control function present and operating to assure that errors do not occur.
7. Failure to assure that each person engaged in the packing or holding of a drug product has the education, training, and experience to enable that person to perform the assigned functions, as required by 21 CFR 211.25(a). For example, one of the employees designated by you as knowledgeable in filling Oxygen U.S.P. cylinders could not answer basic questions.
8. Failure to quarantine drug products before release by quality control, as required by 21 CFR 211.142(a). For example, both industrial grade and Oxygen U.S.P. cylinders are stored in intermingled storage. [X] of the [X] cylinders were industrial grade oxygen.
9. Failure to maintain batch production and control records, as required by 21 CFR 211.188.

In addition, [X] liquid VGL cylinders, declared by your firm to contain industrial grade oxygen, were labeled to contain Oxygen U.S.P. This causes these containers to be adulterated under the Act, Section 501(b), in that it purports to be a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below the standards set forth in such compendium. Your explanation that the units would not be used for Oxygen U.S.P. because the cylinders were too dirty is no excuse for such adulteration.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As President, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Regulations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Ms. Shelly L. Maifarth, Compliance Officer, at the above address.

Sincerely,



Thomas A. Allison
District Director

cc:

Mr. Adam Trujillo, Regional Administrator
Health Care Financing Administration, DHHS Region VIII
1600 Broadway, Suite 700
Denver, Colorado 80202-4967

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