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

7 November 1996

**WARNING LETTER BUF 97-4**

**CERTIFIED MAIL  
RETURN RECEIPT REQUEST**

Joseph S. Carnevale, President  
Arcadia Pharmacy, Inc.  
d/b/a Wayne Pharmacy Healthcare  
217 South Main Street  
Newark, New York 14513

Dear Mr. Carnevale:

An inspection of your firm was conducted by Food and Drug Administration (FDA) Investigator Gale A. Chartier, on 17-18 & 22 October 1996. This inspection revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act), and the regulations promulgated thereunder.

Your drug product, Oxygen USP, is adulterated within the meaning of Section 501(a)(2)(B) of the Act because the methods use in, or the facilities or controls used for the manufacture, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (CGMP), as prescribed by Title 21, Code of Federal Regulations (CFR), parts 210 and 211, such as:

- 1) Failure to establish scientifically sound and appropriate test procedures for the assay of Oxygen USP.
- 2) Failure to establish written procedures designed to assure the drug products have the identity and strength they purport or are represented to possess.
- 3) Failure to properly calibrate the oxygen analyzer used for the assay of Oxygen USP in that your firm failed to perform the calibration testing at the intervals specified in the manufacturer's instruction manual.
- 4) Failure to use a properly calibrated oxygen analyzer to test each lot of bulk oxygen to determine conformance with appropriate specifications for identity and strength.
- 5) Failure to use a properly calibrated oxygen analyzer to assay the filled high pressure cylinders of Oxygen USP for identity and strength, prior to release.



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6) Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used and returned.

7) Failure to establish written procedures designed to assure correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

At the conclusion of the inspection, Investigator Chartier presented you with an FDA-483, Inspectional Observations, listing the objectionable conditions and practices.

It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm, and set up procedures whereby such violations will not recur. Failure to take such action may result in regulatory action, such as seizure, without further notice.

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the awarding of contracts. We also are advising the Health Care Financing Administration (HCFA) of our inspection of your firm. HCFA may elect to defer or discontinue payment for any health care product found in violation of State or Federal law.

Please notify this office in writing, within 15 days, of the specific steps you have taken, or intend to take, to correct these violations. Your response should be directed to:

Joseph H. Erdmann, Team Leader  
Food and Drug Administration  
P.O. Box 7197  
250 South Clinton Street - Suite 602  
Syracuse, New York 13260

Sincerely,



E. Pitt Smith  
District Director

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