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BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 9, 1997

WARNING LETTER BUF 97-24

J. David Mahoney, President and Owner
Albany Welding Supply Co. Inc.
20 Center Street
Albany, NY 12204

Dear Mr. Mahoney:

During the August 7, 8 and 11, 1997 inspection of your medical gas repacking facility at 20 Center Street, Albany, NY 12204, Food and Drug Administration (FDA) Investigator Nancy A. Saxenian found serious violations of the Food, Drug and Cosmetic Act (the ACT). Medical oxygen and nitrogen processed and packed by your firm are considered drugs within the meaning of Section 201 (g) of the Act. Your medical gases are considered adulterated within the meaning of Section 501 (a)(2)(B) of the Act, since the controls used for the manufacture, processing, packing or holding of the products are not in conformance with current Good Manufacturing Practices (cGMPs) Regulations for Drugs (Title 21, Code of Federal Regulations, Parts 210 and 211) as follows:

- Failure to properly calibrate the Oxygen Analyzer, used for the assay of Oxygen, U.S.P., in that your firm did not have the high priority nitrogen standard required to calibrate the "zero" on the meter [21 CFR 211.160 (b)(4)]. Your firm is using a calibration gas of .4305% +/- .0043% Nitrogen and Oxygen balance; the manufacturer's instruction manual requires high-purity Nitrogen (with a minimum purity of 99.9%) be used. Also, your firm is not performing a weekly "zero" check as required by the manufacturer's instruction manual. Additionally, documentation should be maintained for the performance of the "zero" check.

- Failure to establish the test method used to determine the strength and identity of Nitrogen, NF will provide results equivalent to or superior to the compendial test method [21 CFR 211.165(e)]. The compendial method for assay of Nitrogen NF specifies gas chromatography with limits of not less than 99.0%, by volume, of N₂.

Further, your firm is filling Nitrogen high pressure cylinders on a manifold system not dedicated to N₂ and you are testing for the presence of Oxygen at <7 ppm by use of a Teledyne Trace Oxygen Analyzer, Model 311. Documentation should be submitted to FDA demonstrating this method of testing is equivalent to or superior to the compendial test method.



-Written procedures do not address the receipt and testing of bulk incoming oxygen and nitrogen [21 CFR 211.80(a)].

-Failure to calibrate the master thermometer at suitable intervals [21 CFR 211.160(b)(4)]. Your records indicate the master thermometer used to calibrate other has not been calibrated during the preceding year.

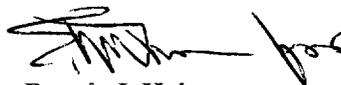
You should take prompt action to correct these violations and establish procedures whereby such violations will not recur. Failure to achieve prompt corrections may result in regulatory action - **without further notice**. This may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts. By copy of this letter, we are specifically 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.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy attached) you still have questions regarding acceptable methods for complying with these requirements, you may contact William J. Thompson at our Buffalo office (716/551-4461, Extension 3124).

Please notify this office, in writing, within 15 days of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to William J. Thompson, Team Leader, at the above address.

Sincerely,



Brenda J. Holman
District Director

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Attachments: -Compressed Medical Gases Guideline
-Fresh Air '97 - A Look at FDA's Medical Gas Requirements