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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207  
Telephone: 313-226-6260

WARNING LETTER  
97-DT-13

August 6, 1997

Mr. Gary Kay, Owner  
Prescription Oxygen Services  
824 Swinton St.  
Sault Sainte Marie, MI 49783

Dear Mr. Kay:

Inspections of your medical oxygen transfilling operation were conducted on July 9 and 18, 1997 by Investigator Kelley Clark. The medical oxygen transfilled by your firm was misbranded within the meaning of Sections 502(f)(1), 502(g), 502(o), and adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Oxygen USP is a drug within the meaning of Section 201(g) of the Act.

The medical oxygen was adulterated based on inspectional evidence, which revealed serious deviations from Current Good Manufacturing Practice for Finished Pharmaceuticals, Part 211 (21CFR211).

- 1) Failure to establish detailed written procedures for production and process controls covering all aspects of your operation designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.
- 2) Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.
- 3) Failure to test incoming component and/or the finished product to determine conformance with appropriate specifications for identity and strength.

Handwritten signature and date: 9/18/97

Page 2 - Mr. Gary Kay, Owner, Prescription Oxygen Services  
Sault Sainte Marie, MI 49783 - 97-DT-13

The medical oxygen is misbranded.

- 1) The medical oxygen was transfilled in an establishment not duly registered under Section 510 of the Act and the article has not been listed as required by Section 510(j).
- 2) The article, Oxygen USP is regarded as a prescription drug and its labeling fails to bear adequate directions for use in accordance with 21 CFR 201.100(c)
- 3) The article, Oxygen USP labeling fails to indicate whether or not the oxygen has been produced by the air-liquefaction process as required by the United States Pharmacopeia.

The above is not intended to be an all-inclusive list of violations at your firm. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

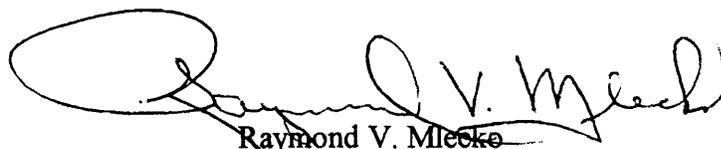
We acknowledge the fact that you have recalled all outstanding transfilled medical oxygen in trade channels. Investigator Clark has advised that you have discontinued the transfilling of medical oxygen as well. In the event that you should desire to initiate the transfilling of any medical gases, please notify the Detroit FDA office so that we may send you registration forms as well as answer any questions regarding the Law and Regulations.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct these violations and to prevent their recurrence. Since you have discontinued transfilling and recalled all transfilled medical oxygen, a statement to that effect will suffice.

Page 3 - Mr. Gary Kay, Owner, Prescription Oxygen Services  
Sault Sainte Marie, MI 49783 - 97-DT-13

Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance  
Officer, U.S. Food & Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207  
(Telephone: 313-226-6260 ext. 137).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Raymond V. Mlecko". The signature is fluid and cursive, with a large loop at the beginning and a long tail extending to the right.

Raymond V. Mlecko  
Acting District Director  
Detroit District