



**PURGED** *PK*

February 25, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 17

Donald Elliott  
President  
A & B Welding Supply Company, Inc.  
914 East Chicago Street  
Rapid City, South Dakota 57701

Dear Mr. Elliott:

During a recent inspection of your medical oxygen transfilling facility 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 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:

- \* Failure to maintain complete records of the periodic calibration of laboratory instruments, apparatus, gauges and recording devices [21 CFR 211.194(d)]. For example, the calibration of the  Oxygen Analyzer is not documented.

Page Two

Donald Elliott  
February 25, 1999

- \* Failure to calibrate instruments, apparatus, gauges and recording devices at suitable intervals in accordance with an established written program containing specific directions [21 CFR 211.160(b)(4)]. The vacuum gauge used for the pre-fill evacuation step is not calibrated nor have written procedures been developed for calibration.
- \* Failure to properly test drug product containers and closures by the quality control unit before release for use [21 CFR 211.84(a)]. For example, a post-fill leak test is not performed on the valve when set in a closed position.
- \* All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed [21 CFR 211.192]. For example, all production records for medical Oxygen USP are not reviewed and approved prior to release.
- \* In addition, your Oxygen USP labels intended for use on the liquid Dewers fail to bear, at a minimum, "Rx only." Lack of the prescription legend misbrands your medical Oxygen USP.

These violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to 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 your facility to be in compliance with all of the requirements of the Federal Food, Drug and Cosmetic Act.

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

Page Three

Donald Elliott  
February 25, 1999

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 correction will be completed. Your reply should be sent to Acting Compliance Officer John Quaife at the address indicated on the letterhead.

Sincerely,

A handwritten signature in cursive script, appearing to read "James A. Rahto".

James A. Rahto  
Director  
Minneapolis District

JTQ/ccl