



9/3/97

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

May 7, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Keith Dillard, President
Whitmore Oxygen Company
6880 South 2300 East
Salt Lake City, Utah 84121

Ref. # - DEN-97-18

URGENT

Dear Mr. Dillard:

During an inspection of your firm, Whitmore Oxygen Company, 1211 South Industrial Parkway, Provo, Utah on April 2 and 3, 1997, Consumer Safety Officer James E. Moore determined that your firm transfills Liquid Medical Oxygen U.S.P. to patient home units, and Liquid Medical Carbon Dioxide, U.S.P. and Nitrogen, N.F. for physicians' use. Medical Oxygen, Nitrogen and Carbon Dioxide are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your products, Oxygen U.S.P., Carbon Dioxide, U.S.P. and Nitrogen, N.F., are adulterated under section 501(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of these products 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 properly calibrate the [redacted] Oxygen analyzer used for the assay of Oxygen, U.S.P., in that your firm did not have the high purity nitrogen standard required to calibrate the "zero" on the meter and does not calibrate the [redacted] in accordance with the directions found in the operating instructions [21 CFR 211.160(b)(4)].
2. Failure to test each lot of incoming bulk oxygen to determine conformance with appropriate specifications for identity and strength in that your firm does not perform carbon dioxide and carbon monoxide tests and does not have a current air liquefaction statement from your supplier [21 CFR 211.84(d)(2)].

3. Failure to provide adequate documentation that each significant step in the manufacture, processing, packing or holding of each batch of drug was accomplished and reviewed [21 CFR 211.188(b)]. For example, batch records for Medical Oxygen did not include labeling inspection, volume or contents gauge inspection of the cryogenic home vessels. Also, several serial numbers were not documented.
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 follow written production and process control procedures in the execution of various production and process control functions in that your firm has failed to follow your standard operating procedures with regards to the routine maintenance of patient home units [21 CFR 211.100(b)].
6. Failure to establish written procedures designed to assure that correct labels and labeling are used [21 CFR 211.130]. For example, your patient home units do not bear the statement, "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."
7. Failure to assay liquid cylinders of medicinal Nitrogen and Carbon Dioxide for identity and strength, prior to release [21 CFR 211.165(a)].

At the conclusion of this inspection, Consumer Safety Officer Moore issued a written report of observations (FDA 483) to Mr. Donald Salzetti, District Manager. 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.

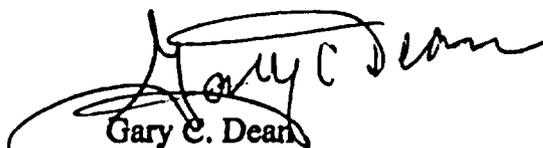
I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed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

PURGE

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 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 E. Dean
District Director

Enclosures:
As Stated in Letter

cc: Mr. Donald S. Salzetti
District Manager
Whitmore Oxygen Company
1211 South Industrial Parkway
Provo, Utah 84603

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

PURGE