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Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, NJ 07054
Telephone: (973) 526-6000
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WARNING LETTER

**Certified Mail
Return Receipt Requested**

99-NWJ-12

February 2, 1999

Donald R. Lynch
President
LORS Medical Corporation
544 Julian Allsbrook Highway
Roanoke Rapids, NC 27870

Dear Mr. Lynch:

During the December 29, 1998 through January 8, 1999 inspection of your oxygen repackaging facility located at 37 Oakwood Avenue, Orange, NJ 07050, our investigator documented deviations from Current Good Manufacturing Practices for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211) and General Drug Labeling Provisions (Title 21, Code of Federal Regulations, Part 201). These deviations cause your drug product, Oxygen, USP, to be *a*) adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, and *b*) misbranded within the meaning of Sections 502(b), (c), and (o) and Section 503(f)(4) of the Federal Food, Drug and Cosmetic Act.

Those deviations included:

- Failure to perform identity and purity testing on Liquid Oxygen, USP following transfilling from cryogenic vehicle vessels to cryogenic home units or the filling of either type of vessel following return to service following repair or replacement [21 CFR 211.165].
- Failure to test each lot of bulk oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 84(d)(2)]. Specifically, you do not obtain or maintain certificates of analysis indicating the identity and purity of the Liquid Oxygen, USP from your supplier, nor do your firm's employees witness your Liquid Oxygen, USP supplier performing identity and purity testing.
- Failure to perform adequate prefill operations on both vehicle mounted cryogenic vessels and home cryogenic vessels prior to filling with Liquid Oxygen, USP [21 CFR 211.84(d)(3)]. Specifically, you maintain no documentation of valve checks, volume determination, and suitability of external labeling on both types of vessels.

- Failure to maintain documentation of appropriate maintenance of the vehicle mounted vessel (and the attached volume and pressure gauges) used in the packing and holding of Liquid Oxygen, USP [21 CFR 211.67(a)].
- Failure to perform production record review to determine compliance with all established and approved written procedures prior to release of transfilled Liquid Oxygen, USP [21 CFR 211.192]. All Daily Filling Record and Calibration Logs for the period January 1 – December 24, 1998, indicate record review was performed on dates following transfilling. One record, dated January 20, indicated no production review.
- Failure to demonstrate by your Daily Filling Record and Calibration Logs that each significant step in the packing and holding of Liquid Oxygen, USP was performed [21 CFR 211.188(b)]. 1998 Daily Filling Records and Calibration Logs dated April 10, April 20, June 10, August 11, and October 7 denote no batch or lot number for a total of 40 compressed gas cylinders containing Oxygen, USP. 1998 Daily Filling Record and Calibration Logs dated January 29 and September 21 denoted no batch or lot number for four cryogenic home vessel on-site fills.
- Failure to label compressed gas cylinders, vehicle mounted vessels and cryogenic home vessels containing Oxygen, USP with the following prescription legend: "Caution: Federal law prohibits dispensing without prescription." [FD&C Act 503(b)(4)(A)]
- Failure to adequately label your vehicle mounted vessels and cryogenic home vessels [21 CFR 201.1(a), 21 CFR 201.10(c)(2) and 21 CFR 211.130(c)]. Specifically, both container types do not bear labeling of the name and address of the filler and distributor, the Oxygen, USP contained therein was produced via air liquefaction, and compressed gas cylinders bear multiple lot numbers.
- Failure to list your Oxygen, USP drug product with the Agency [21 CFR 207.21].
- Failure to perform timely maintenance and service on four Nidek Mark 5 brand Oxygen Concentrators distributed by your firm [21 CFR 211.67(a)]. Specifically, 9,000-hour service was performed on each concentrator at meter readings ranging from 20,864 to 33,474 hours.

The above deviations are not intended to be an all-inclusive list of violations. As a repackager of drug products for human use, you are responsible for assuring that your overall operation and the product you distribute are in compliance with the law.

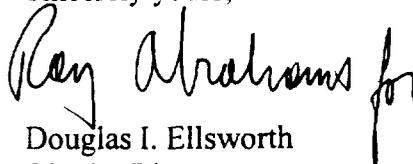
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days upon receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

By copy of this letter, we are advising the U.S. Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

A handwritten signature in black ink that reads "Ray Abrahamson for". The signature is written in a cursive, flowing style.

Douglas I. Ellsworth
District Director

Cc: Mr. Raheem Ali
Field Service Technician
LORS Medical Corp.
37 Oakwood Avenue
Orange, NJ 07050

Beneficiary Services and Providers Branch Chief for New Jersey
U.S. Health Care Financing Administration
Region II
26 Federal Plaza, Room 3811
New York, NY 10278-0063