



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

M36217
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

March 15, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerry Miller, President
Physician's Choice Medical, LLC.
7000 Broadway Boulevard
Suite 200-Bldg 2
Denver, Colorado 80221

Ref #: DEN-00-21

Dear Mr. Miller:

During an inspection of your firm, Physician's Choice Medical, LLC., located at 7000 Broadway Boulevard, Suite 200-Bldg 2, on January 31 – February 1, 2000, Consumer Safety Officer Eric S. Myskowski determined that your firm transfills Liquid Medical Oxygen U.S.P. to patient home cryogenic 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, 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 included, but were not limited to the following:

1. Failure to establish written procedures that ensure medical oxygen being transfilled into cryogenic home units has the identity and strength it is represented to possess, as required by 21 CFR 211.100 (a). For example, the firm has not developed any written procedures to address the following areas: pre-fill and post-fill operations; employee training; and the calibration and maintenance of home units and related equipment such as pressure gauges, vacuum gauges, valves, etc.
2. Failure to provide training that is adequate to enable employees to perform their assigned duties and functions as required by 21 CFR 211.25 (a). For example, there is no written evidence that employees have received proper training in the transfilling of Medical Oxygen and current Good Manufacturing Practice.

March 15, 2000

3. Failure to establish written procedures covering the receipt, identification, storage, handling, and examination of all labeling issued, used, and returned to the firm as required by 21 CFR 211.130. For example, when the drivers fill a home oxygen unit, when a vessel is returned to the firm for routine maintenance, or when it is no longer needed, a labeling review is conducted. No written procedures were found in the firm that were designed and followed to assure that correct label, labeling and packaging materials are used for Medical Oxygen products.

At the conclusion of this inspection, Consumer Safety Officer Myskowski issued a written report of observations (FDA 483) to Mr. Charles R. Johnson, Operations Director. 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 Practice Regulations.

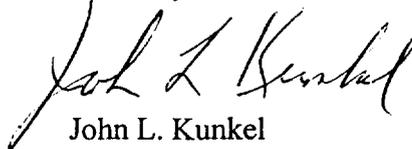
By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled "Compressed Medical Gases Guideline," a copy of the "Fresh Air '98" 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.

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 Mr. Steven C. Madzo, Acting Compliance Officer, at the above address.

Sincerely,



John L. Kunkel
Acting District Director