



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

ma439m

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

March 8, 1999

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Gary J. Carson, President  
OxyCare  
120 Sibley Avenue  
Ardmore, PA 19003

GEN.	SPEC.
RELEASE	
F# _____	DATE 3/9/99
Reviewed by: <i>[Signature]</i>	

Dear Mr. Carson:

On February 22, 1999, Food and Drug Administration (FDA) Investigator Edward D. McDonald conducted an inspection of your facility located at 120 Sibley Avenue in Ardmore, Pennsylvania, regarding the manufacture and distribution of oxygen, USP, for medical use. At the conclusion of the inspection, a Form FDA 483, List of Inspectional Observations (copy attached) was issued to and discussed with you. The FDA-483 dated February 22, 1999 lists serious deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations Part 211. Consequently, your product, compressed medical Oxygen USP, is adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with CGMP regulations as follows:

1. Failure to perform identity and purity tests on each batch/lot of transfilled gaseous medical oxygen USP prior to release [21 CFR 211.165(a)].
2. Failure to document purity tests results for each fill of finished product compressed medical oxygen USP manufactured [21 CFR 211.165(a)].
3. Failure to calibrate and maintain the ~~\_\_\_\_\_~~ Oxygen Analyzer in accordance with the manufacturer's instructions [21 CFR 211.160(b)(4)].

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4. Failure to calibrate the transfilling manifold pressure and vacuum gauges used during the transfilling of medical oxygen USP [21 CFR 211.160 (b)(4)].

5. Failure to possess documentation that the following testing and inspection was performed on each batch of medical oxygen, USP: (a) Prefill tests/inspections: color check, hydrostatic date check, visual check; (b) Fill tests: leak test, final pressure and temperature; (c) Postfill test: leak test [21 CFR 211.84(d)(3)].

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all requirements of the CGMP regulations are being met as well as all other requirements of the Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters regarding drugs and devices so that they may take this information into account when considering the award of contracts.

We are providing you with copies of the Compressed Medical Gas Guideline, Fresh Air "98", and 21 CFR Part 211 for your information and review.

Please advise this office in writing with fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be sent to the attention of Compliance Officer, James C. Illuminati at the above-referenced address.

Sincerely,



Thomas D. Gardine  
District Director  
Philadelphia District

jci