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AUG 18 2000

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

Warning Letter

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Murray Lappe, M.D.  
President  
eScreen, Inc.  
5900 Wilshire Blvd.  
Los Angeles, California 90036

Dear Dr. Lappe:

We are writing to you because the Food and Drug Administration (FDA) has reviewed information that revealed a serious regulatory problem involving the product known as eScreen Drugs of Abuse. This device continues to be promoted and commercialized through your web site at the Internet address: <http://www.eScreen.com>

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 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.

Although you submitted a premarket notification for this device [redacted] it was not cleared, and you are prohibited from marketing this device. However, the Product & Services page of your web site indicates that, "eScreen currently has hundreds of locations and is rolling out across the country."

On June 12, 2000, Dr. Steven Gutman, Director, Division of Clinical Laboratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, sent you a [redacted].

of the [redacted] in your [redacted] that were  
[redacted], FDA believes that you [redacted]  
in [redacted] days with [redacted]  
[redacted]  
[redacted]  
[redacted]

Because you do not have marketing clearance from FDA for OTC distribution of this device, 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, IVD Devices Branch, Center for Devices and Radiological Health, 2094 Gaither Road, HFZ-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

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contacting our Division of Small Manufacturers Assistance  
at 1-800-638-2041 or through the Internet at  
<http://www.fda.gov>.

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, Chief, IVD Devices Branch, or Broden Staples at  
301-594-4588.

Sincerely yours,



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