



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

April 3, 2001

VIA Federal Express

Joseph Sansone, President
Pediatric Services of America, Inc.
310 Technology Parkway
Norcross, Georgia 30092

WARNING LETTER
(01-ATL-40)

Dear Mr. Sansone:

Investigator Patricia F. Hudson conducted an inspection of your medical oxygen transfilling facility in Norcross, Georgia on March 7-9, 2001 and March 16, 2001. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Parts 210 and 211. These deviations cause your transfilled drug product, Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all medical oxygen transfilled and distributed by your facility conforms to the appropriate final specifications prior to release. Certificates of Analysis were missing for ten (10) lots of bulk liquid Oxygen received between the period 12/99 through 2/01. You have failed to test or verify the results of these lots of bulk oxygen to determine conformance with appropriate specification for identity and strength. Your firm does not always witness the testing of bulk liquid Oxygen received. A review of (10) Certificates of Analysis between the period 11/98 through 2/01 revealed that they were not signed and/or dated by a representative of your firm. No other testing was performed by your firm prior to filling cryogenic home vessels from these lots.

You have failed to maintain adequate batch production and control records to document each significant step in the transfilling of your drug product. A review by a responsible individual should have detected many of the record keeping deficiencies noted in the batch records. Your firm received liquid Oxygen from [REDACTED] and [REDACTED]. Your firm did not perform a verification of analysis of [REDACTED] in 1999 and there is no documentation to show that verification of analysis of bulk liquid oxygen supplied by [REDACTED] has ever been performed. Also, records documenting calibration and maintenance of your liquid Oxygen scales are not maintained.

You have failed to ensure that established written procedures are being followed by employees at your firm. Liquid Oxygen Fill Logs were not reviewed and signed off by a qualified individual. Annual training was not documented in the employee's file. Oxygen label tracking is not being maintained for the accountability of labels.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions. This training must be in the particular operation that the employee performs and include current good manufacturing practice as it relates to the employee's functions. Production records have been routinely reviewed and approved by personnel with no training in, or knowledge of, the applicable requirements. On 12/19/98, one of your employees witnessed the testing of bulk liquid oxygen received (lot number 406122898-1), however your firm had no record of this employee's training on the analytical methodology.

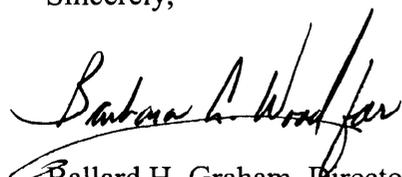
At the conclusion of the inspection, our investigator issued her Inspectional Observations (FDA 483) findings to you and discussed her findings. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all-inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office in writing within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented.

Your response should also address any proposed actions regarding any oxygen lots currently in distribution, which have not been properly tested. Your response should be directed to the Food and Drug Administration, Atlanta District Office, 60 8th Street N.E., Atlanta, GA 30309, Attention: Karen Y. Dodson, Compliance Officer.

Sincerely,



Ballard H. Graham, Director
Atlanta District

cc: Jeffrey B. Craven, Administrative Director
Pediatric Services of America, Inc.
6145-A Northbelt Parkway
Norcross, Georgia 30071