DEPARTMENT OF HEALTH & HUMAN SERVICES M955N PUBLIC HEALTH SERVIC

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

May 30, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Tom Jenkins, President
Jenkins and Woolf
375 Elm Street
Idaho Falls, Idaho 83403

Ref. # - DEN-97-17

Dear Mr. Jenkins:

During an inspection of your firm, Wasatch Medical Supply, Inc., 2992 South Main Street, Salt Lake City, Utah on February 24 - 25, 1997, Consumer Safety Officer James E. Moore determined that your firm transfills Liquid Medical Oxygen U.S.P. to patient home units. 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 product, Oxygen U.S.P., is adulterated under section 501(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 (21 CFR), parts 210 and 211. Deviations noted during the inspection included, but were not limited to the following:

1. Failure to test each lot of incoming bulk oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 211.84(d)(2)]. For example, your firm failed to either witness the testing of the bulk liquid oxygen supplied by [redacted] or perform an identity test on each vessel received or filled by the supplier.

2. Failure to establish written procedures designed to assure that Oxygen U.S.P., which is transferred into home units, has the identity and strength it is purported to or represented to possess [21 CFR 211.100(a)]. For example, there are no written procedures established regarding the following: analysis of liquid Oxygen, U.S.P.; transfilling of patient home units; repair and maintenance of home units; employee training; equipment calibration; equipment cleaning and complaint files.

3. Failure to provide adequate documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished and reviewed [21 CFR 211.188(b)]. For example, there are no batch records covering the processing of Medical Oxygen.

4. Failure to provide training sufficient to enable employees to perform their assigned functions [21 CFR 211.25(a)]. For example, there is no written evidence that employees have received proper training in the transfilling of Medical Oxygen.

5. Failure to perform and document adequate pre-fill operations on each medical oxygen cylinder, prior to filling [21 CFR 211.84(d)(3)]. For example, there are no procedures or records which show that the external vessel, valve, volume or contents gauge, or product label are inspected prior to filling.

6. Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used, and returned. [21 CFR 211.125(c)].

At the conclusion of this inspection, Consumer Safety Officer Moore issued a written report of observations (FDA 483) to Ms.Heather M. Mendenhall, Customer Service. A copy of that report is enclosed for your reference.

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.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at all your medical gas facilities and appropriate action be taken to assure that similar violations are not occurring at other locations.

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 Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

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.

PURCH

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 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. Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,

Gary C. Deen
for District Director

Enclosures:
As Stated in Letter

cc: Ms. Judy Anderson
Vice President
Wasatch Medical Supply, Inc.
2992 South Main Street
Salt Lake City, Utah 84115

Ms. Mary Kay Smith
Regional Administrator
Health Care Finance Administration, DHHS Region VIII
Byron G. Rogers Federal Building
1961 Stout Street, Fifth Floor
Denver, Colorado 80294-3538