



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

M 1992N

Telephone (973) 526-6005

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

August 6, 1998

WARNING LETTER

Thomas S. Freund, Ph.D., President
Health Science Laboratories and Services, Inc.
One South Corporate Drive
Riverdale, New Jersey 07457

FILE NO: 98-NWJ-33

CFN: 2247771

Dear Dr. Freund:

An inspection of your pharmaceutical testing laboratory conducted by Food and Drug Administration investigators between June 22 and July 1, 1998, found significant deviations from current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). 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).

Our investigation found:

- 1) The laboratory assessment of the stability characteristics used to support the extension of the expiration date of [REDACTED] was deficient in that:
 - a) A modified USP method was used to assay the active ingredient, tetrahydrozoline HCl, contrary to Analytical Test Reports 9732932D1 through D5 which refer to the USP 23 for the test procedure. The procedure used is not in writing and there is no data to support its accuracy and reliability.
 - b) An out of specification (OOS) result was obtained on a sample of [REDACTED]. This result was averaged with in specification results. Although this average was still OOS, it was wrongly recorded as a within specification result on Analytical Test Report 9732932D5.
 - c) The HPLC test methodology used to assay the Polyethylene Glycol (PEG)-400 in [REDACTED] was not validated. The methodology for this assay is not written.

- d) The tetrahydrozaline standard used was not a USP standard.
 - e) The temperature and humidity of the room temperature stability chamber was not monitored during the stability testing of [REDACTED]
 - f) During the stability testing of [REDACTED] humidity readings of the accelerated stability chamber were observed to be outside the USP range of 70%-80% relative humidity (RH).
 - g) A second individual did not review the notebook, worksheets, and analytical test reports for accuracy and completeness.
 - h) The lot numbers of the Fluid Thioglycollate media (FTG) and Tryptic Soy Broth (TSB) were not documented during the sterility testing of [REDACTED]
- 2) Sterility procedures were deficient in that:
- a) There are no written gowning procedures.
 - b) Paper disposable uniforms are used more than once and were noted hanging next to soiled laboratory coats in the gowning room.
 - c) One analyst was observed in the sterility suite wearing a ripped uniform, uncovered/soiled tennis shoes, and jewelry. Another analyst was observed handling non-sterile items in the gowning room after leaving the sterility suite and re-entering the suite without re-gowning or re-gloving.
- 3) A failure to maintain written procedures for the following:
- a) Cleaning the sterility suite.
 - b) Investigation of OOS results.
 - c) Maintenance of laboratory equipment.

The above is not intended to be an all-inclusive list of violations. As a pharmaceutical testing laboratory, you are responsible for assuring that your overall operation is in compliance with the law.

You should take prompt action to correct these violations and to

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establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

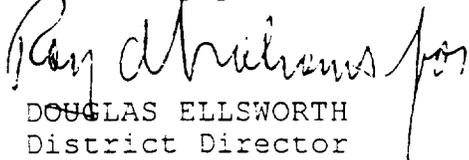
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We acknowledge that you have submitted to this office a written response dated July 8, 1998, concerning our investigator's observations noted on the form FDA 483. The response indicates that appropriate corrective action is being taken or planned, however we cannot provide specific comments as to the adequacy of this action until we have the completed and approved procedures you reference in your letter.

Please notify this office in writing, within 15 working days of receipt of this letter as to the status of the corrective actions you outlined in your response. Also, please advise us as to whether or not your facility will repeat the stability study for

Correspondence concerning this matter should be directed to the Food and Drug Administration, Attention Richard T. Trainor, Compliance Officer.

Sincerely yours,


DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

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