



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

51344d

**CERTIFIED MAIL-RETURN RECEIPT REQUEST**

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

June 6, 2001

Gary L. Dreher  
President and CEO  
AMDL, Inc.  
2492 Walnut Ave., Suite 100  
Tustin, CA 92780

WL-52-01

Dear Mr. Dreher:

During an inspection of your firm located in Tustin, California, on April 19 to 20, 2001, our investigator determined that your firm manufactures in vitro diagnostic tests. In vitro diagnostic test products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to control procedures for conducting quality audits [21 CFR 820.22]. Specifically, your firm has no documentation describing any internal activities conducted by your firm for the years 2000 and 2001 to determine whether your quality system activities comply with your quality system requirements.
2. Failure to implement an organization structure that is adequate to assure quality system requirements are met. [21 CFR 820.20(b)]. Specifically, your written quality system procedures refer to responsibilities for positions that do not exist such as a Quality Systems Manager. Additionally, several quality systems procedures are not followed and quality systems checks are not conducted.

This letter is 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 Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are

determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

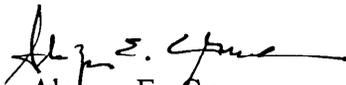
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar 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 completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse  
District Director  
Los Angeles District Office

Cc: State Department of Public Health  
Environmental Health Services  
Attn: Chief, Food and Drug Branch  
601 North 7<sup>th</sup> Street, MS-35  
Sacramento, CA 94234-7320