



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region D1051B

Telephone (201) 331-2906

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

December 9, 1997

WARNING LETTER

RELEASE

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED
Mr. Ellis DeCresce
President/Owner
Family Medical Supply Co.
671 Montgomery St.
Jersey City, NJ 07306

REVIEWED BY CJK 1/15/98
CO. DATE

FILE: 98-NWJ-09

Dear Mr. DeCresce:

During an inspection of your firm located at 671 Montgomery St., Jersey City, NJ, on October 23, 24, and 29, 1997, an investigator from this office documented deviations from the current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) regarding your firm's manufacturing/transfilling operation of Liquid Oxygen, USP, a prescription drug product. These deviations cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

Your firm, by failing to assay incoming bulk Compressed Oxygen cylinders or bulk LOX cylinders, cannot assure the identity and strength of Liquid Oxygen, USP. In the absence of testing incoming bulk LOX, or witnessing of the supplier's testing, or maintaining all valid Certificates of Analysis for bulk LOX, your firm has failed to complete USP testing on each vessel filled and shipped to customers from your firm.

Your firm also failed to assay the finished product, ie: filled high pressure Compressed Oxygen D & E size cylinders or filled LOX cryogenic home vessels, for identity and strength, prior to shipment.

Your firm failed to conduct pre-fill or post-fill inspections for each high pressure Compressed Oxygen cylinders or LOX cryogenic home vessel filled.

Your firm failed to examine high pressure Compressed Oxygen cylinders and LOX cryogenic home vessels, filled by your firm, for correct labels. For example:

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1. Most of the D & E size high pressure Compressed Oxygen cylinders filled by your firm lacked labels indicating:

- a. The official name of the product
- b. The cylinder contents, in units of measure
- c. Whether the oxygen was produced by the air liquefaction process
- d. Adequate directions for use
- e. "Caution: Federal law prohibits dispensing without prescription."

2. Your firm had two cryogenic vessels in use during the inspection: The [REDACTED] cryogenic home vessel lacked labels for adequate directions for use, and the "Caution: Federal law prohibits dispensing without prescription" label. The [REDACTED] cryogenic home vessel lacked labels for designation of whether the oxygen was produced by the air liquefaction process, and adequate directions for use.

Your firm failed to maintain distribution records for Compressed Oxygen and LOX. The last entry in your distribution log (which shows a corresponding lot number with a customer) was 12/13/96. However, your invoices show that you have distributed both Compressed Oxygen and LOX from 5/21/97 through the ending date of the inspection (10/29/97).

Your firm's Warehouse Supervisor, who is responsible for performing the Compressed Oxygen and LOX filling operations, had no knowledge of any written procedures for the following oxygen filling operations: training, pre-fill & post-fill operations, analytical testing, labeling, calibration & maintenance of equipment, distribution, recalls, & complaint handling. This Supervisor also has never had cGMP training related to filling operations.

Your firm failed to calibrate the vacuum pump and pressure indicating gauges used on the Compressed Oxygen filling manifold.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations.

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

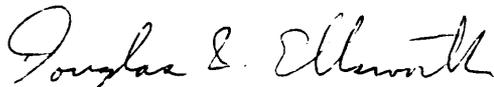
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You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey, 07054, Attention: Joy R. Kozlowski, Acting Compliance Officer.

Sincerely,



DOUGLAS I. ELLSWORTH
District Director
New Jersey District

JRK:np

Distribution

bcc: HFR-MA340 (DCB/JRK/JKT/WL File)
HFR-MA350 (DIB/Gp 6-Monitor/Gp 1-Remache/Rothschild)
HFR-MA320 (PSAU)
HFD-322 (CDER - Division of Manufacturing & Product Quality
Attn: Duane S. Sylvia)
HFA-224
HFC-240 (MPQAS)
HFC-210 (Division of Compliance Policy)
HFI-35 (FOI - stamped & purged copy)
EF (Family Medical Supply Co., Jersey City, NJ)

CFN: 2222162
Trak3 No: 98-73