



DEPARTMENT OF HEALTH & HUMAN SERVICES

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10/21/97

Public Health Service
Food and Drug Administration

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

October 21, 1997

Ref: 98-DAL-WL-05

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Leon Wills, President
Canadian Valley Pharmacy, Inc.
2005 West Parkview
El Reno, Oklahoma 73036

Dear Mr. Wills:

During a September 16 and 17, 1997, 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 as prescribed by Title 21, Code of Federal Regulations, (21 CFR), Parts 210 and 211, as follows:

- Failure to assay the filled high pressure cylinders of Oxygen U.S.P. for identity and strength, prior to release [21 CFR 211.165(a)]. For a single compressed medical gas, at least one cylinder must be assayed on a multi-cylinder manifold each time the cylinders are changed on the manifold.
- Failure to perform adequate pre-fill, in-process fill, and post-fill operations on each high pressure cylinder, prior to filling cylinders with Oxygen U.S.P. [21 CFR 211.84(d)(3)].
- Failure to document the pre-fill, in-process fill, and post-fill valve integrity and other safety checks made on cryogenic home respiratory units [21 CFR 211.188(b)].

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- Failure to properly calibrate the Oxygen analyzer used for the assay of Oxygen U.S.P., in that your firm did not use the squeeze bulb aspirator when performing the low end calibration of the Servomex 570A Oxygen Analyzer [21 CFR 211.160(b)(4)].
- Failure to assay the contents for identity and strength of two Oxygen supply cylinders used to fill lots 239A701 and 245A701 since no certificates of analysis were received with these cylinders [21 CFR 211.84(d)(2)].
- Failure to properly use your quarantine area for drug products awaiting refilling, shipment, or testing [21 CFR 211.142]. Our investigator noted returned, quarantined and released Oxygen U.S.P. cylinders stored together in this area.
- Failure to follow written procedures designed to assure the use of correct labeling and packaging materials and to prevent labeling mix-ups [21 CFR 211.130].

The above identification of violations is not intended to an all-inclusive list of violations and deficiencies that may exist. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder, are being met at your medical gas manufacturing and transfilling operation.

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 such 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 Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above address.

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Sincerely,



SJR

Joseph R. Baca
Dallas District Director

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