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DEPARTMENT OF HEALTH & HUMAN SERVICES

RB 4/29/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

April 26, 1999

WARNING LETTER # STL-99-03

Mr. Raj B. Panjwani, President
General Therapeutics Corporation
3650 Windsor Place
St. Louis, MO 63113

Dear Mr. Panjwani:

On February 9-26, 1999 an inspection was conducted at 3650 Windsor Place, St. Louis, Missouri of your drug manufacturing operations by investigators representing the Federal Food and Drug Administration (FDA). Our investigators documented deviations from the Current Good Manufacturing Practice (CGMP) regulations (Title 21, Code of Federal Regulations, Parts 210 and 211) which cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) and 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations noted include but are not limited to the following: 1) Standard Operating Procedures and manufacturing written procedures are not specific to your process and do not adequately identify the steps you follow in the manufacture of an OTC drug product or do not contain proper information for your process. These deficiencies were detailed at length in the FDA483 presented to you at the close-out meeting (a copy of the FDA483 is enclosed for your information); 2) raw materials are improperly stored in the facility; 3) equipment used in the production of Diurex Gel-Caps is not properly maintained or cleaned adequately; 4) reserve samples of Diurex active ingredients are not available and no documentation was presented to verify the examination of the reserve samples; 5) general sanitation of the facility used to produce the OTC drug products is poor. It was documented there are damaged production areas, leaks in the building, inadequate employee cleaning facilities, and areas of the warehouse kept in a manner that are conducive to rodent and insect attraction.

The above-identified list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to make sure your manufacturing of OTC drug products is done within the CGMPs for pharmaceuticals and to ensure your facility is maintained in a sanitary manner to prevent adulteration of your product. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Additionally, export approval requests may not be approved until the noted violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in immediate regulatory action without further notice. Such actions include product seizure and injunction.

You should notify this office in writing, within fifteen (15) days of receipt of this letter, of the specific steps that are being taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days state the reason for the delay and provide specific timeframes for corrections to be completed.

Your reply should be sent to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District Office

Enclosure – FDA 483