



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

January 7, 2000

Our Reference No. 2952287

Mr. Douglas B. Bennett
Bennett Medical Services
P. O. Box 11401
Reno, NV 89510

WARNING LETTER

Dear Mr. Bennett:

On October 20-25, 1999, FDA Investigator Edward D. Harris conducted an inspection at your medical oxygen transfilling and distribution facility located at 1155 West 4th Street, #105, Reno, Nevada 89503. The medical oxygen filled by this facility is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

This inspection revealed that medical oxygen transfilled and distributed by your facility is adulterated within the meaning of Section 501(a)(2)(B) of the FD&C Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Parts 210 and 211, as indicated below:

1. You have failed to use an official test procedure for the assay of Oxygen, USP. There is no documentation that the sensitivity and accuracy of the test procedure will produce identity and strength results equivalent or superior to those obtained using the official test procedure [21 CFR 211.165(e)].
2. You have failed to adequately test Oxygen, USP for identity and strength prior to release for distribution [21 CFR 211.165(a)].
3. You have failed to calibrate your equipment in accordance with an established written program [21 CFR 211.160(b)(4)].
4. You have failed to perform adequate prefill operations on each product cylinder prior to filling [21 CFR 211.84(d)(3)].
5. You have failed to maintain appropriate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance [211 CFR 21.188(b)].
6. You have failed to establish written procedures with respect to the testing of Oxygen USP; the calibration of the oxygen analyzer; and the documentation of prefill and postfill inspections of product cylinder home units [21 CFR 211.100(a)].

7. You have failed to establish written procedures designed to assure that correct labels and labeling are used for the product cylinders, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(b)].
8. You have failed to establish written procedures for the handling of any complaints regarding the drug product [21 CFR 211.198].

At the conclusion of the inspection, Investigator Harris issued Form FDA 483, Inspectional Observations, to Jerry Stewart, Manager Therapy Department. A copy of the FDA 483 was discussed with you on October 25, 1999. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may exist at your facility. It is your responsibility to ensure that all requirements of the FD&C Act are met.

We request that you take prompt action to correct these violations. Failure to promptly correct these deviations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

You are requested to notify this office within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step taken to ensure that similar violations will not recur. If corrective action cannot be completed within this time limit, state the reason for the delay and the time needed to complete the corrections.

Your reply should be sent to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070, Attention: Steven R. Gillenwater, Medical Gas Monitor.

Enclosed are copies of the Current Good Manufacturing Practice Regulations (21 CFR 210 and 211); the Compressed Medical Gases Guideline; and "Fresh Air '98, A Look at FDA's Medical Gas Requirements," speech by Duane S. Sylvia of the FDA Center for Drug Evaluation and Research. The Compressed Medical Gases Guideline and Mr. Sylvia's speech contain useful information on how to comply with the regulations.

Sincerely,



Darrell T. Lee
Acting Director
San Francisco District

Enclosures:

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