



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI-35
8/10/99
11/2
M 3105M

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 1999

WARNING LETTER

VIA FEDERAL EXPRESS

Jonathan Shedler, Ph.D.
President
Digital Diagnostics, Inc.
225 North Mill Street, Suite 207
Aspen, Colorado 81611

Dear Dr. Shedler:

The Food and Drug Administration's (FDA), Center for Devices and Radiological Health (CDRH) has reviewed the user manual and Frequently Asked Questions sheet you provided with your [REDACTED], letter regarding the Quick PsychoDiagnostics Panel. The Quick PsychoDiagnostics Panel (QPD) is a computer-administered psychological test used to diagnose psychiatric diseases.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), the QPD Panel is considered to be a medical device because it is used to diagnose a medical condition. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps to protect the public health by ensuring that newly introduced medical devices are 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 your QPD Panel before offering it for sale. The kind of information you need to submit to obtain this clearance is described in the enclosed materials. After you submit this information, FDA will evaluate it and decide whether your Quick PsychoDiagnostics Panel may be legally marketed.

The FDA does exempt manufacturers of computer-administered psychological tests from obtaining premarket clearance, provided that the manufacturers of the tests, provide their users with the algorithm(s), as this will represent competent human intervention.

Page 2 - Dr. Shedler

Because you do not have marketing clearance for your Quick PsychoDiagnostics Panel (QPD Panel), marketing this 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 QPD Panel, 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 what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. 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 Fleadia Farrah, Diagnostic Devices Branch, Office of Compliance (HFZ-322), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Denver District Office. Please send a copy of your response to the District Director, Denver District Office (HFR-SW240), 6th and Kipling Street, Denver, Colorado 80225-0087.

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>.

Page 3 - Dr. Shedler

If you have specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Ms. Fleadia Farrah at (301) 594-4591.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure