



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

January 17, 1997

97-DAL-WL-#13

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Wayne R. Duncan
President
Natwel Supply Corporation
702 Culebra Road
San Antonio, Texas 78201

Dear Mr. Duncan:

During the December 11/12 & 17, 1996, inspection of your medical gas manufacturing and transfilling facility, a Food and Drug Administration (FDA) investigator found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, 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 establish a quality control unit having the responsibility and authority to approve or reject components and the authority for review of production records to assure drug product quality, in violation of 21 CFR § 211.22;
- * Failure to assay each batch of filled high pressure cylinders of Oxygen U.S.P. for identity and strength of active ingredient prior to release, in violation of 21 CFR § 211.165(a);
- * Failure to document the scheduled calibration of the oxygen analyzer used for the assay of Oxygen U.S.P., in violation of 21 CFR § 211.160(b)(4);
- * Failure to provide employee training in CGMP and production procedures enabling employees to perform their assigned functions in the manufacturing and filling of medical oxygen U.S.P., in violation of 21 CFR § 211.25;

- * Failure to perform adequate prefill operations on each high pressure cylinder, prior to filling, in violation of 21 CFR § 211.84(d)(3);
- * Failure to prepare batch production and control records for each batch of drug produced and failure to document that each significant step in the manufacture, processing, packing, or holding of each batch is accomplished, in violation of 21 CFR § 211.188(b);
- * Failure to provide review and approval of all production and control records for compliance with established procedures prior to release of the drug product, in violation of 21 CFR § 211.192;
- * Failure to maintain records of periodic calibration of the thermometers, pressure and vacuum gauges, in violation of 21 CFR § 211.194(d);
- * Failure to document approval of and failure to follow established written production and process control procedures, in violation of 21 CFR § 211.100(b);
- * Failure to establish written procedures for production and process controls designed 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 the filling of Oxygen U.S.P. in different colored high pressure cylinders, in violation of 21 CFR § 211.100(a);
- * Failure to establish and use a quarantine area for drug product containers awaiting finish product testing for quality, strength, and purity determination prior to release for distribution, in violation of 21 CFR § 211.142;
- * Failure to establish written procedures designed to assure the use of correct labels and the reconciliation of the quantities of labels issued, used, and returned to stock, in violation of 21 CFR § 211.125;
- * Failure to establish written procedures designed to assure the use of correct labeling and packaging materials and the prevention of label mixups during handling of filled cylinders awaiting labeling and lot/batch identification operations, in violation of 21 CFR § 211.130;
- * Failure to establish written procedure for the handling of all written and oral complaints relating to drug product quality, including procedures for the review, investigation, and evaluation of each complaint, in violation of 21 CFR § 211.198;

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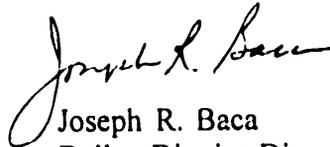
The above identification of violations is not intended to be an all-inclusive list of the violations and deficiencies that may exist. It is your responsibility to insure that all requirements of the Act and regulations promulgated thereunder, are being met at all your medical gas manufacturing and transfilling operations. At the conclusion of the inspection a List of Inspectional Observations (FORM FDA-483) was issued to Mr. Steve Mulder, Operations Vice President. A copy of this form is enclosed for your information.

Additionally, the investigator observed filled cylinders of Oxygen U.S.P. awaiting distribution fail to bear complete and accurate product information and required information relating to the manufacturer or distributor of the product. These drug products are considered misbranded within the meaning of Section 502 of the Act.

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. I have enclosed a copy of a Regulatory Letter issued to you by this office on December 7, 1990, following a previous FDA inspection. The letter cites several, similar violations to those encountered during the latest inspection.

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,


Joseph R. Baca
Dallas District Director

Enclosure

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