

June 6, 1997

WARNING LETTER
CHI-32-97

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ameet Patel
President/Owner
Allied Laboratories, Ltd.
716 North Iowa Avenue
Villa Park, IL 60181

Dear Mr. Patel:

FDA Investigators, Ruben Delagarza and Nick F. Lyons, conducted an inspection of your facility April 17, 24, 25, and May 1, 1997.

Serious deviations from the Federal Food, Drug, and Cosmetic Act (Act) concerning your testing of drug products by your contract laboratory were documented by the investigators. The drugs tested by your facility are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that you have failed to comply with the Current Good Manufacturing Practices regulations as prescribed by Title 21, Code of Federal Regulations (21 CFR), Parts 210 and 211, as follows:

Failure to maintain written procedures for maintenance and calibration of laboratory instruments used for testing drug products.

Failure to establish change control procedures.

Failure to have records to support assays for drug products.

Failure to have written installation qualification and system suitability for your High Performance Liquid Chromatograph (HPLC).

Failure to validate your autoclave.

The same listed deviations were found during an inspection of your facility on December 8-10, 1992. A Warning Letter dated December 28, 1992, was issued to Mr. Irvine Domsy, Laboratory Director. Mr. Domsy indicated by his response letter of January 14, 1993, that corrections had been implemented.

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Incidentally, the inspection shows that your facility has failed to register with the Food and Drug Administration (FDA) for 1996, as required by the Act. Your firm must register with the FDA. If you require registration information, please contact Ms. Linda Whitehead, Chicago District Office Registration Monitor. She can be reached by telephone at 312-353-5863, ext 142.

The above identification of violations is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA Chicago District recommends against the award of contracts for affected products. We are also recommending withholding any product approvals associated with your testing laboratory.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions may 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 regarding the specific steps you have taken to correct the above 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 the delay and the time within which the corrections will be completed.

Your response should be sent to Jerome Bressler, Assistant District Director for Compliance.

Sincerely,

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Raymond V. Mlecko
District Director

Enclosure: Form FDA-483

cc: Irvine T. Domsky
Laboratory Director
Allied Laboratories
716 N. Iowa Avenue
Villa Park, IL 60181