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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**Warning Letter**

MAY 31 2001

**Certified Mail**  
**Return Receipt Requested**

Kyle Creasy  
President  
KCC Enterprises  
10151 University Blvd.  
Suite 256  
Orlando, Florida 32817

Dear Mr. Creasy:

We are writing to you because a review of your web site ([www.drugtestsuccess.com](http://www.drugtestsuccess.com)) revealed a serious regulatory problem involving the product known as the Instant Drug Test, which is made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is 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 Food and Drug Administration (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 for the Ecstasy, 1, 2 or 5 panel assays before you began offering your products for sale. Although Mr. Jeff Thomas informed Mr. Broden Staples of our staff that you purchase these assays from [REDACTED], our records do not show that [REDACTED] obtained a clearance or approval for these assays. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your product may be legally marketed.

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

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.

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 Betty Collins, Chief, In Vitro Diagnostic Devices Branch, 2094 Gaither Road, HFA-321, Rockville, Maryland 20850.

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>.

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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 Betty Collins at 301-594-4588.

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. D. Spears". The signature is stylized and cursive.

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health