



September 12, 1997

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

97-DAL-WL-#43

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

David M. Duvall, President  
Jimmie Jones Sooner Airgas, Inc.  
31 N. Peoria  
Tulsa, Oklahoma 74120

Dear Mr. Duvall:

During the July 29-31, 1997, inspection of your medical gas manufacturing facility, a Food and Drug Administration (FDA) investigator found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). Similar violations were also encountered at your facility located at 1700 S. Agnew Ave., Oklahoma City, Oklahoma, inspected on July 21, 22, 28, and August 11, 1997.

The inspections were conducted in follow-up to a complaint from a home respiratory care (HRC) firm on July 11, 1997. The HRC firm received a delivery of Liquid Oxygen U.S.P. in 4500 cu.ft. containers (GP-45's) on July 10, 1997, from Jimmie Jones Sooner Airgas, Inc., 1008 S. Second St., Lawton, Oklahoma. The user reported that during transfilling of HRC home units on July 10, 1997, and upon purging of a transfill hose between use of GP-45's, the GP-45 unit, Serial #D84112384SD, Lot #F10H177B pressured the hose to the point of dislodging an inline filter, followed by the expulsion of an amber colored sticky substance.

The inspections show your medical Oxygen U.S.P. products are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacture, processing, packing, or holding of the drugs are not in conformance with Current Good Manufacturing Practice (CGMP) Regulations for Drugs as prescribed by Title 21, Code of Federal Regulations (21 CFR), Part 210 and 211, as follows:

- \* Failure to perform adequate prefill operations on each serviced container prior to filling, or as an alternative, requiring a certificate of testing from the servicing firm documenting acceptance of the serviced unit to meet the requirements for drug use [21 CFR § 211.84(d)(3)];
- \* Failure to retest or reexamine for identity, quality, strength, and purity and approve or reject drug product containers and closures as necessary,

e.g., after storage for long periods or after exposure to air, heat, or other conditions that may adversely affect the containers or closures [21 CFR §211.87];

- \* Failure to provide container closure systems designed to provide adequate protection against foreseeable external factors in storage and use that can cause contamination of the drug product [21 CFR §211.94(b)];
- \* Failure to ensure equipment cleaning and failure to have adequate procedures and schedules designed to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug beyond established requirements [21 CFR §211.67(a) & (b)];
- \* Failure to establish written procedures for production and process controls that are adequate to assure drug products have the identity, strength, quality and purity they purport or are represented to possess, in that a procedure is not established for assuring that containers, closures, valves, and lines are clean and free of contaminants before and after filling, during storage and holding, and prior to distribution to the end user [21 CFR §211.100(a)];
- \* Failure to establish and use an adequate finished drug storage area and storage conditions designed to ensure drug product containers awaiting distribution are not subjected to elements and conditions that may affect the identity, strength, quality, and purity of the product [21 CFR §211.142].

The investigators determined the GP-45 in question had been filled on May 15, 1997, at your Tulsa facility following its return from a service firm. The unit was then held for an extended period which resulted in the product venting from the container. Following shipment of the unit to Oklahoma City, the GP-45 was refilled on June 26, 1997, and delivered to your distribution facility in Lawton, Oklahoma, on June 29, 1997. The GP-45 was again held at the distribution facility for an extended period until shipped on July 10, 1997, to the HRC firm attempting to use the unit for filling canisters for supplying in-home breathing oxygen.

During all periods of storage of the unit it was held without covers or other means of protection for valves, and valve outlets. Our investigator observed the amber colored substance present in the liquid valve outlet and on the side of the container wall immediately below the valve outlet. The Dallas District Laboratory has determined this substance appears to be a mixture of several hexose carbohydrates.

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I am in receipt of your letters responding to the observations of the FDA-483's issued at both the Tulsa and Oklahoma City locations. Your responses do not satisfactorily address correction of the violations. You have not provided proposals that would satisfactorily assure total CGMP compliance and the quality of the medical oxygen manufactured and distributed by your various facilities. Of greatest concern to this office is your position that once filled containers of medical oxygen are placed on the dock for distribution or sent to a customer, they are considered to be out of the control of your quality control unit. You express this position, although you indicate it is possible that airborne contaminants or an insect nest can occur overnight in valve outlets. For purposes of ensuring compliance with the Act and related regulations your drug products are considered to be under your control throughout the operations of manufacturing, packaging, and holding for distribution.

It is your responsibility to insure all requirements of the Act and regulations promulgated thereunder, are being met at all your medical gas manufacturing, transfilling, and distribution facilities. This responsibility extends to the point at which the product is received by the end user free of contamination.

We request that you take prompt action to correct these violations. Failure to achieve prompt correction may result in enforcement action being initiated by FDA without further notice. These actions may include seizure of violative product, and/or injunctive action against you and your firm. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for your medical gas products.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, stating the action you will take to assure complete compliance with the Good Manufacturing Practice Regulations. Your response should include any documentation of corrective action you have taken to correct the violations encountered at the time of the inspection. Please direct your response to James R. Lahar, Compliance Officer, at the above address.

Sincerely,



SOR Joseph R. Baca  
Dallas District Director

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