



Telephone (973) 526-6009

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

December 8, 1998

**WARNING LETTER**

Mel Weiss, President  
Consumer Product Testing Company  
70 New Dutch Lane  
Fairfield, New Jersey 07004

**File No.: 99-NWJ-06**

Dear Mr. Weiss:

From October 21 through November 6, 1998, an inspection was conducted of your testing laboratory located at 70 New Dutch Lane in Fairfield, New Jersey, by an Investigator from this office. This inspection revealed significant deviations from the current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals, found in Title 21, Code of Federal Regulations. Such deviations cause finished pharmaceuticals to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The significant cGMP deviations noted are as follows:

1. Failure to provide an accurate review of data by the Peer Reviewer and Quality Assurance Unit.  
For example, during the review of 3-hour dissolution data for Diltiazem HCl tablets, Lots 720D01, 662D01 and 691D01, an incorrect calculation was applied to the original data and reported to the client.
2. Failure to comply with your own procedures for documenting Laboratory Investigations (SOP WI-QT130009-00G), concerning the invalidation of test results.  
For example:
  - Diltiazem HCl 60, 90 and 120 mg tablets, 3-hour dissolution data was initially invalidated, without documentation or investigation.
  - Results for three samples of [REDACTED] tablets, for Loss on Drying data, were invalidated twice, without documentation or investigation. Data from the third test result was used.
  - Initial results of Sieve Analysis for bulk Magnesium Hydroxide was invalidated without explanation.

3. Failure to comply with your own procedures for completing investigation reports concerning out-of-specification results and/or not conducting investigations on a timely basis.

For example:

- Chromium Assay results for study samples, Q98-1386, [REDACTED], Lot GUB0397A and Q98-1387, [REDACTED], Lot GFH0497B, were sent to the client, however, testing records showed erratic assay values. An investigation report cited out-of-specification results, but was not reviewed by QA. Two analysts retested samples and the final results were derived from these re-tests without a completed investigation.
- Procedure of investigation reports (SOP WI-XT130076-00A) states investigations are to be completed, issued and reviewed within 30 business days. The initial failing results for the above study samples (Q98-1386 and Q98-1387) remained open for more than three months, without completion. Additionally, an interim report was not issued for this occurrence, per SOP.

4. The water system used to produce USP Purified/HPLC grade water for analytic work and reagent production was inadequately validated and monitored. Out-of-specification results were not included in the validation report covering the April 1997-June 1998 cycle.

For example:

- Microbiological testing results on 2/4/98 and 7/7/98, exceeded the total cfu/ml specification, without resampling, or investigating a potential contamination.
- Daily qualification of the water system resulted in 17 occasions during validation and 20 times since validation, in which the resistivity fell below the established range of 16.3-18.1 mega ohms. There was no documentation or shutdown of the system, in accordance with SOP WI-QE090063-00D, to investigate these occurrences.
- Water used daily, specifically on weekends, was not monitored per procedure to ensure the quality of HPLC Grade Water.

5. Original test methods were modified without further study or documentation to justify the changes made.

For example:

- Agitation time was changed from 45 to 75 minutes for Diltiazem HCl 120mg, when it failed to originally meet the percent difference between replicate samples.
- During the USP Sieve Analysis testing for bulk Magnesium Hydroxide, sample Q98-1776, additional sieve analysis was conducted and initial results were invalidated, without justification.

The above is not intended to be an all-inclusive list of deviations of your testing facility. As a pharmaceutical testing laboratory, you are responsible for assuring that your overall operation is in compliance with all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated under it.

**Consumer Product Testing Company  
Fairfield, NJ 07004**

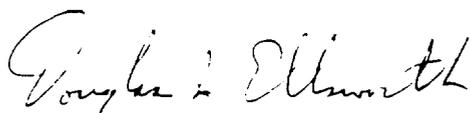
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You should take prompt action to correct these deviations and establish procedures to prevent recurrence. Failure to promptly correct these deviations may result in further regulatory action without further notice, such as injunction.

We have reviewed your written response dated November 20, 1998 and find your proposed corrective actions to be acceptable. The effectiveness of these actions will be evaluated during the next inspection of your testing facility. It should be noted that several observations cited during this recent inspection, such as failure to follow your own procedures and lack of completed investigation reports, were cited during the previous two inspections. This implies that your prior corrective actions have not been effective in demonstrating compliance with cGMPs. We recommend that you conduct a thorough evaluation of your facility and consider use of an independent third party to review your operations prior to any future requests for a reinspection or meeting with District officials. Meanwhile, your testing facility will remain unacceptable for drug pre-approval applications.

Any additional information you may wish to submit regarding this matter should be submitted within 15 days of receipt of this letter. Please direct your further response to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District Office

**CERTIFIED MAIL -**  
**RETURN RECEIPT REQUESTED**