



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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
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81071d

February 13, 2001

WARNING LETTER

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Shon A. Spencer
Manager/Owner
Cryogenic Medical Gases
4785 Elati St., #35
Denver, CO 80216

Ref. # DEN- 01-19

Dear Mr. Spencer:

During an inspection of your firm, Cryogenic Medical Gases, Denver, Colorado, on January 17 & 18, 2001, Consumer Safety Officers Karen G. Hirshfield and Linda M. Cherry determined that your firm distributes gas and liquid Medical Oxygen U.S.P. to respiratory care companies and a rehabilitation hospital. 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 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, 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 document the actual analytical results for nitrogen (zero) or oxygen (span) standards and the certificate of analysis for the nitrogen calibration standard does not state the purity of the nitrogen.
2. Failure to establish complete written procedures designed to assure that correct labels and labeling are used, as required by 21 CFR 211.130(b). For example, your written procedure for labeling does not identify or contain examples of the current and approved cryogenic and compressed gas labels.

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3. Failure to maintain complete records of the periodic calibration of instruments, apparatus and gauges as required by 21 CFR 211.194(d). For example, there is incomplete documentation of the periodic calibration of thermometers used in checking fill and settling pressure (every ~~10~~ days per your SOP), and manifold vacuum gauges (~~10~~ per your SOP).

Review of labeling used on cylinders of compressed medical oxygen filled by your firm reveals the products are also misbranded with the meaning of Section 502(b)(2) of the Act in that labeling fails to contain a statement of the quantity of contents as required by 21 CFR 201.51. With respect to this violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen U.S.P. in liters at 70° F (21.1° C) and one (1) atmosphere.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As manager/Owner, 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.

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 H. Tom Warwick, Compliance Officer, at the above address.

Sincerely,



Thomas A. Allison
District Director