DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m3844.1

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

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-41

June 14, 2000

Ronald A. Schnitzer
Owner
Sani-Pure Food Laboratories
178-182 Saddle River Road
Saddle Brook, NJ 07663

Dear Mr. Schnitzer:

Our District inspected your contract testing laboratory located at 178-182 Saddle River Road, Saddle River, New Jersey, from March 1 through April 3, 2000, and found significant deviations from the regulations covering Current Good Manufacturing Practices for Finished Pharmaceuticals. These deviations cause the drug products you analyze to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations included:

1. You or your employees performed repeat testing on products without first conducting an investigation. No explanation into the reason for repeat testing and invalidating the previous results was documented. Further, the initial results were not communicated to your customers; only the repeated and passing results were communicated. Specific examples include:

   a. [redacted] analyzed for total ephedra alkaloids content; and
   b. [redacted] composite sample of seven lots, analyzed for acid neutralizing capacity.

2. Following flood damage in September, 1999 to your facility and equipment, you or your employees failed to evaluate the raw data storage conditions, re-calibrate or re-qualify repairable analytical equipment, or implement any procedures or changes to existing procedures to alleviate future damages.

3. You (specifically) are not documenting raw data when you perform inductively coupled plasma emission spectrograph or high-pressure liquid chromatograph analyses. This raw data includes:

sample preparation, standard preparations and usage, system suitability, actual assay data, and any and all calculations involving the above.

4. Your firm has not validated analytical methods currently in use for determining metal content in sunscreens and AOAC official methods for analyzing drug products or ingredients.

5. Your firm does not have a quality assurance program in place to: *a)* qualify analytical equipment prior to their use, and *b)* calibrate and maintain analytical equipment according to manufacturers' specifications.

6. The computer software your firm uses to determine metals analysis is deficient. It has no security measures to prevent unauthorized access of the software, no audit trails, and data can be copied or changed at will, with no documentation of the copying or changes. Your procedures do not require the documentation of calculation or entry errors. There is no documentation to indicate that analysts are trained in the software and its applications.

7. Your firm has no system for the receipt and storage of standards and analytical chemicals. Expired standards were used in the calibration of equipment. Working solutions were not properly labeled or documented in laboratory notebooks or other records in that the data did not bear complete information, including the analyst or preparer's identity, solution designation, strength, and expiry dates.

8. The integrity of raw data produced by various laboratory instrumentation is questionable. For individual pieces of equipment, including the [redacted] either no equipment qualification was performed, no calibration was performed prior to their use, no audit trail exists for data collection and entry, or their inclusion in method or system validation was not made.

9. Your firm's laboratory records and recordkeeping are deficient. Corrections to laboratory raw data were noted to be obscured with white correction fluid or improperly voided (no initials, date, reason or explanation of change). Laboratory worksheets did not contain information of the analytical method used to perform the analysis in question. Analytical calculations were not recorded in laboratory notebooks. There is no other demonstrable record of said calculations. Laboratory records did not contain documentation of a second individual's review and verification of the original data.

10. You and your employees performing analyses of drug products are not trained in Current Good Manufacturing Practices applicable to your operation. Further, your supervisory employees have not documented any of their subordinates as being qualified to execute the analytical work to which they have been assigned.

11. After your damage by floodwaters, you did not qualify your microbiological laboratory as being sterile and the equipment used therein as undamaged and suitable prior to the resumption of

microbiological analyses. Our Investigator and Chemist documented the analysis of samples for microorganisms after the September, 1999 flood.

Also, you or your employees discarded documentation of analytical work performed prior to September 1999. As a consequence, that documentation was not available for review during our inspection. The lost documentation, attributable to flood waters entering your facility, was improperly stored to prevent such an occurrence. In addition, photocopies, electronic data or some other facsimile to the lost documentation were not generated. In the future, you should develop more secure record storage facilities and procedures to prevent record loss due to natural disasters or other unforeseen circumstances.

The violations specified in this letter may not include all deficiencies present at your facility. It is your responsibility, as a pharmaceutical testing laboratory, to ensure that your overall operation and the products you manufacture are not in violation of the law or regulations.

You should take actions to correct the above violations, as well as any other violations you have knowledge of. Corrections should include the establishment or refinement of systems and procedures designed to prevent future violations. If you fail to perform these corrections, FDA may execute serious regulatory action(s), which can include the permanent injunction of operations and/or individuals and the criminal prosecution of your firm and/or responsible individuals. These actions can occur with no prior warning.

You have 15 days time from the receipt of this letter to advise us of any or all corrections you have or plan to undertake to correct the violations. Please direct your reply to the attention of Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Drive, Third Floor, Parsippany, New Jersey 07054. If you have any questions concerning this letter, you may telephone Mr. Sooter at (973) 526-6008.

Sincerely yours,

Roy Abrahams for

Douglas I. Ellsworth
District Director