



April 19, 2000

WARNING LETTER NO. 2000-NOL-21

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mrs. Ann L. Newman, Co-Owner  
A & D Healthcare  
3803 Norwood Lane  
Mobile, AL 36618

Dear Mrs. Newman:

During an inspection of your manufacturing facility, located at 3803 Norwood Lane, Mobile, AL conducted on December 1-3, 1999, our investigators documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, oxygen, to be adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The controls used for manufacture, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (Title 21, *Code of Federal Regulations*, Parts 210 and 211), such as:

- Failure to establish scientifically sound and appropriate procedures for the assay of Oxygen U.S.P. [21 CFR 211.84(d)(2), 21 CFR 211.160(b) and 21 CFR 211.165(a)];
- Failure to establish that the test procedure used to determine the strength and identity of Oxygen U.S.P. will provide test results that are equivalent or superior to the official test procedure [21 CFR 211.84(d)(2), 21 CFR 211.160(b) and 21 CFR 211.165(a)];
- Failure to assay at least one cylinder per uninterrupted filling sequence for both identity and strength prior to release [21 CFR 211.165(a)];
- Failure to establish adequate written procedures for the production of drug products and process controls designed to assure that the drug products have the identity and strength they purport or are represented to possess [21 CFR 211.100];
- Failure to test each lot of bulk oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 211.84(d)];

- Failure to perform adequate pre-fill operations, and to establish adequate written procedures for the pre-fill operation, on high-pressure cylinders prior to filling them [21 CFR 211.84(d)(3)];
- Failure to establish adequate batch production records for each batch of drug product produced, including documentation that each significant step in the manufacturing, processing, or holding of the batch was accomplished [21 CFR 211.188];
- Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.125(c), 21 CFR 211.122(a)&(c) and 21 CFR 211.130(b)];
- Failure to establish written procedures for the receiving of any complaints [21 CFR 211.198(a)];
- Failure to properly calibrate equipment used in the manufacture of Oxygen U.S.P. in that instruments and gauges are not calibrated in suitable intervals in accordance with an established written program, the vacuum gauge had never been calibrated and the thermometer had not been calibrated since June 1998 [21 CFR 211.68(a)];
- Failure to establish written procedures to determine the expiration date of a drug product [21 CFR 211.137(a)];
- Failure to identify each batch with a lot or control number [21 CFR 211.130(c)];
- Failure to have the standard operating procedures used by the firm signed and dated indicating approval by the firm's appropriate official and quality control unit [21 CFR 211.100(a)];
- Failure to establish a quality control unit at the firm [21 CFR 211.22(a)];
- Failure to have a master label on file in the master production and control records [21 CFR 211.186(b)];
- Failure to establish separate quarantine areas for the holding of empty and filled cylinders of Oxygen U.S.P. [21 CFR 211.42(b)]; and,
- Failure to document employees training in CGMP's in the production of oxygen [21 CFR 211.25(a)].

The above identification of violations is not intended to be an inclusive list of deficiencies. It is your responsibility to assure to adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they make take this information into account when considering the award of contracts.

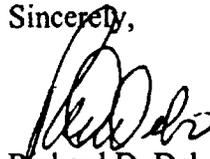
You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA-483. However,

it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that 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 this delay and the time in which the corrections will be completed.

Your response should be directed to Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127, telephone number (504) 253-4519. Should you have any questions concerning the contents of this letter, or if you desire a meeting with agency staff, please contact Ms. Asente.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard D. Debo". The signature is stylized and cursive.

Richard D. Debo  
Acting District Director  
New Orleans District

Enclosure: FDA-483