

HFI-35

Public Health Service

NEW 2/11/17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

D1193B

WARNING LETTER

FLA-97-25

February 13, 1997

Dave A. Wentzka, President
All American Medical Services, Inc.
4350 NW 19th Ave., Suite 1
Pompano Beach, Florida 33064

Dear Mr. Wentzka:

Inspection of your medical gas filling operation on January 27 and 29, 1997, by FDA investigator Philippe L. Noisin, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Good Manufacturing Practice (GMP) Regulations [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. In addition, your refilled oxygen products are misbranded within the meaning of Section 502(o) of the Act in that they are being produced in an establishment that is not registered as required by Section 510 of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not adequately tested for purity and identity prior to release for distribution. The [REDACTED] Oxygen Analyzer used by your firm is not an acceptable test device for oxygen purity in that the accuracy of the device is not equivalent to the USP test accuracy of $\pm 0.1\%$.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for cylinder filling and testing, calibration and maintenance of equipment, labeling, handling of complaints, employee training, or supervision. Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required

pre and post fill cylinder inspections and testing. The investigator documented leak tests, temperature, and pressure readings recorded on batch records even though your firm does not have the equipment to perform such tests. No documentation is available to show that batch records are reviewed and approved by a supervisor prior to release, and there is no assurance that personnel have been adequately trained.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm also reveals the products to be misbranded within the meaning of Sections 502(b)(1) and (2) of the Act in that labeling fails to bear the place of business of the manufacturer, packer, or distributor, and a statement of the quantity of contents. As the refiller, your firm is considered to be the manufacturer. If the distributor is named on the label, the name shall be qualified in accordance with 21 CFR 201.1(h)(5).

With respect to the above referenced 502(b)(2) 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.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

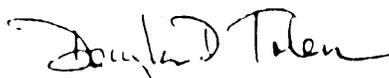
In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

A handwritten signature in cursive script that reads "Douglas D. Tolen".

Douglas D. Tolen
Director
Florida District