



DEPARTMENT OF HEALTH & HUMAN SERVICES

m2260 n
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 11, 1998

WARNING LETTER NYK 1999-15

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John Byrnes, President and Chief Operating Officer
Lincare, Inc.
19337 US 17N
Suite 500
Clearwater, FL 33764

Dear Mr. Byrnes:

An inspection of your Oxygen, USP transfilling facility located at 382 West First Street, Oswego, New York was conducted October 19 - 21, 1998. Our investigator, Russ E. Davis documented serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereafter.

At the conclusion of the inspection, Investigator Davis presented David K. Svedman, Center Manager, with a written list of objectionable conditions and practices (FDA 483). Your product, Compressed Oxygen USP is adulterated within the meaning of Section 501(a)(2)(B) of the Act because the controls used for manufacture, processing, packing or holding this product are not in conformance with current good manufacturing practices regulations (Title 21, Code of Federal Regulations (CFR, Parts 210 and 211) such as:

1. Failure to properly calibrate the Servomex 570A Oxygen Analyzer (Analyzer) in accordance with the manufacturer's instructions. The Analyzer is used to conduct identity and purity testing on transfilled Oxygen USP. Transfilled cylinders of Oxygen USP are released for commercial distribution based of these test results.
2. Failure to obtain a Certificate of Analysis from your supplier for each incoming shipment of Oxygen USP as required by your written instructions, see Oxygen Transfilling Manual, Section 6, Transfilling Procedures (Source Oxygen).

For additional deviations, please refer to the FDA 483, Inspectional Observations, issued October 21, 1998. A copy is enclosed with this letter.

Lincare, Inc.
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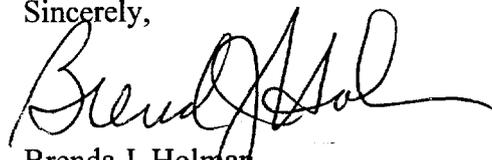
We are in receipt of your firm's letter dated November 18, 1998 to Ms. Brenda Holman, District Director, from Debbie N. Lewis, National Safety Manager, written in response to the above FDA 483. Ms. Lewis's comments for each item appears adequate. However, we will perform a more intensive evaluation of the adequacy during our next inspection.

A concern which is not addressed in your letter is the fact that your Center Manager, David K. Svedman, received Warning Letter BUF 96-4 dated January 12, 1996, see attached. At the time, Mr. Svedman was Owner, Home Oxygen Medical Equipment, Inc., the firm/location your firm reportedly purchased in January 1998 and is this subject of this letter. The deviations listed in the 1996 Warning Letter are similar to those listed on your recent FDA 483. As a result we request to be advised of what steps, if any, your firm intends to take to assure yourselves and us that Mr. Svedman will not only take the necessary steps to bring operations into compliance, but that the corrections will be lasting..

It is your responsibility to insure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should insure all corrections as detailed in Ms. Lewis's letter are taken promptly and after taken, measure their adequacy. Failure to take action may result in regulatory action, such as seizure, without further notice. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) days of the information we have requested concerning Mr. Svedman. Your response may be directed to William J. Thompson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman", with a long horizontal flourish extending to the right.

Brenda J. Holman
District Director