



M41087

AUG 18 2000

Warning LetterFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850Certified Mail
Return ReceiptAcon Laboratories, Inc.
11175 Flintkote Avenue, Suite F
San Diego, California 92121

Dear Sir/Madam:

We are writing you because the Food and Drug Administration (FDA) obtained information from your Internet site <http://www.aconlab.com/new.html> that revealed a serious regulatory problem-involving the following products: Acon Rapid Syphilis Test, hCG Pregnancy Tests, LH Ovulation Test, LH Home Ovulation Test, HbsAg Hepatitis B Surface Antigen Tests, HCV Hepatitis C Virus Tests, HIV1/2 Human Immunodeficiency Virus 1/2 Test, Leishmania Tests, MOP Morphine Tests, THC Marijuana Tests, COC Cocaine Tests Amp Amphetamine Tests, MET Methamphetamine Tests, PCP Phencyclidine tests, and Multi-Drug Test Panels. These products appear to be manufactured and/or commercially distributed by your firm.

Under a United States law, the Food, Drug and Cosmetic (Act), these products are considered to be medical devices because they are used to diagnose and/or treat a medical condition. This law requires that manufacturers of medical devices obtain FDA marketing clearance for their products before they can offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective, and will perform as intended/labeled. A guidance document and labeling requirements for marketing these devices can be found at <http://www.fda.gov/cdrh/ode/.html>.

Our records indicate that you did not obtain marketing clearance or submit premarket notifications before offering your products for sale over-the counter. If you do not have marketing clearance for your devices they are in

Page 2 - Sir/Madam

violation of a federal law to sell the devices in the U.S. and may result in the FDA taking regulatory action.

Please provide this office, within fifteen (15) working days after you receive this letter, with: 1) A complete copy of the labeling for your devices (including the product insert and outer package labeling), 2) documents that indicate you have obtained FDA marketing clearance or a premarket notification for your devices or purchased such clearance from another firm and 3) the name of the manufacturer and address.

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

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 products, or assessing civil money penalties. Also, other Federal Agencies are informed about the warning letters we issue, such as this one, so 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 receive 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 FDA at the above listed address.

If you have more specific questions about FDA marketing requirements that may affect your device, or about the

Page 3 - Sir/Madam

content of this letter, please contact Ms. Betty Collins,
Chief, In Vitro Diagnostic Devices Branch, Office of
Compliance, CDRH or Robert G. Brett, Consumer Safety
Officer at (301) 594-4588.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

*Runzel
R2213*