



DEPARTMENT OF HEALTH & HUMAN SERVICES

D1260B

Public Health Service  
Mid-Atlantic Region

Telephone (201) 331-2901

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

March 13, 1997

WARNING LETTER

CERTIFIED MAIL -  
RETURN RECEIPT REQUESTED

RELEASE

Mr. Donald Kirson  
President  
Kirson Medical Equipment, Inc.  
8801 Kelso Drive  
Baltimore, MD 21221

REVIEWED BY JPR 3/13/97  
C.O. DATE

FILE: 97-NWJ-23

Dear Mr. Kirson:

During an inspection of your firm located at Kirson Medical Equipment Co., Absecon, NJ, between February 3 through February 7, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's manufacturing/transfilling of liquid oxygen, USP. These deviations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act as follows:

1. Your firm cannot assure the identity of liquid oxygen, USP received in a drug product container or vehicle mounted vessel, and used in the manufacture and distribution of medicinal gases for home respiratory care patients. For example:
  - A. Liquid oxygen, USP received between January 1994 until present, lot numbers XA13E23, dated 1/13/97 and lot number XK19D13, dated 11/19/96, were received and transfilled by Kirson Medical Equipment Co., for distribution to respiratory care patients, without Kirson having witnessed the testing performed by the suppliers.
  - B. Your firm has not periodically verified the reliability of the supplier's analysis, where liquid oxygen, USP is received under a certificate of assay (COA) and the testing is not witnessed by a Kirson representative.
2. Your written procedures and/or process controls, designed to assure that the drug product (liquid oxygen, USP) has the strength and identity it purports or is represented to possess, failed to specify and/or contain the following:

- A. A quality control unit or designate with the responsibility and authority to approve and/or reject all components, drug product containers, drug products, and the authority to review production records.
  - B. Your master production (Driver Technician Manual) and control records, failed to identify the complete steps involved in the witnessing, testing and transfilling of liquid oxygen, USP.
  - C. Labeling controls for cryogenic home units.
  - D. A training program for those employees engaged in manufacturing/transfilling of liquid oxygen, USP.
3. Your firm's Standard Operating Procedures concerning the receipt, testing and transfilling of liquid oxygen USP, were not followed. For example:
- A. The delivery person(s) failed to adhere to the Kirson Driver Technician Manual since the driver's name, lot number of product transfilled, and the patient who received the drug product, was omitted.
  - B. The method of determining the disposition and/or traceability of each lot of liquid oxygen, USP dispensed was not maintained on the Oxygen Lot Number Record Sheets from 5/28/96 through 7/19/96.
4. Your [REDACTED] digital platform scale used to weigh the quantity of liquid oxygen, USP transfilled into cryogenic home units for distribution to respiratory care patients has not been calibrated since it was placed into service over two years ago.

We acknowledge the receipt of your response on February 24, 1997, to the list of Inspectional Observations (FDA-483) issued to your Absecon, New Jersey, firm on February 7, 1997. Your response appears to be adequate. We will confirm the actual corrective actions during the next inspection of your facility.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against the award of contracts for affected products.

Kirson Medical Equipment Co.  
Warning Letter (97-NWJ-23)

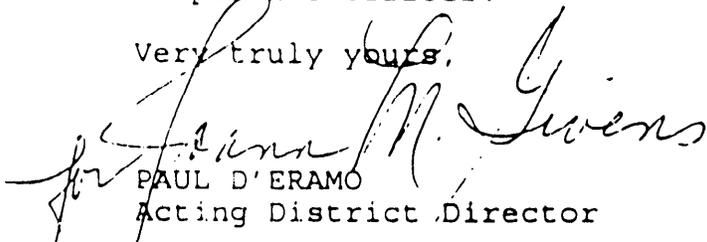
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Should your firm have additional comments concerning the FDA-483 or the above points, it should notify this office in writing, within 15 working days of receipt of this letter.

Your reply should be sent to the Food and Drug Administration, Newark District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,

  
PAUL D'ERAMO  
Acting District Director

VPR:slw

cc: Mr. Joseph R. Laudisio  
General Manager  
Kirson Medical Equipment Co.  
2516 Fire Road  
Absecon, NJ 08201