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PURGED

February 27, 1998

WARNING LETTER

Refer to MIN 98-15

Joy Calkins
President and CEO
Extendicare Inc.
3000 Steeles Avenue East
Markham, Ontario, Canada L3R 9W2

Dear Ms. Calkins:

During our inspection of your oxygen transfilling facility on January 28, 30, and February 2, 1998, located in Green Bay, WI, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to periodically verify, and document the verification of, the reliability of your bulk USP Liquid Oxygen supplier's analysis.
2. Failure to properly calibrate your Oxygen Analyzer used for the identity assay of USP Liquid Oxygen, in that your firm did not use a standard reference gas to calibrate the Oxygen Analyzer and no Certificate of Analysis is available for the oxygen used to calibrate your Oxygen Analyzer.
3. Failure to establish adequate batch production and control records for each batch

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of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.

4. Failure to establish written procedures for:
 - a. performing and documenting identity tests for USP Liquid Oxygen
 - b. the use of the Oxygen Analyzer Calibration Log
 - c. the receiving of any complaints

In addition, your USP Liquid Oxygen is adulterated in that the Certificate of Analysis (COA) you receive lacks the test method used to determine the identity and strength of your bulk USP Liquid Oxygen.

The cryogenic vessels at the inspected facility were observed to be misbranded within the meaning of Section 502 and 503(b)(4) of the Act in that your cryogenic vessels lack labeling for your USP Liquid Oxygen. Your labels need to include (a) the name and place of business of the manufacturer, packer, or distributor; (b) statement of identity for your USP Liquid Oxygen; and (c) "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."

At the conclusion of our inspection form FDA-483 was issued to Mr. Dennis C. Isles, Manager, UPC, Green Bay, WI. The violations of the GMPs cited on that form and in this Warning Letter are serious and require immediate attention and correction. A copy of the FDA-483 issued to Mr. Isles is enclosed.

The above indication 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. 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction. This is official notification that FDA expects ALL your locations to be in compliance.

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This is the third Warning Letter issued to you in one year (February 21, 1997, Pittsburgh, PA; October 10, 1997, Appleton, WI; and February 26, 1998, Green Bay, WI), and representatives from your company met with FDA officials, at our Philadelphia District Office, on November 25, 1997 to discuss on going GMP problems for your facility located in Pittsburgh, PA. We strongly suggest you review the GMP compliance status at all your facilities and take appropriate action.

The Minneapolis District is presenting a one day educational workshop on compressed medical gases, March 11, 1998 at the Ramada Inn Hotel in Fond du Lac, WI. We highly encourage representatives from your facilities to attend. An invitation to the workshop is enclosed.

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 the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

Enclosures: FDA-483, 2/2/98
Invitation to Medical Gas Workshop