



February 26, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-12-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph Sansone
President/CEO/Chairman
Pediatric Services of America
310 Technology Parkway
Westlake Business Center
Norcross, GA 30092

Dear Mr. Sansone:

During an inspection of your oxygen repackaging facility, located at 2725 Curtiss Street, Downers Grove, IL, conducted from December 5 through 7, 2000, FDA Investigator Jeanne M. Morris documented significant deviations from Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceutical Regulations, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. These deviations cause your firm's Oxygen, USP, to be adulterated within the meaning of Section (501)(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding, are not in conformance with cGMP regulations. These deviations include, but are not limited to, the following:

- Failure to adequately calibrate the [REDACTED] Oxygen Monitor, which is used to perform the identity test of incoming liquid oxygen, at suitable intervals in accordance with the manufacturer's instruction manual [21 CFR 211.160(b)(4) & 21 CFR 211.194(d)]. For example, the inspection revealed the instrument is not calibrated on a daily basis, calibration grade gas is not used for calibration, and the two-point linearity check is not conducted.
- Failure to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)]. For example, the inspection revealed that documentation is not maintained to assure the Certificate of Analysis of the incoming liquid oxygen is reviewed prior to releasing product as required by procedure 4-07.
- Failure to establish and follow written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products [21 CFR 211.130]. For example, the inspection revealed that your firm does not apply the labels specified in procedure 4-11 to C41 vessels of Oxygen, USP, filled at this firm.

The inspection also documented that your firm's Oxygen, USP, is misbranded within the meaning of Section 502(g) of the Act in that its labeling fails to indicate whether or not the oxygen has been produced by the air-liquefaction process as required by the United States Pharmacopeia (USP XXIII).

The above list of violations, as well as the Form FDA-483, issued to Cynthia R. Parsons, Director of PSA Healthcare, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm's Oxygen, USP, is in compliance with the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into consideration when considering the award of contracts. A copy of the Form FDA-483, List of Observations, is attached.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your response should be directed to the attention of Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Enclosure

cc: Cynthia R. Parsons, Director
Pediatric Services of America Healthcare
2725 Curtiss Street
Downers Grove, IL 60515