



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

WARNING LETTER

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

Telephone: 215-597-4390

97-PHI-45

October 17, 1997

CERTIFIED MAIL
RECEIPT REQUESTED

William Schultz Sr., President and CEO
Eastern Home Care and Oxygen
31 East 5th Street
Mt. Carmel, PA 17851

Dear Mr. Schultz:

On September 10, 11, and 19, 1997, Food and Drug Administration (FDA) Investigator Carol Rehkopf conducted an inspection of your firm Mira Associates, Inc., located at 611 Priestly Avenue, Northumberland, Pennsylvania, regarding the business aspect relating to the manufacture and distribution of liquid and gaseous oxygen, USP, for medical use. The medical oxygen manufactured by your company is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

During the inspection, Investigator Rehkopf documented deviations from the labeling requirements for prescription drugs as well as deviations from Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as codified in 21 CFR Parts 210 and 211. At the conclusion of this inspection, a Form FDA-483 (copy attached), List of Inspectional Observations, was issued to and discussed with Thomas Brokenshire, Operations Manager.

Consequently, the medical oxygen you manufacture is misbranded within the meaning of Section 502 of the Act, in that it is a prescription drug and fails to possess adequate labeling. During our inspection Investigator Rehkopf observed several medical oxygen cylinders from lots ~~XXXXXXXXXX~~, and ~~XXXXXXXXXX~~ with very badly worn labels which were unreadable. One cylinder observed possessed no labeling. These cylinders were documented as filled and released. As a result, these tanks of medical oxygen lack adequate instruction for use and lack the required caution statements.

Additionally, your product is adulterated within the meaning of

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F# _____ DATE 10/20/97

Reviewed by: *[Signature]*

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Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with the Current Good Manufacturing Practice Regulations as follows:

1. Procedures for label control are deficient in that,

(a) Procedures designed to assure that correct labels are used for drug products are not followed [21 CFR 211.130], in that,

Labels for filled medical oxygen cylinders (lot nos. [REDACTED] and [REDACTED] were either not present or were worn to the point of being unreadable;

(b) Medical oxygen labels currently used at the firm differ from the approved master label [21 CFR 211.130(d)], and;

(c) Medical oxygen labels are not stored in a controlled location [21 CFR 211.125].

2. The temperature gauge, serial number [REDACTED], used during the fill operation of medical oxygen was observed shattered during the inspection [21 CFR 211.67].

3. Failure to perform prefill operations on cryogenic vessels in patient homes prior to filling with medical oxygen [21 CFR 211.84(d)(3)].

4. There are no written procedures in place to require a quality control review of product control and production records. There has been no review of any production records by quality control from January 1997 through August 1997 [21 CFR 211.192].

This letter, as well as the Form FDA-483, which was presented Mr. Brokenshire at the close of the inspection, are not meant to be all-inclusive. 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 take corrective action may result in a regulatory action without further notice. These actions include, but are

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not limited to 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.

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 James C. Illuminati, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Diana J. Kolaitis
District Director
Philadelphia District

jci

Enclosure: As stated

cc: Thomas D. Brokenshire, FDA Liaison
Mira Associates, Inc.
611 Priestly Avenue
Northumberland, PA 17857

PA Department 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 Services
Robert E. Bastian, Director