



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Mid-Atlantic Region 430

Telephone (201) 331-2904

September 17, 1997

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

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Manohar R. Bhambhani, President  
Sciencetech Laboratories Inc.  
197 Meister Avenue  
North Branch, New Jersey 08876

RELEASE

REVIEWED BY AE 9/22/97  
C.O. DATE

FILE NO.: 97-NWJ-49

Dear Mr. Bhambhani:

An inspection was conducted of your testing laboratory located at 197 Meister Avenue, North Branch, New Jersey, by the U.S. Food and Drug Administration on August 6 through August 22, 1997. The inspection revealed significant deviations from current good manufacturing practices (21 CFR 210/211) concerning the performance of analyses, a lack of validation of testing methods, a lack of written procedures and/or following written procedures relating to analytical methodology. The violations were presented to your attention on a FD-483 List of Observations, at the close of the inspection. These CGMP deviations cause articles of drug assayed for release for further manufacture and/or release for commercial distribution to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, in that the methods used in and the controls used for the manufacturing, processing, and holding of drug products are not in conformance with current GMP regulation part 210 and 211.

1. No traceability or accountability for the analytical worksheets used to record all raw data from analytical testing.
2. [REDACTED] conducted HPLC testing, although system suitability was not shown. For example:
  - a. During the testing of Tretinoin Cream 0.025% lot 4833 (2/95), Tretinoin Cream 0.10% lot 4834 (9/96), and Tusnel Cough Syrup lot 7B12 (3/97), data from 1 of the 5 standard injections was excluded from the %RSD system suitability calculations. If the data was included in the calculations the system suitability requirements would not have been met.

3. The firm has no validation data to support the adequacy of their method modifications, in that there is no documentation that describes, explains, justifies, supports or approves these method modifications.
  - A. Procedures as written in HPLC Lab [REDACTED] did not accurately reflect what was performed during the actual analyses. Examples:
    1. During testing on 5/9/97 the prepared in-house reference standards and the samples were run at a wavelength of [REDACTED]. Method [REDACTED] stated that the wavelength should be [REDACTED]. No information could be provided as to why a wavelength of [REDACTED] was used.
    2. During the testing on 10/4/96 and 10/7/96, an injection volume of [REDACTED] was used. [REDACTED] specified an injection volume of [REDACTED]. No documentation could be provided that indicated why the injection volume was changed. It was noted that the analytical worksheets for the 5/9/97 testing did not indicate the injection volume or flow rate used.
    3. The tailing factor and resolution calculations for system suitability determination were not calculated during the 10/4/96, 10/7/96 and 5/9/97 analyses. These calculations were specified in [REDACTED].
  - B. During the 12/96 and 7/96, HPLC assay testing of Tretinoin Cream lots 4561 and 4834 [REDACTED] the flow rate and injection volume specified in the method were not used. No documented investigation could be provided that detailed why the run parameters were changed.
4. The HPLC computer software ([REDACTED]), which is used for data acquisition, calculations, and system control, is not validated in that areas such as system operations, system maintenance, change control, data back-up and archival, system security and disaster recovery have not been evaluated.

5. Failure to provide written analytical methods used in the testing of samples. For example:
  - a. Documentation indicated that HPLC Lab Method [REDACTED] was used to test Tusnel Cough Syrup (Pharmakon Labs) lot 7B12, but a written copy of the method could not be provided.

We have received your response letter dated September 12, 1997, regarding the inspectional observations made on the FD-483. Your response which includes both your comments and intended corrective actions appears to be adequate and we will confirm the adequacy of those corrections during our next FDA inspection.

The above list of violations are not to be considered as an all-inclusive list of the violations at your facility. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder are being met. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

Any additional information you may wish to submit regarding this matter or any questions you may have should be directed to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



DOUGLAS ELLSWORTH  
District Director  
New Jersey District Office

AC:slw