



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127-2601

Telephone: 504-253-4519  
Fax: 504-253-4520

February 28, 2003

**WARNING LETTER NO. 2003-NOL-08**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Joseph D. Sansone, Chairman  
President and Chief Executive Officer  
Pediatric Services of America, Inc.  
310 Technology Parkway  
Norcross, Georgia 30092

Dear Mr. Sansone:

During the January 8 - 10 and 14, 2003, inspection of your facility, located at 204 Row One, Lafayette, Louisiana, our investigator documented deviations from the Current Good Manufacturing Practice regulations. These deviations cause your drug product, liquid medical oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (CGMP), Title 21, *Code of Federal Regulations* (CFR), Part 211. You may find guidance and more information regarding these regulations through links in FDA's Internet page at <http://www.fda.gov> and in the National Archives and Records Administration Internet page at <http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html>. Specific observations made during the inspection include:

- You have failed to witness the testing of at least 31 lots of incoming liquid Oxygen USP for purity and strength prior to filling the cryogenic home units [21 CFR 211.165(a)];
- You have failed to retain production and testing records for liquid Oxygen USP distributed from your facility prior to August 14, 2002 [21 CFR 211.180]; and,
- You have failed to review all testing and batch records for liquid Oxygen USP distributed from your facility since August 14, 2002 [21 CFR 211.192].

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the CGMP regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may 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 Mr. Michael C. Thomas, Location Director, made a verbal commitment to correct the observed deficiencies. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the 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 this delay and the time within which the corrections will be completed.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address. Should you have any questions concerning the contents of this letter, please contact Mr. Rivero at telephone number (504) 253-4519.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483

cc: Michael C. Thomas, Location Director  
Pediatric Services of America, Inc.  
204 Row One  
Lafayette, Louisiana 70508