



December 15, 1997

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-6

David L. Hall  
President  
Stat-Lab Technologies, Inc.  
720 South 313th Street  
Federal Way, WA 98003

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell, WA 98041-3012

Telephone: 425-486-8788  
FAX: 425-483-4996

### WARNING LETTER

Dear Mr. Hall:

We are writing to you because on October 9, 1997, Engineer Teri L. Colbert from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the three pregnancy test kits which are marketed by your firm. These kits are labeled as: the hCG Standard Dip and Read Pregnancy Test, the hCG Standard Urine/Serum Pregnancy Test, and the SureStep HCG Pregnancy Test.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. Because you do not have marketing clearance from FDA, marketing your products is a violation of the law. In legal terms, the products are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

During the inspection, it was revealed that these pregnancy test strips are manufactured and shipped to your firm by [REDACTED]. A firm such as yours which places its own name on a device and does not change any other labeling or otherwise affect the device is exempted from the prenotification requirements provided that one of two requirements is met.

These are if the device was in commercial distribution before May 28, 1976, or if a premarket notification submission was filed by another person. This exemption is located in the Federal Regulations at 21 Code of Federal Regulations (CFR) 807.85.

Review of the labeling (package inserts) for your firm's three devices by the Center for Devices and Radiological Health/Office of Device Evaluation disclosed significant differences from the labeling for the cleared devices. Hence, your products do not meet the requirement for exemption. The following are the differences requiring new 510(k)s for your devices:

1. The hCG Standard Dip and Read has: serum added as a matrix, a different procedure, different clinical trial/correlation information, and includes recovery data.
2. The hCG Standard Urine/Serum Pregnancy Test has differences in: the sensitivity, the procedure (*i.e.*, the length of time before lines appear), the clinical trial and correlation, and includes recovery data.
3. The SureStep hCG Pregnancy Test differs in the reaction time and stability of results as well as in the accuracy data included.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

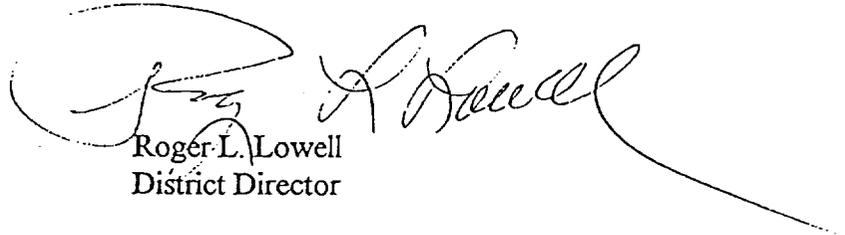
It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Thomas S. Piekarski, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

David L. Hall, President  
Stat-Labs Technologies, Inc.  
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If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Robert G. Brett at 301-594-4588.

Sincerely,



Roger L. Lowell  
District Director

Enclosure:  
21 Code of Federal Regulations (CFR) 807.85

cc:  
Sarah L. Hall  
Vice President  
Stat-Lab Technologies, Inc.  
720 South 313th Street  
Federal Way, WA 98003