



**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION

4/1/97  
 D1275B

PHILADELPHIA DISTRICT

**WARNING LETTER**

800 U.S. Courthouse  
 5th and Chestnut Streets  
 Philadelphia, PA 19106

Telephone: 215-597-4390

March 20, 1997

97-PHI-19

**Certified Mail**  
**Return Receipt Requested**

David T. Logero, President  
 Eastern Medical Services, Inc.  
 1309 East Market Street  
 Warren, Ohio 44483

GEN.	SPEC.
RELEASE	
F# _____	DATE _____
Reviewed by: <u>Wm. W. Krueger</u>	

Dear Mr. Logero:

On February 20 and 24, 1997, Investigator James O'Donnell of the US Food and Drug Administration conducted an inspection of your medical oxygen transfilling operation located in Greenville, PA. At the conclusion of the inspection, he presented an FDA Form 483, List of Inspectional Observations, to Gary Cannon, General Manager of that facility. A copy is attached for your information. This form lists serious deviations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations (21 CFR) part 211. Consequently, your product, Oxygen, USP, is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the methods used in, or the facility used for their manufacture do not conform to CGMP regulations as follows:

1. You have failed to establish that the test procedure used to determine the strength and purity of medical oxygen, USP will provide test results that are equivalent or superior to the official test procedure. The ~~oxygen analyzer~~ oxygen analyzer you have been using since October, 1996 reads in increments of 1%. This device does not provide a sufficiently accurate reading of the purity of the medical oxygen being tested. [21 CFR 211.165(e)].
2. You have failed to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units. You have done no testing of the bulk storage tank since October, 1996 [21 CFR 211.165(a)].
3. You have failed to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess. You have no written procedures covering acceptance/release criteria for medical oxygen, test methods and instrument maintenance, or product storage and quarantine

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procedures [21 CFR 211.100(a)].

4. Persons engaged in the processing, packing and holding of drug products shall have training and experience in performing their assigned duties. Your employees have received no training in the filling and testing of medical oxygen [21 CFR 211.25(a)].

We also note that not all cylinders have been assigned correct lot numbers. It is essential that a coding system is in effect to assure that product can be tracked if required. Also, production records must be reviewed for completeness and signed off by a supervisor.

For your information, we have attached a copy of "Fresh Air". This document provides the principles and practices of medical gas packaging to assist you in an effort to be in compliance. This guideline does not contain legal requirements, but does provide procedures which are acceptable to the FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all of your company's operations are in compliance with the Act and regulations. You should take prompt action to correct these deviations. Failure to correct these deviations promptly may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days upon receipt of this letter, of the specific steps you have taken to correct the violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,



Diana Kolattis  
District Director  
Philadelphia District

Enclosures: FDA-483  
Fresh Air '96'

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**cc: Gary Cannon, Greenville, PA**

**Pennsylvania State Dept of Health**  
**Health and Welfare Building**  
**7th and Forster Streets**  
**P.O. Box 90**  
**Harrisburg, PA 17120**  
**Attn: Division of Primary Care and Home Health Service**  
**Robert E. Bastian, Director**